REVIEW ARTICLE

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Endoscopic management of malignant biliary obstructions

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Abstract

Malignant biliary obstruction (MBO), both distal and hilar, represents an ensemble of different clinical conditions frequently encountered in everyday practice. Given the frequent unresectability of the disease at presentation and the increasing indications for neoadjuvant chemotherapy, endoscopic biliary drainage is generally required during the course of the disease. With the widespread use of interventional endoscopic ultrasound (EUS) and the introduction of dedicated devices, EUS-guided biliary drainage has rapidly gained acceptance, together with transpapillary endoscopic biliary drainage and the percutaneous approach. This comprehensive review describes the current role of endoscopy for distal and hilar MBO supported by evidence, with a focus on the current hot topics in this field.

Keywords Malignant biliary obstruction, biliary drainage, endoscopic retrograde cholangiopancreatography, endoscopic ultrasound-guided drainage

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Introduction

Malignant biliary obstruction (MBO) represents a clinical condition that encompasses a broad spectrum of scenarios frequently encountered in everyday practice in endoscopic units. MBO is traditionally divided into distal MBO (DMBO) and hilar MBO (HMBO), according to the site of biliary system obstruction: extrahepatic or intrahepatic duct/hilar confluence. The most common etiologies of DMBO are pancreatic head adenocarcinoma and extrahepatic cholangiocarcinoma. Other reasons are gallbladder cancer, ampullary cancer, lymphoma, and malignant metastases [1-3]. Hilar cholangiocarcinoma, also known as a Klatskin tumor, is the main reason for HMBO, followed by gallbladder cancers, hepatocellular carcinomas, lymphomas, and metastatic malignancies [4-6].

The Klatskin tumor is currently classified according to the Bismuth-Corlette classification, which takes into consideration the site of hepatic ducts invaded by the tumor [7]. A precise classification of HMBO is crucial, as it strongly influences the choice of drainage and the surgical strategies [8,9]. The majority of patients with MBO already have an advanced stage at presentation, in particular for HMBO, so that curative resection is possible only in a minority of patients [7].

In both preoperative and palliative settings, transpapillary endoscopic biliary drainage (TBD) through endoscopic retrograde cholangiopancreatography (ERCP), traditionally represents the standard approach. However, in the last 2 decades, endoscopic ultrasound-guided biliary drainage (EUS-BD), thanks to several technical improvements, has rapidly become widespread and has gained an important role in the management of MBO [10-12] (Figs. 1 and 2).

TBD

TBD in unresectable DMBO

ERCP with transpapillary stenting is the gold standard for decompressing unresectable DMBO, with a success rate of up to 95% [13]. ERCP is preferred over both surgical and percutaneous approaches: TBD shows significantly lower

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morbidity and mortality compared with surgery, with a higher probability of recurrent biliary obstruction [14].

In comparison with percutaneous TBD (PTBD), TBD is associated with lower rates of adverse events and need for reintervention, a shorter hospital stay and lower total costs. Moreover, PTBD is associated with a poorer quality of life and risk of catheter dislodgement due to the presence of an external catheter [10,11,15-17].

Stent patency is an essential issue in the palliation of DMBO: many studies demonstrated that self-expandable metal stents (SEMS) provide significant longer patency compared with plastic stents, associated with lower rates of cholangitis, reinterventions, hospitalization and chemotherapy interruptions [18,19]. For patients with an expected survival time of less than 3 months, some endoscopists prefer to place a plastic stent, as the most economical option. However, a randomized trial has shown no differences between plastic stents and SEMS in total treatment costs (including costs of hospitalization) for patients with a short survival time and for patients with metastatic disease [19].

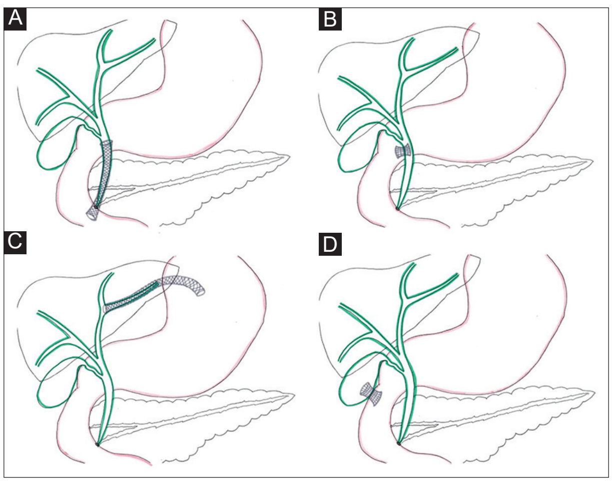

Figure 1 Endoscopic drainage of DMBO. (A) TBD with SEMS; (B) EUS-guided choledocoduodenostomy with LAMS; (C) EUS-guided hepaticogastrostomy with SEMS; (D) EUS-guided gallbladder drainage
DMBO, distal malignant biliary obstruction; TBD, transpapillary endoscopic biliary drainage; SEMS, self-expandable metal stent; EUS, endoscopic ultrasound; LAMS, lumen-apposing metal stent

While guidelines clearly recommend the use of SEMS for TBD in patients with unresectable DMBO, uncertainty still exists about the best type of SEMS. These stents can be divided into uncovered SEMS (U-SEMS) and covered SEMS (C-SEMS), which in turn may be fully covered SEMS (FC-SEMS) or partially covered SEMS (PC-SEMS).

Because of their mesh design, U-SEMS are susceptible to occlusion by tissue ingrowth (from either tumor or epithelial hyperplasia). For this reason, C-SEMS were introduced in the 1990s to improve the patency of SEMS by preventing tissue ingrowth [20].

On the other hand, C-SEMS are associated with a higher risk of stent migration, and a perceived greater risk of cholecystitis and/or pancreatitis because of the blockage of the cystic or pancreatic duct by the covered mesh of the stent [20,21]. Moreover, even though C-SEMS are less prone to tumor ingrowth, they present higher rates of tumor overgrowth (usually at the intraductal extremity of the stent) and sludge formation, leading to biliary obstruction and need for reintervention [22].

Many studies, including randomized controlled trials (RCTs) and meta-analyses, have compared FC-SEMS with U-SEMS for DMBO: overall, no type of SEMS showed a clear superiority to the other types in terms of patency, safety and patient survival [20,23-25].

A meta-analysis of 11 RCTs (1272 patients) compared the outcomes of FC-SEMS, PC-SEMS and U-SEMS for the drainage

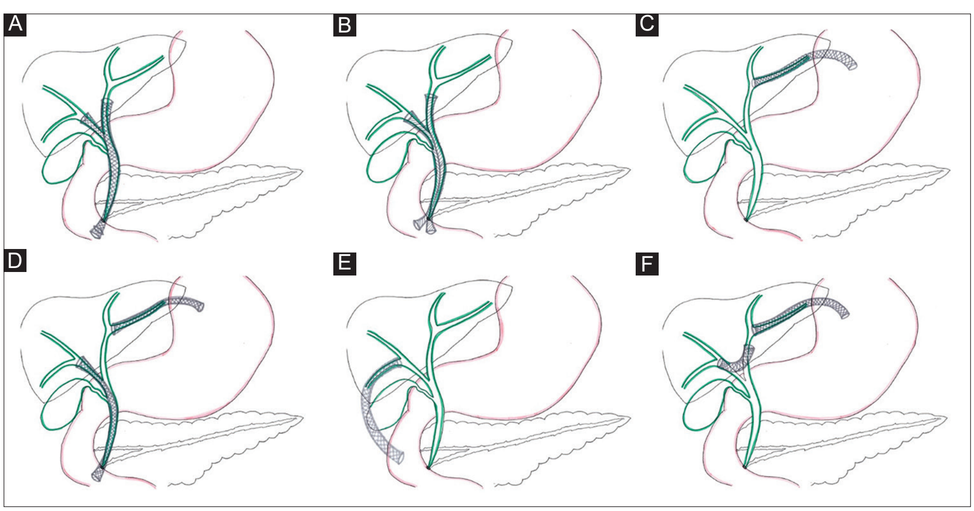

Figure 2 Endoscopic drainage of HMBO. (A) TBD with bilateral stent-in-stent technique; (B) TBD with bilateral stent-by-stent technique; (C) EUS-guided hepaticogastrostomy; (D) CERES (Combined ERCP and endosonography); (E) EUS-guided hepaticoduodenostomy; (F) Bridging method
HMBO, hilar malignant biliary obstruction; TBD, transpapillary endoscopic biliary drainage; EUS, endoscopic ultrasound; CERES, combined endoscopic retrograde cholangiopancreatography and EUS

of MDBO, including both endoscopic and percutaneous SEMS placement: although there was no statistically significant difference, C-SEMS showed a 32% risk reduction for both stent failure and patient mortality, as compared with U-SEMS. It is notable that PC-SEMS and U-SEMS exhibit no difference in any outcome, while rates of adverse events (including cholecystitis, cholangitis, pancreatitis, perforation, and bleeding) did not differ significantly between the types of SEMS [26].

A more recent meta-analysis reported that the time to recurrent biliary obstruction was significantly longer for C-SEMS (mean difference, 45.51 days; 95% confidence interval [CI] 11.79-79.24) [27]. Regarding C-SEMS, a meta-analysis by Vanella found that time to recurrent biliary obstruction was shorter for FC-SEMS (238, 95%CI 191-286 days; I^2=63.1%) vs. PC-SEMS (369, 95%CI 290-449 days; I^2=71.9%), with considerable heterogeneity. The 2 types of covered SEMS showed no difference in adverse event rates, with small differences in the rate of ingrowth (FC-SEMS 0.5% vs. PC-SEMS 2.9%) and migration (FC-SEMS 9.8% vs. PC-SEMS 4.3%) [28]. Specific stent designs to overcome the main limitations have been investigated, including antireflux covered SEMS, anti-migration systems as well as drug-eluting metal stents (paclitaxel-incorporated stents), with different results [10].

Regarding stent-related complications, 2 major concerns about C-SEMS have persisted over the years, as a result of conflicting results in the literature concerning cholecystitis and post-ERCP pancreatitis (PEP). The risk of cholecystitis after SEMS placement ranges from 5-10% [11]. One potential explanation is the occlusion of the cystic duct by the covered membrane of a C-SEMS: despite the higher rate of cholecystitis with the placement of FC-SEMS compared with U-SEMS, randomized trials comparing different types of stent failed to demonstrated a statistically significant difference [29]. In fact, recent American College of Gastroenterology guidelines suggest favoring U-SEMS when the opening of the cystic duct will be covered by the stent, given the potentially increased risk of cholecystitis associated with FC-SEMS [11].

With regard to pancreatitis, there are worries about the use of SEMS and the risk of PEP because of the obstruction of the pancreatic outflow: for this reason, a partial (or complete) endoscopic biliary sphincterotomy (EBS) could theoretically reduce the risk of PEP. However, meta-analyses showed no difference in PEP rates, but a higher risk of bleeding, cholangitis, and overall adverse events in cases of EBS prior to stenting [30]. No significant differences in terms of PEP rates between C- and U-SEMS have been reported [26,30]. Therefore, as no clear advantages have been demonstrated in terms of PEP reduction, the guidelines do not suggest the routine use of EBS prior to stent placement [10].

TBD in resectable DMBO

Preoperative BD is not recommended as routine, as it has not been demonstrated to be beneficial in terms of overall survival rates; on the contrary, a meta-analysis (25 studies) has reported that preoperative BD is associated with higher rates of overall complications (odds ratio [OR] 1.40, 95%CI 1.14-1.72) and wound infections (OR 1.94, 95%CI 1.48-2.53) [31]. However, preoperative BD is indicated in cases of cholangitis, symptomatic jaundice or delayed surgery, or before neoadjuvant chemotherapy [10,11].

In the last few years, there has been a significant push in favor of neoadjuvant chemotherapy for all resectable tumors (and not only in borderline resectable cases), supported by better reported oncological outcomes, but resulting in a greater necessity of biliary stenting with high patency, in order to minimize delays in chemotherapy because of reinterventions [11,32].

A careful choice of biliary stent is mandatory in resectable and borderline resectable tumors: SEMS are associated with better outcomes as compared with plastic stents in terms of patency, cholangitis and need for reintervention, with a favorable cost-effectiveness profile [33]. Even in patients who undergo upfront surgery, SEMS are generally recommended above plastic stents, because these patients often wait several weeks prior to surgery. Moreover, when placed below the biliary bifurcation, SEMS have not demonstrated any particular technical difficulty, nor any effect on surgical outcomes and complications [34]. In patients undergoing neoadjuvant chemotherapy, SEMS show longer patency and a shorter delay in oncological therapy [32,35].

In surgical patients with DMBO, FC-SEMS is recommended above U-SEMS, because of their easier removability. Furthermore, when a U-SEMS is placed in potentially resectable patients, guidelines suggest positioning the proximal end of the stent at least 15 mm below the biliary confluence, in order to preserve enough intact biliary duct to permit an appropriate surgical bilio-enteric anastomosis [11].

TBD in unresectable HMBO

The 3 established methods for palliation of HMBO are TBD, PTBD and surgical bypass. As in DMBO, the surgical approach is less used, given the efficacy of less invasive techniques. Recently, EUS-BD has been introduced as a further alternative drainage modality (Fig. 2).

The management of Bismuth types I and II HMBO is technically similar to that of extrahepatic biliary strictures. Indeed, the guidelines suggest endoscopic drainage in this setting, as it is less invasive than a percutaneous approach [10]. By contrast, in patients with Bismuth types III and IV, it is unclear whether one approach is superior to the other. European guidelines suggest the use of PTBD or a combination of PTBD and ERCP, according to local expertise; similarly, more recent American guidelines suggest that the choice should be based on disease and patient characteristics (comorbidities, life expectancy, patient's ability to tolerate anesthesia), local practice patterns (availability of skilled and experienced advanced endoscopists) and the patient's preferences [9,11,36].

Single-center studies comparing both these methods have shown conflicting results [37,38]. PTBD seems to provide higher clinical and technical success rates with a lower risk of cholangitis [38]. However, it is associated with pain and discomfort at the skin puncture site, a greater risk of infection and bleeding, and a high reintervention rate [39]. Not least, the presence of an external percutaneous catheter significantly affects the patient's quality of life, representing an important issue in their decision-making during informed consent. Recent studies of palliative endoscopic BD using SEMS reported higher technical and clinical success rates, along with longer stent patency, without any increase in adverse events, even for multiple or bilateral BD [40,41].

Regarding endoscopic BD in HMBO, controversy also still exists regarding the optimal type of stent, drainage area, required drained liver volume, and bilateral stenting method [42]. One critical aspect is the optimal amount of liver to drain in order to obtain adequate BD in patients with high grade HMBO. According to a study by Vienne *et al*, draining at least 50% of the liver volume was a significant predictor of drainage effectiveness in HMBO, in terms of a lower risk of cholangitis and longer patient survival: this approach requires bilateral biliary stenting in most cases [43].

Assuring sufficient drainage of 50% of the total liver volume is particularly important in patients with impaired liver function; on the other hand, excessive multi-stenting, particularly in the atrophic area, should be avoided, to reduce the risk of infection and cholangitis [44]. Moreover, it is fundamental to drain all substantive ductal systems into which contrast has been injected (whether intentionally or not), because incomplete drainage is a known predictor of infection and sepsis [11]. For these reasons it is clear that a great deal of preprocedural planning, with a careful review of cross-sectional imaging, is fundamental, along with a high level of skill in performing therapeutic biliary endoscopy.

Guidelines agree upon the choice of SEMS compared with plastic stents in patients with HMBO. U-SEMS have many advantages over plastic stents: an open wire mesh that does not occlude side branches of intrahepatic ducts or the cystic ducts, a larger diameter that provides more prolonged stent patency, and an easier passage through the biliary strictures thanks to a thin delivery catheter with a sharp tip. Plastic stents and SEMS have been compared in several trials and meta-analyses, with the latter showing higher patency rates, lower reintervention rates and favorable cost-effectiveness [18,42,45]. Plastic stents are still recommended as temporary drainage for patients with an undetermined surgical or palliative plan, or when the endoscopist may not know the best side to be drained [4,11].

Nevertheless, SEMS occlusion caused by tumor ingrowth or overgrowth occurs in 20-50% of cases: in these cases, it is frequently impossible to remove the embedded stent, while endoscopic stent revision is often a very challenging procedure, sometimes requiring PTBD as salvage BD [40,46].

Unilateral (or single) stenting is technically easier than bilateral (or multisectorial) stenting; as a consequence, it has been associated with higher technical and clinical success rates and a lower incidence of complications [47]. However, as mentioned above, in Bismuth III/IV strictures, multiple biliary segments often need to be drained. A randomized study in patients with advanced HMBO reported that bilateral drainage using SEMS had superior stent patency, a lower reintervention rate, and a similar adverse event rate as compared with unilateral drainage [48].

Bilateral stenting using SEMS can be performed using the "stent by stent" (SBS) or the "stent in stent" (SIS) technique. In the SBS technique, 2 SEMS are inserted parallel to each other into both left and right hepatic ducts. In the SIS technique, the second SEMS is inserted to the contralateral hepatic duct by crossing the wire mesh of the first SEMS, resulting in a Y-shaped configuration more similar to the physiologic anatomy.

To date, no consensus has been reached on the optimal approach and the choice of the appropriate technique should be based on the endoscopist's experience, the technical difficulty and the degree of bile duct dilation. A recent randomized controlled trial by Lee *et al* showed no significant differences between the 2 approaches in terms of technical feasibility, adverse events or stent patency duration [49]. Recurrent biliary obstruction after bilateral SEMS stenting is not uncommon in patients with HMBO, ranging from 3-45% [40,46]. Endoscopic revision can be technically challenging, but usually represents the first approach, as it is less invasive. Percutaneous or EUS-guided interventions are alternatives when primary endoscopic intervention using ERCP fails [50].

TBD in resectable HMBO

In patients with resectable HMBO, preoperative BD is not routinely recommended [10], as it has been related to worse postoperative outcomes in patients with a predicted future liver remnant (FLR) of ≥30%. Some studies reported that preoperative BD of hilar cholangiocarcinoma is associated with a higher postoperative morbidity rate, in particular because of infections, and no significant difference in postoperative mortality [51].

However, in selected patients, such as those presenting with cholangitis or with a predicted insufficient FLR volume following surgery, preoperative BD appears to be indicated to improve liver function and decrease jaundice. In particular, when FLR is less than 30%, portal vein embolization in combination with BD of future remnant liver seems to reduce the risk of hepatic insufficiency by promoting hepatic parenchyma regeneration and hypertrophy [4]. For these reasons, the indication for preoperative drainage in patients with HMBO should be discussed by a multidisciplinary team, based on patient characteristics and center experience.

In cases when drainage is required in the preoperative setting, there is no consensus as to the optimal modality of BD [9], and even less regarding the best modality of BD in relation to Bismuth-Corlette classification [36]. Data from the literature are inconsistent when it comes to the best modality of drainage in this setting, endoscopic or percutaneous. TBD is generally preferred, as it avoids external drainage; however, it has lower technical success rates and higher rates of complications, such as pancreatitis and cholangitis, compared with PTBD, probably due to the high technical complexity of such endoscopic procedures [52,53].

Table 1 Technical and clinical success rates, adverse event rates, advantages and disadvantages of the main available techniques for drainage of malignant biliary obstruction

Technique	Technical success	Clinical success	Adverse events	Advantages	Disadvantages
TBD [86]	94.7%	94.2%	22.3%	Widely available "Physiologic" biliary drainage	Failure in case of inaccessible papilla/duodenal infiltration/altered anatomy Tumor ingrowth/overgrowth
PTBD [16,17]	91.8%	80.8%	23%	Widely available Access to all intrahepatic bile duct branches High technical success rates	External drainage Pain High rates of complications (reintervention, dislodgement, infection) Reported risk of seeding
EUS-CDS [3]	93%	96%	11%	One-step technique with EC-LAMS Lower risk of pancreatitis than TBD	High rate of long-term stent dysfunction
EUS-HGS [70,95]	96%	90 - 92%	16-18%	Far from tumor Drainage of both for distal and hilar MBO	Multistep complex technique High expertise Only left lobe access Severity of adverse events
EUS-GBD [84]	100%	81%	10%	One-step technique Rescue in distal MBO with failure of TBD/other EUS-BD	Patency of cystic duct Not applicable to cholecystectomy patients
EUS-AS [77,81]	92%	97%	10-14%	Applicable in altered anatomy Combined approach with EUS-HGS	Technical complexity Fewer dedicated devices

TBD, transpapillary biliary drainage; PTBD, percutaneous transhepatic biliary drainage; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-HGS, EUS-guided hepaticogastrostomy; EUS-GBD, EUS-guided gallbladder drainage; EC-LAMS, electrocautery-enhanced lumen apposing metal stent; MBO, malignant biliary obstruction; EUS-BD, EUS-guided biliary drainage

Nevertheless, a major concern has historically been the association between PTBD and higher rates of peritoneal metastasis as compared with TBD [54]. Mainly because of this issue, recent guidelines from the American Society for Gastrointestinal Endoscopy advise against the routine use of PTBD as first-line therapy compared with TBD [9]. However, a recent meta-analysis showed a lack of statistical difference between TBD and PTBD in terms of seeding metastasis. The authors hypothesized that one possible explanation could be that the definition of seeding metastasis differed among the studies analyzed [36].

Regarding the type of TBD in resectable HMBO, European Society of Gastrointestinal Endoscopy (ESGE) guidelines suggest the use of plastic stents or nasobiliary drains, and discourage the use of SEMS, because of insufficient data and the risk of precluding curative surgery [10]. Despite these recommendations, a recent study considering patients with potentially resectable perihilar cholangiocarcinoma showed no difference in surgical outcome between plastic stents and SEMS, with successful complete intraoperative SEMS removal in all patients and a significant lower rate of cholangitis with SEMS [55].

EUS-BD

EUS-BD represents a treatment option for the relief of jaundice that can be achieved through an extrahepatic or intrahepatic approach: the former is represented by direct transluminal stenting from the duodenum (EUS-guided choledochoduodenostomy [EUS-CDS]), while the intrahepatic approach can involve direct transluminal stenting of the left intrahepatic biliary ducts from the stomach (EUS-guided hepaticogastrostomy [EUS-HGS]), or the right intrahepatic biliary ducts from the duodenum (EUS-guided hepaticoduodenostomy), or antegrade transpapillary stent placement (EUS-AS) (Fig. 1). In addition, the EUS-assisted rendezvous technique (EUS-RV), using either extra- or intrahepatic access, can provide access to the papilla in cases of ERCP failure, thus permitting subsequent traditional ERCP. Finally, EUS-guided gallbladder drainage (EUS-GBD) has recently become an alternative as a rescue in cases of conventional EUS-BD failure [12]. An overview of the efficacy, safety, advantages and disadvantages of the main available techniques for BD of MBO is presented in Fig. 3.

Since its first report in 2001 by Giovannini *et al* [56], EUS-BD has evolved rapidly, thanks to the introduction of dedicated devices. The introduction of EUS-BD, as an alternative to or in combination with standard TBD and/or PTBD, has greatly enlarged the spectrum of drainage possibilities for both DMBO and HMBO: an algorithm of DMBO and HMBO management is proposed in Table 1.

EUS-CDS

Until few years ago, EUS-CDS was a multistep technique with the use of non-dedicated ERCP accessories, under echo-endoscopic and fluoroscopic guidance. In recent years, the

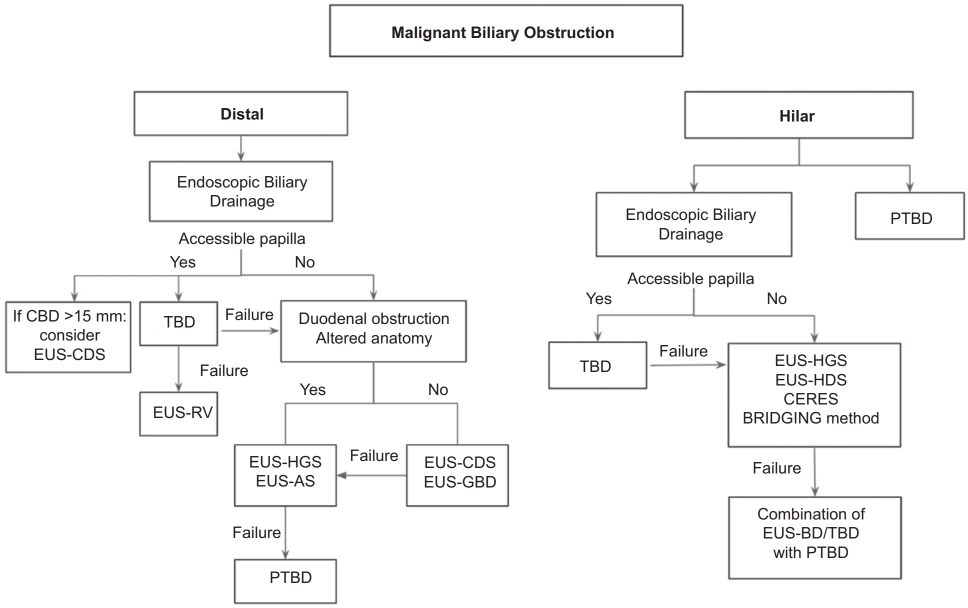

Figure 3 Proposed algorithm for the management of distal and hilar malignant biliary obstruction
CBD, common bile duct; EUS-CDS, EUS-guided choledodochoduodenostomy; TBD, transpapillary biliary drainage; EUS-RV, EUS-guided rendezvous; EUS-HGS, EUS-guided hepaticogastrostomy; EUS-AS, EUS-guided antegrade stenting; PTBD, percutaneous transhepatic biliary drainage; EUS-HDS, EUS-guided hepaticoduodenostomy; CERES, combined ERCP and endosonography

advent of dedicated stents, such as the lumen-apposing metal stent (LAMS), has increased the efficacy and safety profile of EUS-BD, allowing a rapid spread of this approach in the management of biliary obstructions.

LAMS are self-expanding fully-covered stents, characterized by a "yo-yo" shape with bilateral large flanges and a short body that enables a high-force apposition between 2 hollow organs with a significant reduction of the risk of leak or stent migration.

To overcome the limits of a multistep procedure, electrocautery-enhanced LAMS (EC-LAMS) have been developed, revolutionizing the world of interventional EUS. EC-LAMS are provided with an electrocautery-enhanced delivery system that allows direct organ access in a single step, with no need for prior needle puncture, guidewire manipulation or dilation of the fistula. EC-LAMS permits a free-hand and single-step procedure, minimizing the technical steps, and procedural and fluoroscopy times, with potentially higher rates of success and lower adverse event rates [57,58].

LAMS have different measures, both in length and in diameter, generally a 6 or 8-mm inner diameter LAMSs is used for EUS-CDS. A common bile duct dilation of at least 15 mm is generally recommended when performing EUS-CDS; with ascites representing a relative contraindication [12]. A technique involving intra-channel release of the proximal stent flange minimizes the risk of stent maldeployment and theoretically may obviate the need for fluoroscopy [59].

The efficacy of EUS-CDS has been reported in several studies and RCTs, with high technical and clinical success rates [60,61]. Recently, a large multicenter retrospective study by Fugazza *et al*, investigating the outcomes of EUS-CDS using LAMS after failed ERCP in DMBO (256 patients), has confirmed high technical and clinical success rates (93.3% and 96.2%, respectively) with an acceptable adverse event rate of 10.5% [3].

A recent systematic review and meta-analysis (31 studies, 820 patients) comparing LAMS vs. SEMS for EUS-CDS reported a slight superiority of LAMS over SEMS, especially in terms of safety, although this did not reach statistical significance: the authors reported similar pooled rates of technical and clinical success (94.8% vs. 92.7% and 93.6% vs. 91.7%, respectively) and pooled rates of procedure-related adverse events and overall adverse events (6.2% vs. 12.2% and 17.1% vs. 18.3%, respectively). The analysis was mainly limited by the lack of RCTs comparing LAMS and SEMS for EUS-CDS [62].

EUS-CDS procedure-related advent events are represented by bleeding, cholangitis or stent misdeployment or dislodgement, leading to leakage of bile and/or gastrointestinal content, perforation or pneumoperitoneum. If promptly recognized, misdeployment can generally be managed by intraprocedural stent-in-stenting [12,63]. Other rarely reported adverse events are hemobilia, cholecystitis, arteriobiliary fistula and pseudoaneurysm, with mortality rates from 0-3% [64]. A meta-analysis reported a pooled adverse events rate of 14% for EUS-CDS (4% cholangitis, 4% bleeding, 4% bile leak, 3% perforation) [65].

The most common long-term complication and disadvantage of the LAMS is represented by stent obstruction, due to food debris, sludge, tumor overgrowth or kinking of the stent, frequently leading to cholangitis. Stent patency is a critical aspect in the palliative setting: stent obstruction and cholangitis often lead to a delay in the patient's oncological management.

A recent multicenter retrospective study by Vanella *et al* (93 patients) analyzed long term LAMS dysfunction, which occurred in 31.8% of patients after a mean of 166 days (95%CI 91-241), with a mean dysfunction-free survival of 394 days (95%CI 307-482) and the presence of duodenal invasion being the only independent predictor of LAMS dysfunction. In addition, the authors have proposed a classification of types of stent dysfunction (types 1-5): the most frequent was stone impaction (33.3%), followed by food impaction (18.5%) and LAMS invasion or compression on the duodenal side (11.1%) [66].

Stent occlusion can be generally managed by endoscopic reintervention, usually by placing one or more plastic stents through the original stent. Some recent multicenter studies [67]. have shown a reduction in obstruction rate with the insertion of a coaxial plastic stent within the LAMS, although another retrospective recent study found no significant difference [68].

EUS-HGS

EUS-HGS is a technically demanding procedure and is normally performed only in referral centers with high expertise. The ESGE guidelines suggest that EUS-CDS should be preferred over EUS-HGS in the management of DMBO, as the former has been associated with a lower rate of adverse events [12,65]. However, in cases where it is impossible to reach the duodenum, such as gastric outlet obstruction or post-surgical altered anatomy, the intrahepatic approach using EUS-HGS could represent the best alternative. Dilation of the left intrahepatic ducts is mandatory when using this approach. Contraindications are massive ascites, coagulopathy or cancer infiltration of the target gastric wall.

EUS-HGS is a complex, multistep procedure, performed entirely with a therapeutic echoendoscope under EUS and fluoroscopy imaging, with sequential use of many accessories, such as a 19-G fine-needle aspiration needle, guidewire, cystotome, balloon dilators or needle knife, and finally a biliary stent.

Either plastic stents or covered SEMS have been used. Recently, dedicated stents have been developed, characterized by a proximal covered part and a distal uncovered part, to overcome the risk of intrahepatic biliary duct occlusion, and the risk of bile leak and peritonitis across the fistula [69].

In expert hands, EUS-HGS showed technical and clinical success rates of 96% (range 65-100%) and 90% (range 66-100%), respectively, with an overall adverse event rate of 18% (range 0-50%) [70]. This technique has been described both in the setting of MDBO and in HMBO, alone or in combination with transpapillary drainage, allowing different modalities of drainage to be performed (such as the bridging method, or CERES-combined ERCP and endosonography), as shown in Fig. 2 [71-73].

The types of adverse events related to EUS-HGS are often more serious and life-threatening compared with other techniques, such as perforation, bilio- or pneumoperitoneum, mediastinitis or intraperitoneal migration of the stent; for this reason, EUS-HGS still remains a select procedure restricted to highly experienced interventional endoscopists [74].

In EUS-BD of DMBO without duodenal obstruction, both EUS-CDS and EUS-HGS are efficient alternatives (Fig. 1). Some randomized trials and meta-analyses compared the outcome of EUS-CDS and EUS-HGS in DMBO, without finding a significant difference in efficacy and safety [75,76]. Other studies reported a higher risk of complications and reintervention for EUS-HGS, with high heterogeneity between studies [77,78].

Recently, in a subgroup analysis, Giri *et al* reported a significantly higher adverse event rate with HGS than with CDS (15.5% vs. 11.9%, respectively; P=0.05) [77]. In view of its apparently better safety, the guidelines suggest preferring EUS-CDS over EUS-HGS for decompression of DMBO [12], although future prospective studies are warranted comparing the 2 techniques, with the use of EC-LAMS for EUS-CDS, and new dedicated hybrid SEMS for EUS-HGS, respectively.

EUS-RV

In cases of ERCP failure with an accessible papilla, EUS-RV represents an alternative that allows transpapillary stenting via ERCP over a guidewire previously inserted through EUS-guided intra- or extrahepatic biliary access. Overall, the reported technical success rates of EUS-RV ranged between 72% and 98%, with a mean of 84% [12,79]. Reported adverse event rates ranged from 13-34%, with higher rates following intrahepatic puncture [80].

EUS-AS

In this technique, after biliary access has been achieved and a guidewire advanced through the stricture into the small bowel lumen, a metal stent is deployed over the guidewire in an antegrade fashion through the papilla or anastomosis (in case of altered anatomy). Like the transpapillary approach, this technique has the advantage of preserving normal anatomy; however it is technically difficult and prone to failure. A recent systematic review (9 studies, 210 patients) reported an overall technical success rate of 92% and an overall adverse event rate of 14%, mainly post-procedure pancreatitis [12,81].

EUS-GBD

Conventionally, cases of endoscopic drainage failures are managed by PTBD; recently EUS-GBD has emerged as a suitable rescue alternative to treat DMBO when both TBD and EUS-BD fail. EUS-BD can fail because of the presence of intervening vessels, inadequate window for puncture, inability to advance a guidewire or a stent into the bile duct, duodenal stenosis or presence of a duodenal stent, thickened bile duct wall or non-dilation of the intrahepatic ducts.

EUS-GBD is currently recommended by ESGE guidelines as the preferred method (as opposed to percutaneous gallbladder drainage and transpapillary gallbladder drainage) to obtain BD in high-risk surgical patients with acute cholecystitis [12]. The concept of gallbladder drainage for MBO was adopted from surgery: surgical cholecysto-enteric anastomosis for BD has been reported, although it was associated with very high rates of morbidity and mortality.

Nowadays, EUS-GBD is mainly performed using EC-LAMS, with a free-hand technique. The gallbladder wall can be punctured either via the antrum or the duodenal bulb, depending on which provides the best access window. Cystic duct patency is fundamental for the clinical effectiveness of the BD; furthermore, proximity of the cystic duct opening to the site of malignant obstruction may be a risk factor for recurrent obstruction.

In 2016, Imai *et al* reported the first case series on the feasibility of EUS-GBD for drainage of DMBO, using a multistep technique and PC-SEMS [82]. Since then, with the advent of LAMS and EC-LAMS, several studies have evaluated the efficacy and safety of EUS-GBD as a rescue treatment in patients with DMBO following failed TBD and/or EUS-BD, showing high technical and clinical success rates, with an acceptable adverse events rate [83,84].

A recent systematic review and meta-analysis (5 studies, 104 patients) of the efficacy and safety of EUS-GBD as a rescue procedure in the management of MBO reported a 100% technical success rate, a pooled rate of clinical success of 85%, and a pooled rate of adverse events of 13%. No fatal adverse events were reported. The pooled rate of stent dysfunction was 9%, mainly related to food impaction in the stent complicated by recurrent cholecystitis, all of which resolved with endoscopic revision of the stent and antibiotic therapy [85]. In conclusion, EUS-GBD may represent a possible alternative for decompression of the biliary system in cases where conventional approaches have failed (TBD and/or EUS-BD), provided that cystic duct patency has been confirmed.

Hot topics for EUS-BD

EUS-BD as primary BD

In the setting of primary BD in inoperable patients, the guidelines recommend that TBD should be preferred, although the latest ESGE guidelines suggest also considering primary EUS-BD at high-volume expert centers [10,12]. It is still unclear which approach, TBD or primary EUS-BD, has better efficacy and safety in unresectable DMBO. The main advantages of EUS-BD (EUS-CDS and EUS-HGS) over TBD are the theoretical elimination of the risk of PEP, and the improvement in stent patency because of the distance of the stent from the tumor mass [86].

In 2018, 3 RCTs compared the outcomes of the 2 techniques in primary DMBO drainage, all of them performing EUS-BD with a multistep technique and non-dedicated stents [87-89]. Overall, EUS-BD and TBD showed similar efficacy and safety in DMBO. In their trial, Paik and colleagues reported a significantly longer duration of patency, with lower rates of adverse events and reintervention with EUS-BD [87].

Likewise, a meta-analysis by Bishay *et al*, which included 396 patients in 5 studies (3 RCTs and 2 retrospective studies), reported no significant difference in overall clinical success (relative risk [RR] 0.98, 95%CI 0-93-1.03) and overall adverse events (RR 0.84, 95%CI 0.35-2.01), although in the EUS-BD group no cases of PEP were reported (RR 0.22, 95%CI 0.05-1.02). Moreover, there was no difference in the rates of stent obstruction (RR 0.32, 95%CI 0.11-0.99) and reintervention (RR 0.65, 95%CI 0.29-1.47) [90]. Recently, 2 multicenter RCTs compared primary EUS-CDS with EC-LAMS vs. TBD with SEMS (either covered [91,92] or uncovered [91]) for biliary decompression of patients with unresectable [91,92] or borderline resectable [91] DMBO. The primary outcome was 1-year stent patency/dysfunction, and in both trials EUS-BD did not reach superiority over TBD. Overall, EUS-BD exhibited shorter procedural times than TBD, without a significant difference in clinical success or adverse event rates. Again, in borderline resectable patients, there was no difference in surgical outcomes between the 2 techniques [91].

Other RCTs are currently ongoing to compare primary EUS-BD vs. TBD in DMBO. Given the current literature, EUS-BD appears to be an efficient alternative to TBD, when performed by expert hands, and can assume a primary role in BD, especially when a difficult ERCP is expected.

EUS-BD in resectable MBO

ESGE guidelines on endoscopic BD recommend TBD with SEMS in resectable or borderline resectable patients [10]. This recommendation was confirmed in more recent ESGE guidelines, which suggest considering EUS-BD only in cases of ERCP failure, because of the lack of quality evidence [12].

Small retrospective studies have reported high success rates of EUS-BD as preoperative drainage, without any significant difference in surgical outcomes [57,93]. A randomized trial comparing EUS-BD vs. TBD for primary BD in patients with pancreatic cancer did not show any difference in surgical outcome in a small subgroup of patients (n=10) who underwent surgery after preoperative neoadjuvant therapy [89].

A recent international multicenter retrospective study, comparing EUS-BD vs. ERCP drainage before hepatobiliary surgery in 145 patients, has reported higher rates of surgical technical and clinical success (97% vs. 83% and 97% vs. 75%, respectively) and shorter hospital stays after surgery (19 days vs. 10 days) in the EUS-BD group [94]. However, more prospective data are needed to confirm the safety of EUS-BD in this group of patients and to compare EUS-BD and TBD in terms of surgical outcomes.

Regarding HMBO, there is a lack of data regarding EUS-BD in a preoperative setting, with no studies directly comparing this technique to PTBD and/or TBD. The guidelines recommend TBD over PTBD in hilar biliary strictures, mainly because of the risk of tumor seeding [9]. Overall, the evidence regarding these issues is limited and further investigation is warranted.

Double drainage of MBO and gastric outlet obstruction (mGOO)

DMBO and malignant mGOO can occur simultaneously at the diagnosis or during the course of pancreatic malignancy. Moreover, mGOO represents one of the main causes of failure of TBD because of the impossibility to access the papilla.

Traditionally, these types of patients were referred for surgical gastroenterostomy (SGE) and hepaticojejunostomy (SHJ), with the advantage of long-lasting palliation, but at the cost of significant rates of morbidity and mortality. Until a few years ago, endoscopic alternatives consisted of enteral stenting (ES) with percutaneous BD, or through-the-mesh endoscopic stent placement.

Compared with SGE, ES is a safer procedure, with shorter hospital stays and rapid relief of obstructive symptoms. On the other hand, ES with SEMS is associated with high rates of long-term stent dysfunction and need for re-intervention, mainly secondary to stent ingrowth.

With the recent advent of EC-LAMS, EUS-guided gastroenterostomy (EUS-GE) has become the best minimally invasive alternative to surgery in patients with mGOO, given its higher clinical success and lower recurrence rates as compared with ES [95]. For these reasons, recent guidelines recommend ES in cases of short life expectancy (<3 months), preferring EUS-GE in other cases, in expert centers [12].

Synchronous endoscopic biliary and duodenal stenting is a feasible technique, with reported technical success ranging from 82-94% [96]. However, particularly in patients who have a duodenal stent already in place, TBD is more likely to fail, because of difficult cannulation, malignant encasement of the papilla or duodenal SEMS ingrowth. In these cases, performing a EUS-CDS with LAMS through the mesh of the enteral stent can represent a valid option, with high technical success [97].

Recently, same-session EUS-guided double bypass (EUS-HGS and EUS-GE) has been investigated, given the potential better patency on both biliary and enteral sides [98]. A recent multicenter retrospective study of 154 patients compared same-session EUS-guided double bypass to surgical double bypass (SHJ and SGE). The authors reported similar technical and clinical success rates, with fewer overall and severe adverse events using the EUS approach than with surgery, despite the former being applied to a patient population with more comorbidities [99].

Concluding remarks

With the advent of EUS-guided BD, a broad range of endoscopic drainage techniques have become available for patients with MBO, both distal and hilar. Nowadays, EUS and ERCP are clearly complementary techniques, instead of alternatives. Thus, a tailored and multidisciplinary management of MBO appears to be even more important, in order to offer the patient the best drainage modality in terms of efficacy, safety and long-term patency. At present, chemotherapy, both neoadjuvant and palliative, has consistently improved, prolonging patients' survival; thus, patency of BD has become a central issue in patients with MBO, in order to allow access to therapy as soon as possible, with the fewest possible interruptions due to stent dysfunction. Especially in complex biliary strictures, a multidisciplinary intervention with a partnership between the endoscopist and the interventional radiologist, ideally within a hybrid suite, could offer the patient the best therapy. Future well-designed, prospective multicenter studies will help us determine the best algorithm for both palliative and preoperative BD.

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