Ultrasound-guided biliary drainage: a new era of endoscopic surgery

Drenagem biliar ecoguiada: uma nova era da cirurgia endoscópica

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\textbf{ABSTRACT}

Despite the success rate of endoscopic retrograde cholangiopancreatography (ERCP), in about 10\% of the cases, there is failure to access the biliary tree. In this context, the endoscopic ultrasound (EUS), which was originally only used for diagnosis and staging, today has a therapeutic importance. The purpose of this update is to demonstrate the various forms of ultrasound-guided biliary drainage, as well as to compare it with percutaneous transhepatic biliary drainage (PTBD).


\section*{INTRODUCTION}

The important technological evolution led the endoscopic ultrasound (EUS), which was previously only a diagnostic mode, to a therapeutic level\textsuperscript{1}, now being a well-established technique for obtaining tissue samples, injection with fine needle and drainage of collections and abscesses adjacent to the gastrointestinal tract (GIT). Widespread adoption of minimally invasive surgical and radiological procedures naturally led to increased EUS use in the treatment and/or alleviation of gastrointestinal diseases, including ultrasound-guided biliary drainage (UGBD).

In patients with preserved GIT, selective catheterization of the bile duct by endoscopic retrograde cholangiopancreatography (ERCP) achieves success in more than 90\% of cases. When access to the bile duct is not viable, percutaneous transhepatic biliary drainage (PTBD), or even surgical drainage, have been used as alternatives\textsuperscript{2-5}. However, the long recovery time, delays in the initiation of chemotherapy and percutaneous discomfort of PTBD impair the use of such therapies. In this context, UGBD is an alternative, less invasive method in case of ERCP failure\textsuperscript{6}.

Wiersema et al.\textsuperscript{7} were the first to publish on the ultrasound-guided biliary access in 1996, reporting seven patients successfully submitted to ultrasound-guided cholangiography after failed ERCP\textsuperscript{7}. However, they did not perform ultrasound-guided biliary drainage in their series. In 2001, Giovannini et al.\textsuperscript{8} published the first case of successful creation of a fistula guided by the EUS between the duodenal bulb and the common bile duct, using a plastic prosthesis in a patient with malignant biliary obstruction caused by an unresectable pancreatic head tumor. This was the first report of an ultrasound-guided choledochoduodenostomy. Mallery et al.\textsuperscript{9}, in 2004, introduced a new relevant concept, the rendezvous ultrasound-guided biliary drainage technique, where a guidewire is inserted through the needle after the puncture of the biliary tract. This wire is advanced into the duodenum and then endoscopically retrieved with a duodenoscope, followed by ERCP. Several studies have been published since then on various UGBD techniques and results\textsuperscript{10-21}.

UGBD can be performed by three methods. The rendezvous is the technique in which a guidewire is inserted through the papilla in the intrahepatic or extrahepatic bile duct and recovered by a duodenoscope after subsequent biliary intervention. Another option is the implantation of a direct transluminal stent using a transgastric or transduodenal approach (without access to the papilla)\textsuperscript{22,23}. The third approach, less common, is an antegrade passage of a transpapillary biliary stent (or transanastomotic)\textsuperscript{24,25}.

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Rendezvous

A sectoral EUS is used to achieve initial biliary access in a dilated segment, proximal to the site of obstruction. The tip of the EUS will be positioned in the gastric fundus or duodenal bulb to access the intrahepatic or extrahepatic biliary tract, respectively. The fine-needle aspiration (FNA) with a 19 or 22 gauge needle is used to access the bile duct, and confirmed by contrast injection under fluoroscopy. The guidewire is then advanced into the biliary tree, the UE and the needle is angulated to facilitate the anterograde passage of the guidewire through the site of the obstruction and then to the papilla. The EUS is removed, leaving the guidewire. A duodenoscope is passed to the papilla and a handle or biopsy forceps, and the guidewire is grasped and pulled through the apparatus with subsequent implantation of a stent.

To perform this technique it is essential that the duodenal anatomy is preserved, which often becomes the main limitation of this technique\(^{26}\).

**Direct Transluminal Drainage**

In this technique, the entire procedure is performed using the UE. After the biliary tract is accessed as described above, the puncture site is dilated with a dilatation catheter or a balloon dilator and the stent is passed through some devices for placement. These devices are selected based on characteristics of the patient’s anatomy and obstruction. The stent insertion is then performed in an anterograde fashion\(^{27,28}\). This technique is chosen when the wire may be positioned through the papilla or due to any anatomy change (biliary obstruction by a tumor) or technical complication (awkward position)\(^{26}\).

As for the stents, there is a tendency to use an entirely covered, self-expandable, metallic stent (SEMS), instead of a plastic stent (PS). The use of the SEMS could potentially prolong the stent patency period compared with PS. Moreover, the radial expansion of a SEMS may hypothetically minimize the possibility of complications such as bile peritonitis, pneumoperitoneum, because the leak is immediately sealed by the SEMS itself. However, stent migration is a serious complication that may still occur even with the use of a SEMS, especially shortly after the procedure\(^{29}\).

**Choledochoduodenostomy (CDS)**

The CDS technique involves the creation of a fistula between the duodenum and the extrahepatic biliary tree, thus requiring an extra-hepatic puncture approach. The extrahepatic bile duct can easily be seen and punctured from the duodenal bulb, even if only minimally dilated. This procedure can also be performed in patients with ascites due to the duodenum retroperitoneal position\(^{30}\). The CDS cannot be used in cases of proximal biliary stricture. Another technical aspect is the impossibility to perform CDS in patients with altered anatomy of the upper gastrointestinal tract.

The process begins by placing the EUS in the duodenal bulb in the long handle position and locating the extrahepatic bile duct. The EUS in the bulb normally stays in a relatively stable position. The bile duct is then accessed and a cholangiography performed, followed by dilation and stent placement. The puncture angle is a very important aspect of the process and should be observed carefully. The puncture angle should aim at the wire to advance towards the hepatic confluence. This should be guided by radiography, since the bile duct presents almost parallel to the spine. With respect to dilatation of the biliary tree, it should be calibrated for the passage of the dilatation system. This can be accomplished by a needle knife, a cystotome or a dilator (Figures 1, 2 and 3).

**Figure 1.** Tumor infiltration in the duodenum.
Hepatogastrostomy (HGS)

The intrahepatic biliary system can be reached either by a transesophageal, a transgastric or a transjejunal way (altered anatomy), the hepatic segment III being the most often accessed due to its best view, especially when the stent should be inserted through the cardia or lesser curvature\textsuperscript{26,31,32}.

The technique commonly begins with the sono- graphic observation of a dilated left hepatic duct. The EUS is positioned close to the cardia. In patients with large hiatal hernias, the puncture should be performed in a more distal gastric segment. Biliary puncture, dilatation and stent placement are then performed similarly to the CDS. An important concept during HGS is to leave about 3cm of stent in the gastric lumen to compensate for the stomach distancing from the liver during breathing.

The HGS technique is useful in patients with proximal biliary strictures and distal gastrectomy. In such cases, there is no sonographic window to access the extrahepatic bile duct due to the absence of antrum\textsuperscript{11} (Figures 4, 5 and 6).

Anterograde Drainage

In cases where the transpapillary wire access is obtained by UE, but not by the rendezvous due to a luminal obstruction, then placing an anterograde biliary stent through the obstruction point is a viable conduct\textsuperscript{31}.

This technique involves the following steps. The dilated biliary segment is accessed with a FNA needle followed by cholangiography. A hydrophilic guidewire is inserted through the needle in order to overcome the stenosis. The needle is then removed and the stenotic area is dilated to 7Fr or 8.5Fr using an ERCP catheter (eg: Soehendra bile Dilation Catheter, Wilson-Cook Medical, Winston-Salem, North Carolina). With the tip of the dilatation catheter into the bile duct, the hydrophilic guide wire is then replaced by a stiffer guidewire (e.g., 0.035 inch Jagwire, Boston Scientific, Natick, MA). Placement of the stent is carried by anterograde advancing the stent through the EUS therapeutic channel over the guide wire; the stent is then released at the level of stenosis in a transpapillary or transanastomotic way\textsuperscript{33,34}.

Results of ultrasound-guided biliary drainage

Despite the growing international experience and increase in the number of publications in recent years, concern remains about the safety and effectiveness of these techniques in comparison with the standard ones. Most data, despite involving small series of specialized centers, suggests that UGBD can be performed with great therapeutic success (87%), but is associated with 10-20% of morbidity (mild to moderate majority) and rare significant adverse events\textsuperscript{6}. Recently, Artifon et al.\textsuperscript{35} published the first prospective, randomized study comparing UGBD with transhepatic percutaneous biliary drainage (TPBD) in 25 patients (13 CDS- EUS and 12
TPBD) with malignant biliary obstruction and ERCP failure. Both groups were similar in terms of quality of life, total bilirubin (16.4 vs. 17.2, p=0.7), alkaline phosphatase (539 vs. 518, p=0.7) and gamma-glutamyl transferase (554.3 vs. 743.5, p=0.56). All procedures were technically and medically successful in both groups. On the seventh day of follow-up, there was a significant reduction of total bilirubin levels in both groups (CDS-EUS, from 16.4 to 3.3, p=0.002, and TPBD, from 17.2 to 3.8, p=0.01), although there was no difference between the two groups (3.3 vs. 3.8, p=0.2). There was also no difference regarding the complication rates between the groups (p=0.44): CDS-EUS 2/13 (15.3%) and TPBD 3/12 (25%). The cost was similar between the two groups (US$ 5,673 for CDS-EUS vs. US$ 7,570 for TPBD, p=0.39). Therefore, this randomized study showed that EUS conducted through a transluminal route (choledochoduodenostomy) had a similar success rate, complication rate, and costs compared with TPBD. Although this small prospective, single-center study offers hope that UGBD may be an acceptable alternative to TPBD, large prospective studies conducted by experts could also provide valuable information about the complications related to the procedure, efficiency and changes used to improve patient outcomes.

Shah et al. reported their experience with UGBD in patients with surgically altered anatomy and failed ERCP21. They attempted cholangiography guided by EUS in 70 patients, with a success rate of 97% (68); 66 patients had cholangiographic results that required intervention. UGBD using the rendezvous technique was attempted in 50 patients and was successful in 74% (37), failing in 13. Direct transluminal interventions (hepato-gastrostomy, choledochoduodenostomy, anterograde stent placement) were attempted in the remaining 16 patients and were successful 13 (81%). There were six complications, most treated conservatively. One perforation that required surgical intervention occurred in a sphincterotomy after a successfully performed rendezvous.

Recently, Park et al. reported their experience with UGBD in a large prospective cohort treated by a single experienced operator in a large volume center in Korea36. These authors previously reported a relatively high rate of adverse effects of 20% for UGBD and the most recent study aimed to assess whether the modified technique of “enhanced guidewire manipulation” could improve the safety and efficacy of UGBD. The approach modified by Park et al. includes: 1) bile duct puncture angle optimization with the EUS needle; 2) use of smaller diameter guidewires to prevent failures; 3) introduction of a 4Fr catheter to guide the direction of the guidewire through the distal stenosis / papilla; and 4) a preference to catheterize the segment II intrahepatic bile duct to allow the wire to progress towards the hilum36. In this study, 45 patients with benign or malignant biliary obstruction were submitted to the same UGBD session after failed ERCP. They obtained technical success in 41 (91%) patients, defined as a well-located stent or balloon dilation along with the contrast medium flow through the biliary stent. Functional success, defined as the reduction
of cholestatic indexes below 75% of pretreatment value within one month after the procedure, was obtained in 39 (95%) of these patients. Five (11%) adverse events occurred in four patients: pancreatitis, focal biliary peritonitis, limited pneumoperitoneum, intraperitoneal stent migration and bilioma. The last complication occurred in an approach guided by the EUS with a “stent-in-stent” placement. Overall, three patients had mild complications and one patient had one moderate complication, according to the ASGE Lexicon classification system. In this study, technical success and complications were similar to other studies.

As stated above, the primary intention of Park’s study was to evaluate if the “enhanced guidewire manipulation” may decrease by 20% (n=11) the adverse events rate that other authors have reported in a previous study of 55 patients who underwent UGBD. To assess whether the authors successfully fulfilled this purpose, it is important to evaluate the potential reasons of complications in these 11 patients (classified as mild in seven and moderate in four). Interestingly, nine of the 11 patients underwent fistula dilation using a needle knife, its use being independently associated with adverse events (OR 12.4, p=0.01). In a more recent study, needle knife fistula dilation was used in only five patients. Therefore, we recommend avoiding the use of needle knife when possible.

Gupta et al. conducted a multicenter study on the long-term outcomes of 246 UGBD patients. They used the intrahepatic approach in 60% of cases. They achieved success of biliary drainage in 87% of cases, with a success rate similar in extrahepatic and intrahepatic approaches (84.3% vs. 90.4%, p=0.15). The higher rate of clinical success was observed in malignancies when compared with benign disease (90.2% vs. 77.3%, p=0.02). Complications for all techniques included: pneumoperitoneum (5%), bleeding (11%), bile leakage / peritonitis (10%) and cholangitis (5%), with no statistically significant difference between the intrahepatic and extrhepatic approaches and between benign and malignant diseases.

It is important to note that the results of the studies discussed above come from tertiary centers, with large volumes of procedures and highly qualified interventional endoscopists. We believe that these procedures should ideally be carried out by one or more experienced endoscopists trained in ERCP and EUS, and in institutions where surgery and interventional radiology are available if ones encounters adversity.

**Rendezvous (REN) vs. Direct Transluminal (TL) Technique**

Most endoscopists prefer the REN approach, since it avoids the need for a permanent bilioenteric fistula and the need to dilate the fistula path, which can lead to complications such as bleeding, pneumoperitoneum and pneumomediastinum. However, this approach may not be possible if the guidewire does not cross the papilla due to a difficult angulation or the presence of an insurmountable distal biliary stricture. The results comparing REN and TL in terms of efficacy and adverse events are not well known. Khashab et al. compared REN with TL in a study with 35 patients undergoing UGBD (REN 13, TL 20) for malignant distal biliary obstruction and ERCP failure. Technical success was achieved in 33 (94%) patients and clinical success in 32/33 (97%) patients. The average post-procedure bilirubin was 1.38mg/dL in the REN group and 1.33mg/dL in the TL group (p=0.88). Similarly, the length of stay was not different between the two groups (p=0.23). There was no significant difference in the rate of ad-
verse events between REN and TL groups (15.4% vs. 10%, p=0.64). Long-term outcomes were comparable between the two groups, with one stent migration in the REN group in 62 days, and one stent occlusion in the TL group at 42 days post-UGBD. The authors concluded that UGBD is safe and effective when performed by experienced operators. Occlusion of the stent is not common in long-term follow. Both REN and TL techniques appeared to be equally effective and safe.

There are at least three potential noteworthy REN disadvantages. Firstly, even by experienced specialists REN is successful in only 75% of cases and requires an accessible papilla, which cannot be possible in patients with altered upper gastrointestinal anatomy. In the study by Park et al., the REN approach (or transpapillary anterograde stenting) was not possible in 11 (24%) patients and failed in nine (20%). The second difficulty with biliary drainage by REN is the prolonged procedure time, which is due to several factors, including: 1) the need for manipulation of the guidewire through the distal stenosis and the papilla; 2) exchange of the EUS for a duodenoscope; and 3) the need for retrograde biliary cannulation. Another potential REN disadvantage is the risk of acute pancreatitis due to the manipulation of the papilla.

Given that REN fails or is not technically possible in at least 25% of patients, is associated with prolonged procedure time and may lead to pancreatitis and other complications, it is essential that the endoscopist strives to improve and minimizing the risks associated with the TL technique to provide a full arsenal for patients with stenosis or malignant and benign biliary obstruction. However, the adoption by some endoscopists of the stent in the bilioenteric fistula has been slow due to concerns about the potential risks, especially bilioma and pneumoperitoneum. Nevertheless, our experience suggests that the insertion of a transluminal stent is safe when biliary drainage is achieved with success. It is important to point out the risk of biliary fistula formation if the obstruction is not relieved. Some measures can ensure the successful and safe placement of the transluminal stent. Firstly, one should not dilate the transluminal tract until the guidewire has reached a good position for the stent placement. Secondly, one should dilate the tract only to a diameter to allow the stent insertion, avoiding aggressive expansion, which may predispose to the formation of a biliary fistula. Thirdly, dilation using cautery should be avoided, due to the potential risk of complications, especially bleeding and bile leakage. Fourthly, fully coated metallic stents and carbon dioxide insufflation should be used to minimize the risk of bile fistula and pneumoperitoneum, respectively.

One benefit of the TL technique is the possibility of distal drainage of the tumor, while avoiding the obstructions and compressions. We agree with the statement from many experts that the REN technique should be preferably attempted first, but we believe that a transluminal approach is an acceptable, effective and safe alternative, if the above measures are followed.

**Choledochoduodenostomy (CDS) vs. Hepatogastrostomy (HGS)**

Artifon et al. conducted a randomized study comparing the results of CDS and HGS in 49 patients with unresectable malignant distal biliary obstruction and failed ERCP. The technical success rate was 91% for CDS and 96% for HGS (p=0.61). Likewise, clinical success was similar in both groups (77% vs. 91%, p=0.23). The average procedure time (48.4min vs. 47.8min, p=0.84) and the mean quality of life scores during follow-up were similar. The overall rate of adverse events was 16.3% (12.5% in the CDS group and 20% in the HGS one). The authors concluded that the CDS and HGS techniques are similar in terms of efficacy and safety and that the two techniques are valid alternatives for biliary drainage in patients with malignant distal biliary obstruction and failed ERCP.

Poincloux et al. recently compared the results obtained over a period of seven years with patients with failed ERCP and submitted to CDS or HGS performed by the same endoscopist. Sixty-six patients underwent HGS, with a 94% effectiveness, and 33 patients were subjected to CDS, with a 90% effectiveness. Statistically, there was no difference in success between the two procedures (p=0.69) or in the rate of major complications (10.6% for the HGS group and 6.7% for the CDS group, p=1).
Intra-hepatic vs. Extra-hepatic access routes to UGBD

UGBD using the REN or TL techniques requires a needle puncture of an intrahepatic or extrahepatic duct in a patient with preserved upper gastrointestinal anatomy. However, the best access route is not yet established for either technique. In cases of UGBD by REN, Dhir et al. recently found that an extrahepatic REN (via transduodenal puncture) was associated with significantly shorter procedure time, less post-procedure pain, lower bile leakage and pneumoperitoneum. In addition, they found that success is probably greater with extrahepatic REN, as confirmed by Park et al. (93% vs. 50%). Similarly, in the case of UGBD by TL, the extrahepatic route (choledochoduodenostomy) is probably safer than an intrahepatic one (hepatogastrostomy). Therefore, it appears that the extrahepatic access during UGBD is better and safer than an intrahepatic one, performed either via REN or via TL.

Dhir et al. compared the success and complications rates in 68 patients undergoing UGBD by different techniques. UGBD was successful in 65 patients (95.6%). There was no significant difference in success rates for the different techniques. Complications have been observed in 14 patients (20.6%) and mortality in three (4.4%). Complications were significantly higher for the intrahepatic route compared with the extrahepatic (transduodenal) (30.5% vs. 9.3%, p=0.03). There was no significant difference in complication rates between placements of transpapillary and transluminal stents, or REN. The logistic regression analysis showed that the transhepatic access is the only independent risk factor for complications (p=0.03). The authors concluded that UGBD could be performed with high success rates, regardless of the choice of the access route, the stent direction or drainage pathway. However, complications are significantly higher with the intrahepatic access. They recommended that the extrahepatic (transduodenal) access be chosen for UGBD, and stent placement by the REN technique when both pathways are available.

Why does the intrahepatic pathway lead to increased risk of complications? First, an intra-hepatic route involves a needle puncturing into the peritoneal cavity, pneumoperitoneum and danger of bile leakage into the peritoneal cavity. Secondly, the movement of the liver during breathing can lead to both stent migration, with consequent bilomas, and to trauma to the biliary tree (which increases the risk of post-procedural pain and bile leakage). Another factor is that the smaller caliber of the intrahepatic ducts may not allow the placement of larger diameter, 8-10 mm metallic stents, which theoretically can predispose to pneumoperitoneum and bile leakage due to incomplete sealing of the bilioenteric fistula. The extrahepatic access, moreover, has many advantages, including the duodenum proximity with the dilated bile duct, the retroperitoneal location of the bile duct, which benefits patients with ascites, and a relatively fixed biliary tree, with minimal respiratory influence, better visualization of the biliary tract. Nonetheless, more prospective studies comparing the safety of different techniques are still needed.

UGBD vs. PTBD

Data from various centers confirm the efficacy and safety of DBEG. However, comparative data with other techniques, for example, PTBD, are limited. These data are essential to decide whether patients with failed ERCP are best conducted with UGBD or PTBD. There is only one small, randomized controlled trial comparing UGBD and PTBD in 25 patients with malignant biliary obstruction and ERCP failure. This study found that both procedures have efficacy, safety and equivalent cost. The main limitation of the study was that it evaluated only the direct procedure costs. This probably overestimated the cost-effectiveness of PTBD, which is associated with increased long-term costs due to the need for frequent interventions.

More recently, Khashab et al. retrospectively compared UGBD and PTBD in 73 patients (22 UGBD, 51 PTBD). Although the technical success was greater in the PTBD group (100% vs. 86.4%, p = 0.007), clinical success was similar (92.2% vs. 86.4%, p=0.40). PTBD was associated with a higher rate of adverse events (index procedure: 39.2% vs. 18.2%; all procedures, including reintervention: 80.4% vs. 15.7%). Stent patency and survival were similar between the two groups. The total costs were more than twice as high in the PTBD group.
(p=0.004), primarily due to a significantly higher reintervention rate (80.4 vs. 15.7%, p=0.001). The authors concluded that UGBD and PTBD are comparatively effective in the treatment of malignant distal biliary obstruction after failed ERCP. However, UGBD is associated with decreased adverse event rates and is significantly cheaper due to less need for reoperation.

Access through UGBD has several advantages with respect to PTBD. The proximity of the transducer along the bile duct, possibility of elucidating the cholestasis etiology, using doppler to prevent accidental puncture of the vascular structures and the possibility of access the bile ducts from multiple pathways. Dilated intrahepatic bile ducts can be accessed in the liver through the distal esophagus or stomach, or the common bile duct can be accessed by the proximal duodenum, and occasionally the gastric antrum. This choice of bile ducts access routes allows the success of endoscopic drainage even in patients with duodenal obstruction, or subjected to bypass surgery. Other advantages include UGBD viability, even in patients with ascites and hepatic metastases, as well as migration of percutaneous catheters, their associated complications (e.g., skin irritation, leakage) and negative impact on quality of life. Furthermore, UGBD can be performed during the same endoscopy session after ERCP failure, which avoids the necessity of repeated interventions and allow timely biliary drainage, with more rapid bilirubin decrease, allowing more rapid onset of chemotheraphy and radiotherapy, if necessary. Thus, obtaining the term for UGBD before ERCP avoids the need for repeated endoscopic interventions and allow timely bile duct drainage and the start of early chemotherapy/radiation therapy, if necessary.

A final consideration about UGBD is when to perform the procedure on a patient with a benign or malignant biliary obstruction. Dhir et al. proposed that a single UGBD procedure could be a viable alternative to ERCP in patients with malignant distal biliary obstruction. They conducted a multicenter, retrospective study to compare the results of stenting for malignant distal biliary obstruction by ERCP and EUS. UGBD patients underwent a choledochoduodenostomy (CDS) or anterograde drainage (AG) after one or more unsuccessful ERCP attempts, while patients in the ERCP group underwent SEMS retrograde placement. The study included 208 patients, 104 in the ERCP arm and 104 in the UGBD (68 EUS-CDS and 36 EUS-AG). The SEMS placement was successful in 98 patients of the ERCP group and 97 in the UGBD group (94.23% vs. 93.26%, p=1.00). The frequency of adverse events was similar (8.65% and 8.65%, respectively). The post-procedure pancreatitis rate was higher in the ERCP group (4.8% vs. 0%, p=0.059). The authors concluded that in patients with malignant distal biliary obstruction that require SEMS placement, the short-term results of UGBD and ERCP are comparable.

Hara et al. recently conducted a prospective study on UGBD for primary therapy of malignant biliary obstruction, ie no ERCP attempt, in 17 patients. They achieved both technical and clinical successes in 94% of patients, without serious complications. While this approach may prevent post-ERCP pancreatitis, we believe that the current role of UGBD should be for salvage therapy in patients with failed ERCP.

**UGBD Guidelines**

We recommend obtaining informed consent for possible UGBD with the term for ERCP in patients at high risk for failure in biliary cannulation, with, for example: altered anatomy; prior ERCP failure; periampullary cancer with duodenal invasion; and duodenal stent at the papilla level. This approach requires a long talk with the patient about other potential approaches should the cannulation fail, such as surgery or percutaneous drainage. UGBD is a safe and effective procedure after failed ERCP when performed by rendezvous or direct transluminal techniques. The extrahepatic access route is preferred for distal malignant obstructions and is associated with lower incidence of adverse events. UGBD

**FINAL CONSIDERATIONS**

UGBD is a safe and effective procedure after failed ERCP when performed by rendezvous or direct transluminal techniques. The extrahepatic access route is preferred for distal malignant obstructions and is associated with lower incidence of adverse events. UGBD
is less invasive than the transparieto-hepatic drainage and the limited data available suggest equivalent efficacy and safety. However, its use is still limited to tertiary centers with high technology available. Indications and methods for UGBD are still being standardized and therefore the approach should be individualized for each patient, based on the endoscopist’s experience and the patient’s anatomy. In addition, controlled, randomized, multicenter clinical trials are needed for defining the optimal technique.

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