Article published online: 2021-12-22

Thieme

Therapeutic endoscopic ultrasound: European Society of Gastrointestinal Endoscopy (ESGE) Guideline

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published online 22.12.2021

Bibliography
Endoscopy 2022; 54: 185–205
DOI 10.1055/a-1717-1391
ISSN 0013-726X
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This article is published by Thieme.
Georg Thieme Verlag KG, Rüdigerstraße 14,
70469 Stuttgart, Germany

Supplementary material
Supplementary material is available under
https://doi.org/10.1055/a-1717-1391

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MAIN RECOMMENDATIONS

1 ESGE recommends the use of endoscopic ultrasound-guided biliary drainage (EUS-BD) over percutaneous transhepatic biliary drainage (PTBD) after failed endoscopic

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retrograde cholangiopancreatography (ERCP) in malignant distal biliary obstruction when local expertise is available.
Strong recommendation, moderate quality evidence.

2 ESGE suggests EUS-BD with hepaticogastrostomy only for malignant inoperable hilar biliary obstruction with a dilated left hepatic duct when inadequately drained by ERCP and/or PTBD in high volume expert centers.
Weak recommendation, moderate quality evidence.

3 ESGE recommends that EUS-guided pancreatic duct (PD) drainage should only be considered in symptomatic patients with an obstructed PD when retrograde endoscopic intervention fails or is not possible.
Strong recommendation, low quality evidence.

4 ESGE recommends rendezvous EUS techniques over transmural PD drainage in patients with favorable anatomy owing to its lower rate of adverse events.
Strong recommendation, low quality evidence.

5 ESGE recommends that, in patients at high surgical risk, EUS-guided gallbladder drainage (GBD) should be favored over percutaneous gallbladder drainage where both techniques are available, owing to the lower rates of adverse events and need for re-interventions in EUS-GBD.
Strong recommendation, high quality of evidence.

6 ESGE recommends EUS-guided gastroenterostomy (EUS-GE), in an expert setting, for malignant gastric outlet obstruction, as an alternative to enteral stenting or surgery.
Strong recommendation, low quality evidence.

7 ESGE recommends that EUS-GE may be considered in the management of afferent loop syndrome, especially in the setting of malignancy or in poor surgical candidates.
Strong recommendation, low quality evidence.

8 ESGE suggests that endoscopic ultrasound-directed transgastric ERCP (EDGE) can be offered, in expert centers, to patients with a Roux-en-Y gastric bypass following multidisciplinary decision-making, with the aim of overcoming the invasiveness of laparoscopy-assisted ERCP and the limitations of enteroscopy-assisted ERCP.
Weak recommendation, low quality evidence.

SOURCE AND SCOPE

This Guideline is an official statement of the European Society of Gastrointestinal Endoscopy (ESGE). It provides guidance on the performance of therapeutic endoscopic ultrasound. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system was adopted to define the strength of recommendations and the quality of evidence.

1 Introduction

Since its development, endoscopic ultrasound (EUS) has become an established diagnostic modality that allows visualization of previously inaccessible anatomical regions with the capability of obtaining tissue for diagnosis. Optimization of imaging quality and Doppler, coupled with the development of linear array echoendoscopes with large therapeutic channels, has allowed access to fluid collections, the pancreatic and biliary ducts, as well as luminal structures adjacent to the gastrointestinal (GI) tract. With the use of fine-needle aspiration (FNA) needles and guidewires under real-time endosonographic and fluoroscopic control, these structures can be accessed to allow therapeutic procedures.

Given the tremendous advances made in this field, the European Society of Gastrointestinal Endoscopy (ESGE) has elected to publish guidelines on the use of therapeutic EUS. A previous ESGE guideline addressed EUS-guided management of fluid collections in acute necrotizing pancreatitis [1]. The current guideline will focus on EUS-guided drainage of the pancreaticobiliary system and its use in GI-tract anastomosis. This guideline will be published in conjunction with an ESGE technical review where practical aspects related to these procedures, as well as salvage procedures should adverse events (AEs) occur, will be comprehensively described.

2 Methods

ESGE commissioned this guideline and appointed a coordinating team (S.v.d.M., J.H., R.W., M.Br.). A team of experts across different domains in therapeutic EUS was convened in May 2020. Two task force leaders were appointed (M.Ba. and M.P.M.) and their team members were instructed to scrutinize the literature for relevant articles pertaining to their fields of expertise. Topic-specific clinical key questions were generated by each task force. Searches were performed on Medline (via Pubmed) and the Cochrane library up to June 2021. The level of evidence for each question was scored according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system into high, moderate, low, or very low [2]. Recommendations were drafted and the strength of each was determined as strong or weak. In addition, various web meetings were held to discuss and resolve issues, and formulate recommendations.

In July 2021, a final draft was sent to all group members for review. After all authors approved the final version, the manuscript was submitted to *Endoscopy* for publication. ESGE acknowledges that the field of therapeutic EUS is rapidly changing and that continued efforts will be required in the future to

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ABBREVIATIONS

AE	adverse event
EDGE	endoscopic ultrasound-directed transgastric endoscopic retrograde cholangiopancreatography
EA-ERCP	enteroscopy-assisted endoscopic retrograde cholangiopancreatography
EA-ERP	enteroscopy-assisted endoscopic retrograde pancreatography
ERCP	endoscopic retrograde cholangiopancreatography
ERP	endoscopic retrograde pancreatography
ESGE	European Society of Gastrointestinal Endoscopy
EUS	endoscopic ultrasound
EUS-BD	EUS-guided biliary drainage
EUS-CDS	EUS-guided choledochoduodenostomy
EUS-GBD	EUS-guided gallbladder drainage
EUS-GE	EUS-guided gastroenterostomy
EUS-HGS	EUS-guided hepaticogastrostomy
EUS-RV	EUS-assisted rendezvous
FNA	fine-needle aspiration
GI	gastrointestinal
GOO	gastric outlet obstruction
GRADE	Grading of Recommendations Assessment, Development and Evaluation
LA-ERCP	laparoscopy-assisted ERCP
LAMS	lumen-apposing metal stent
MPD	main pancreatic duct
OR	odds ratio
PD	pancreatic duct
PTBD	percutaneous transhepatic biliary drainage
PTGBD	percutaneous gallbladder drainage
RCT	randomized controlled trial
RR	relative risk
RV-ERP	rendezvous-assisted endoscopic retrograde pancreatography
RYGB	Roux-en-Y gastric bypass
SEMS	self-expandable metal stent
WEST	wireless endoscopic simplified technique

update and maintain these guidelines as additional high quality published data are generated.

3 Definitions

In general, terminology in therapeutic EUS procedures is not standardized. In this overview, ESGE aims to provide a framework by which these procedures should best be defined.

3.1 EUS-assisted vs. EUS-guided techniques

An "EUS-assisted" technique refers to the use of EUS to facilitate another procedure. The prime example of an EUS-assisted technique is rendezvous, where EUS facilitates the introduction of a guidewire across the papilla, stricture, or anastomosis to within reach of a duodenoscope. The linear echoendoscope is then exchanged for a duodenoscope to complete the procedure. An EUS-assisted technique is therefore an "indirect technique" performed using two endoscopes.

"EUS-guided" interventions refer to procedures performed exclusively under EUS guidance and are considered "direct techniques". These procedures can be performed in multiple steps following access to the target organ with an FNA needle and guidewire that allows insertion of various tools and placement of a stent. Alternatively, an all-in-one electrocautery-enhanced platform may be used, with placement of a lumen-apposing metal stent (LAMS), using "freehand" introduction of the device into the target structure without prior placement of a guidewire. The latter technique may obviate the need for multiple accessory exchanges. Some EUS-guided interventions may further be assisted by the use of additional accessories, such as nasobiliary or other catheters, or balloons, to facilitate these procedures.

While indirect techniques enable retrograde drainage by endoscopic retrograde cholangiopancreatography (ERCP), direct techniques may allow antegrade or transmural drainage. Antegrade procedures reinstate the normal flow direction by bridging a stenosis and/or the papilla, whereas transmural drainage redirects the flow away from the normal drainage route by creating a new anastomosis.

4 Biliary and pancreatic duct drainage

ERCP remains the standard of care for the endoscopic management of many pancreaticobiliary disorders; however, conventional ERCP may not be feasible in patients with surgically altered GI anatomy, luminal obstruction preventing access to the major and minor papilla, or failed cannulation of the pancreatic and bile ducts. The therapeutic role of EUS has evolved to become a complementary technique to ERCP to provide adequate drainage in such patients. EUS allows visualization of the intra- and extrahepatic biliary tree and the pancreatic duct (PD), and serves as a platform for various successful drainage strategies, as described above and in the sections that follow.

Procedural consent for EUS-guided pancreaticobiliary drainage procedures should emphasize the technical aspects of the procedure, as well as the potential AEs. The complexity and risks associated with these procedures should not be understated. In selected clinical scenarios, procedural consent for EUS-guided drainage should be obtained prior to conventional ERCP, in anticipation of failed cannulation, to achieve adequate drainage within the same session.

Expert consensus and current guidelines recommend that EUS-guided pancreaticobiliary drainage procedures should be performed by dedicated pancreaticobiliary endoscopists in rooms equipped with both EUS and fluoroscopy [3–6], with sur-

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gical and interventional radiology support available in the event of failure or severe AEs.

4.1 Key question 1: What are the main approaches that employ EUS to achieve biliary drainage?

EUS-guided biliary drainage (EUS-BD) can be performed by one of three methods. With EUS-assisted rendezvous (EUS-RV), an EUS-FNA needle is advanced under endosonographic guidance into an intra- or extrahepatic bile duct, allowing guidewire passage through the papilla for subsequent retrieval using a duodenoscope, thereby allowing conventional biliary ERCP to be performed.

Alternatively, EUS-guided direct transluminal stenting using either a transgastric (EUS-guided hepaticogastrostomy [HGS]) or transduodenal (EUS-guided choledochoduodenostomy [CDS]) approach may be performed without accessing the papilla. With these two techniques, the entire procedure is performed using the echoendoscope, with either the common bile duct or intrahepatic bile ducts being connected to the duodenum or stomach, respectively, using a stent.

A further method that may be considered is antegrade transpapillary (or transanastomotic) stent placement. With this technique, a guidewire is advanced and manipulated across the stenosis, either via the transpapillary or transanastomotic route, prior to stent placement.

4.2 Key question 2: What are the technical and clinical success rates of each approach?

4.2.1 What are the definitions of "technical success" and "clinical success"?

In EUS-RV techniques, guidewire passage from the biliary system into the small bowel that allows conventional ERCP to be performed defines technical success, while clinical success is attributable to the outcomes of the subsequently performed ERCP. For all other EUS-BD procedures in patients with malignant biliary obstruction, correct transmural or transpapillary stent placement resulting in flow of bile into the GI tract identifies technical success, while a post-procedural (i.e. within 2–4 weeks) reduction in bilirubin of 50%–75% from preprocedural values indicates clinical success.

For patients with benign disease, successful biliary access defines technical success, while resolution of the clinical indication for which EUS-guided biliary intervention was performed indicates clinical success.

4.2.2 Do different EUS-BD approaches have different success rates in malignant disease?

Available data from retrospective studies, randomized controlled trials (RCTs), and meta-analyses have reported comparable technical and clinical success rates for EUS-CDS and EUS-HGS (**Tables 1s** and **2s**, see online-only Supplementary material) [7–37]. Pooled data from studies directly comparing these two techniques in 303 and 329 patients respectively, estimated technical and clinical success rates of 94% and 88% for EUS-CDS, and 96% and 87% for EUS-HGS (**Table 3s**) [10, 18, 19, 30, 38–46]. No comparative studies of the remaining approaches are available.

Most studies describing EUS-RV procedures in malignant biliary obstruction also contain data on patients with benign disease (**Table 4s**) [28, 47–52], thereby limiting the generalizability of the outcomes data. Overall, technical success rates of EUS-RV procedures ranged between 72% and 98% (**Table 4s**), with a mean of 84%, similar to that which is reported in meta-analyses [53]. In the only available studies describing the outcomes of EUS-guided antegrade stent placement in patients with surgically altered anatomy, technical and clinical success rates varied from 86% to 95% and 71% to 95%, respectively (**Table 5s**) [33, 54]. Finally, EUS-guided gallbladder drainage (EUS-GBD) to decompress malignant distal biliary obstruction has shown excellent results, with 100% technical success, and clinical success ranging between 91.7% and 92.7%, albeit in a limited number of patients. It is currently regarded as a salvage procedure should other techniques fail (**Table 6s**) [55, 56].

4.2.3 Do different EUS-BD approaches have different success rates in benign disease?

EUS-BD outcomes reported in patients with benign disease include those in whom ERCP failed [57–60] or where ERCP could not be performed owing to surgically altered anatomy [58, 59, 61, 62]. Both the indications for EUS-BD and the approach used vary widely among the published studies, making comparisons difficult to interpret. EUS-RV was the primary technique in three studies [57, 60, 63], while in the remaining studies transmural "tubular" self-expandable metal stent (SEMS) placement via various drainage pathways (i.e. HGS, CDS, or hepaticojejunostomy) was performed [58, 59, 61, 62]. Technical success ranged between 77% and 83% in those studies involving EUS-RV [57, 60, 63]. When transmural drainage with a SEMS was used, technical and clinical success approached 100% [24, 58, 59, 61], with only one study reporting technical and clinical failures in 8% of patients [62].

4.3 Key question 3: What are the indications for EUS-BD?

EUS-BD has primarily been used as rescue therapy after failed ERCP. EUS-BD enables direct access to the bile ducts from either the stomach or the duodenum without the need to reach the papilla. As such, EUS-BD is feasible in patients with an endoscopically inaccessible papilla, as well as in patients with surgically altered anatomy.

When cannulation of the bile duct fails during ERCP, multiple strategies can be adopted using EUS-BD. The optimal drainage strategy depends on the underlying disease (benign/malignant) and the location of the obstruction (distal/hilar). In benign disease, such as common bile duct stones, EUS-BD allows placement of a guidewire across the papilla to facilitate ERCP via EUS-RV [64].

In malignant biliary obstruction, EUS-RV techniques may also enable placement of a transpapillary stent [65]. Alternatively, other options include the creation of a new anastomosis (EUS-HGS, EUS-CDS) upstream from the obstruction, potentially avoiding post-procedural pancreatitis. In malignant distal

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biliary obstruction, all options including EUS-RV procedures, EUS-CDS, EUS-HGS, EUS-guided antegrade stent placement, and EUS-GBD may be considered, whilst in malignant hilar obstruction only EUS-guided antegrade stent placement and EUS-HGS are feasible alternatives. EUS-HGS can be complementary to ERCP in patients with an unresectable hilar stricture and inadequate drainage of the left hepatic duct [23, 33, 66, 67]. Similarly, EUS-guided hepaticoduodenostomy may aid in drainage of the right biliary system [68, 69]. EUS-CDS, EUS-guided hepaticoduodenostomy and EUS-HGS have the additional benefit of the drainage point being distant from the malignant stricture, circumventing the risk of tumor ingrowth and offering the theoretical advantage of longer stent patency.

Experience with EUS-BD is growing. In addition to serving as rescue therapy, EUS-BD is now also being evaluated versus ERCP in ongoing randomized studies for primary biliary drainage in malignant distal biliary obstruction.

4.3.1 What are the contraindications for EUS-BD?

In some settings EUS-BD cannot be safely performed. These include the presence of intervening blood vessels and severe coagulopathy. Ascites may interfere with the trajectory of the needle and should also be regarded as a contraindication, as it is for percutaneous transhepatic biliary drainage (PTBD). In some patients, preprocedural drainage of ascites may be helpful to secure access to the biliary ducts [70]. If the bile ducts are not sufficiently dilated, that will also preclude the use of EUS-BD.

4.4 Key question 4: How does EUS-BD compare with the alternative approaches?

4.4.1 Is EUS-BD preferable to PTBD after failed biliary drainage in distal malignant disease?

RECOMMENDATION

ESGE recommends the use of EUS-guided biliary drainage over percutaneous transhepatic biliary drainage after failed ERCP in malignant distal biliary obstruction when local expertise is available.

Strong recommendation, moderate quality evidence.

PTBD is a widely available and efficient technique performed by interventional radiologists; however, it may be associated with significant morbidity [71]. Most available studies comparing EUS-BD and PTBD have included patients with distal malignant biliary obstruction. Small single-center, prospective or retrospective studies have shown comparable technical success (86 %–100 %), with similar or higher clinical success and fewer AEs, when using EUS-BD (**Table 7 s**) [32, 72–75]. In an RCT including 66 patients, comparable clinical success was accompanied by a significantly lower incidence of AEs in the EUS-BD cohort [76]. These results were further confirmed in a meta-analysis of nine studies including 483 patients, which demonstrated comparable technical success between EUS-BD and PTBD, although EUS-BD was associated with higher clinical success and fewer AEs [77].

4.4.2 Is EUS-BD preferable to PTBD after failed biliary drainage in proximal (hilar) malignant disease?

RECOMMENDATIONS

ESGE recommends, for cases with malignant hilar biliary obstruction, multidisciplinary consultation to determine the most effective biliary drainage strategy, either as a bridge to surgery or as definitive palliative therapy.

Strong recommendation, low quality evidence.

ESGE suggests EUS-guided biliary drainage with hepaticogastrostomy only for malignant inoperable hilar biliary obstruction with a dilated left hepatic duct when inadequately drained by ERCP and/or percutaneous transhepatic biliary drainage in high volume expert centers.

Weak recommendation, moderate quality evidence.

Endoscopic management of hilar strictures is challenging and should be performed in tertiary referral centers. It requires a thorough understanding of the anatomy, including anatomical variants, the extent of the disease, surgical resectability of the tumor, and the primary objective of biliary drainage (in preparation for surgery or as palliation). These complex situations require upfront discussions during multidisciplinary meetings involving interventional endoscopists, hepatopancreaticobiliary surgeons, digestive oncologists, and interventional radiologists to decide the optimal endoscopic biliary drainage strategy and avoid situations such as SEMS placement in potentially resectable settings or futile drainage of atrophic liver segments.

In complex Bismuth type III and IV strictures, the ESGE guidelines in 2017 recommended the use of PTBD over ERCP or a combination of PTBD and ERCP [78]. This recommendation was mainly based on a meta-analysis showing that PTBD obtained adequate biliary drainage more frequently than ERCP in these settings (odds ratio [OR] 2.53, 95 %CI 1.57–4.08) [67]. Furthermore, in Bismuth type III and IV, drainage of more than 50 % of the liver volume should be attempted, which often requires bilateral stenting or stenting of both right-sided anterior and posterior ducts to achieve this goal. However, ERCP remains frequently used for malignant hilar strictures and may have fewer AEs and achieve more complete biliary drainage in expert hands [79].

In unresectable malignant hilar strictures, EUS-BD is currently used as salvage therapy after previous metal stent placement. In addition, in surgically unresectable disease, even without previous biliary interventions, EUS-BD may be considered in addition to ERCP to optimize biliary drainage. Three retrospective studies have shown the efficacy of EUS-BD in malignant hilar biliary obstruction, with technical success rates exceeding 90 % [23, 33,80]. One prospective, multicenter study compared a combination of ERCP and EUS-BD to bilateral PTBD in 36

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patients. The combined ERCP/EUS-BD approach provided a lower rate of recurrent biliary obstruction at 3 and 6 months, with similar AE and mortality rates [81].

4.4.3 Is EUS-BD preferable to ERCP for primary biliary drainage in malignant distal biliary obstruction?

RECOMMENDATION

ESGE recommends ERCP for primary drainage of malignant distal biliary obstruction, but EUS-guided biliary drainage could also be used in this setting for inoperable patients at high volume expert centers.

Strong recommendation, moderate quality evidence.

EUS-BD has been compared with ERCP in three RCTs for primary drainage of malignant distal biliary obstruction [8, 29, 82]. Similar high technical and clinical success rates were reported, although the largest study showed fewer AEs and longer stent patency favoring EUS-BD (**Table 8 s**). All of the studies used SEMSs for both EUS-BD and ERCP. Ongoing RCTs are currently evaluating the use of LAMSs for EUS-BD in comparison to ERCP.

EUS-BD has not been reported to complicate subsequent surgical resection in patients with resectable tumors; however, only two retrospective studies, including a limited number of patients, have assessed the outcomes of preoperative LAMS placement on surgical outcome [8, 83]. Because of the lack of quality evidence, EUS-BD cannot be advocated at present for primary biliary drainage in patients who will be considered for surgery or in borderline resectable patients, where surgery may still become an option following chemotherapy. In this setting ERCP should currently remain first-line therapy, but EUS-BD can be considered if ERCP fails [78].

4.4.4 Is EUS-BD preferable to repeat ERCP or PTBD after failed biliary cannulation in patients with benign

RECOMMENDATION

ESGE suggests an EUS-guided rendezvous technique after a second failed ERCP in benign biliary disease and normal gastrointestinal anatomy in high volume expert centers.

Weak recommendation, low quality evidence.

Repeat ERCP in tertiary referral centers achieves high technical success (75 %–100 %) and a low AE rate (3 %–8 %), and should be the first-line approach following failed ERCP [84, 85]. When repeat ERCP fails, alternatives include PTBD or EUS-BD. In benign biliary disease, EUS-RV is the preferred technique, provided that the bile ducts are sufficiently dilated, as it does not permanently alter the bilioenteric anatomy. The technical success of the EUS-RV technique in benign disease (77 %) is lower than in malignant disease (90 %) and AEs are more likely to occur (27 %), owing to limited bile duct dilatation and technical difficulty in accessing small intrahepatic ducts [63, 86]. Although no comparative studies are currently available, PTBD is also challenging in patients with benign disease, leading to a significant AE rate (21 %) and the frequent need for repeat procedures [71]. Therefore, EUS-BD should be considered after a second ERCP failure in centers where expertise is available, preferably during the same session.

4.4.5 Is EUS-BD preferable to enteroscopy-assisted ERCP in patients with biliary obstruction and surgically altered anatomy?

RECOMMENDATIONS

ESGE suggests EUS-guided biliary drainage (EUS-BD) only after failed enteroscopy-assisted ERCP in the management of benign post-surgical biliary obstruction or common bile duct stones.

Weak recommendation, low quality evidence.

ESGE suggests EUS-BD in malignant post-surgical biliary obstruction and a long biliary limb with dilated intrahepatic bile ducts.

Weak recommendation, low quality evidence.

In post-surgical anatomy, either a pediatric colonoscope or an enteroscope may be used to reach the papilla or surgical anastomosis, depending on the length of the biliary loop. Enteroscopy-assisted ERCP (EA-ERCP) is considered less invasive than EUS-BD and is associated with fewer AEs [87]. In addition, in EA-ERCP dedicated consumables are available that allow sphincterotomy and balloon extraction of stones. The drawbacks of EA-ERCP include difficulty in reaching the biliary orifice and lack of a scope elevator, as well as the limited diameter of the working channel of classic enteroscopes. Some recent enteroscopes have though been equipped with 3.2-mm working channels, which can facilitate SEMS placement.

Post-surgical malignant biliary obstruction normally comprises recurrence of malignant disease at the level of the surgical anastomosis. Under these circumstances EUS-guided antegrade stenting or HGS is technically successful in 96 %–100 % of cases and allows the placement of SEMSs [27, 88].

In benign disease, owing to the aforementioned advantages, including lower AE rate and the availability of dedicated consumables, EA-ERCP may be preferred over EUS-BD as the initial approach. This is especially relevant in the setting of biliary stone disease, where a biliary sphincterotomy will be required [87]. EUS-BD procedures in benign biliary diseases are more complex than in the management of malignant disease. Nevertheless, EUS-BD facilitates stricture dilation and stone clearance in 72 %–100 % of patients [89–91], and is therefore a reasonable alternative after failed EA-ERCP in patients with benign biliary obstruction and post-surgical anatomy.

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4.5 Key question 5: What are the most common adverse events associated with EUS-BD?

RECOMMENDATION

ESGE suggests that current evidence supports the use of EUS-guided choledochoduodenostomy over EUS-guided hepaticogastrostomy in distal biliary obstruction owing to its lower rate of adverse events.

Weak recommendation, low quality evidence.

Complications following EUS-BD are usually reported as procedure-related, early (<14 days), or late (>14 days) AEs [92]. AEs in EUS-BD occur most commonly following transmural puncture, which can result in either trauma to blood vessels or leakage of GI and/or biliary contents. In addition, stent maldeployment during the procedure or stent dislodgement after the procedure may be associated with spillage of bile and GI secretions into the peritoneal cavity or retroperitoneal space. This risk, has been mitigated to some extent by newer stent designs. It should be noted that large volume or recurrent ascites increases the risk for AEs [93, 94].

Pooled AE rates for EUS-BD (EUS-CDS and EUS-HGS combined) were 16 % in a meta-analysis of 756 patients [95]. For EUS-CDS alone, a meta-analysis of 572 patients reported a pooled rate of 14 %, the most common AEs being cholangitis (4 %), bleeding (4 %), bile leak (4 %), and perforation (3 %) [94]. Abdominal pain occurred commonly (up to 18 %) but was usually mild [33]. Also rarely reported were pneumoperitoneum, hemobilia, cholecystitis, arteriobiliary fistula, pseudoaneurysm, and inadvertent portal vein puncture [30, 35, 93, 94, 96, 97]. Mortality ranged from 0 % to 3 % [96]. Poincloux et al. reported a high mortality of 6 %; however, the mortality rate was lower in the second 50 cases compared with the first (decreasing from 10 % to 2 %), suggesting a learning curve effect [30]. The most common long-term AE is stent occlusion, with the median time of occurrence ranging from 5 to 12 months [30, 93, 96]. This can often be resolved during a second procedure, either by stent-in-stent placement or drainage of alternative segments [33, 93].

In a randomized trial of 125 patients comparing EUS-BD with ERCP as a primary intervention, there was a lower rate of procedure-related and late AEs in EUS-BD (6 % vs. 19 % [P = 0.001]; 4 % vs. 19 % [P = 0.01]) respectively [29]. The increase in procedure-related AEs was mostly due to pancreatitis in the ERCP group, although rectal NSAIDs were not administered in this study. In addition, there was a higher rate of stent patency at 6 months (85 % vs. 49 %; P = 0.001) and a longer mean stent patency time (208 vs. 165 days) when using EUS-BD. In contrast, two meta-analyses, incorporating three randomized trials and additional non-randomized cohort comparisons, failed to demonstrate a significant difference between EUS-BD and ERCP (relative risk (RR) 0.68 and 1.05, respectively) [95, 98]. In these two analyses, EUS-BD was associated with significantly lower rates of post-procedural pancreatitis (RR 0.12 and 0.26), which was at least in part offset by higher rates of biliary peritonitis, bleeding, and pneumoperitoneum (RR 5.16) [95]. However, EUS-BD was associated with higher long-term stent patency compared with ERCP [98].

In two meta-analyses, the pooled AE rates for EUS-CDS were lower than for EUS-HGS, but this only reached clinical significance in one study (15 % vs. 21 %; P = 0.1 and 20 % vs. 29 %; P = 0.01) [35, 94]. Two older meta-analyses reported either no difference in AE rates between EUS-CDS and EUS-HGS or a reduced AE rate in EUS-CDS (OR 0.40) [36, 37].

For EUS-RV procedures, reported AE rates range from 13 % to 34 %, with higher rates following intrahepatic puncture [47, 49]. Post-procedural pain is most commonly observed, with other AEs including pneumoperitoneum or pneumomediastinum also being described [99]. Cholangitis, peritonitis, and bleeding were all reported infrequently. Pancreatitis occurred in 2 %–5 % [49, 60, 99]. Mortality was infrequently reported and ranged from 0 % to 10 % [27, 47, 49, 50, 60, 99, 100].

4.6 Key question 6: What are the main approaches that employ EUS to achieve PD drainage?

EUS-guided PD drainage may be considered in the management of symptomatic PD obstruction when conventional endoscopic methods have failed, and in patients who are not considered surgical candidates or, prefer a minimally invasive approach [101, 102].

EUS-guided PD drainage can be considered a salvage procedure after technical failure of endoscopic retrograde pancreatography (ERP) or as an alternative to enteroscopy-assisted ERP (EA-ERP) in patients with surgically altered anatomy [103].

There are two main approaches that are used for EUS-guided PD drainage. Rendezvous-assisted ERP (RV-ERP), similarly to biliary EUS-RV techniques, requires antegrade transpapillary/transanastomotic passage of a guidewire to enable cannulation of the main pancreatic duct (MPD) via ERP [104, 105].

The second approach, transmural or antegrade EUS-guided PD drainage is considered when RV-ERP either fails or is not technically feasible. This technique involves the transmural passage of a pancreatic stent, directly through the lumen wall (gastric or enteral), following creation of a fistulous tract into the MPD. The pancreatic stent may then be advanced in an antegrade fashion across either the papilla or surgical anastomosis, or alternatively it may be deployed transmurally into the stomach or small bowel. Variations of EUS-guided PD drainage include: pancreaticogastrostomy, pancreaticoenterostomy, gastropancreaticoenterostomy (also known as ring drainage), and pancreaticobulbostomy.

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4.7 Key question 7: What are the technical and clinical success rates of each approach?

RECOMMENDATIONS

ESGE recommends that EUS-guided pancreatic duct (PD) drainage should only be considered in symptomatic patients with an obstructed PD when retrograde endoscopic intervention fails or is not possible.
Strong recommendation, low quality evidence.

ESGE recommends that EUS-guided PD drainage should only be performed in high volume expert centers owing to the complexity of this technique and the high risk of adverse events associated with it.
Strong recommendation, low quality evidence.

ESGE recommends rendezvous EUS techniques over transmural PD drainage in patients with favorable anatomy owing to its lower rate of adverse events.
Strong recommendation, low quality evidence.

RV-ERP is preferable to transmural EUS-guided PD drainage as the underlying pathology associated with chronic pancreatitis, such as the presence of an MPD stricture or stones, can be more effectively managed using a retrograde approach. Also, RV-ERP allows physiologic drainage of pancreatic secretions across the papilla or surgical anastomosis, rather than through a fistulous tract [106]. Additionally, the use of RV-ERP avoids the need to use thermal energy and/or balloon dilation of the tract during creation of a pancreaticogastric fistula, thereby decreasing the number of AEs, including leakage of gastric or pancreatic content into the retroperitoneal space [103, 104].

EUS-guided PD drainage is technically challenging, has limited indications, and is generally performed at select high volume centers, therefore only small series have been reported. Technical contraindications for EUS-guided PD drainage include the inability to localize the MPD endosonographically, the presence of significant intervening vasculature in the intended puncture path, and there being multiple MPD strictures [104, 107, 108].

The definition of technical success in EUS-guided PD drainage has differed according to the reported series, with end points such as obtaining a pancreatogram, PD cannulation, PD stenting and/or drainage, or stricture dilation, and/or stent placement included [109]. However, in the context of EUS-guided PD drainage, technical success is best defined as successful stent placement, while clinical success should be defined as pain relief, using a visual analogue score, that may be subcategorized as partial or complete.

Since Francois et al. first reported the pancreaticogastrostomy procedure approximately two decades ago, there have been several retrospective and fewer prospective series of EUS-guided PD drainage with modest numbers [110]. The overall technical success of antegrade drainage was 138/155 (89 %) [104]. Few prospective studies have evaluated EUS-PD. Kahaleh et al. described successful pancreaticogastrostomy in 10/13 patients with symptomatic chronic pancreatitis after failed ERP [111]. Follow-up at 14 months showed the average MPD caliber significantly decreased and pain scores improved. An additional study, using a fully covered SEMS, in 25 patients with chronic pancreatitis and ductal obstruction after failed ERP also demonstrated significant improvement in their pain scores [112].

4.8 Key question 8: What are the indications for EUS-guided PD drainage?

In patients with MPD obstruction and normal anatomy, ERP remains the preferred method of endoscopic drainage. ERP transpapillary therapy fails in 3 %–10 % of cases owing to complete PD obstruction and/or disconnection of the MPD [113]. Only when ERP fails, and surgery is undesirable or excessively high risk, should alternative endoscopic therapies such as EUS-guided PD drainage or EA-ERP (in surgically altered anatomy) be considered. Complete PD obstruction by a large PD stone is better managed by extracorporeal shock wave lithotripsy or surgery.

The aim of EUS-guided PD drainage is to relieve the ductal hypertension that is responsible for pain or recurrent acute pancreatitis in patients with a dilated MPD. The primary indication for EUS-guided PD drainage is an inaccessible papilla or failed papillary cannulation of the PD [104, 106, 111, 114–116]. This frequently arises in patients with symptomatic chronic pancreatitis with a tight ductal stricture, disconnected PD, or pancreaticojejunostomy anastomotic stricture following pancreaticoduodenectomy. EUS-guided PD drainage can be considered if surgical drainage carries an unacceptable risk, as surgery provides better long-term symptomatic benefit than endoscopic decompression. EUS-guided PD drainage can also be considered for patients desiring a minimally invasive approach [101, 102]. If both EUS-guided PD drainage approaches are technically feasible, RV-ERP should be considered in preference to antegrade or transmural drainage [105].

4.8.1 What are the contraindications for EUS-guided PD drainage?

In some instances, EUS-guided PD drainage may be contraindicated, including inability to localize the MPD endosonographically or when the PD is not sufficiently dilated, as well as the presence of significant intervening vasculature in the intended puncture path, and multiple MPD strictures [104, 107, 108].

4.9 Key question 9: How does EUS-guided PD drainage compare with the alternative approaches?

4.9.1 How does EUS-guided PD drainage compare with enteroscopy-assisted ERP?

Until recently, before the development of therapeutic EUS and the implementation of EUS-guided PD drainage, EA-ERP was considered an option to manage symptomatic patients after pancreaticoduodenectomy with anastomotic strictures and a dilated MPD. If EA-ERP was not possible, a redo surgical intervention remained the only alternative [104].

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EA-ERP is reasonably safe with widespread procedural familiarity [103]. However, the reported technical success rate may be as low as 8% [117]. Therefore, nowadays EUS-guided PD drainage is often preferred instead of EA-ERP. Chen et al. compared EUS-guided PD drainage to EA-ERP following pancreaticoduodenectomy [103]. Their study compared 43 patients who underwent EUS-guided PD drainage (antegrade/transmural in 40 patients; RV-ERP in 3 patients) to 35 patients who underwent EA-ERP. EUS-guided PD drainage was found to be superior to EA-ERP, both in terms of technical success (92.5% vs. 20%; $P<0.001$) and clinical success (87.5% vs. 23.1%; $P<0.001$). EA-ERP was associated with fewer AEs than EUS-guided PD drainage (2.9% vs. 37.5%; $P<0.001$), although no serious AEs occurred in either group.

4.9.2 How does EUS-guided PD drainage compare with ERP in pancreaticojejunostomy?

A recent systematic review compared the outcomes of ERP to EUS-guided PD drainage in patients with pancreaticojejunostomy strictures [109]. This study included 13 studies, in which 77 patients underwent ERP-guided drainage, 145 patients EUS-guided drainage, and 12 patients underwent both modalities. An EUS-guided approach was significantly superior to ERP regarding technical parameters, such as PD opacification (87% vs. 30%; $P<0.001$), cannulation success (79% vs. 26%; $P<0.001$), and stent placement (72% vs. 20%; $P<0.001$). The EUS-guided approach also appeared superior in terms of pain resolution. There are no comparative trials of EUS-guided PD drainage versus surgical intervention.

4.10 Key question 10: What are the most common adverse events associated with EUS-guided PD drainage?

EUS-guided PD drainage is one of the most technically challenging and risky endoscopic procedures currently performed. Available data on the AEs of EUS-guided PD drainage suggest that the overall AE rate varies from 15%–27% [104, 118–120]. The data are however extremely heterogeneous and difficult to interpret. The current literature frequently pools dissimilar patients (e. g. native anatomy and surgically altered anatomy), equipment (e. g. thermal and non-thermal ductal access), and procedural techniques (e. g. EUS-guided pancreatic rendezvous and EUS-guided pancreaticogastrostomy), therefore leading to difficulty in interpretation.

A recent systematic review (13 studies, 409 patients), showed the overall AE rate of EUS-guided PD drainage to be 15% [109]. No significant differences were noted with respect to AE rates of EUS-guided PD drainage when comparing patients with native pancreatic anatomy to those with surgically altered pancreatic anatomy (15% vs. 11%). The most commonly reported AEs included: post-procedure pain (7%), acute pancreatitis (2%), infected peripancreatic collections (2%), and perforation (1%). Less commonly reported AEs, occurring in < 1% of patients, included bleeding, PD leakage, and pseudoaneurysm formation. AE rates were higher in EUS-guided transmural pancreaticogastrostomy compared with RV-ERP [104, 118–120]. In one study using a fully covered SEMS in 25 patients with chronic pancreatitis with ductal obstruction after failed ERP, no major AEs (i. e. stent migration, stent dysfunction, infection, and/or stent-induced ductal stricture) occurred during follow-up of over 7 months [112].

5 Gallbladder drainage

Laparoscopic cholecystectomy represents the gold standard treatment in the management of acute cholecystitis and is associated with low postoperative morbidity and shorter length of hospital stay compared with open surgery [121, 122]. However, owing to advanced age, frailty, or co-morbidities, some patients may not initially be, or may never become, surgical candidates. In these patients, especially when they are at risk for developing sepsis and organ failure, gallbladder drainage may be required. This has traditionally been provided by the percutaneous approach. In recent years, EUS-GBD has become an alternative to percutaneous gallbladder drainage (PTGBD).

5.1 Key question 11: What are the main approaches that employ EUS to achieve gallbladder drainage?

EUS-GBD may be performed using a transgastric or transduodenal approach. The transduodenal approach is most commonly used because the position of the stent is less affected by peristalsis, than if deployed in the distal stomach. In addition, the risk of food impaction with a stent placed in the duodenum may be lower [123, 124]. In patients who may be considered for cholecystectomy in the future, a transgastric approach may be more favorable because the surgical repair of a gastric wall defect is less complex [124].

5.2 Key question 12: What are the technical and clinical success rates of EUS-GBD?

A multicenter prospective study reported the outcomes of EUS-GBD using LAMSs in 30 high risk surgical patients with acute cholecystitis [125]. In this study, technical and clinical success were 90% and 87%, respectively. Cholecystitis due to LAMS occlusion occurred in 7% of patients. Another retrospective study reported the use of EUS-GBD using SEMSs in 63 patients with acute cholecystitis, who were unsuitable for cholecystectomy owing to high surgical risk or advanced malignancy, and showed a technical success rate of 98% and a clinical success rate of 95% [126].

A meta-analysis, including 233 patients from 13 studies using LAMSs in high risk surgical patients with acute cholecystitis or biliary obstruction, showed that the technical and clinical success, and overall AE rates of EUS-GBD were 94%, 93%, and 18%, respectively [127] (**Table 9s**).

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5.3 Key question 13: What are the indications for EUS-GBD?

RECOMMENDATION

ESGE suggests that EUS-guided gallbladder drainage can be considered as a rescue procedure in patients with inoperable distal malignant biliary obstruction when ERCP and EUS-biliary drainage have failed, provided that the cystic duct is patent.

Weak recommendation, low quality of evidence.

Since its introduction, many studies have reported the feasibility, safety, and effectiveness of EUS-GBD compared with PTGBD in patients with acute cholecystitis. Specifically, EUS-GBD has been associated with fewer re-interventions and re-admissions compared with PTGBD, when performed in tertiary centers experienced in advanced therapeutic EUS. However, many of these studies were limited by their retrospective design, low patient numbers, potential publication bias, and variable technical approaches (LAMS vs. SEMS vs. plastic stents) [125, 126, 128–130].

As previously mentioned, EUS-GBD has also been used as a rescue strategy for biliary drainage in distal malignant biliary obstruction. Data on the efficacy and outcome of EUS-GBD in this setting are limited. Imai et al. demonstrated, in a retrospective study, that EUS-GBD with fully covered SEMS placement was safe and efficient after failed ERCP or unsuccessful EUS-BD in patients with inoperable distal biliary malignancy [55]. They reported that, in 12 patients, the technical and clinical success, AE, and stent dysfunction rates were 100 %, 92 %, 17 %, and 8 %, respectively. Early AEs occurred in two patients and included peritonitis and stent dysfunction (entrapment of the cystic duct by the growing tumor). A median survival time after the procedure of 105 days (range 15–236 days) was observed [55]. Other authors have retrospectively reported EUS-GBD with LAMS placement as the first intervention in nine patients with malignant distal biliary obstruction and showed technical success, clinical success, and AE rates of 100 %, 78 %, and 0 % respectively [131]. Although these studies suggest that EUS-GBD can be considered as a rescue procedure when ERCP or EUS has failed, special care should be taken to confirm cystic duct patency before using this strategy.

5.4 Key question 14: How does EUS-GBD compare with the alternative approaches?

5.4.1 How does EUS-GBD compare with PTGBD?

RECOMMENDATIONS

ESGE recommends EUS-guided gallbladder drainage (EUS-GBD) or percutaneous gallbladder drainage (PTGBD) in patients at high surgical risk with acute cholecystitis requiring gallbladder drainage.

Strong recommendation, high quality of evidence.

ESGE recommends that, in patients at high surgical risk, EUS-GBD should be favored over PTGBD where both techniques are available, owing to the lower rates of AEs and need for re-intervention in EUS-GBD.

Strong recommendation, high quality of evidence.

EUS-GBD seems to be an effective alternative to PTGBD in high risk surgical patients. Studies that have compared EUS-GBD with PTGBD have shown comparable technical and clinical success rates, and fewer AEs following EUS-GBD. An RCT designed to compare EUS-GBD with PTGBD in 59 high risk patients with acute cholecystitis showed comparable results for both procedures with respect to technical feasibility and AEs [132]. Another RCT showed significantly better outcomes in very high risk patients who were unfit for cholecystectomy who underwent EUS-GBD compared with those who underwent PTGBD [133]. This study performed in 80 patients showed that EUS-GBD significantly reduced the 30-day and 1-year AE rates, led to fewer re-interventions after 30 days, and reduced the rates of unplanned readmission and recurrent cholecystitis.

A recent meta-analysis comparing EUS-GBD to PTGBD for the management of acute cholecystitis in 495 patients reported no statistically significant differences in terms of technical and clinical success rates between these two techniques. However, significantly lower post-procedural pain scores and re-intervention rates were observed in the EUS-GBD group [134]. Data have also shown that EUS-GBD may be used as a bridge to surgery [135]. Finally, larger comparative studies are needed to confirm these results.

5.4.2 How does EUS-GBD compare with transpapillary gallbladder drainage?

RECOMMENDATION

ESGE recommends EUS-guided gallbladder drainage over transpapillary gallbladder drainage, given the suboptimal technical efficacy of transpapillary gallbladder drainage.

Strong recommendation, low quality of evidence.

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EUS-GBD has also been compared with transpapillary gallbladder drainage in patients with acute cholecystitis who cannot undergo surgery [123, 133, 136]. A multicenter retrospective study compared EUS-GBD using LAMSs, PTGBD, and transpapillary gallbladder drainage in high risk surgical patients with acute cholecystitis. Technical success was achieved in 88 %, 94 %, and 98 %, respectively (P = 0.004), whilst clinical success rates were lower with transpapillary gallbladder drainage compared with EUS-GBD and PTGBD (80 %, 90 %, and 97 %, respectively; P < 0.001). Fewer overall AEs (2 % vs. 5 % vs. 20 %; P = 0.01), shorter hospital stay (16 vs. 18 vs. 19 days; P = 0.01), and fewer unplanned admissions (4 % vs. 11 % vs. 49 %; P < 0.001) were observed with EUS-GBD and transpapillary gallbladder drainage compared with PTGBD [137]. A meta-analysis of 857 high risk surgical patients with acute cholecystitis comparing EUS-GBD with transpapillary gallbladder drainage showed higher technical and clinical success rates with EUS-GBD. A lower rate of recurrent cholecystitis was shown with EUS-GBD, while there was no statistically significant difference in terms of overall AE rates between the two procedures [138].

5.5 Key question 15: What are the most common adverse events associated with EUS-GBD?

A multicenter prospective study reported cholecystitis due to LAMS occlusion in 7 % of patients [125]. Another retrospective study showed that AEs, such as duodenal perforation (1.6 %) and small pneumoperitoneum (3.2 %), occurred infrequently and resolved with conservative treatment [126]. The long-term outcomes were favorable, with inconsequential distal stent migration and acute cholecystitis due to stent occlusion occurring in four patients (7.1 %) during a median follow-up of 275 days (range 40–1185 days). Stent occlusions were successfully treated endoscopically, with a re-intervention rate of 3.6 % and a cumulative stent patency rate of 86 % at 3 years.

A meta-analysis, including 233 patients from 13 studies using LAMSs in high risk surgical patients with acute cholecystitis or biliary obstruction, showed stent obstruction or dislodgement, perforations, and recurrent cholangitis/cholecystitis in 8 %, 7 %, and 4 % of patients, respectively [127]. A pooled analysis of 166 patients reported an overall AE rate of 12 % [123].

6 EUS-guided gastrointestinal anastomosis

RECOMMENDATION

ESGE recommends multidisciplinary discussion of all patients being considered for an EUS-guided gastrointestinal anastomosis and careful evaluation for adverse events after the procedure.

Strong recommendation, low quality evidence.

EUS-guided GI anastomosis refers to a technique where the walls of two luminal structures are apposed by the placement of a LAMS under EUS guidance. By placement of this dumbbell-shaped fully covered SEMS, fusion of the individual layers occurs, turning into a mature anastomosis within days. Procedures where this concept applies include EUS-guided gastroenterostomy (EUS-GE), where a LAMS is placed between the stomach and a duodenal or jejunal loop to circumvent a gastric outlet obstruction (GOO), or gastro-gastrostomy, where a LAMS is placed between the gastric pouch and excluded stomach for access following Roux-en-Y gastric bypass (RYGB). These procedures should be performed by trained interventional endoscopists capable of recognizing and endoscopically managing procedure-related AEs.

6.1 Key question 16: What are the main approaches that employ EUS to create a gastroenterostomy?

Various techniques have been developed to create an EUS-GE, with the aim of overcoming two main challenges: (a) locating the segment distal to the GOO; and (b) stabilizing the targeted loop for subsequent puncture and stent introduction.

6.1.1 Direct EUS-GE technique over a guidewire

A linear echoendoscope is used to visualize the saline-filled duodenum or jejunum. A transgastric puncture is performed with a 19G FNA needle and a guidewire is advanced into the target small bowel. The electrocautery-tipped delivery device is advanced over the guidewire and the distal flange is deployed under EUS guidance. The device is then gently retracted, approximating the small bowel to the gastric wall, before the proximal flange is released under endoscopic and fluoroscopic guidance.

6.1.2 Wireless endoscopic simplified technique

After the small bowel distal to the GOO has been filled with saline, a linear echoendoscope is advanced into the stomach. After the saline-filled small bowel target has been located, the electrocautery tip is advanced directly, using a free-hand technique under endosonographic control, without the aid of a guidewire or confirmatory 19G FNA needle puncture. The same steps for deployment are followed to release the stent as for the over-the-guidewire technique [139, 140].

6.1.3 Assisted EUS-GE technique

Assisted EUS-GE techniques refer to approaches using dilation balloons, stone extraction balloons, or double-balloon enteroscopes [141–143]. In the balloon-assisted techniques, a guidewire is inserted across the malignant GOO and the balloon catheter is advanced under fluoroscopic guidance into the jejunum. Under EUS guidance, the fluid-filled balloon or occluded jejunal segment is punctured with a 19G FNA needle and a guidewire is advanced into the jejunal lumen. A LAMS is then inserted and deployed over the guidewire, similarly to the direct technique.

6.2 Key question 17: What are the technical and clinical success rates of EUS-GE?

Technical success does not seem to differ according to technique, ranging from 92 % to 100 % [144]. The overall technical success rate was 94 %, with 68 % of the procedures being performed by the direct EUS-GE approach, in a meta-analysis

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including 12 studies and 290 patients [144]. Assisted EUS-GE could potentially decrease the rate of stent dislodgement or misdeployment. This however was not demonstrated in a recent comparative study comparing direct EUS-GE with the assisted technique, which reported success rates of 94 % vs. 95 %, respectively, with comparable safety but a shorter procedural time for the direct method (30 vs. 90 minutes) [145].

6.2.1 Which EUS-guided technique is superior in creating a gastroenterostomy?

Technical success is similar between the various techniques for creating an EUS-GE [144] (**Table 10 s**). A recently published study using the wireless endoscopic simplified technique (WEST) showed high procedural success and a low AE rate, suggesting that the additional use of balloons or maneuvers aimed at stabilizing the target loop may not be required [139, 140]. While no high quality prospective comparison exists, most data and experience originate from reports of cohorts using the direct method or WEST [140, 145–148].

6.3 Key question 18: What are the indications for EUS-GE?

6.3.1 EUS-GE in malignant gastric outlet obstruction

The most widely accepted indication for EUS-GE is malignant GOO. This is most often caused by pancreatic, gastric, ampullary, or biliary/gallbladder cancers that infiltrate or cause external compression of the duodenum, preventing transit of solids and eventually fluids to the distal small bowel [149, 150]. In the event of locally advanced or metastatic disease, where surgical resection is not an option, appropriate management of obstructive symptoms is justified to optimize the patient's nutritional status and improve their quality of life [151].

Traditionally, treatment options for GOO have consisted of surgical (open/laparoscopic) gastrojejunostomy or endoscopic placement of an enteral SEMS. Three underpowered RCTs comparing these approaches have reached inconsistent results [152–154]. Surgical bypass has been demonstrated to achieve better long-term outcomes, at the cost of increased invasiveness and prolonged hospital stay. Conversely, enteral stenting provided rapid resumption of oral intake, yet showed a high rate of symptom recurrence requiring re-intervention [152–155]. This has led various authors to suggest that enteral stenting should be reserved for patients with a short life expectancy of less than 3 months [153, 156].

EUS-GE may combine the theoretical advantages of both of these approaches, creating a relatively large gastroenteric anastomosis, while using a minimally invasive technique at a distance from the primary tumor. Results from clinical experience with this technique are detailed in **Table 7 s**. Published cohorts of more than 10 cases have been described in 15 studies (with partial cohort overlap), all but one of these being retrospective [140, 145–149, 157–165]. The results from these studies were included in five recent pooled analyses and systematic reviews including almost 300 patients [144, 166–169]. The technical and clinical success rates of EUS-GE are reported to range from 91 % to 94 % and 88 % to 90 %, respectively [147, 164]. AE rates were reported as between 7 % and 12 %, with AEs encompassing abdominal pain, bleeding, infections, perforations, and leakage from the EUS-GE site.

6.3.2 Is there a role for EUS-GE in benign gastric outlet obstruction?

RECOMMENDATIONS

ESGE suggests that an EUS-guided gastroenterostomy be created for patients who are poor surgical candidates with refractory benign gastric outlet obstruction (GOO).
Weak recommendation, low quality evidence.

ESGE recommends that, upon resolution of the cause of the benign GOO, the lumen-apposing metal stent should be removed.
Strong recommendation, low quality evidence.

EUS-GE has also been used in benign GOO, for instance in patients with chronic pancreatitis, peptic ulcer disease, caustic injury, or even superior mesenteric artery syndrome [140, 148, 170–172]. In benign GOO, endoscopic balloon dilation has been used as an alternative to surgery; however, it often results in suboptimal outcomes, with early recurrence of symptoms, and is associated with a non-negligible risk of perforation [173, 174]. Because some of these patients are poor surgical candidates, EUS-GE has been proposed as an alternative to surgery.

One argument against the use of EUS-GE in benign GOO has been the lack of long-term data. A recent pooled analysis has shown a mean (SD) LAMS indwelling time of 88 (33) days. In this study, LAMS placement was associated with a low risk of symptom recurrence due to food obstruction. If food impaction occurred, it could be easily resolved endoscopically (10 %) [159, 161, 169]. The most frequent AE identified that needed revision was ulceration at the stent site [169]. As a general principle, LAMSs should be removed once the underlying disease has resolved. In patients with persistent non-resolving duodenal obstruction, LAMS patency should be assessed over time, facilitating timely exchange when indicated.

Two recent studies specifically included only patients with benign GOO for which LAMSs were placed [148, 157]. In the most recent, 22 patients were included [148]. LAMS placement was successful in 21 cases. During follow-up, GOO recurred in five patients with a LAMS in place (23 %) after a mean dwell time of 228 days. LAMSs were electively removed in 18 patients after resolution of the GOO, and the recurrence rate after LAMS removal was 6 %. In this cohort of patients with benign GOO, surgery was prevented in 83 % of cases. When surgery was eventually required, it was executed after a mean of 270 days. The data suggest that EUS-GE has the potential to obviate the need for surgery in many of these patients, while potentially providing a bridge toward safer surgery in others owing to the restoration of adequate nutritional status. Further studies are

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needed to clarify the role of EUS-GE in the management of benign GOO.

6.3.3 Is there a role for EUS-GE in afferent loop syndrome?

RECOMMENDATION

ESGE recommends that EUS-guided gastroenterostomy may be considered in the management of afferent loop syndrome, especially in the setting of malignancy or in poor surgical candidates.

Strong recommendation, low quality evidence.

EUS-guided anastomoses have also been used in the management of afferent loop syndrome, following pancreaticoduodenectomy, Roux-en-Y hepaticojejunostomy, or Billroth II gastrectomy. This clinical entity may be caused by a benign stenosis, such as visceral adhesions, radiation enteritis, kinking of the small bowel, internal hernias, or recurrence of malignant disease, and can present as jaundice, with or without cholangitis and/or abdominal pain, nausea, and vomiting. In these circumstances, a minimally invasive alternative is desirable as surgery may be challenging and percutaneous biliary drainage has notable drawbacks.

The dilated and bile-filled obstructed loop can be identified by the echoendoscope placed in an adjacent lumen, either the stomach, duodenum, or proximal jejunum, and drained through placement of a LAMS. Multiple case reports and some small retrospective case series have described this procedure [175–179]. The largest published series to date (retrospective, multicenter, n = 18), which used mainly LAMSs of 15 mm in diameter, showed 100 % technical success and clinical improvement rates (89 % complete resolution), with re-intervention required in 17 % of patients [175]. The rates of clinical success and re-intervention were significantly better than those of a control group who underwent enteroscopy-assisted luminal stenting. Given the relative rarity of afferent loop syndrome, it is unlikely that high quality prospective studies will be performed. With the current retrospective data in mind, EUS-GE seems a safe and effective approach in treating afferent loop obstruction.

6.3.4 What are the contraindications for EUS-GE?

RECOMMENDATION

ESGE recommends that, in gastric outlet obstruction, EUS-guided gastroenterostomy should not be performed in the presence of significant malignant or refractory ascites, diffuse malignant infiltration of the gastric wall, or extensive peritoneal carcinomatosis.

Strong recommendation, low quality evidence.

The classic contraindications for interventional endoscopic procedures, such as uncontrolled coagulopathy, apply to EUS-GE. As EUS-GE is often used in the setting of malignancy, manifestations of advanced tumor burden should be actively excluded before EUS-GE is considered.

Several authors have reported the use of EUS-GE in patients with ascites [140, 180]. However, the presence of ascites is often reflective of the extent of malignant involvement of the peritoneum. Patients with malignant ascites due to high peritoneal tumor burden are also those who have the lowest expected benefit from EUS-GE. In addition, the presence of ascites may also be reflective of diffuse peritoneal tumor implants and additional sites of obstruction may be "unmasked" by creation of an EUS-GE. Lastly, if the FNA needle or electrocautery catheter tip have to traverse through ascites, it introduces an additional risk of infection [140]. A small amount of ascites is not considered a contraindication for EUS-GE but a longer duration of prophylactic antibiotics will be required.

EUS-GE should be avoided in patients with extensive malignant infiltration of the gastric wall because of the potential negative effects on gastric motility and an increased need for cutting current, which may increase the post-procedure bleeding risk.

6.4 Key question 19: How does EUS-GE compare with the alternative approaches?

6.4.1 How does EUS-GE compare with surgical gastroenterostomy and duodenal stenting in malignant GOO?

RECOMMENDATION

ESGE recommends EUS-GE, performed in an expert setting, for malignant gastric outlet obstruction, as an alternative to enteral stenting or surgery.

Strong recommendation, low quality evidence.

Among the four studies that have compared EUS-GE to surgery, EUS-GE systematically showed shorter time to oral intake, time to chemotherapy initiation, hospital stay, and reduced costs, while significantly more AEs were seen in patients who underwent surgery [140, 146, 147, 163]. In two studies that compared EUS-GE with enteral stenting, higher clinical success rates were seen in the EUS-GE group, who also had a lower risk of recurrent obstruction and less need for re-intervention [149, 180].

Based mostly on retrospective comparative data, EUS-GE seems, in the expert setting, to be a valuable alternative to surgery and enteral stenting for the management of GOO. RCTs are currently underway to provide high quality confirmation of these results.

6.5 Key question 20: What are the most common adverse events associated with EUS-GE?

Potential procedural-related AEs that have been described include: (i) stent maldeployment resulting in perforation [147] or leakage [157, 161] with peritonitis; (ii) stent misplacement; (iii) stent migration or dislodgement; (iv) bleeding (intraluminal, intramural, or intraperitoneal) [147, 148, 161, 181]; and (v)

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anesthesia-related AEs, including aspiration of gastric contents in the setting of GOO [163]. Among post-procedural AEs, the most common include abdominal pain [146, 149] and erosion/ulceration of the contralateral wall due to the mesh of the stent [180]. Systematic reviews and meta-analyses on EUS-GE have reported periprocedural AEs in 11%–12% of patients [144, 167, 168]. Most of the reported AEs were graded as mild or moderately severe, although severe or even fatal AEs occurred in 2.9%–5.6% of cases.

Stent maldeployment can be adequately managed by endoscopy in the large majority of cases, reducing the likelihood of severe AEs, such as peritonitis, and/or death [147, 164, 182]. Long-term AEs in patients with EUS-guided lumen-to-lumen anastomoses include stent migration [148, 183, 184], obstruction by food residue [148], and tissue ingrowth [180] or overgrowth [145].

7 Biliary drainage in patients who have undergone Roux-en-Y gastric bypass

7.1 Key question 21: How can biliary drainage be achieved using EUS-guided gastro-gastrostomy in patients following Roux-en-Y gastric bypass?

Patients are more prone to biliary disease following RYGB and conventional ERCP using a duodenoscope is not possible following this type of surgery. Various techniques have been developed to achieve biliary drainage in this setting.

A combined surgical/endoscopic approach may be used, commonly referred to as laparoscopy-assisted ERCP (LA-ERCP). In this procedure, temporary access to the bile duct is created through a surgical port, allowing the duodenoscope to be inserted into the stomach and advanced to the papilla. This approach is often chosen when ERCP needs to be combined with same-session laparoscopic cholecystectomy.

The papilla may also be accessed by using a single- or double-balloon enteroscope, which is advanced up to the biliary limb and eventually up to the level of the papilla. This technique (EA-ERCP) has some disadvantages. It may be extremely cumbersome to advance the enteroscope and the endoscopist may ultimately fail to reach the papilla in up to 30% of patients. In addition, cannulation using a forward-viewing endoscope can be particularly challenging and special enteroscope-compatible accessories are required.

Biliary access may also be obtained using a percutaneous approach (PTBD) [185]. Recent advances in the development of LAMSs have made it possible to connect the gastric pouch and excluded stomach to gain access to the papilla using a duodenoscope. This technique is referred to as EUS-directed transgastric ERCP (EDGE).

7.2 Key question 22: What are the technical and clinical success rates of EDGE?

The main advantage of EDGE, compared with other modalities for biliary drainage in patients with RYGB, is that the ERCP can be done using a standard duodenoscope. Since its introduction as a therapeutic option, various case series have been published that have described the technical success of EDGE and subsequent ERCP [186]. A recent systematic review evaluated nine case series and eight case reports. In the case series, 169 patients underwent EDGE with a technical success rate of 99% (168/169) for gastrogastrostomy/jejunogastrostomy creation and 98% (166/169) for subsequent ERCP [184].

7.3 Key question 23: How does EDGE compare with the alternative procedures?

7.3.1 How does EDGE compare with enteroscopy-assisted ERCP?

RECOMMENDATION

ESGE suggest that endoscopic ultrasound-directed transgastric ERCP (EDGE) can be offered, in expert centers, to patients with a Roux-en-Y gastric bypass following multidisciplinary decision-making, with the aim of overcoming the invasiveness of laparoscopy-assisted ERCP and the limitations of enteroscopy-assisted ERCP.

Weak recommendation, low quality evidence.

A recent study that compared LA-ERCP with EA-ERCP found both techniques to be similar with regards to technical success, AE rates, and procedure time [187] (**Table 11 s**). In a retrospective study comparing EA-ERCP, LA-ERCP, and EDGE, EDGE was found to be associated with higher success and lower AE rates [188]. In addition, another retrospective study that compared all three approaches revealed higher technical success for EDGE and LA-ERCP when compared with EA-ERCP (100% vs. 94% vs. 75%, respectively; $P=0.02$), with the latter requiring significantly more procedure time (79 vs. 158 vs. 102 minutes, respectively; $P<0.001$) [189].

Similar results were found in a systematic review and meta-analysis of over 1200 patients [190]. This study observed superior technical and clinical success when EDGE was compared with EA-ERCP, although the latter was associated with a lower risk of AEs when compared with both EDGE and LA-ERCP (8.4% vs. 21.9% vs.17.4%, respectively). It seems reasonable to deduce from these low quality non-randomized studies that EDGE is a safe and effective alternative to surgery. The current evidence also suggests that EDGE is more effective and less time-consuming than EA-ERCP, but that it is associated with more AEs.

Most physicians would, for practical considerations, opt for LA-ERCP in patients where the gallbladder is still in situ as this procedure can be combined with cholecystectomy. EDGE should be considered in patients where cholecystectomy has already been performed or when re-interventions are deemed likely [191].

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7.4 Key question 24: What are the most common adverse events with EDGE?

A recent systematic review reported AEs related to the EDGE procedure in 24 % of cases (41/169) [184]. Most of the EDGE-related AEs (31/41) were minor, with 19/41 due to intraprocedural stent migration and eight due to stent maldeployment – these AEs could all be managed endoscopically – while post-procedural abdominal pain was reported in the remaining patients. Moderate AEs were observed in nine patients (5.3 %), with bleeding occurring in five and persistent fistula and perforation each in two patients. Only one perforation from stent maldeployment required surgery.

In EDGE procedures, the stent is removed once biliary problems are definitively resolved. In cases of persistence of a large fistula after LAMS removal, weight gain can occur. Given that EDGE placement is often required for a short period, the procedural benefits outweigh the potential likelihood of weight gain [183].

8 Conclusions

Advances within therapeutic EUS are evolving rapidly, with technical innovations and emerging clinical applications developing in parallel. As a result, high quality data seem to trail behind the everyday use of these techniques. While these approaches have quickly demonstrated their role in clinical care, various knowledge gaps persist. In many cases, our current unresolved questions are amenable to an RCT, such as the ongoing trials comparing EUS-GE to surgical gastrojejunostomy and EUS-GBD to laparoscopic cholecystectomy. These studies will be invaluable to our understanding of the role of such procedures. However, it should be noted that in other scenarios an RCT may not be feasible, as is the case for EUS-guided PD drainage because of its relative rarity and the lack of a standardized comparator. In scenarios such as this, retrospective comparative data may be our ceiling. For a suggested list of topics for possible future research, please see **Appendix 1 s**.

Disclaimer

The legal disclaimer for ESGE guidelines [192] applies to this Guideline.

Acknowledgments

The authors would like to sincerely thank Professor Marianna Arvanitakis, Hôpital Erasme Brussels, and Professor Takao Itoi, Tokyo Medical University, for their review of this manuscript. The authors are furthermore grateful for the comments provided by: Dr. Mauro Manno (Azienda USL di Modena), Professor Klaus Mergener (University of Washington, Seattle), Professor Riadh Sadik (Sahlgrenska University, Gothenburg), Dr. Leonardo Sosa-Valencia (IHU Strasbourg), Professor Mette Versterhus (University of Bergen), and Dr. Alexander Waldthaler (Karolinska University Hospital, Stockholm).

Competing interests

M. Barthet has received a research grant from Boston Scientific (2015 to present). K.F. Binmoeller has received fees for training and education from Boston Scientific (2015 to present). M. Bronswijk has received consultancy fees from Prion Medical and Taewoong Medical (both 2021). M.A. Khashab receives consultancy fees from BSCI, Medtronic, Olympus, Pentax, GI Supply, and Apollo (all ongoing). A. Larghi has received consultancy fees from Boston Scientific and Pentax Medical, and educational fees from Taewoong Medical; he receives research support from Medtronic. R. Law receives consultancy fees from Medtronic (2020 to present) and Conmed (2021). M. Perez-Miranda receives consultancy fees from Lumendi and Olympus (both 2020 to present) and consultancy and speaker's fees from Boston Scientific (2021). S. van der Merwe has received consultancy fees from Boston Scientific and Cook Endoscopy (both 2012 to present); he was the Boston Chair in Interventional Endoscopy (2018 to 2021) and is the Cook Chair in Portal Hypertension (2021). J.E. van Hooft has received lecture fees from Medtronics (2014, 2015, and 2019), Cook Medical (2019), and Abbivie (2021), and consultancy fees from Boston Scientific (2014 to 2017) and Olympus (2021); her department received research support from Abbott (2014 to 2017) and Cook Medical (2014 to 2019). P.G. Arcidiacono, A. Badaoui, S. Everett, T. Hucl, R. Kunda, S. Lakhtakia, M. Rimbas, and R.L.J. van Wanrooij declare that they have no conflict of interest.

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