J Hepatobiliary Pancreat Sci (2017) 24:537–549
DOI: 10.1002/jhbp.496

GUIDELINE

Indications and techniques of biliary drainage for acute cholangitis in updated Tokyo Guidelines 2018

Shuntaro Mukai · Takao Itoi · Todd H. Baron · Tadahiro Takada · Steven M. Strasberg · Henry A. Pitt · Tomohiko Ukai · Satoru Shikata · Anthony Yuen Bun Teoh · Myung-Hwan Kim · Seiki Kiriyama · Yasuhisa Mori · Fumihiko Miura · Miin-Fu Chen · Wan Yee Lau · Keita Wada · Avinash Nivritti Supe · Mariano Eduardo Giménez · Masahiro Yoshida · Toshihiko Mayumi · Koichi Hirata · Yoshinobu Sumiyama · Kazuo Inui · Masakazu Yamamoto

Published online: 5 October 2017

The author's affiliations are listed in the Appendix.

Correspondence to: Tadahiro Takada, Department of Surgery, Teikyo University School of Medicine, 2-11-1 Kaga, Itabashi-ku, Tokyo 173-8605, Japan
e-mail: t-takada@jshbps.jp

DOI: 10.1002/jhbp.496

Abstract The Tokyo Guidelines 2013 (TG13) include new topics in the biliary drainage section. From these topics, we describe the indications and new techniques of biliary drainage for acute cholangitis with videos. Recently, many novel studies and case series have been published across the world, thus TG13 need to be updated regarding the indications and selection of biliary drainage based on published data. Herein, we describe the latest updated TG13 on biliary drainage in acute cholangitis with meta-analysis. The present study showed that endoscopic transpapillary biliary drainage regardless of the use of nasobiliary drainage or biliary stenting, should be selected as the first-line therapy for acute cholangitis. In acute cholangitis, endoscopic sphincterotomy (EST) is not routinely required for biliary drainage alone because of the concern of post-EST bleeding. In case of concomitant bile duct stones, stone removal following EST at a single session may be considered in patients with mild or moderate acute cholangitis except in patients under anticoagulant therapy or with coagulopathy. We recommend the removal of difficult stones at two sessions after drainage in patients with a large stone or multiple stones. In patients with potential coagulopathy, endoscopic papillary dilation can be a better technique than EST for stone removal. Presently, balloon enteroscopy-assisted endoscopic retrograde cholangiopancreatography (BE-ERCP) is used as the first-line therapy for biliary drainage in patients with surgically altered anatomy where BE-ERCP expertise is present. However, the technical success rate is not always high. Thus, several studies have revealed that endoscopic ultrasonography-guided biliary drainage (EUS-BD) can be one of the second-line therapies in failed BE-ERCP as an alternative to percutaneous transhepatic biliary drainage where EUS-BD expertise is present.

Keywords Cholangitis · Drainage · Endoscopic retrograde cholangiopancreatography · Endoscopic sphincterotomy · Gallstones

Introduction

Acute cholangitis varies in severity, ranging from a mild form which can be treated by conservative therapy to a severe form which leads to a life-threatening state (e.g. shock state and altered sensorium). In particular, the severe form often causes mortality in the elderly [1]. Early biliary drainage should be performed for Grade II (moderate) and Grade III (severe) cases according to the severity grading of the updated Tokyo

Guidelines of 2013 (TG13) [2–4]. Biliary drainage, which is the most essential therapy for acute cholangitis, is traditionally divided into three types: (1) surgical, (2) percutaneous transhepatic, and (3) endoscopic transpapillary drainage. Of these therapies, surgical intervention causes the highest mortality rate [1]. Recently, mortality due to acute cholangitis has decreased owing to the development of percutaneous transhepatic cholangial drainage (PTCD) [5] and endoscopic transpapillary biliary drainage [6, 7]. Nevertheless, acute cholangitis can still be fatal unless it is treated early and properly.

The Tokyo Guidelines of 2007 (TG07) was the first global guidelines in which fundamental biliary drainage techniques for acute cholangitis were described [8]. Subsequently, TG07 was revised to TG13, which include the indications and procedures of newly developed biliary drainage techniques such as endoscopic ultrasonography-guided biliary drainage (EUS-BD) and balloon enteroscope-assisted bile duct drainage in patients with surgically altered anatomy [9]. As several reports of these newly developed biliary drainage techniques or the methods and timing of stone removal after or simultaneously with drainage have been published, TG13 needs to be updated. Thus, the Tokyo Guidelines Revision Committee was assembled and the committee discussed six argument points on biliary drainage for acute cholangitis as mentioned below. In this article, we describe the latest drainage techniques for acute cholangitis and the treatment methods for stone removal in the updated Tokyo Guidelines 2018 (TG18).

Indications and techniques of biliary drainage

In the updated TG18, biliary drainage is recommended for acute cholangitis regardless of the degree of severity except in some cases of mild acute cholangitis in which antibiotics and general supportive care are effective [10].

Q1. What is the most preferable biliary drainage for acute cholangitis? (Surgical vs. endoscopic transpapillary vs. EUS-guided vs. percutaneous transhepatic biliary drainage?)

We recommend endoscopic transpapillary biliary drainage for acute cholangitis (recommendation 1, level B).

***Refer to Q6 in acute cholangitis patients with surgically altered anatomy.**

Endoscopic transpapillary biliary drainage should be considered as the first-line drainage procedure because of its less invasiveness and lower risk of adverse events than other drainage techniques despite the risk of post-endoscopic retrograde cholangiopancreatography (ERCP) pancreatitis [11–14]. The internal drainage by endoscopic transpapillary biliary drainage produces less pain after the procedures than the external drainage by percutaneous transhepatic biliary drainage (PTBD), also known as percutaneous transhepatic cholangial drainage (PTCD) [15]. PTCD places more burden on patients owing to cosmetic problems, skin inflammation, or bile leakage, compromising the patient's quality of life. A single treatment session for a bile duct stone is possible with the endoscopic transpapillary approach, making the hospitalization duration shorter. However, in patients with an inaccessible papilla due to upper gastrointestinal tract obstruction, or when skilled pancreaticobiliary endoscopists are not available in the institution, PTCD is a useful alternative drainage procedure [5, 16]. Furthermore, PTCD can be used as a salvage therapy when conventional endoscopic transpapillary drainage has failed owing to difficult selective biliary cannulation. Recently, EUS-BD has been developed and reported as a novel useful alternative drainage technique when standard endoscopic transpapillary drainage has failed [17, 18].

From the results of a randomized controlled trial (RCT) and meta-analysis that compared EUS-BD with PTCD as an alternative drainage technique after failed endoscopic transpapillary biliary drainage, the technical success and clinical success rates were approximately the same at 90–100%, but the rates of PTCD adverse events such as post-procedure bleeding, cholangitis, and bile leakage were higher than those of EUS-BD adverse events (Table 1) [19–24]. However, almost all reports about EUS-BD come from high-volume centers and performed by skilled pancreaticobiliary endoscopists. A national survey in Spain wherein most of the institutions involved were not high-volume centers reported a technical success rate of only 67.2% from 106 patients [25]. Their data indicated that EUS-BD remains an unestablished procedure and is not an easy technique to perform. Therefore, when skilled pancreaticobiliary endoscopists are available in an institution, EUS-BD is recommended as an alternative drainage procedure. Otherwise, PTCD should be selected, or transfer of the patient to a high-volume center should be considered.

Percutaneous transhepatic cholangial drainage

Before the widespread use of transabdominal ultrasonography, needle puncture of the bile duct was conducted under fluoroscopy [5]. Currently, needle puncture is safely performed under ultrasonography to avoid intervening blood vessels [16]. Therefore, in the current PTCD procedure, operators should continuously observe the bile duct by ultrasonography regardless of the presence of dilation.

Table 1 Comparison of outcomes between EUS-BD and PTBD as an alternative drainage procedure

Author	Year	Design	Method	*n*	Technical success (%)	Clinical success (%)	Adverse events (%)
Artifon et al. [20]	2012	RCT	EUS-BD	13	100	100	15.3
			PTBD	12	100	100	25
Bapaye et al. [22]	2013	Cohort	EUS-BD	25	92	N/A	20
			PTBD	26	100	N/A	46.1
Khashab et al. [23]	2014	Cohort	EUS-BD	22	86.4	86.4	18.2
			PTBD	51	100	92.2	39.2
Sharaiha et al. [24]	2015	Cohort	EUS-BD	47	93.3	62.2	6.6
			PTBD	13	91.6	25	53.8
Lee et al. [21]	2016	RCT	EUS-BD	34	94.1	87.5	8.8
			PTBD	32	96.9	87.1	31.2

EUS-BD endoscopic ultrasound-guided biliary drainage, *N/A* not available, *PTBD* percutaneous transhepatic biliary drainage, *RCT* randomized controlled trial

PTCD is performed as previously described [5]. In brief, ultrasonography-guided transhepatic puncture of the intrahepatic bile duct is initially performed using an 18-G to 22-G needle. After confirming the backflow of bile, a guidewire is advanced into the bile duct. Finally, a 7-Fr to 10-Fr catheter is placed in the bile duct under fluoroscopic control over the guidewire. Puncture using a small-gauge (22-G) needle is safer in patients without biliary dilation than in patients with biliary dilation. According to the Quality Improvement Guidelines developed by American radiologists, the success rates of drainage are 86% in patients with biliary dilation and 63% in patients without biliary dilation [16].

Surgical drainage

Open drainage for decompression of the bile duct is performed as a surgical intervention. When surgical drainage in critically ill patients with bile duct stones is performed, prolonged operations should be avoided and simple procedures, such as T-tube placement without choledocholithotomy, are recommended [26]. At present, surgical drainage is extremely rare because of the widespread use of endoscopic drainage or PTCD for acute cholangitis therapy.

Endoscopic transpapillary biliary drainage

Endoscopic transpapillary biliary drainage has become the gold standard technique for acute cholangitis, regardless of a benign or malignant pathology, because it is a minimally invasive drainage method [6]. Endoscopic transpapillary biliary drainage is divided into two types: endoscopic nasobiliary drainage (ENBD) for external drainage and endoscopic biliary stenting (EBS) for internal drainage. Basically, both types of endoscopic biliary drainage can be performed in all forms of acute cholangitis. In the case of biliary drainage for acute cholangitis therapy, a precise endoscopic technique is mandatory because long and unsuccessful procedures may lead to serious complications in critically ill patients. Therefore, endoscopists who perform endoscopic transpapillary biliary drainage should acquire knowledge and skills of selective biliary cannulation techniques including the double guidewire, pancreatic guidewire, and precut techniques [27].

Q2. Which procedure should be used for endoscopic transpapillary biliary drainage? ENBD or EBS?

We suggest that either ENBD or EBS may be considered for biliary drainage according to the patient's background and preference (recommendation 1, level A).

Three RCTs and two cohort studies on the comparison between ENBD and EBS have shown no statistically significant difference in clinical settings [28–32]. In the updated TG18, the meta-analysis which included the three RCTs showed no statistically significant difference in the technical success rate (OR 2.50, 95% CI: 0.36–17.36) (Fig. 1), clinical success rate (OR 1.85, 95% CI: 0.65–5.31) (Fig. 2), adverse events rate (OR 0.98, 95% CI: 0.24–3.96) (Fig. 3), and reintervention rate (OR 0.82, 95% CI: 0.03–19.89) (Fig. 4) between ENBD and EBS. Two RCTs showed that the visual analogue scale score was higher in the ENBD group than in the EBS group. Therefore, it should be borne in mind that if patients experience discomfort from the transnasal tube placement, they are likely to remove the tube themselves, particularly elderly patients. EBS is an internal drainage technique that produces neither discomfort nor loss of electrolytes or fluid as its advantages. On the other hand, ENBD is an

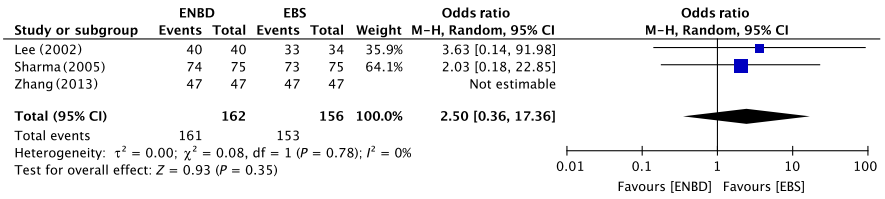

Fig. 1 Forest plot analysis of technical success rate of ENBD versus EBS

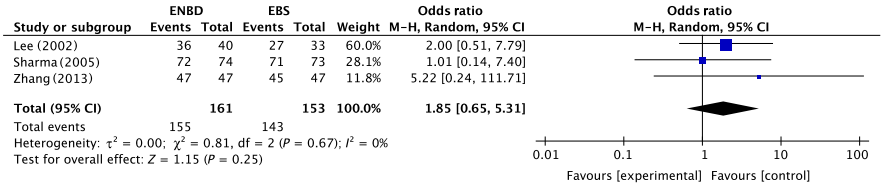

Fig. 2 Forest plot analysis of clinical success rate of ENBD versus EBS

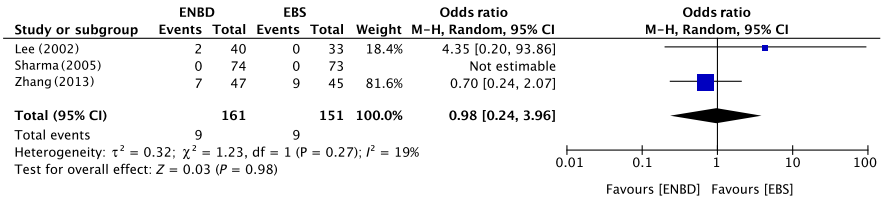

Fig. 3 Forest plot analysis of adverse events rate of ENBD versus EBS

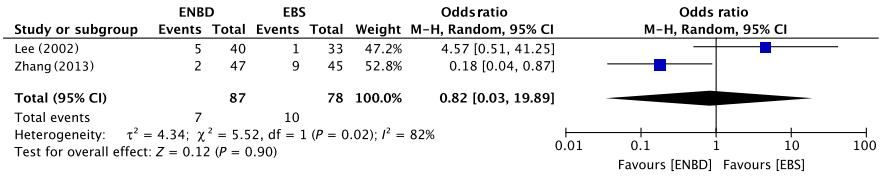

Fig. 4 Forest plot analysis of re-intervention rate of ENBD versus EBS

external drainage technique that allows monitoring or washing of the bile via the transnasal tube, particularly if the bile is very purulent. Two retrospective studies have shown that the stent occlusion from EBS was more frequent than the stent occlusion from ENBD in patients with hilar cholangiocarcinoma; thus, ENBD may be more suitable in patients with cholangitis due to hilar biliary obstruction [33, 34].

Therefore, the balance between the advantages and disadvantages of each drainage procedure is approximately equal. In the updated TG18, we suggest that either ENBD or EBS may be considered for biliary drainage by procedure according to the cause of the cholangitis, bile property, and patient's preference.

Endoscopic nasobiliary drainage

Endoscopic nasobiliary drainage procedures are described in detail in TG07 [8]. In brief, after selective biliary cannulation, a 5-Fr to 7-Fr nasobiliary tube is placed in the bile duct as an external drainage over the guidewire (Fig. 5).

Endoscopic biliary stenting

The EBS procedure is also described in detail in the previous clinical practice guidelines [8]. In brief, after selective biliary cannulation, a 7-Fr to 10-Fr plastic stent is placed in the bile duct as an internal drainage over the guidewire (Fig. 6). There are two different stent shapes, a straight type and a double pigtail type. The straight type has a single flap with a side hole (Amsterdam type) or radial flaps without a side hole (Tannenbaum type) on both sides. The double pigtail type prevents inward and outward stent migration. To our knowledge, there is currently no comparative study between the straight type and pigtail type stents. Therefore, either stent can be selected according to the endoscopist's preference.

Endoscopic ultrasonography-guided bile duct drainage

The EUS-BD technique and its devices are not yet well established. For EUS-BD, three approaches are currently used: (1) EUS-guided intrahepatic bile duct drainage by

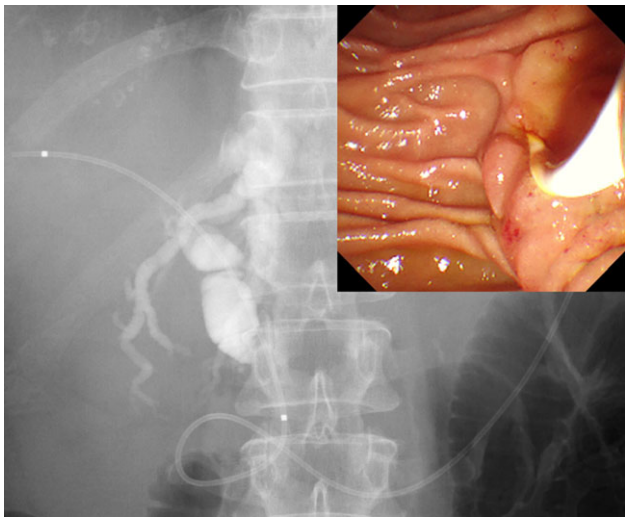

Fig. 5 Endoscopic nasobiliary drainage using a 5-Fr nasobiliary tube

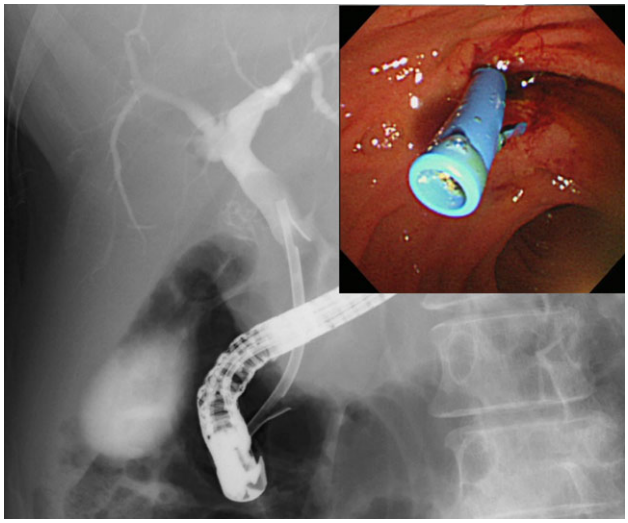

Fig. 6 Endoscopic biliary stenting using a 10-Fr plastic stent

the transgastric or transjejunal approach; (2) EUS-guided extrahepatic bile duct drainage by the transduodenal or transgastric approach; and (3) EUS-guided antegrade stenting. The choice of the drainage method and drainage route depends on the presence of a gastric outlet obstruction and the stricture site of the bile duct [35]. Several published data on EUS-guided intrahepatic bile duct drainage and extrahepatic bile duct drainage have shown a high technical success rate of 95%, with 93–100% (intention-to-treat) clinical response rates [16–18, 36–44]. It has been reported that the technical success rate of EUS-guided antegrade stenting (77%) is inferior to those of EUS-guided intrahepatic bile duct drainage and extrahepatic bile duct drainage owing to the difficulty of guidewire passage and stent delivery system insertion across the strictures; however, EUS-guided antegrade stenting is an interesting option because of the theoretical physiological bile flow in patients with inaccessible ampulla [45]. The most serious issue during and after EUS-BD is the development of adverse events such as peritonitis. In fact, previous studies have reported early adverse event rates of 10–30%, although the severities of most of these adverse events were mild or moderate [46, 47]. As the procedure is not yet established, EUS-BD should be performed by endoscopists who are skilled in both EUS and ERCP.

Theoretically, the intrahepatic bile duct and liver, including the extrahepatic bile duct do not adhere to the GI tract. Therefore, bile leakage may occur during the procedure. If the procedure fails, bile peritonitis can occur. Standard 19-G and 22-G fine needles are advanced into the bile duct under EUS visualization after confirming the absence of intervening blood vessels to prevent bleeding. After the contrast medium is injected into the bile duct for cholangiography, a 0.025-inch to 0.035-inch guidewire for the 19-G needle or a 0.018-inch to 0.021-inch guidewire for the 22-G needle is advanced into the bile duct. Needle tract dilation is performed using a standard or tapered catheter, a cautery dilator, a dilation catheter, and/or a dilating balloon as necessary. Finally, a plastic stent or a self-expandable metal stent selected as the case may be is placed into the bile duct [48]. Recently, several dedicated stents such as a newly designed 8-Fr plastic stent dedicated for EUS-hepaticogastrostomy (Fig. 7a) or a novel lumen-apposing biflanged metal stent dedicated for EUS-guided choledochoduodenostomy (Fig. 7b) have been developed to reduce the adverse event rates of EUS-BD [49–51].

Treatment of major papilla and removal of bile duct stones

Endoscopic sphincterotomy

Endoscopic sphincterotomy (EST) has two major advantages for endoscopic biliary drainage as follows: (1) EST separates the bile duct and pancreatic duct and can therefore prevent occlusion of the pancreatic duct orifice by placement of a large-bore biliary stent (>10-Fr plastic stent or a self-expandable metal stent); and (2) EST can achieve not only drainage but also removal of bile duct stones at a single session. However, the efficacy and safety of EST in patients with acute cholangitis remain controversial because of EST-induced complications such as hemorrhage [52, 53]. Details of the EST procedures are described in TG07 [8]. In brief, after selective biliary cannulation, the pull-type sphincterotomy incision is performed below the transverse fold.

The push-type sphincterotome is used for EST in patients with Billroth II gastrectomy or Roux-en-Y anastomosis. When the transverse fold is not present, the superior margin of the papilla bulge is used as a landmark to determine the length of the sphincterotome. An electrosurgical generator with a controlled cutting system is used for EST.

Q3. Is endoscopic sphincterotomy necessary in endoscopic transpapillary biliary drainage?

We suggest that the addition of EST may not be required in endoscopic transpapillary biliary drainage (recommendation 2, level A).

***Refer to Q4 if stone removal at a single session is considered.**

From the results of previous RCTs and cohort studies which included patients who had plastic stent (<7-Fr) or nasobiliary tube placement, the prevention of post-ERCP pancreatitis by the addition of EST to biliary drainage was not observed [54–58]. Therefore, it is considered that the addition of EST is not required in acute cholangitis because this induces complications (e.g. hemorrhage). Acute cholangitis is one of the risk factors of post-EST hemorrhage. In particular, the use of EST in patients with severe cholangitis complicated by coagulopathy or the administration of antithrombotic agents should be avoided.

Endoscopic papillary balloon dilation

Endoscopic papillary balloon dilation (EPBD) is usually used instead of EST for the removal of bile duct stones [59]. To date, there has been apparently no comparative study on the use of EPBD during biliary drainage to treat acute cholangitis due to bile duct stones. A previous systematic review has revealed that EPBD is less successful for stone removal, requires higher rates of mechanical lithotripsy, and carries a higher risk of pancreatitis; however, it also has statistically significant lower rates of bleeding [60]. Thus, EPBD appears to be useful for the treatment of patients with coagulopathy and acute cholangitis caused by a small stone. Theoretically, as EPBD aims to preserve the function of the sphincter of Oddi, EPBD alone without biliary drainage is contraindicated for the therapy of acute cholangitis. In addition, EPBD should be avoided in patients with biliary pancreatitis. After selective biliary cannulation, a small balloon with a diameter of up to 10 mm, depending on the diameters of the bile duct and stone, is advanced into the bile duct across the papilla. Then, the sphincter of Oddi is gradually dilated by inflation of the balloon until the balloon waist disappears. The bile duct stone is then cleared using a basket catheter and a balloon catheter.

Endoscopic papillary large balloon dilation

Endoscopic sphincterotomy or EPBD has been used as the gold standard therapy for the removal of bile duct stones. However, in patients with large bile duct stones, endoscopic mechanical lithotripsy (EML) may be required as an additional procedure [61, 62]. Since 2003, endoscopic papillary large balloon dilation (EPLBD) with or without EST has been developed to facilitate the removal of large or difficult bile duct stones, in which the size of the large balloons used ranged from 12 to 20 mm [63, 64]. Stone removal by EPLBD has been shown to have a high success rate, and this might reduce the need for EML and the procedure time without increasing the risk of severe pancreatitis or bile duct perforation [65–70]. The EPLBD procedure is as follows.

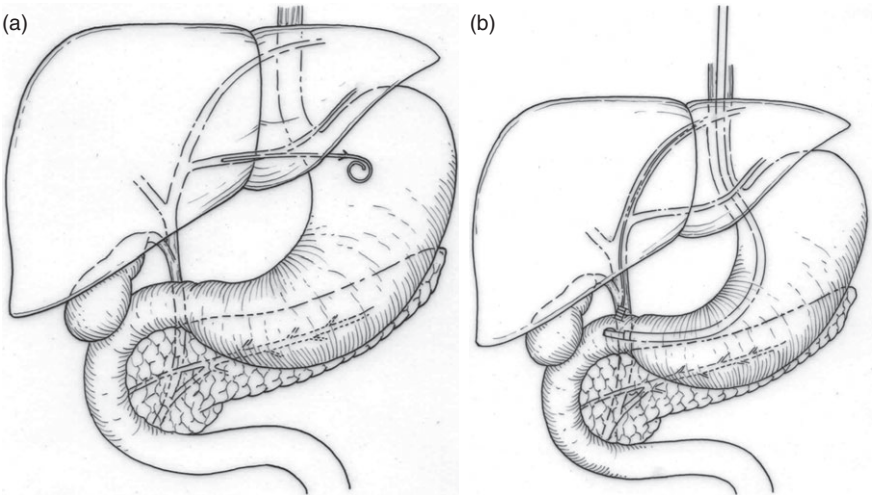

Fig. 7 Endoscopic ultrasonography-guided bile duct drainage. (**a**) Endoscopic ultrasonography-guided hepaticogastrostomy using a dedicated 8-Fr plastic stent. (**b**) Endoscopic ultrasonography-guided choledochoduodenostomy using a lumen-apposing biflanged metal stent

Large balloon dilation is performed using standard dilating balloons immediately after EST. The balloon catheter is passed over a guidewire and positioned across the papilla. The balloon is then gradually inflated with a contrast medium under endoscopic and fluoroscopic guidance until an adequate size is achieved to allow stone removal without lithotripsy regardless of the disappearance of the balloon waist. The stones are then removed from the bile duct using mechanical lithotripsy, a basket catheter, or a retrieval balloon.

Q4. Which is the preferred procedure for acute cholangitis associated with choledocholithiasis? Stone removal at a single session or at two sessions?

We suggest that bile duct stone removal following EST at a single session may be considered in patients with mild or moderate acute cholangitis (recommendation 2, level C).

Bile duct stone is the most frequent cause of cholangitis [71]. Previously, two-session treatment has been recommended for acute cholangitis with bile duct stone, which involves biliary drainage as an initial treatment and endoscopic stone removal after improvement of cholangitis [72]. This recommendation is based on previous reports that additional stone removal by EST at a single session increased the incidence of hemorrhagic complications [52, 53]. However, these reports included cases of severe cholangitis accompanied by coagulopathy. Importantly, the use of EST in patients with severe cholangitis complicated by coagulopathy should be avoided because of the risk of hemorrhagic complication. These findings may not always be applicable to mild-to-moderate cholangitis without coagulopathy. One multicenter prospective study and two retrospective studies of mild-to-moderate acute cholangitis associated with bile duct stone have shown that the cholangitis cure rate and the hemorrhagic complication rate of single-session treatment are equivalent to those of two-session treatment [73–75]. Stone removal at a single session can shorten the hospital stay, thereby reducing medical cost and the patient's burden. Recently, EPLBD with or without EST has been performed as a useful technique for the removal of a large stone or multiple stones. A previous RCT has revealed that EPLBD after EST at a single session in patients with acute cholangitis carries risks or may produce severe adverse events such as hemorrhage or perforation because of a possibly friable bile duct from inflammation and increased blood flow around the bile duct [76]. Although further evaluation including a randomized controlled study is required, the updated TG suggest that bile duct stone removal following EST at a single session may be considered in patients with mild or moderate acute cholangitis except in patients under anticoagulant therapy or with coagulopathy. However, the updated TG18 recommend bile duct stone removal at two sessions after drainage in patients with a large stone or multiple stones if EPLBD is required.

Q5. What is the best approach to patients with acute cholangitis who have coagulopathy or are receiving antithrombotic agents? Biliary stenting, EPBD or EST?

We recommend biliary stenting in patients with acute cholangitis who have coagulopathy (recommendation 1, level D).

We suggest that the approach to patients with acute cholangitis who are receiving antithrombotic agents must be selected according to the risks of bleeding and thromboembolism.

In the clinical guidelines for the handling of antithrombotic agents from the European Society of Gastrointestinal Endoscopy, American Society for Gastrointestinal Endoscopy and Japan Gastroenterological Endoscopy Society, the original treatment by EST is considered as a high-risk procedure for bleeding [77–79]. Therefore, the bleeding risk of EST may even be higher in patients with acute cholangitis who have coagulopathy or who are receiving antithrombotic agents because cholangitis has been shown to be a risk factor of bleeding after EST [80–82]. PTCD has a high risk of bleeding when performed in the liver because of the abundance of blood vessels. Thus, PTCD should be avoided in patients with acute cholangitis who have coagulopathy or are receiving antithrombotic agents [83, 84]. Therefore, it is recommended that ENBD or EBS be initially performed in patients with acute cholangitis who have coagulopathy or are receiving antithrombotic agents as these are low-risk procedures for bleeding. After improvements of the coagulopathy and cholangitis, bile duct stone treatment should be performed and antithrombotic agents should be discontinued.

On the other hand, the easy discontinuation of antithrombotic agents to avoid the risk of bleeding presents the risk of causing thromboembolism, which is an even more serious rebound phenomenon than bleeding [85]. From the results of cohort and case-control studies indicating that the bleeding risk of EST are not significantly different between patients with and without the administration of aspirin (an antiplatelet agent), the clinical guidelines for handling antithrombotic agents suggests that EST without discontinuing aspirin can be performed if patients have a high risk of thromboembolism [76–78, 80, 82, 86, 87]. However, as bleeding increases in high-risk procedures when a thienopyridine derivative (an antiplatelet agent) is administered, the

clinical guidelines recommend its discontinuation 5–7 days before performing high-risk procedures for bleeding [88]. If patients have a high risk of developing thromboembolism, it is recommended that aspirin or cilostazol be substituted for the thienopyridine derivative in consultation with the prescribing doctor. The administration of anticoagulant agents is one of the risk factors of bleeding after EST, thus heparin substitution is recommended [89]. Regarding the treatment of the major papilla for the removal of bile duct stones, EPBD is an alternative technique. A meta-analysis has shown that the rate of bleeding as an adverse event of EPBD was significantly less than that of EST, thus EPBD is classified as a low-risk procedure for bleeding [90]. In patients with potential coagulopathy such as those with chronic liver cirrhosis or those with difficulty in discontinuing antithrombotic agents, EPBD can be a better technique for the treatment of the major papilla. Therefore, the timing or the method of treatment either by EST or EPBD should be decided by evaluating the bleeding and thromboembolism risks of individual cases.

Treatment of cholangitis in patients with surgically altered anatomy

Q6. What is the best approach to patients with acute cholangitis and surgically altered anatomy?

We recommend balloon enteroscopy-assisted ERCP (BE-ERCP) for patients with acute cholangitis and surgically altered anatomy when skilled pancreaticobiliary endoscopists are available in the institution (recommendation 2, level C).

An RCT of patients with failed ERCP showed an adverse event rate of 25%–31% for PTCD and 8%–15% for EUS-BD. On the other hand, a systematic review of BE-ERCP in patients with surgically altered anatomy showed an adverse event rate of 3.4%. Therefore, BE-ERCP is clearly a less invasive and safer procedure than PTCD or EUS-BD [91–108]. Furthermore, as BE-ERCP enables treatment of the causes of cholangitis such as bile duct stone or anastomotic stricture at a single session, it appears that BE-ERCP is useful if the procedure is technically successful. However, BE-ERCP is technically challenging, time-consuming, and requires specialized equipment. Therefore, the updated TG18 recommend BE-ERCP for patients with acute cholangitis and surgically altered anatomy if the procedure is performed by experienced endoscopists who are skilled in both balloon enteroscopy and ERCP. If the endoscopist is not proficient at this technique or if BE-ERCP is difficult even though it is performed by an experienced endoscopist, PTCD and EUS-BD may be considered as alternative methods, or referral to a highly specialized institution may be considered.

Balloon enteroscopy-assisted bile duct drainage

Endoscopic retrograde cholangiopancreatography in patients with surgically altered anatomy can be challenging. Roux-en-Y anastomosis has been thought to preclude endoscopic access for ERCP because of the extensive lengths of the afferent limbs that must be traversed to reach the major papilla or hepaticojejunostomy site. Recently, single-balloon enteroscopy (SBE) and double-balloon enteroscopy (DBE) have enabled successful ERCP in patients with surgically altered anatomy. Several investigators have reported various success rates (40–95%) with adverse events rates below 5% (Table 2). However, since balloon enteroscopy may be unsuccessful and time-consuming, its indication should be cautiously decided. Although the ideal operators are those who are skilled in both balloon enteroscopy and ERCP, in some institutions, GI endoscopists advance an endoscope to the papilla or anastomotic site and then pancreaticobiliary endoscopists perform ERCP. Therefore, if the operators are not good at balloon enteroscopy, therapy using this technique should be avoided. The SBE and DBE systems consist of a video enteroscope, a sliding tube with a balloon, and a balloon controller. The DBE system has a balloon at the endoscope tip in addition to the overtube balloon. When a long-type balloon enteroscope with an effective length of 200 cm and an inner channel diameter of 2.8 mm was used, long wire accessories and long devices were required. To overcome these limitations, a short-type balloon enteroscope with an effective length of 152 cm and an inner channel diameter of 3.2 mm has recently been developed [94, 98]. When a short-type balloon enteroscope was used, conventional ERCP instruments could be used.

Endoscopes are usually advanced to the papilla or anastomotic site using pushing and pulling techniques. An injection catheter and a tapered catheter are used for initial cannulation. In patients with Roux-en-Y reconstruction, selective biliary cannulation is occasionally challenging because of the difficulty in obtaining a favorable view of the papilla. In such cases, a technique in which the endoscope is advanced at the inferior duodenal angle and moved in the retroflex position is useful for obtaining a better view of the papilla [106]. When selective biliary cannulation is not possible, a needle knife is used for precutting. After a successful biliary cannulation, guidewires are inserted into the bile duct. Finally, a nasobiliary

Table 2 Outcomes of balloon enteroscopy-assisted ERCP

Author	Year	Enteroscopy	*n*	Scope insertion success (%)	Technical success (%)	Adverse events (%)
Aabakken et al. [91]	2007	DBE	13	94	85	0
Emmett et al. [92]	2007	DBE	14	85	80	0
Maaser et al. [93]	2008	DBE	11	82	64	0
Shimatani et al. [94]	2009	DBE	103	98	95	5
Itoi et al. [95]	2010	SBE	13	92	77	0
Wang et al. [96]	2010	SBE	16	81	75	13
Saleem et al. [97]	2010	SBE	56	70	66	0
Itoi et al. [98]	2011	DBE	9	100	100	11
Siddiqui et al. [99]	2013	DBE	79	90	81	5
Yamauchi et al. [100]	2013	SBE	21	91	87	13
Obana et al. [101]	2013	SBE	19	79	53	5
Azeem et al. [102]	2013	SBE	58	91	76	0
Shah et al. [103]	2013	SBE/DBE	129	71	63	12
Trindade et al. [104]	2015	SBE	56	88	71	5
Kawamura et al. [105]	2015	SBE	27	89	70	0
Ishii et al. [106]	2016	SBE/DBE	123	94	88	7
Khashab et al. [107]	2016	SBE/DBE	49	78	65	4

DBE double-balloon enteroscopy, *SBE* single-balloon enteroscopy

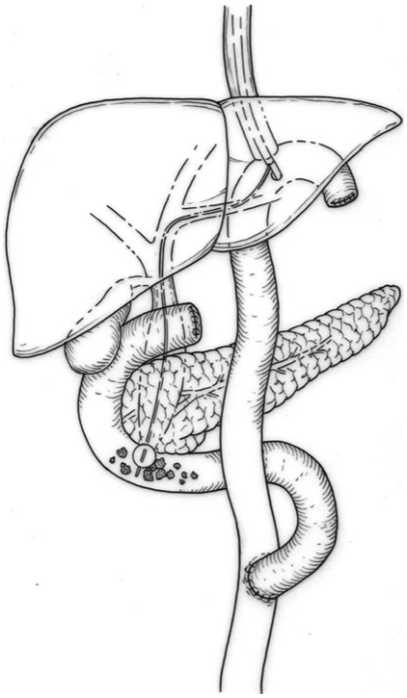

Fig. 8 Endoscopic ultrasonography-guided antegrade approach to a patient with Roux-en-Y anastomosis

drainage catheter, a plastic stent, or a self-expandable metallic stent is placed into the bile duct for biliary decompression. In cases requiring EST, the sphincterotome and needle knife are advanced into the bile duct over or alongside the guidewire. In cases of EPBD or EPLBD, a balloon dilation catheter is used for the papilla or hepaticojejunostomy site. A basket catheter, a retrieval balloon catheter, and a mechanical lithotripter are used for stone removal.

Endoscopic ultrasonography-guided bile duct drainage

Although BE-ERCP allows the enteroscope to advance to the major papilla or anastomotic site, the success rate of scope intubation to the targeted site is not always 100% because of the very long afferent loop (gastric bypass) and severe adhesion of the intestines even in high-volume centers. Furthermore, the final procedural success rate, as evaluated by stenting and stone removal among others, is not always 100% for several reasons (i.e. difficult cannulation or large stones). In such a case, PTCD has been traditionally conducted. Recently, several studies have revealed that EUS-BD can be a second-line therapy in failed BE-ERCP as an alternative to PTCD [109, 110] (Fig. 8).

Acknowledgments We would like to express our deep gratitude to the Japanese Society of Hepato-Biliary-Pancreatic Surgery, the Japanese Society of Abdominal Emergency Medicine, the Japanese Society of Surgical Infection, and the Japan Biliary Association, for their substantial support and guidance in the preparation of this article. We would also like to express our deep gratitude to the Japanese Society of Hepato-Biliary-Pancreatic Surgery for the Article Processing Managing Office of the Tokyo Guidelines 18 for

preparing this publication. We appreciate all secretariats of the Japanese Society of Hepato-Biliary-Pancreatic Surgery for their technical support.

Conflict of interest Anthony Yuen Bun Teoh has received consultant fees from Boston Scientific Corporation, USA, Cook Medical, USA, and Taewoong Medical, Korea.

Appendix: author's affiliations

Shuntaro Mukai and Takao Itoi, Department of Gastroenterology and Hepatology, Tokyo Medical University Hospital, Tokyo, Japan; Todd H. Baron, Division of Gastroenterology and Hepatology, University of North Carolina at Chapel Hill, Chapel Hill, NC, USA; Tadahiro Takada, Fumihiko Miura and Keita Wada, Department of Surgery, Teikyo University School of Medicine, Tokyo, Japan; Steven M. Strasberg, Section of HPB Surgery, Washington University in St. Louis, St. Louis, MO, USA; Henry A. Pitt, Lewis Katz School of Medicine at Temple University, Philadelphia, PA, USA; Tomohiko Ukai, Department of Family Medicine, Mie Prefectural Ichishi Hospital, Mie, Japan; Satoru Shikata, Director, Mie Prefectural Ichishi Hospital, Mie, Japan; Anthony Yuen Bun Teoh, Department of Surgery, The Chinese University of Hong Kong, Shatin, Hong Kong; Myung-Hwan Kim, Department of Gastroenterology, University of Ulsan College of Medicine, Seoul, Korea; Seiki Kiriyama, Department of Gastroenterology, Ogaki Municipal Hospital, Gifu, Japan; Yasuhisa Mori, Department of Surgery and Oncology, Graduate School of Medical Sciences, Kyushu University, Fukuoka, Japan; Miin-Fu Chen, Division of General Surgery, Linkou Chang Gung Memorial Hospital, Taoyuan, Taiwan; Wan Yee Lau, Faculty of Medicine, The Chinese University of Hong Kong, Shatin, Hong Kong; Avinash Nivritti Supe, Department of Surgical Gastroenterology, Seth G S Medical College and K E M Hospital, Mumbai, India; Mariano Eduardo Giménez, Chair of General Surgery and Minimal Invasive Surgery "Taquini", University of Buenos Aires, Argentina DAIC IM Foundation, Buenos Aires, Argentina; Masahiro Yoshida, Department of Hemodialysis and Surgery, Ichikawa Hospital, International University of Health and Welfare, Chiba, Department of EBM and Guidelines, Japan Council for Quality Health Care, Tokyo, Japan; Toshihiko Mayumi, Department of Emergency Medicine, School of Medicine, University of Occupational and Environmental Health, Fukuoka, Japan; Koichi Hirata, Department of Surgery, JR Sapporo Hospital, Hokkaido, Japan; Yoshinobu Sumiyama, Director, Toho University, Tokyo, Japan; Kazuo Inui, Department of Gastroenterology, Second Teaching Hospital, Fujita Health University, Aichi, Japan; Masakazu Yamamoto, Department of Surgery, Institute of Gastroenterology, Tokyo Women's Medical University, Tokyo, Japan.

References

1. Kimura Y, Takada T, Strasberg SM, Pitt HA, Gouma DJ, Garden OJ, et al. TG13 current terminology, etiology, and epidemiology of acute cholangitis and cholecystitis. J Hepatobiliary Pancreat Sci. 2013;20:8–23.
2. Kiriyama S, Takada T, Hwang TL, Akazawa K, Miura F, Gomi H, et al. Clinical application and verification of the TG13 diagnostic and severity grading criteria for acute cholangitis: an international multicenter observational study. J Hepatobiliary Pancreat Sci. 2017;24:329–37.
3. Gomi H, Takada T, Hwang TL, Akazawa K, Mori R, Endo I, et al. Updated comprehensive epidemiology, microbiology, and outcomes among patients with acute cholangitis. J Hepatobiliary Pancreat Sci. 2017;24:310–8.
4. Kiriyama S, Takada T, Strasberg SM, Solomkin JS, Mayumi T, Pitt HA, et al. TG13 guidelines for diagnosis and severity grading of acute cholangitis (with videos). J Hepatobiliary Pancreat Sci. 2013;20:24–34.
5. Takada T, Hanyu F, Kobayashi S, Uchida Y. Percutaneous transhepatic cholangial drainage: direct approach under fluoroscopic control. J Surg Oncol. 1976;8:83–97.
6. Nagai N, Toki F, Oi I, Suzuki H, Kozu T. Continuous endoscopic pancreatocholedochal catheterization. Gastrointest Endosc. 1976;23:78–81.
7. Sohendra N, Reynders-Frederix V. Palliative bile duct drainage. A new endoscopic method of introducing a transpapillary drain. Endoscopy. 1980;12:8–11.
8. Tsuyuguchi T, Takada T, Kawarada Y, Nimura Y, Wada K, Nagino M, et al. Techniques of biliary drainage for acute cholangitis: Tokyo Guidelines. J Hepatobiliary Pancreat Surg. 2007;14:35–45.
9. Itoi T, Tsuyuguchi T, Takada T, Strasberg SM, Pitt HA, Kim MH, et al. TG13 indications and techniques for biliary drainage in acute cholangitis (with videos). J Hepatobiliary Pancreat Sci. 2013;20:71–80.
10. Gomi H, Solomkin JS, Takada T, Strasberg SM, Pitt HA, Yoshida M, et al. TG13 antimicrobial therapy for acute cholangitis and cholecystitis. J Hepatobiliary Pancreat Sci. 2013;20:60–70.
11. Lai EC, Mok FP, Tan ES, Lo CM, Fan ST, You KT, et al. Endoscopic biliary drainage for severe acute cholangitis. N Engl J Med. 1992;24:1582–6.
12. Leung JW, Chung SC, Sung JJ, Banez VP, Li AK. Urgent endoscopic drainage for acute suppurative cholangitis. Lancet. 1989;10:1307–9.
13. Boender J, Nix GA, de Ridder MA, Dees J, Schutte HE, van Buuren HF, et al. Endoscopic sphincterotomy and biliary drainage in patients with cholangitis due to common bile duct stones. Am J Gastroenterol. 1995;90:233–8.
14. Lau JY, Chung SC, Leung JW, Ling TK, Yung MY, Li AK. Endoscopic drainage aborts endotoxaemia in acute cholangitis. Br J Surg. 1996;83:181–4.
15. Umeda J, Itoi T. Current status of preoperative biliary drainage. J Gastroenterol. 2015;50:940–54.
16. Saad WE, Wallace MJ, Wojak JC, Kundu S, Cardella JF. Quality improvement guidelines for percutaneous transhepatic cholangiography, biliary drainage, and percutaneous cholecystostomy. J Vasc Interv Radiol. 2010;21:789–95.
17. Giovannini M, Moutardier V, Pesenti C, Bories E, Lelong B, Delpero JR. Endoscopic ultrasound-guided bilioduodenal

anastomosis: a new technique for biliary drainage. Endoscopy. 2001;33:898–900.
18. Itoi T, Itokawa F, Sofuni A, Kurihara T, Tsuchiya T, Ishii K, et al. Endoscopic ultrasound-guided choledochoduodenostomy in patients with failed endoscopic retrograde cholangiopancreatography. World J Gastroenterol. 2008;14:6078–82.
19. Sharaiha RZ, Khan MA, Kamal F, Tyberg A, Tombazzi CR, Ali B, et al. Efficacy and safety of EUS-guided biliary drainage in comparison with percutaneous biliary drainage when ERCP fails: a systematic review and meta-analysis. Gastrointest Endosc. 2017;85:904–14.
20. Artifon EL, Aparicio D, Paione JB, Lo SK, Bordini A, Rabello C, et al. Biliary drainage in patients with unresectable, malignant obstruction where ERCP fails: endoscopic ultrasonography-guided choledochoduodenostomy versus percutaneous drainage. J Clin Gastroenterol. 2012;46:768–74.
21. Lee TH, Choi JH, Park do H, Song TJ, Kim DU, Palk WH, et al. Similar efficacies of endoscopic ultrasound-guided transmural and percutaneous drainage for malignant distal biliary obstruction. Clin Gastroenterol Hepatol. 2016;14:1011–9.
22. Bapaye A, Dubale N, Aher A. Comparison of endosonography-guided vs. percutaneous biliary stenting when papilla is inaccessible for ERCP. United European. Gastroenterol J. 2013;1:285–93.
23. Khashab MA, Valeshabad AK, Afghani E, Singh VK, Kumbhari V, Messallam A, et al. A comparative evaluation of EUS-guided biliary drainage and percutaneous drainage in patients with distal malignant biliary obstruction and failed ERCP. Dig Dis Sci. 2015;60:557–65.
24. Sharaiha RZ, Kumta NA, Desai AP, DeFilippis EM, Gabr M, Sarkisian AM, et al. Endoscopic ultrasound-guided biliary drainage versus percutaneous transhepatic biliary drainage: predictors of successful outcome in patients who fail endoscopic retrograde cholangiopancreatography. Surg Endosc. 2016;30:5500–5.
25. Vila JJ, Pérez-Miranda M, Vazquez-Sequeiros E, Abadia MA, Pérez-Millán A, González-Huix F, et al. Initial experience with EUS-guided cholangiopancreatography for biliary and pancreatic duct drainage: a Spanish national survey. Gastrointest Endosc. 2012;76:1133–41.
26. Saltzstein EC, Peacock JB, Mercer LC. Early operation for acute biliary tract stone disease. Surgery. 1983;94:704–8.
27. Mukai S, Itoi T. Selective biliary cannulation techniques for endoscopic retrograde cholangiopancreatography procedures and prevention of post-endoscopic retrograde cholangiopancreatography pancreatitis. Expert Rev Gastroenterol Hepatol. 2016;10:709–22.
28. Lee DW, Chan AC, Lam YH, Ng EK, Lau JY, Law BK, et al. Biliary decompression by nasobiliary catheter or biliary stent in acute suppurative cholangitis: a prospective randomized trial. Gastrointest Endosc. 2002;56:361–5.
29. Sharma BC, Kumar R, Agarwal N, Sarin SK. Endoscopic biliary drainage by nasobiliary drain or by stent placement in patients with acute cholangitis. Endoscopy. 2005;37:439–43.
30. Zhang RL, Cheng L, Cai XB, Zhao H, Zhu FC, Wan XJ. Comparison of the safety and effectiveness of endoscopic biliary decompression by nasobiliary catheter and plastic stent placement in acute obstructive cholangitis. Swiss Med Wkly. 2013;143:w13823.
31. Park SY, Park CH, Cho SB, Yoon KW, Lee WS, Kim HS, et al. The safety and effectiveness of endoscopic biliary decompression by plastic stent placement in acute suppurative cholangitis compared with nasobiliary drainage. Gastrointest Endosc. 2008;68:1076–80.
32. Otani K, Ueki T, Matsumura K, Maruo T, Minoda R, Otsuka Y, et al. Comparison between endoscopic biliary stenting and nasobiliary drainage in patients with acute cholangitis due to choledocholithiasis: is endoscopic biliary stenting useful? Hepatogastroenterology. 2015;62:558–63.
33. Kawakami H, Kuwatani M, Onodera M, Haba S, Eto K, Ehira N, et al. Endoscopic nasobiliary drainage is the most suitable preoperative biliary drainage method in the management of patients with hilar cholangiocarcinoma. J Gastroenterol. 2011;46:242–8.
34. Kawakubo K, Kawakami H, Kuwatani M, Haba S, Kudo T, Taya YA, et al. Lower incidence of complications in endoscopic nasobiliary drainage for hilar cholangiocarcinoma. World J Gastrointest Endosc. 2016;10:385–90.
35. Mukai S, Itoi T. How should we use endoscopic ultrasonography-guided biliary drainage techniques separately? Endosc Ultrasound. 2016;5:65–8.
36. Burmester E, Niehaus J, Leineweber T, Huetteroth T. EUS-cholangio-drainage of the bile duct: report of 4 cases. Gastrointest Endosc. 2003;57:246–51.
37. Giovannini M, Dotti M, Bories E, Moutardier V, Pesenti C, Danisi C, et al. Hepaticogastrostomy by echo-endoscopy as a palliative treatment in a patient with metastatic biliary obstruction. Endoscopy. 2003;35:1076–8.
38. Kahaleh M, Hernandez AJ, Tokar J, Adams RB, Shami VM, Yeaton P. Interventional EUS-guided cholangiography: evaluation of a technique in evolution. Gastrointest Endosc. 2006;64:52–9.
39. Artifon EL, Chaves DM, Ishioka S, Souza TF, Matuguma SE, Sakai P. Echoguided hepatico-gastrostomy: a case report. Clinics (Sao Paulo). 2007;62:799–802.
40. Bories E, Pesenti C, Caillol F, Lopes C, Giovannini M. Transgastric endoscopic ultrasonography-guided biliary drainage: results of a pilot study. Endoscopy. 2007;39:287–91.
41. Park DH, Koo JE, Oh J, Lee YH, Moon SH, Lee SS, et al. EUS-guided biliary drainage with one-step placement of a fully covered metal stent for malignant biliary obstruction: a prospective feasibility study. Am J Gastroenterol. 2009;104:2168–74.
42. Horaguchi J, Fujita N, Noda Y, Kobayashi G, Ito K, Obana T, et al. Endosonography-guided biliary drainage in cases with difficult transpapillary endoscopic biliary drainage. Dig Endosc. 2009;21:239–44.
43. Yamao K, Bhatia V, Mizuno N, Sawaki A, Ishikawa H, Tajika M, et al. EUS-guided choledochoduodenostomy for palliative biliary drainage in patients with malignant biliary obstruction: results of long-term follow-up. Endoscopy. 2008;40:340–2.
44. Binmoeller KF, Nguyen-Tang T. Endoscopic ultrasound-guided anterograde cholangiopancreatography. J Hepatobiliary Pancreat Sci. 2011;18:319–31.
45. Iwashita T, Doi S, Yasuda I. Endoscopic ultrasound-guided biliary drainage: a review. Clin J Gastroenterol. 2014;7:94–102.
46. Park DH, Jang JW, Lee SS, Seo DW, Lee SK, Kim MH. EUS-guided biliary drainage with transluminal stenting after failed ERCP: predictors of adverse events and long-term results. Gastrointest Endosc. 2011;74:1276–84.
47. Khashab MA, Levy MJ, Itoi T, Artifon EL. EUS-guided biliary drainage. Gastrointest Endosc. 2015;82:993–1001.
48. Itoi T, Isayama H, Sofuni A, Itokawa F, Kurihara T, Tsuchiya T, et al. Stent selection and tips of placement technique of EUS-guided biliary drainage: trans-duodenal and trans-gastric stenting. J Hepatobiliary Pancreat Sci. 2011;18:664–7.
49. Glessing BR, Mallery S, Freeman ML, Newcomb MD, Arain MA. EUS-guided choledochoduodenostomy with a lumen-apposing metal stent before duodenal stent placement for malignant biliary and duodenal obstruction. Gastrointest Endosc. 2015;81:1019–20.

50. Mukai S, Itoi T, Tsuchiya T, Tanaka R, Tonozuka R. EUS-guided intrahepatic bile duct stone extraction via choledochoduodenostomy created by a lumen-apposing metal stent. Gastrointest Endosc. 2016;83:832–3.
51. Park DH, Lee TH, Paik WH, Choi JH, Song TJ, Lee SS, et al. Feasibility and safety of a novel dedicated device for one-step EUS-guided biliary drainage: a randomized trial. J Gastroenterol Hepatol. 2015;30:1461–6.
52. Sugiyama M, Atomi Y. The benefits of endoscopic nasobiliary drainage without sphincterotomy for acute cholangitis. Am J Gastroenterol. 1998;93:2065–8.
53. Hui CK, Lai KC, Yuen MF, Ng M, Chan CK, Hu W, et al. Does the addition of endoscopic sphincterotomy to stent insertion improve drainage of the bile duct in acute suppurative cholangitis? Gastrointest Endosc. 2003;58:500–4.
54. Giorgio PD, Luca LD. Comparison of treatment outcomes between biliary plastic stent placements with and without endoscopic sphincterotomy for inoperable malignant common bile duct obstruction. World J Gastroenterol. 2004;10:1212–4.
55. Zhang RL, Zhao H, Dai YM, Zhu F, Li L, Li BW, et al. Endoscopic nasobiliary drainage with sphincterotomy in acute obstructive cholangitis: a prospective randomized controlled trial. J Dig Dis. 2014;15:78–84.
56. Margulies C, Siqueira ES, Silverman WB, Lin XS, Martin JA, Rabinovitz M, et al. The effect of endoscopic sphincterotomy on acute and chronic complications of biliary endoprostheses. Gastrointest Endosc. 1999;49:716–9.
57. Wilcox CM, Kim H, Ramesh J, Trevino J, Varadarajulu S. Biliary sphincterotomy is not required for bile duct stent placement. Dig Endosc. 2014;26:87–92.
58. Sofi AA, Nawras A, Alaradi OH, Alastal Y, Khan MA. Does endoscopic sphincterotomy reduce the risk of post-endoscopic retrograde cholangiopancreatography pancreatitis after biliary stenting? A systematic review and meta-analysis. Dig Endosc. 2016;28:394–404.
59. Komatsu Y, Kawabe T, Toda N, Ohashi M, Isayama M, Tateishi K, et al. Endoscopic papillary balloon dilation for the management of common bile duct stones: experience of 226 cases. Endoscopy. 1998;30:12–7.
60. Weinberg BM, Shindy W, Lo S. Endoscopic balloon sphincter dilation (sphincteroplasty) versus sphincterotomy for common bile duct stones. Cochrane Database Syst Rev. 2006; CD004890.
61. Higuchi T, Kon Y. Endoscopic mechanical lithotripsy for the treatment of common bile duct stone. Experience with the improved double sheath basket catheter. Endoscopy. 1987;19:216–7.
62. Moriai T, Hasegawa T, Fuzita M, Kimura A, Tani T, Makino I. Successful removal of massive intragastric gallstones by endoscopic electrohydraulic lithotripsy and mechanical lithotripsy. Am J Gastroenterol. 1991;86:627–9.
63. Ersoz G, Tekesin O, Ozutemiz AO, Gunsar F. Biliary sphincterotomy plus dilation with a large balloon for bile duct stones that are difficult to extract. Gastrointest Endosc. 2003;57: 156–9.
64. Jeong S, Ki SH, Lee DH, Lee JI, Lee JW, Kwon KS, et al. Endoscopic large-balloon sphincteroplasty without preceding sphincterotomy for the removal of large bile duct stones: a preliminary study. Gastrointest Endosc. 2009;70:915–22.
65. Minami A, Hirose S, Nomoto T, Hayakawa S. Small sphincterotomy combined with papillary dilation with large balloon permits retrieval of large stones without mechanical lithotripsy. World J Gastroenterol. 2007;13:2179–82.
66. Heo JH, Kang DH, Jung HJ, Kwon DS, An JK, Kim BS, et al. Endoscopic sphincterotomy plus large-balloon dilation versus endoscopic sphincterotomy for removal of bile-duct stones. Gastrointest Endosc. 2007;66:720–6.
67. Itoi T, Itokawa F, Sofuni A, Kurihara T, Tsuchiya T, Ishii K, et al. Endoscopic sphincterotomy combined with large balloon dilation can reduce the procedure time and fluoroscopy time for of large bile duct stones. Am J Gastroenterol. 2009;104:560–5.
68. Draganov PV, Evans W, Fazel A, Forsmark CE. Large size balloon dilation of the ampulla after biliary sphincterotomy can facilitate endoscopic extraction of difficult bile duct stones. J Clin Gastroenterol. 2009;43:782–6.
69. Teoh AY, Cheung FK, Hu B, Pan YM, Lai LH, Chiu PW, et al. Randomized trial of endoscopic sphincterotomy with balloon dilation versus endoscopic sphincterotomy alone for removal of bile duct stones. Gastroenterology. 2013;144:341–5.
70. Tonozuka R, Itoi T, Sofuni A, Itokawa F, Kurihara T, Tsuchiya T, et al. Efficacy and safety of endoscopic papillary large balloon dilation for large bile duct stones in elderly patients. Dig Dis Sci. 2014;59:2299–307.
71. Gigot JF, Leese T, Dereme T, Coutinho J, Castaing D, Bismuth H. Acute cholangitis. Multivariate analysis of risk factors. Ann Surg. 1989;209:435–8.
72. Miura F, Takada T, Strasberg SM, Solomkin JS, Pitt HA, Gouma DJ, et al. TG13 flowchart for the management of acute cholangitis and cholecystitis. J Hepatobiliary Pancreat Sci. 2013;20:47–54.
73. Jang SE, Park SW, Lee BS, Shin CM, Lee SH, Kim JW, et al. Management for CBD stone-related mild to moderate acute cholangitis: urgent versus elective ERCP. Dig Dis Sci. 2013;58:2082–7.
74. Eto K, Kawakami H, Haba S, Yamato H, Okuda T, Yane K, et al. Single-stage endoscopic treatment for mild to moderate acute cholangitis associated with choledocholithiasis: a multicenter, non-randomized, open-label and exploratory clinical trial. J Hepatobiliary Pancreat Sci. 2015;22:825–30.
75. Ito T, Sai JK, Okubo H, Saito H, Ishii S, Kanazawa R, et al. Safety of immediate endoscopic sphincterotomy in acute suppurative cholangitis caused by choledocholithiasis. World J Gastrointest Endosc. 2016;8:180–5.
76. Lee JC, Moon JH, Choi HJ, Kim DC, Choi MH, Lee TH, et al. Delayed endoscopic papillary large balloon dilation after sphincterotomy for removing large bile duct stones in patients with acute cholangitis. Dig Dis Sci. 2014;59:1302–6.
77. Fujimoto K, Fujishiro M, Kato M, Higuchi K, Iwakiri R, Sakamoto C, et al. Guidelines for gastroenterological endoscopy in patients undergoing antithrombotic treatment. Dig Endosc. 2014;26:1–14.
78. ASGE Standards of Practice Committee; Acosta RD, Abraham NS, Chandrasekhara V, Chathadi KV, Early DS, et al. The management of antithrombotic agents for patients undergoing GI endoscopy. Gastrointest Endosc. 2016;83:3–16.
79. Veitch AM, Vanbiervliet G, Gershlick AH, Boustiere C, Baglin TP, Smith LA, et al. Endoscopy in patients on antiplatelet or anticoagulant therapy, including direct oral anticoagulants: British Society of Gastroenterology (BSG) and European Society of Gastrointestinal Endoscopy (ESGE) guidelines. Gut. 2016;65:374–89.
80. Kim KO, Kim TN, Kim SB, Lee JY. Characteristics of delayed hemorrhage after endoscopic sphincterotomy. J Gastroenterol Hepatol. 2010;25:532–8.
81. Freeman ML, Nelson DB, Sherman S, Haber GB, Herman ME, Dorsher PJ, et al. Complications of endoscopic biliary sphincterotomy. N Engl J Med. 1996;335:909–18.
82. Hamada T, Yasunaga H, Nakai Y, Isayama H, Matsui H, Horiguchi H, et al. Bleeding after endoscopic sphincterotomy or papillary balloon dilation among users of antithrombotic agents. Endoscopy. 2015;47:997–1004.
83. Patel IJ, Davidson JC, Nikolic B, Salazar GM, Schwartzberg MS, Walker TG, et al. Consensus guidelines for periprocedural

management of coagulation status and hemostasis risk in percutaneous image-guided interventions. J Vasc Interv Radiol. 2012;23:727–36.
84. Hamada T, Yasunaga H, Nakai Y, Isayama H, Horiguchi H, Fushimi K, et al. Severe bleeding after percutaneous transhepatic drainage of the biliary system: effect of antithrombotic agents-analysis of 34606 cases from a Japanese nationwide administrative database. Radiology. 2015;274:605–13.
85. Palareti G, Legnani C, Guazzaloca G, Frascaro M, Grauso F, De Rosa F, et al. Activation of blood coagulation after abrupt of stepwise withdrawal of oral anticoagulants-a prospective study. Thromb Haemost. 1994;72:222–66.
86. Hussain N, Alsulaiman R, Burtin P, Toubouti Y, Rahme E, Boivin JF, et al. The safety of endoscopic sphincterotomy in patients receiving antiplatelet agents: a case-control study. Aliment Pharmacol Ther. 2007;25:579–84.
87. Lee MG, Kim J, Lee SH, Lee BS, Lee SJ, Lee YS, et al. Effect of sustained use of platelet aggregation inhibitors on post-endoscopic sphincterotomy bleeding. Dig Endosc. 2014; 26:737–44.
88. Singh M, Mehta N, Murthy UK, Kaul V, Arif A, Newman N. Postpolypectomy bleeding in patients undergoing colonoscopy on uninterrupted clopidogrel therapy. Gastrointest Endosc. 2010;71:998–1005.
89. Rabenstein T, Schneider HT, Bulling D, Nicklas M, Katalinic A, Hahn EG, et al. Analysis of the risk factors associated with endoscopic sphincterotomy techniques: preliminary results of a prospective study, with emphasis on the reduced risk of acute pancreatitis with low-dose anticoagulation treatment. Endoscopy. 2000;32:10–9.
90. Baron TH, Harewood GC. Endoscopic balloon dilation of the biliary sphincter compared to endoscopic biliary sphincterotomy for removal of common bile duct stones during ERCP: a meta-analysis of randomized, controlled trials. Am J Gastroenterol. 2004;99:1455–60.
91. Aabakken L, Bretthauer M, Line PD. Double-balloon enteroscopy for endoscopic retrograde cholangiography in patients with a Roux-en-Y anastomosis. Endoscopy. 2007;39:1068–71.
92. Emmett DS, Mallat DB. Double-balloon ERCP in patients who have undergone Roux-en-Y surgery: a case series. Gastrointest Endosc. 2007;66:1038–41.
93. Maaser C, Lenze F, Bokemeyer M, Ullerich H, Domagk D, Bruewer M, et al. Double balloon enteroscopy: a useful tool for diagnostic and therapeutic procedures in the pancreaticobiliary system. Am J Gastroenterol. 2008;103:894–900.
94. Shimatani M, Matsushita M, Takaoka M, Koyabu M, Ikeura T, Kato K, et al. Effective "short" double-balloon enteroscope for diagnostic and therapeutic ERCP in patients with altered gastrointestinal anatomy: a large case series. Endoscopy. 2009; 41:849–54.
95. Itoi T, Ishii K, Sofuni A, Itokawa F, Tsuchiya T, Kurihara T, et al. Single-balloon enteroscopy-assisted ERCP in patients with Billroth II gastrectomy or Roux-en-Y anastomosis (with video). Am J Gastroenterol. 2010;105:93–9.
96. Wang AY, Sauer BG, Behm BW, Ramanath M, Cox DG, Ellen K, et al. Single-balloon enteroscopy effectively enables diagnostic and therapeutic retrograde cholangiography in patients with surgically altered anatomy. Gastrointest Endosc. 2010;71:641–9.
97. Saleem A, Baron TH, Gostout CJ, Topazian MD, Levy MJ, Petersen BT, et al. Endoscopic retrograde cholangiopancreatography using a single-balloon enteroscope in patients with altered Roux-en-Y anatomy. Endoscopy. 2010;42:656–60.
98. Itoi T, Ishii K, Sofuni A, Itokawa F, Tsuchiya T, Kurihara T, et al. Long- and short-type double-balloon enteroscopy-assisted therapeutic ERCP for intact papilla in patients with a Roux-en-Y anastomosis. Surg Endosc. 2011;25:713–21.
99. Siddiqui AA, Chaaya A, Shelton C, Marmion J, Kowalski TE, Loren DE, et al. Utility of the short double-balloon enteroscope to perform pancreaticobiliary interventions in patients with surgically altered anatomy in a US multicenter study. Dig Dis Sci. 2013;58:858–64.
100. Yamauchi H, Kida M, Okuwaki K, Miyazawa S, Iwai T, Takezawa M, et al. Short-type single balloon enteroscope for endoscopic retrograde cholangiopancreatography with altered gastrointestinal anatomy. World J Gastroenterol. 2013;19:1728–35.
101. Obana T, Fujita N, Ito K, Noda Y, Kobayashi G, Horaguchi J, et al. Therapeutic endoscopic retrograde cholangiography using a single-balloon enteroscope in patients with Roux-en-Y anastomosis. Dig Endosc. 2013;25:601–7.
102. Azeem N, Tabibian JH, Baron TH, Orhurhu V, Rosen CB, Petersen BT, et al. Use of a single-balloon enteroscope compared with variable-stiffness colonoscopes for endoscopic retrograde cholangiography in liver transplant patients with Roux-en-Y biliary anastomosis. Gastrointest Endosc. 2013;77:568–77.
103. Shah RJ, Smolkin M, Yen R, Ross A, Kozarek RA, Howell DA, et al. A multicenter, U.S. experience of single-balloon, double-balloon, and rotational overtube-assisted enteroscopy ERCP in patients with surgically altered pancreaticobiliary anatomy (with video). Gastrointest Endosc. 2013;77: 593–600.
104. Trindade AJ, Mella JM, Slattery E, Cohen J, Dickstein J, Garud SS, et al. Use of a cap in single-balloon enteroscopy-assisted endoscopic retrograde cholangiography. Endoscopy. 2015;47:453–6.
105. Kawamura T, Uno K, Suzuki A, Mandai K, Nakase K, Tanaka K, et al. Clinical usefulness of a short-type, prototype single-balloon enteroscope for endoscopic retrograde cholangiopancreatography in patients with altered gastrointestinal anatomy: preliminary experiences. Dig Endosc. 2015; 27:82–6.
106. Ishii K, Itoi T, Tonozuka R, Itokawa F, Sofuni A, Tsuchiya T, et al. Balloon enteroscopy-assisted ERCP in patients with Roux-en-Y gastrectomy and intact papillae (with videos). Gastrointest Endosc. 2016;83:377–86.
107. Khashab MA, El Zein MH, Sharzehi K, Marson FP, Haluszka O, Small AJ, et al. EUS-guided biliary drainage or enteroscopy-assisted ERCP in patients with surgical anatomy and biliary obstruction: an international comparative study. Endosc Int Open. 2016;4:E1322–7.
108. Skinner M, Popa D, Neumann H, Wilcox CM, Mönkemüller K. ERCP with the overtube-assisted enteroscopy technique: a systematic review. Endoscopy. 2014;46:560–72.
109. Itoi T, Sofuni A, Tsuchiya T, Ijima M, Iwashita T. Endoscopic ultrasonography-guided transhepatic antegrade stone removal in patients with surgically altered anatomy: case series and technical review (with videos). J Hepatobiliary Pancreat Sci. 2014;21:E86–93.
110. Iwashita T, Nakai Y, Hara K, Isayama H, Itoi T, Park DH. Endoscopic ultrasound-guided antegrade treatment of bile duct stone in patients with surgically altered anatomy: a multicenter retrospective cohort study. J Hepatobiliary Pancreat Sci. 2016;23:227–33.