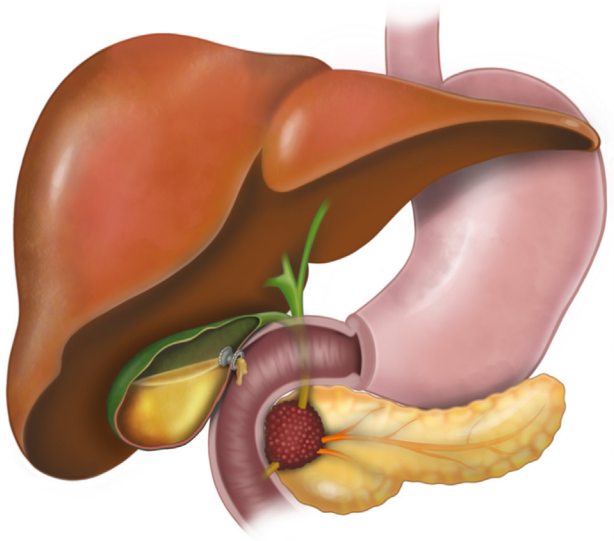
EUS-guided gallbladder drainage using a lumen-apposing metal stent as rescue treatment for malignant distal biliary obstruction: a large multicenter experience

Cecilia Binda, MD,[1] Andrea Anderloni, MD, PhD,[2] Alessandro Fugazza, MD,[3] Arnaldo Amato, MD,[4] Germana de Nucci, MD,[5] Alessandro Redaelli, MD,[6] Roberto Di Mitri, MD,[7] Luigi Cugia, MD,[8] Valeria Pollino, MD,[9] Raffaele Macchiarelli, MD,[10] Benedetto Mangiavillano, MD,[11] Edoardo Forti, MD,[12] Mario Luciano Brancaccio, MD,[13] Roberta Badas, MD,[14] Marcello Maida, MD,[15] Emanuele Sinagra, MD,[16] Alessandro Repici, Prof.,[3,17] Carlo Fabbri, MD,[1] Ilaria Tarantino, MD, PhD[18]

Forlì-Cesena, Pavia, Milan, Lecco, Monza, Palermo, Sassari, Cagliari, Siena, Castellanza, Ravenna, Caltanissetta, Cefalù, Italy

GRAPHICAL ABSTRACT



48 Patients

Technical success	100%
Clinical success	81.3%
Mean percentage of decrease in bilirubin levels after 15 days	66.5 %
Access for LAMS placement	transgastric 58.3% transduodenal 41.7%
Adverse Events	10.4 %

Background and Aims: EUS-guided gallbladder drainage (EUS-GBD) with lumen-apposing metal stents (LAMSs) has been reported as a rescue treatment with encouraging results for the relief of jaundice in patients with distal malignant biliary obstruction (DMBO) and after failure of both ERCP and EUS-guided choledochoduodenostomy.

Methods: This was a multicenter retrospective analysis of all cases of consecutive EUS-GBD with LAMSs used as a rescue treatment for patients with DMBO in 14 Italian centers from June 2015 to June 2020. Primary endpoints were technical and clinical success, whereas the secondary endpoint was the adverse event (AE) rate.

Results: Forty-eight patients (52.1% women) with a mean age of 74.3 ± 11.7 years were included in the study. Biliary stricture was related to pancreatic adenocarcinoma (85.4%), duodenal adenocarcinoma (2.1%), cholangiocarcinoma (4.2%), ampullary cancer (2.1%), colon cancer (4.2%), and metastatic breast cancer (2.1%). The mean diameter of the common bile duct was 13.3 ± 2.8 mm. LAMSs were placed transgastrically in 58.3% of cases and transduodenally in 41.7%. Technical success was 100%, whereas clinical success was 81.3%, with a mean total bilirubin reduction after 2 weeks of 66.5%. The mean procedure time was 26.4 minutes, and the mean hospital stay was 9.2 ± 8.2 days. AEs occurred in 5 patients (10.4%): 3 were classified as intraprocedural and 2 were classified as delayed because they occurred after >15 days. When the American Society for Gastrointestinal Endoscopy lexicon was used, 2 AEs were mild and 3 were moderate (2 buried LAMSs). The mean follow-up was 122 days.

Conclusions: Our study shows that EUS-GBD with LAMSs used as a rescue treatment for patients affected by DMBO represents a valuable option in terms of technical and clinical success rates, with an acceptable AE rate. To the best of our knowledge, this is the largest study concerning the use of this procedure. (Clinical trial registration number: NCT03903523.) (Gastrointest Endosc 2023;98:765-73.)

(footnotes appear on last page of article)

Transpapillary bile duct drainage by means of ERCP is the criterion standard for treating distal malignant biliary obstruction (DMBO).[1,2] However, ERCP may occasionally fail because of altered anatomy, impossibility of reaching the papilla of Vater, or inability to achieve deep cannulation of the common bile duct, for example, in cases of infiltrated ampulla or the presence of tight stenosis.[3] For several years, percutaneous transhepatic biliary drainage has been the conventional nonsurgical option for biliary drainage in the event of failed ERCP. Percutaneous transhepatic biliary drainage is an effective and widely available option, but it carries significant morbidity and potential detriment to patient quality of life.[4]

Multiple studies have reported the usefulness of EUS-guided bile duct drainage (EUS-BD) as an alternative biliary drainage method.[5,6] EUS-BD for DMBO can be performed by means of a choledochoduodenostomy (CDS) or hepaticogastrostomy, depending on the drainage route, when, respectively, an extrahepatic or intrahepatic approach can be used. Although EUS-BD has a high technical success rate and an acceptable risk profile, EUS-BD can fail or may be technically unfeasible for multiple reasons, such as in cases involving a common bile duct <15 mm or altered anatomy.[5-7]

EUS-guided gallbladder drainage (EUS-GBD) is a feasible rescue therapy when ERCP and EUS-BD are unsuccessful or not feasible. In a recent study, at least for 7% of patients with DMBO, EUS-guided biliary drainage was unfeasible, and EUS-GBD was required as a rescue treatment.[8] However, until now, data regarding this procedure are limited, mainly derived from small series of patients.[8-14] The aim of this study was to evaluate the efficacy and safety of EUS-GBD as a rescue therapy for DMBO.

METHODS

In 2019 an educational event on the use of lumen-apposing metal stents (LAMSs) was held in Italy involving gastroenterologists and GI endoscopists from 40 different centers throughout Italy, all of whom had varying degrees of experience performing EUS-guided drainage with LAMSs. This initiative involved about 80% of centers performing such procedures nationwide at the time. The Interventional Endoscopy and Ultrasound group was created and supported an educational program aimed at improving interventional EUS procedures and optimizing the use of LAMSs in clinical practice. To collect clinical data on the efficacy and safety of these procedures in a wide variety of real-life contexts, we planned to conduct a multicenter retrospective analysis of all procedures of EUS-guided drainage with LAMSs for the 3 main "on-label" indications (pancreatic fluid collection and gallbladder and biliary drainages). The study was approved by the institutional review board of each participating center (NCT03903523) and performed in accordance with the Declaration of Helsinki.

The database collected data from 850 cases in which LAMSs were used for its 3 on-label indications. The aim of the study was to evaluate the outcomes of patients who underwent EUS-GBD with LAMSs performed as a rescue treatment for DMBO in 14 Italian centers from June 2015 to June 2020.

Procedures

EUS procedures were performed with a linear-array echoendoscope using carbon dioxide insufflation. Patients underwent deep sedation or general anesthesia. Under EUS guidance, the gallbladder was evaluated. After excluding cystic duct obstruction, the puncture site in the stomach or duodenum was chosen.

When a cold system was used, the gallbladder was punctured with a 19-gauge needle, followed by aspiration of bile or contrast injection to confirm the correct positioning and placement of a .025- or .035-inch guidewire.[15,16] Over the guidewire, the needle track was dilated using a cystotome (settings: pure cut mode, 100 W) and/or a biliary balloon; then the stent delivery system was inserted, and the LAMS was deployed under fluoroscopic and endoscopic control.

If an electrocautery-enhanced LAMS was used, the delivery system was inserted into the working channel and connected to the electrosurgical generator (settings: pure cut mode, 100 W). Access to the gallbladder was gained either using a previously placed guidewire or directly under EUS guidance using the single-stage technique. Once the delivery catheter was inside the gallbladder and the first flange was deployed under EUS guidance, the release of the second flange was performed outside the working channel under direct endoscopic visualization or using the intrachannel technique[17] (Fig. 1).

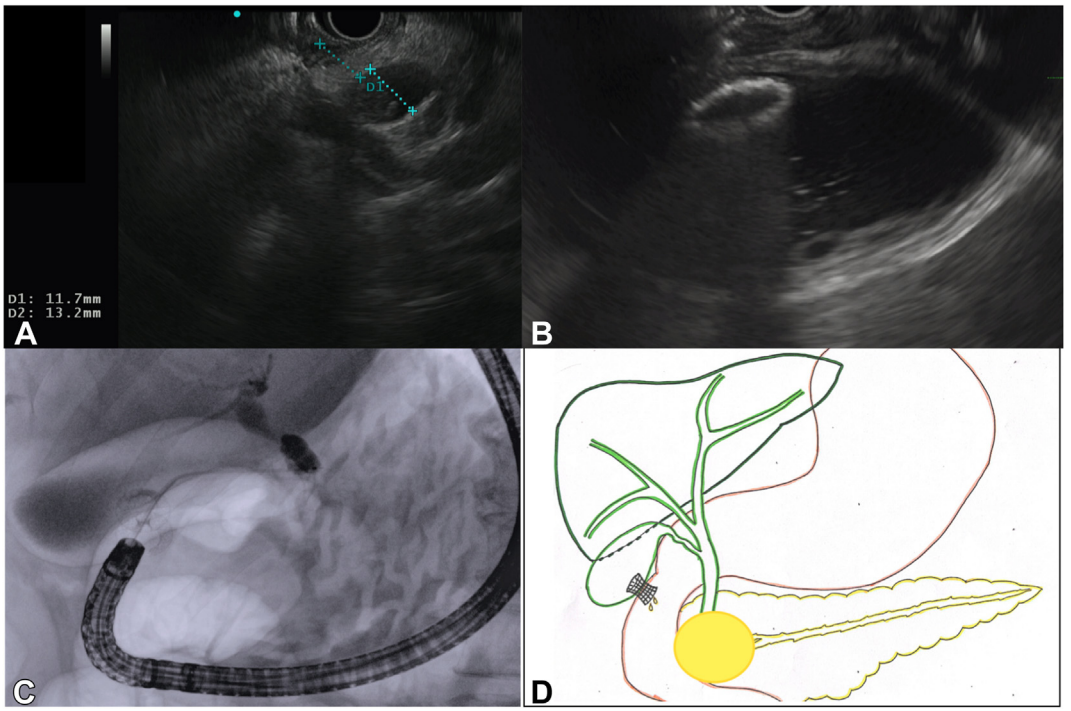


Figure 1. A, Measurement of the common bile duct using EUS. The small diameter (<15 mm) contraindicates EUS-guided choledocoduodenostomy. **B,** EUS view of the first flange of the lumen-apposing metal stent (LAMS) within the gallbladder. **C,** Fluoroscopic confirmation of the correct positioning of the LAMS and communication with the biliary tree. **D,** Representation of EUS-guided gallbladder drainage using LAMSs.

Data

Data were gathered in a central database. For each procedure, patient-related data, demographics, reason for ERCP failure, DMBO etiology, and presence of symptoms of gastric outlet obstruction (GOO) were collected. Procedure details were type and size of the LAMS used, site of approach, deployment technique, and procedural and stent deployment time. Postprocedural data were length of hospitalization, other procedures performed such as duodenal stent placement or EUS-guided gastroenterostomy creation to manage GOO symptoms, surgical resection of the tumor, starting chemotherapy, and adverse events (AEs), with severity graded using the American Society for Gastrointestinal Endoscopy (ASGE) lexicon severity grading system,[18] and their management. AEs were classified as immediate (during the procedure), early, and late (within or after 14 days from the EUS-GBD). Patient follow-up consisted of routine laboratory analyses and clinic visits at the discretion of the responsible endoscopist at each participating hospital.

Outcomes

The primary outcomes for the study were technical and clinical success rates. Technical success was defined as the completion of an EUS-GBD with LAMS placement. Clinical success was defined as a decrease in the bilirubin level of ≥50% within 2 weeks after the procedure and was assessed taking into account the subgroup of patients who achieved technical success. The secondary outcome was the AE rate.

Statistical analysis

Continuous variables are reported as mean ± standard deviation or as median and interquartile range, and categorical variables are summarized as frequencies and percentages. Comparisons of variables were made by the *t*-test or χ^2 test as appropriate. A $P < .05$ was considered to indicate statistical significance. All statistical analyses were performed using SPSS v. 28.0 for Macintosh (SPSS Inc, Chicago, Ill, USA).

RESULTS

Forty-eight consecutive patients were enrolled over the study period; 25 patients (52.1%) were women, and the mean patient age was 74.3 ± 11.7 years. Biliary stricture was related to pancreatic adenocarcinoma in 41 patients (85.4%), duodenal adenocarcinoma in 1 patient (2.1%), cholangiocarcinoma in 2 patients (4.2%), ampullary cancer in 1 patient (2.1%), colon cancer in 2 patients (4.2%), and metastatic breast cancer in 1 patient (2.1%). Eleven patients (22.9%) required duodenal stent placement for GOO symptoms. Antibiotic prophylaxis was adopted for 19 patients (39.6%). Mean hospital stay after the procedure was 9.1 ± 8.2 days, and the mean follow-up was 122 ± 161 days (Table 1).

TABLE 1. Study population characteristics

Characteristics	Values
Male	23 (47.9)
Female	25 (52.1)
Age, y	74.3 ± 11.7
Stricture etiology	
Pancreatic adenocarcinoma	41 (85.4)
Duodenal adenocarcinoma	1 (2.1)
Cholangiocarcinoma	2 (4.2)
Ampullary cancer	1 (2.1)
Others	3 (6.3)
Patients on anticoagulant therapy (withdrawn before procedure)	4 (8.3)
Total bilirubin level before drainage, mg/dL	15.18 ± 6.82
Common bile duct diameter, mm	13.3 ± 2.97
Reasons for failed ERCP	
Failed cannulation	7 (14.6)
Infiltration into the papilla	16 (33.3)
Duodenal obstruction	14 (29.2)
Duodenal stent in situ	1 (2.1)
ERCP not attempted	10 (20.8)
EUS procedure performed in the same session as ERCP	29 (60.4)

Values are n (%) or mean ± standard deviation.

An EUS procedure was performed in the same session as a failed ERCP in 29 patients (60.4%). The mean diameter of the common bile duct was 13.3 ± 2.9 mm. The most commonly used LAMS was 10 × 10 mm in 34 patients (70.8%) followed by an 8 × 8 mm LAMS in 10 patients (20.8%). LAMSs were placed transgastrically in 28 patients (58.3%) and transduodenally in 20 patients (41.7%). In 93.8% of patients (45/48), access to the gallbladder was obtained using a single-stage freehand technique, whereas a guidewire was previously placed in 6.3% of patients (3/48). The mean procedure time (scope in to scope out) was 26.4 minutes.

Outcomes

Technical success was achieved in all 48 patients (100%). Clinical success, defined as a reduction of bilirubin blood level of ≥50% within 2 weeks after the procedure, was obtained in 39 patients (81.3%). The mean percentage of decrease in bilirubin levels at 14 days was 66.5% (12.01 ± 5.56 mg/dL vs 3.34 ± 3.40 mg/dL, $P < .001$) (Table 2). When clinical success was not achieved, an additional percutaneous transhepatic biliary drainage was attempted.

AEs occurred in 5 patients (10.4%): 3 were classified as intraprocedural and 2 were classified as delayed because they occurred after >15 days. When ASGE lexicon grades were used, 2 AEs were mild and 3 were moderate. Of the 3 intraprocedural AEs, 2 were related to bleeding but only 1 required endoscopic hemostasis; the other one was managed conservatively. The third intraprocedural AE was dislodgement of the LAMS and was managed with percutaneous transhepatic cholangiography. The delayed AEs were stent occlusion and a buried stent, and both were managed endoscopically with a second LAMS insertion (Table 3).

TABLE 2. Outcomes of patients who underwent EUS-guided gallbladder drainage with lumen-apposing metal stents performed as a rescue treatment for distal malignant biliary obstruction

Outcomes	Values
Technical success	48 (100)
Clinical success	39 (81.3)
Difference in bilirubin level 15 days after the procedure, mg/dL	10.1 ± 5.53
Percentage of decrease in bilirubin levels after 15 days	66.5
Access for lumen-apposing metal stent placement	
Transgastric	28 (58.3)
Transduodenal	20 (41.7)
Mean procedure time (scope in to scope out), min	26.4
Procedure under fluoroscopic control	15 (31.3)

Values are n (%) or mean ± standard deviation unless otherwise defined.

Moreover, after EUS-GBD, 1 patient, who was able to undergo resection at the time of the procedure, underwent a successful pylorus-preserving pancreaticoduodenectomy, whereas only 11 patients of those who achieved clinical success (11/39, 28%) were able to start chemotherapy. Palliative care for advanced disease was initiated for the remaining patients who achieved clinical success. At univariate analysis, no variables emerged that significantly correlated with clinical success, as shown in Table 4.

DISCUSSION

Over approximately the last 10 years, EUS-GBD has become an increasingly widespread option for the management of several conditions because of the introduction of LAMSs to the market. First, EUS-GBD can be used as a mini-invasive treatment for acute cholecystitis, which has proven to be an effective treatment option for patients who are unfit for surgery.[19] Second, it can be used for the relief of jaundice in DMBO with patent cystic duct cases[8-14] and, more recently, as a possible option for the prevention of acute cholecystitis in patients with DMBO treated with transpapillary self-expandable metal stents and cystic duct involvement[20] (Fig. 2).

The increasing amount of data on the use of EUS-GBD for acute cholecystitis suggests that it has advantages over other mini-invasive treatments.[21] In contrast, data regarding EUS-GBD as a rescue strategy for patients with DMBO after ERCP and/or EUS-BD failure are still sparse and come mainly from case reports and small retrospective series[8-14] (Table 5). Indeed, to the best of our knowledge,

TABLE 3. Adverse events and management in 5 patients

Adverse event	Grading	Timing	Management
Bleeding	Mild	Intraprocedural	Conservative
Bleeding	Mild	Intraprocedural	Endoscopic hemostasis
Dislodgement	Moderate	Intraprocedural	Percutaneous biliary drainage
Buried stent	Moderate	Delayed	Second lumen-apposing metal stent insertion
Occlusion	Moderate	Delayed	Second lumen-apposing metal stent insertion

TABLE 4. Variables associated with clinical success

Variable	Clinical success (n = 39)	Clinical failure (n = 9)	*P* value
Age, y	74.1 ± 12.0	75.3 ± 10.8	.780
Sex			
Female	23 (59.0)	2 (22.2)	.047
Male	16 (41.0)	7 (77.8)	
Etiology			
Pancreatic adenocarcinoma	33 (84.6)	9 (100)	
Duodenal adenocarcinoma	1 (2.6)	0	.663
Cholangiocarcinoma	2 (5.1)	0	
Ampullary cancer	0	0	
Other	3 (7.7)	0	
Total bilirubin predrainage, mg/dL	14.7 ± 6.4	18.6 ± 7.5	.199
Common bile duct diameter, mm	13.2 ± 3.2	13.4 ± 2.2	.868
Prophylactic antibiotic use	16 (42.1)	3 (37.5)	.810
Patients on anticoagulant therapy (withdrawn before procedure)	3 (7.7)	1 (11.1)	.738
Duodenal stent previously placed	3 (7.9)	2 (25.0)	.158
Access			
Single stage	36 (92.3)	9 (100)	.390
Needle + guidewire	3 (7.7)	0	
Fluoroscopic control	13 (33.3)	2 (22.2)	.517
Procedure time, min	26.4 ± 18.3	26.1 ± 12.4	.960
Stent type			
Hot AXIOS*	0	1 (11.1)	
AXIOS (cold)*	7 (17.9)	3 (33.3)	.183
Spaxus†	29 (74.4)	5 (55.6)	
Nagi†	2 (5.1)	0	
Other	1 (2.6)	0	
Beginning of postprocedural enteral diet			
Immediate or within 48 h	35 (89.7)	6 (66.7)	.331
After 48 h	4 (10.3)	3 (33.3)	

Values are n (%) or mean ± standard deviation.
*Hot AXIOS and AXIOS, Boston Scientific, Marlborough, Mass, USA.
†Nagi and Spexus, Taewoong-Medical Co, Ltd, Ilsan, Korea.

our study is the largest series on EUS-GBD as a rescue treatment for the relief of jaundice in patients affected by DMBO.

This study shows that rescue therapy using EUS-GBD is a valid treatment option for patients with MDBO when ERCP and/or EUS-BD fail, achieving a technical success of

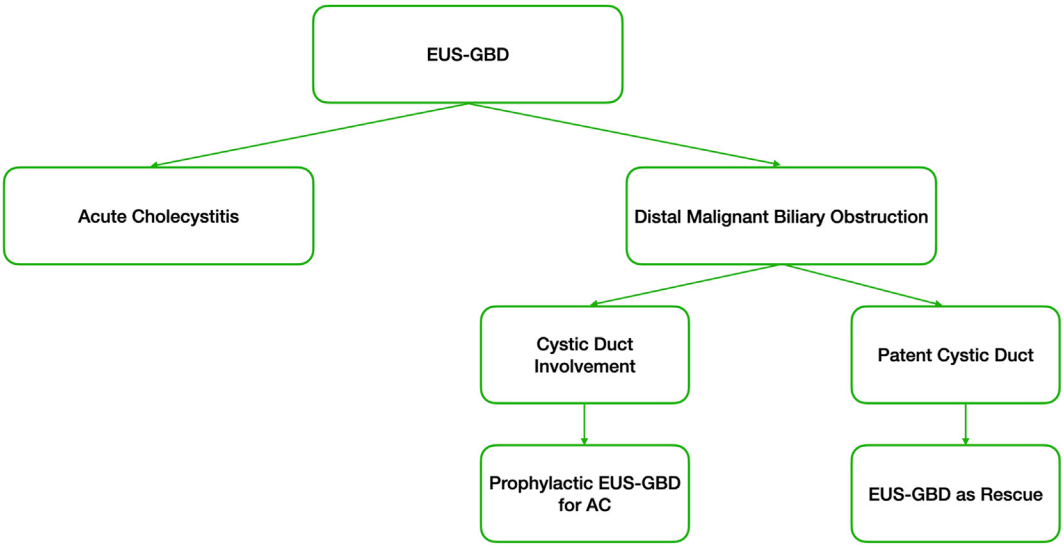


Figure 2. Possible current indications for EUS-GBD. *EUS-GBD*, EUS-guided gallbladder drainage; *AC*, acute cholecystitis.

TABLE 5. Published studies on EUS-gallbladder drainage as rescue treatment

Author, year	Study design	No. of patients	Type of stent	Technical success (%)	Clinical success (%)	Route of drainage: %	Difference in bilirubin (%)	Adverse events (%)
Itoi et al, 2013[9]	Case report	1	LAMS	100	100	Transgastric	NA	0
Imai et al, 2016[10]	Retrospective	12	Self-expandable metal stent	100	91.7	Transgastric: 58.3 Transduodenal: 41.7	NA	16.7
Ligresti et al, 2019[11]	Case report	1	EC-LAMS	100	100	Transgastric	NA	0
Chang et al, 2019[12]	Retrospective	9	EC-LAMS	100	77.8	Transgastric: 44.4 Transduodenal: 55.6	NA	0
Paleti et al, 2019[13]	Retrospective	7	EC-LAMS	100	100	NA	63	0
Issa et al, 2021[8]	Retrospective	28	EC-LAMS (n = 20) LAMS (n = 6) Self-expandable metal stent (n = 2)	100	92.6	Transgastric: 46 Transduodenal: 54	62	17.8
Flor de Lima et al, 2021[14]	Case report	1	EC-LAMS	100	100	Transgastric	NA	0

LAMS, Lumen-apposing metal stent; *EC-LAMS*, electrocautery-enhanced lumen-apposing metal stent; *NA*, not available.

100% and clinical success rate up to 81.3 %. These data are in line with those of a recent meta-analysis that reported pooled technical and clinical success rates of 100% and 85%, respectively.[22]

AEs occurred in 10.4% of the patients involved in our study. However, all AEs were mild or moderate in severity, mainly managed endoscopically, and only in 1 case was percutaneous biliary drainage needed. It should also be underlined that no fatal events occurred. The most common AEs in our series were bleeding and buried LAMSs (4.1% of patients). These results differed from those of the meta-analysis by Kamal et al,[22] which reported a pooled AE rate of 13%, with stent dysfunction the most common AE. Because food impaction has been reported as occurring more frequently when a transgastric approach was used,[23] regardless of the indications for EUS-GBD, the European guidelines suggest the transduodenal route to reduce the risk of stent dysfunction.[24]

It should also be noted that despite the complexity of these patients, who had already undergone attempted ERCP and EUS-BD, no postprocedural pancreatitis occurred in our cohort. As is well documented, biliary drainage by means of ERCP results in postprocedural pancreatitis in up to 5.5% of cases,[25] and although usually mild in severity, this AE may lead to a significant delay in further treatments, namely chemotherapy and surgery. It is also noteworthy that the mean procedural time for EUS-GBD was relatively short (scope in to scope out of 26.4 minutes), which could enhance the role of this procedure in patients who cannot be given prolonged sedation.

Nevertheless, it has to be highlighted that cystic duct patency is necessary for biliary drainage with EUS-GBD to be successful, and therefore tumor involvement of the cystic duct is one of the conditions that needs to be ruled out because it can preclude GBD. Cystic duct patency can be assessed using cross-sectional imaging during preprocedural planning, and it should be confirmed by EUS examination before drainage. Tumor location in the distal or proximal bile duct is an important indicator of the involvement of the cystic duct.[26]

In our study, the mean percentage of decrease in bilirubin levels 14 days after EUS-GBD was 66.5% (12.01 ± 5.56 mg/dL before EUS-GBD vs 3.34 ± 3.40 mg/dL 15 days after EUS-GBD, $P < .001$). Although this mean percentage decrease could be considered satisfactory, it is slightly inferior to that reported for EUS-CDS, namely a reduction of bilirubin after 14 days of 72% (14.7 ± 7.11 mg/dL vs 4.11 ± 3.96 mg/dL).[27] Even though the difference is not substantial, it may lead to a delay in starting chemotherapy, either for palliative or neoadjuvant purposes. To the best of our knowledge, until now, no data are available that make it possible to determine if 1 method of biliary drainage is superior to another in terms of reducing the time period before starting chemotherapy, which may be affected by multiple variables, clinical or organizational or both. However, we believe this could be a worthwhile topic for future studies, given the ever-increasing number of patients who will undergo neoadjuvant chemotherapy in the near future.[28]

Notably, 11 patients (22.9%) required duodenal stent placement to treat GOO symptoms before or after the procedure, and 1 patient (2%) underwent EUS-guided gastroenteric anastomosis for the same reason. GOO was treated in the same session as EUS-GBD in 8 of 12 patients (66.6%). The ability to successfully treat these 2 conditions in the same endoscopic session could be of great importance for this subset of patients.[29]

In this cohort, 1 patient with cholangiocarcinoma with jaundice underwent EUS-GBD after ERCP failure as a bridge to resective surgery. EUS-guided biliary drainage, including EUS-GBD drainage as a rescue therapy, has been mainly reserved and recommended for palliation.[30] This is chiefly because of the belief that EUS-guided biliary drainage could interfere with bilioenteric anastomosis. However, this dogma will probably be overcome in the near future. Indeed, initial reports indicate that EUS-CDS, either with self-expandable metal stents or LAMSs, does not interfere with subsequent surgery, in particular regarding pylorus preservation and biliary and gastric reconstruction, or increase postsurgical AEs.[31,32] The use of EUS-GBD as rescue treatment followed by pylorus-preserving pancreaticoduodenostomy has also been reported, highlighting how this drainage route does not affect subsequent surgery and indicating it could be a valuable bridge-to-surgery option.[11] The authors highlighted how EUS-GBD may have an advantage over EUS-CDS in regard to preserving the integrity of the common bile duct, allowing the surgeon to perform a safe bilioenteric anastomosis.[11] However, although in this study no significant differences in outcomes emerged between transduodenal and transgastric routes, in candidates for surgery, the site of LAMS placement should be carefully evaluated with surgeons. Even if gallbladder removal is usually performed during a pancreaticoduodenectomy, the presence of gastric or duodenal fistulas may affect the choice of performing a standard Whipple resection (which is extended to the gastric antrum) or a pylorus-preserving pancreaticoduodenostomy; therefore, the type of enteric anastomosis is important. Nevertheless, initial evidence regarding acute cholecystitis suggests that the presence of a cholecystoenteric fistula does not impair surgical cholecystectomy and does not increase the AE rate.[33] However, most data come from small series of patients, and larger studies are needed to better evaluate EUS-BD as a bridge to surgery.[34]

Finally, in our study, EUS-GBD was performed in the same session as failed ERCP in at least 60.4% of cases. This result may be because of several factors. First, the endoscopist in charge during the ERCP attempt may not have been trained in both ERCP and interventional EUS, and hence the decision to use EUS-GBD as a rescue treatment was made by a different endoscopist.[35] Second, because this procedure is a rescue treatment, a multidisciplinary assessment with several experts, such as a surgeon and a radiologist, would be advisable, taking into account the availability of and skill levels of staff and resources available at each center.

Third, and not least, informed consent may be an issue in several centers. Indeed, a crucial point is that it is becoming apparent that EUS-guided procedures, regardless of the route chosen for drainage, are effective in the management of biliary obstruction and that they could be performed subsequently after ERCP failure or as the first approach for drainage. As a result, a new type of informed consent form is needed that is "procedure oriented" rather than "goal oriented."[36] This would allow greater flexibility, with greater benefits: Biliary drainage could be achieved using either ERCP or EUS-BD, including EUS-GBD as a rescue therapy option, or, when needed, percutaneous drainage and possibly the palliation of GOO when a duodenal stricture is present, all in the same session.

To the best of our knowledge, with 48 patients included, this study is the largest on this topic to date. However, the present study has several limitations. First, it is retrospective and therefore subject to numerous biases, and some types of information were lacking, mainly regarding the stage of the diseases, comorbidities, and performance status. In addition, several centers with many different endoscopists were involved, resulting in some heterogeneity in data. On the other hand, the number of centers involved (14 hospitals) and the different levels of expertise could also represent a strength of our study, because it would clearly indicate that EUS-GBD with LAMSs is safe and effective in hospitals with heterogeneous levels of expertise, that the reproducibility of the procedure is good, and that EUS-GBD is effective in real-life settings with less-experienced endoscopists.

In conclusion, our multicenter study shows that EUS-GBD is an effective and secure rescue therapy for DMBO after failure of ERCP and/or EUS-BD, with evidence of good reproducibility. Therefore, this procedure should be considered as a valid alternative, and in certain cases a preferable option, to surgical and percutaneous techniques in the management of DMBO after ERCP and EUS-BD failure.

DISCLOSURE

The following authors disclosed financial relationships: C. Binda: Lecturer for Steris, Fujifilm, and Q3 Medical. A. Anderloni: Consultant for Boston Scientific, Olympus, and Medtronic. A. Fugazza: Consultant for Boston Scientific and Olympus. A. Repici: Consultant for Boston Scientific, Fujifilm, and ERBE. C. Fabbri: Lecturer for Steris and Q3 Medical; consultant for Boston Scientific. R. Di Mitri: Consultant for Boston Scientific. All other authors disclosed no financial relationships.

REFERENCES

1. Das A, Sivak MV Jr. Endoscopic palliation for inoperable pancreatic cancer. Cancer Control 2000;7:452-7.
2. Speer AG, Cotton PB, Russell RC, et al. Randomised trial of endoscopic versus percutaneous stent insertion in malignant obstructive jaundice. Lancet 1987;2:57-62.
3. Kahaleh M, Hernandez AJ, Tokar J, et al. Interventional EUS-guided cholangiography: evaluation of a technique in evolution. Gastrointest Endosc 2006;64:52-9.
4. Heedman PA, Åstradsson E, Blomquist K, et al. Palliation of malignant biliary obstruction: adverse events are common after percutaneous transhepatic biliary drainage. Scand J Surg 2018;107:48-53.
5. Paik WH, Lee TH, Park DH, et al. EUS-guided biliary drainage versus ERCP for the primary palliation of malignant biliary obstruction: a multicenter randomized clinical trial. Am J Gastroenterol 2018;113:987-97.
6. Park JK, Woo YS, Noh DH, et al. Efficacy of EUS-guided and ERCP-guided biliary drainage for malignant biliary obstruction: prospective randomized controlled study. Gastrointest Endosc 2018;88:277-82.
7. Bishay K, Boyne D, Yaghoobi M, et al. Endoscopic ultrasound-guided transmural approach versus ERCP-guided transpapillary approach for primary decompression of malignant biliary obstruction: a meta-analysis. Endoscopy 2019;51:950-60.
8. Issa D, Irani S, Law R, et al. Endoscopic ultrasound-guided gallbladder drainage as a rescue therapy for unresectable malignant biliary obstruction: a multicenter experience. Endoscopy 2021;53:827-31.
9. Itoi T, Binmoeller K, Itokawa F, et al. Endoscopic ultrasonography-guided cholecystogastrostomy using a lumen-apposing metal stent as an alternative to extrahepatic bile duct drainage in pancreatic cancer with duodenal invasion. Dig Endosc 2013;25(Suppl 2): 137-41.
10. Imai H, Kitano M, Omoto S, et al. EUS-guided gallbladder drainage for rescue treatment of malignant distal biliary obstruction after unsuccessful ERCP. Gastrointest Endosc 2016;84:147-51.
11. Ligresti D, Tarantino I, Amata M, et al. Bridge-to-surgery gallbladder drainage with a lumen-apposing metal stent in malignant distal biliary obstruction: a choice tailored for the surgeon. Endoscopy 2019; 51:94-5.
12. Chang JI, Dong E, Kwok KK. Endoscopic ultrasound-guided transmural gallbladder drainage in malignant obstruction using a novel lumen-apposing stent: a case series (with video). Endosc Int Open 2019;7: E655-61.
13. Paleti S, Gulati R, Sanchez-Luna SA, et al. EUS-guided gall bladder drainage using lumen apposing metal stent for malignant biliary obstruction [abstract]. Gastrointest Endosc 2019;89:AB308.
14. Flor de Lima M, Nunes N, Chálim Rebelo C, et al. Palliative EUS-guided gallbladder drainage as a salvage treatment of biliary obstruction in inoperable cholangiocarcinoma. GE Port J Gastroenterol 2021;29: 145-7.
15. Teoh AYB, Serna C, Penas I, et al. Endoscopic ultrasound-guided gallbladder drainage reduces adverse events compared with percutaneous cholecystostomy in patients who are unfit for cholecystectomy. Endoscopy 2017;49:130-8.
16. Jang JW, Lee SS, Park DH, et al. Feasibility and safety of EUS-guided transgastric/transduodenal gallbladder drainage with single-step placement of a modified covered self-expandable metal stent in patients unsuitable for cholecystectomy. Gastrointest Endosc 2011;74:176-81.
17. Anderloni A, Attili F, Carrara S, et al. Intra-channel stent release technique for fluoroless endoscopic ultrasound-guided lumen-apposing metal stent placement: changing the paradigm. Endosc Int Open 2017;5:E25-9.
18. Cotton PB, Eisen GM, Aabakken L, et al. A lexicon for endoscopic adverse events: report of an ASGE workshop. Gastrointest Endosc 2010;71:446-54.
19. Kurihara H, Binda C, Cimino MM, et al. Acute cholecystitis: which flowchart for the most appropriate management? Dig Liver Dis 2023;55(9): 1169-77.
20. Robles-Medranda C, Oleas R, Puga-Tejada M, et al. Prophylactic EUS-guided gallbladder drainage prevents acute cholecystitis in patients with malignant biliary obstruction and cystic duct orifice involvement: a randomized trial (with video). Gastrointest Endosc. 2023;97:445-53.
21. Cucchetti A, Binda C, Dajti E, et al. Trial sequential analysis of EUS-guided gallbladder drainage versus percutaneous cholecystostomy in patients with acute cholecystitis. Gastrointest Endosc 2022;95: 399-406.
22. Kamal F, Khan MA, Lee-Smith W, et al. Efficacy and safety of EUS-guided gallbladder drainage for rescue treatment of malignant biliary obstruction: a systematic review and meta-analysis. Endosc Ultrasound 2023;12:8-15.
23. Binda C, Coluccio C, Da Rio L, et al. Endoscopic management of food impaction following endoscopic ultrasound-guided gallbladder drainage using lumen-apposing metal stent. Endoscopy 2023;55(Suppl 1):E484-5.
24. van Wanrooij RLJ, Bronswijk M, Kunda R, et al. Therapeutic endoscopic ultrasound: European Society of Gastrointestinal Endoscopy (ESGE) technical review. Endoscopy 2022;54:310-32.
25. Fugazza A, Troncone E, Amato A, et al. Difficult biliary cannulation in patients with distal malignant biliary obstruction: an underestimated problem? Dig Liver Dis 2022;54:529-36.
26. Nakai Y, Matsubara S, Isayama H, et al. Cystic duct patency in EUS-guided gallbladder drainage as a rescue treatment for malignant biliary obstruction. Gastrointest Endosc 2016;83:1302-3.
27. Fugazza A, Fabbri C, Di Mitri R, et al. EUS-guided choledochoduodenostomy for malignant distal biliary obstruction after failed ERCP: a retrospective nationwide analysis. Gastrointest Endosc 2022;95:896-904.
28. Birrer DL, Golcher H, Casadei R, et al. Neoadjuvant therapy for resectable pancreatic cancer: a new standard of care. pooled data from 3 randomized controlled trials. Ann Surg 2021;274:713-20.
29. Zhang HC, Tamil M, Kukreja K, et al. Review of simultaneous double stenting using endoscopic ultrasound-guided biliary drainage techniques in combined gastric outlet and biliary obstructions. Clin Endosc 2020;53:167-75.
30. 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.
31. Bang JY, Navaneethan U, Hasan M, et al. Stent placement by EUS or ERCP for primary biliary decompression in pancreatic cancer: a randomized trial (with videos). Gastrointest Endosc 2018;88:9-17.

32. Fabbri C, Fugazza A, Binda C, et al. Beyond palliation: using EUS-guided choledochoduodenostomy with a lumen-apposing metal stent as a bridge to surgery. A case series. J Gastrointest Liver Dis 2019;28:125-8.
33. Saumoy M, Tyberg A, Brown E, et al. Successful cholecystectomy after endoscopic ultrasound gallbladder drainage compared with percutaneous cholecystostomy: Can it be done? J Clin Gastroenterol 2019;53(3):231-5.
34. Gaujoux S, Jacques J, Bourdariat R, et al. Pancreaticoduodenectomy following endoscopic ultrasound-guided choledochoduodenostomy with electrocautery-enhanced lumen-apposing stents: an ACHBT-SFED study. HPB 2021;23:154-60.
35. Fabbri C, Coluccio C, Binda C, et al; i-EUS Group. Lumen-apposing metal stents: How far are we from standardization? An Italian survey. Endosc Ultrasound 2022;11:59-67.
36. Spadaccini M, Binda C, Fugazza A, et al. On behalf of the Interventional Endoscopy and Ultrasound (i-EUS) Group. Informed consent for endoscopic biliary drainage: time for a new paradigm. Medicina 2022;58:331.

Abbreviations: AE, adverse event; ASGE, American Society for Gastrointestinal Endoscopy; DMBO, distal malignant biliary obstruction; EUS-BD, EUS-guided bile duct drainage; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-GBD, EUS-guided gallbladder drainage; GOO, gastric outlet obstruction; LAMS, lumen-apposing metal stent.

Use your mobile device to scan this QR code and watch the author interview. Download a free QR code scanner by searching "QR Scanner" in your mobile device's app store.

0016-5107/$36.00
https://doi.org/10.1016/j.gie.2023.06.054

Received October 13, 2022. Accepted June 26, 2023.

Current affiliations: Gastroenterology and Digestive Endoscopy Unit, Forlì-Cesena Hospitals, AUSL Romagna, Forlì-Cesena, Italy (1), Gastroenterology and Digestive Endoscopy Unit, Fondazione IRCCS, Policlinico San Matteo, Pavia, Italy (2), Digestive Endoscopy Unit, Humanitas Clinical and Research Center IRCCS, Milan, Italy (3), Digestive Endoscopy and Gastroenterology Department, Manzoni Hospital, ASST Lecco, Lecco, Italy (4), Gastroenterology and Endoscopy Unit, ASST Rhodense, Milan, Italy (5), Endoscopy Unit, San Gerardo Hospital, Monza, Italy (6), Gastroenterology and Endoscopy Unit, ARNAS Civico Hospital, Palermo, Italy (7), Division of Gastroenterology and Digestive Endoscopy, Department of Emergency, Azienda Ospedaliero Universitaria Sassari, Sassari, Italy (8), Digestive Endoscopy Unit, S. Michele Hospital, Cagliari, Italy (9), Gastroenterology Unit, AOUS Policlinico S. Maria alle Scotte, Siena, Italy (10), Gastrointestinal Endoscopy Unit, Humanitas Mater Domini, Castellanza, Italy (11), Digestive and Interventional Endoscopy Unit, Ospedale Ca' Granda Niguarda, Milan, Italy (12), Division of Gastroenterology, S. Maria delle Croci Hospital, Ravenna, Italy (13), Digestive Endoscopy Unit, University Hospital, Cagliari, Italy (14), Gastroenterology and Endoscopy Unit, S. Elia-Raimondi Hospital, Caltanissetta, Italy (15), Gastroenterology and Endoscopy Unit, Fondazione Istituto G. Giglio, Cefalù, Italy (16), Department of Biomedical Sciences, Humanitas University, Milan, Italy (17), Endoscopy Service, Department of Diagnostic and Therapeutic Services, IRCCS-ISMETT, Palermo, Italy (18).

Reprint requests: Cecilia Binda, MD, Gastroenterology and Digestive Endoscopy Unit, Forlì-Cesena Hospitals, AUSL Romagna, Forlì-Cesena, Italy. E-mail: cecilia.binda@gmail.com.