EUS 2008 Working Group document: evaluation of EUS-guided hepaticogastrostomy

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Drainage of a biliary obstruction can be accomplished in several ways: (1) placement of an internal biliary stent at ERCP, (2) placement of percutaneous transhepatic biliary drainage catheter (PTBD), and (3) surgical anastomosis (ie, hepaticogastrostomy or choledochojejunostomy). Recently, the role of EUS was evaluated in several studies as an alternative treatment modality for the management of patients with obstructive jaundice. This section of the EUS 2008 Working Group Proceedings evaluates the current evidence and potential role of EUS-guided hepaticogastrostomy in the management of patients with obstructive jaundice.

OBSTRUCTIVE JAUNDICE: CURRENT MANAGEMENT APPROACHES AND THEIR LIMITATIONS

ERCP is the criterion standard procedure for establishing biliary decompression, with a success rate that exceeds 90% and a risk of complications that is less than 10%.[1-3] However, surgical diversion, anatomic variation, periampullary diverticula, and tumor invasion are all situations that may result in technical failure. In such circumstances, PTBD and surgical biliary bypass are effective treatment alternatives.[4,5] PTBD has a complication rate of 10% to 30%, with possible development of cholangitis, bile leak, bleeding, fistula formation, peritonitis, empyema, and stent occlusion.[6] Surgical drainage is quite effective, but is associated with 2% to 5% mortality and 17% to 37% morbidity.[6-8]

There have also been small case series that described a percutaneous hepaticogastrostomy approach when using fluoroscopic, laparoscopic, and endoscopic assistance to place a temporary fenestrated gastrostomy tube through the liver with the bumper in the stomach for 2 weeks, followed by a replacement metal biliary stent between the left biliary system and the stomach. This was successful in all 33 patients in whom it was attempted but was associated with 2 procedure-related deaths from bleeding and sepsis.[9,10] Percutaneous hepaticogastrostomy with a metal stent without laparoscopic or endoscopic assistance was also reported to have been performed safely and effectively in 4 patients.[11] Transduodenal EUS-guided biliary-stent placement has also been reported and is discussed in a separate section of the EUS 2008 Working Group Proceedings.

Abbreviation: PTBD, percutaneous transhepatic biliary drainage catheter.

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EUS-GUIDED HEPATICOGASTROSTOMY

Transgastric EUS provides excellent imaging of the left lobe of the liver, especially of dilated intrahepatic ducts in patients with biliary obstruction. By using EUS-guided FNA, it is possible to safely biopsy left liver lobe lesions.[12,13] Given the safety and efficacy of transintestinal EUS puncture and drainage of other extramural fluid collections, such as pancreatic pseudocysts, bilomas, and pelvic abscesses, the development of EUS-guided hepaticogastrostomy seems a logical extension of the technique.[14-16]

Procedure technique

After administration of prophylactic antibiotics, the following steps are undertaken:

1. The linear-array EUS scope is placed against the cardia or lesser curve of the stomach, and EUS is performed to evaluate for a dilated left intrahepatic biliary system. After excluding the presence of regional vasculature by using power or color Doppler US, a dilated peripheral branch of the left intrahepatic system that is closest to the EUS transducer is transgastrically accessed by using a 19-gauge or 22-gauge needle (Fig. 1).
2. After removal of the stylet, bile is aspirated, and radiopaque contrast is injected to visualize the biliary system under fluoroscopy (Fig. 2).
3. A 0.035-inch or 0.021-inch guidewire is then passed via the FNA needle into the left intrahepatic system. Every attempt should be made to pass the wire into the duodenum across the biliary stricture so that rendezvous ERCP drainage can be undertaken with

Figure 1. The left lobe of the liver accessed by EUS-guided FNA.

transpapillary biliary-stent placement. If this is not possible, then the wire can be coiled in the liver hilum for transgastric stent placement.

4. The transmural tract between the stomach and the left intrahepatic system can be dilated by using a 4.5F to 5F ERCP cannula (Fig. 3), a needle-knife, a cystotome (6F or 8.5F), or a 6F bougie. Further dilation may also be performed by using a 4-mm or 6-mm dilating balloon.
5. A plastic stent, with or without a pigtail, or an expandable metal stent is then transgastrically deployed into the left intrahepatic system (Figs. 4 and 5).

Published data on EUS-guided hepaticogastrostomy

A summary of EUS-guided hepaticogastrostomy reported to date is shown in Table 1. Although there is only a small sample size of 19 published cases, the technical success rate was 90% to 100% and the clinical success rate was 75% to 100%. Complications included stent migration, bile leaks, and cholangitis.

In the study by Kahaleh et al,[17] a total of 13 cases underwent transgastric puncture of the left biliary system, with placement of the wire across the papilla into the duodenum for a rendezvous procedure in 11 of the 13 cases. The investigators suggested that, for purposes of introducing a wire across the papilla for a rendezvous procedure, the transgastric route is preferred because of the lower risk of bile leak. Other studies were published that use alternate routes, such as the jejunum, to place a stent into a dilated left biliary system, with generally successful results.[18-21]

Limitations of EUS-guided hepaticogastrostomy

1. The procedure can be attempted only when the left intrahepatic system is dilated; patients with isolated right hepatic obstruction are not candidates for EUS-guided hepaticogastrostomy.

Figure 2. EUS-guided cholangiogram.

2. The procedure cannot be attempted in patients with ascites or coagulopathy.
3. The ability to steer the guidewire into the common hepatic duct can sometimes be technically challenging, because it tends to pass into the right intrahepatic system during guidewire manipulation.
4. The guidewire (and/or Teflon covering [DuPont, Wilmington, Del]) can shear off inside the bile duct because of the sharp tip of the FNA needle.
5. During exchange of accessories, there remains a risk for losing access, because only a short distance of the guidewire remains coiled within the intrahepatic system.
6. This procedure requires an endoscopist who is competent at performing both EUS-FNA and ERCP biliary stenting procedures.

Clinical research agenda

This is an important area for research because preliminary results showed that EUS-guided transgastric biliary stents can be safely and effectively deployed. This technique is potentially applicable to all patients with biliary obstruction not amenable to standard transpapillary stenting at ERCP. It is an especially attractive option for patients with duodenal obstruction or prior gastric surgery. Currently available data are from expert centers, and the procedures have been performed by using various techniques and accessories. The complication rates still need to be determined. Before this procedure can be recommended as a standard treatment alternative for patients after a failed ERCP, EUS-guided hepaticogastrostomy requires further evaluation in a larger cohort of patients by using a standard technique. Because the number of procedures currently performed is small, multicenter trials may be

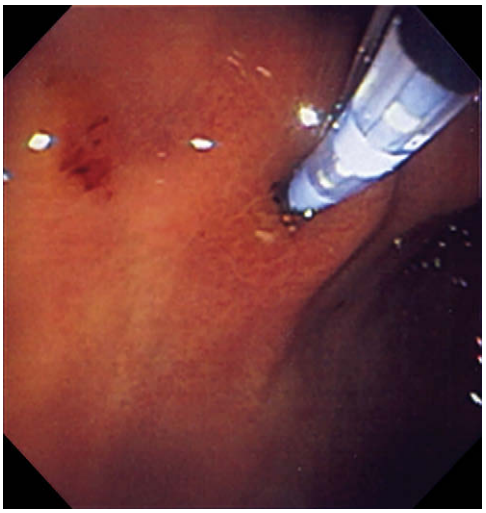

Figure 3. Dilation of the transmural tract with a ERCP cannula.

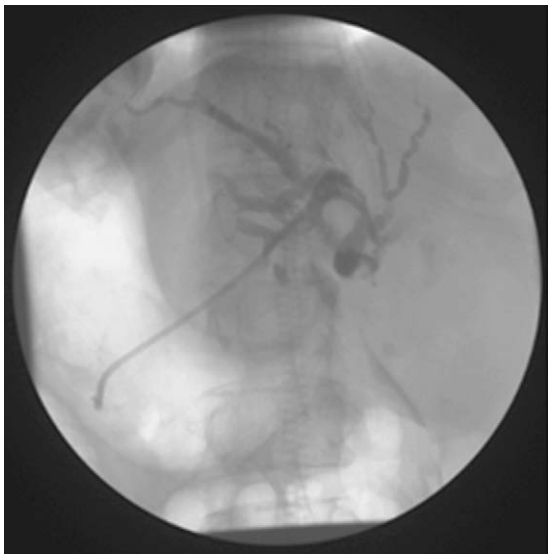

Figure 4. A 7F transgastric stent is deployed.

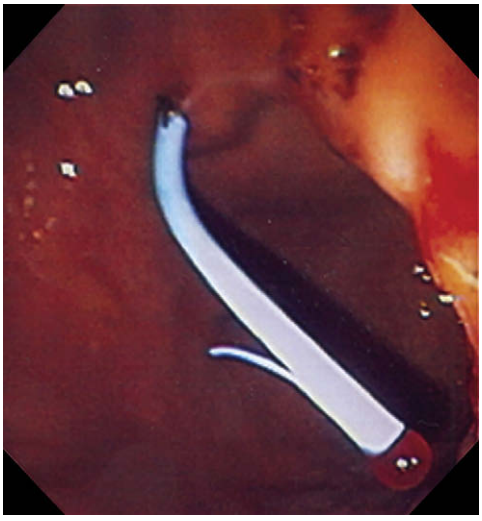

Figure 5. A 7F transgastric stent is deployed with flow of bile as seen on endoscopy.

required to best evaluate the technical and/or treatment outcomes and safety profile of this procedure.

Technical issues that pertain to reducing the risk of bile leaks with this technique require further evaluation. There was migration of covered metal stents, which caused complications, in published studies of 2 patients. Studies will need to address the optimal stents to use, whether plastic stents, uncoated metal biliary stents, coated metal biliary stents, a combination, or some other stent design.

Research will be needed to determine if long-term stenting will be required or if a more permanent fistula could be created either during the initial procedure or after a period of stent placement and then removal. This may also require development of new devices to create sustainable fistulas.

Alternative EUS-guided biliary-drainage approaches include EUS-guided rendezvous techniques and EUS-guided choledochoduodenostomy. The EUS-guided rendezvous technique (either transhepatic or transduodenal approach) appears to be the safest of all 3 approaches, because, once the guidewire is passed across the stricture into the duodenum, transpapillary stenting can be undertaken via the native papilla and into the natural biliary orifice. A major limitation of the rendezvous technique is that it can be attempted only in patients in whom the papilla is accessible by endoscopy. When the papilla is not accessible, biliary drainage can be undertaken only via the hepaticogastrostomy or the choledochoduodenostomy approach. Studies will need to investigate further how often a EUS-assisted rendezvous procedure can be done instead of a hepaticogastrostomy.

Likewise, EUS-guided choledochoduodenostomy can be attempted only in patients with a native anatomy (intact duodenal bulb) and an intact biliary tree. EUS-guided hepaticogastrostomy may be the only treatment option for patients who have undergone a Whipple procedure or other gastric or biliary bypass procedures and those with hilar tumors. Once techniques have been established, studies that compare the technical efficacy and safety of EUS-guided hepaticogastrostomy and EUS-guided choledochoduodenostomy may eventually be required in patients with a normal anatomy to identify the most optimal technique for achieving biliary drainage.

PTBD is the standard of care after a failed ERCP at most institutions. Studies that compare EUS-guided transpapillary rendezvous, as well as EUS-guided hepaticogastrostomy, and PTBD may be required to identify the best modality for approaching biliary obstruction after a failed transpapillary ERCP.

Because EUS-guided hepaticogastrostomy is currently performed mostly at expert ERCP centers that have low ERCP failure rates, it is possible that the need for this

TABLE 1. Summary of studies that evaluated EUS-guided hepaticogastrostomy as technique for biliary drainage

Study, y	No. cases	Needle or dilation device	% Technical success	% Clinical success	Initial stent (no. of cases)	30-Day complications (no. of cases)
Burmester et al,[18] 2003	1	19-Gauge needle, fistulotome	100	100	Plastic	None
Giovannini et al,[22] 2003	1	19-Gauge needle, needle-knife	100	100	Plastic	None
Kahaleh et al,[17] 2006	2	19-Gauge or 22-gauge needle	100	100	Plastic	None
Artifon et al,[23] 2007	1	19-Gauge needle	100	100	Covered SEMS	None
Bories et al,[24] 2007	11	19-Gauge or 22-gauge needle, cystotome	91	100	Plastic (7), covered SEMS (3)	Plastic stents ileus (1); stent occlusion (1); SEMS: stent migration and/or shortening (2), causing biloma (1), and cholangitis (1)
Will et al,[19] 2007	4	19-Gauge needle, 6F bougie, 4- to 6-mm balloon	100	75	Covered SEMS (2), uncovered SEMS (2)	Covered SEMS: cholangitis (1)

SEMS, Self-expanding metal stent.

technique at expert ERCP centers may be low. Conversely, in centers with less ERCP expertise that have higher failure rates (and probably also use PTBD more frequently), this technique might be used more frequently. Therefore, multicenter trials that include both high-volume and low-volume ERCP centers may be needed to compare the technical and/or treatment outcomes and safety profile between PTBD and EUS-guided hepaticogastrostomy.

Device development

The development of a single-step catheter-based EUS needle that allows puncture, followed by advancement of the catheter across the liver (so that the needle can be removed), is required. A steerable catheter or guidewire would help improve the ability to perform rendezvous procedures. Also, guidewires that are less prone to shearing when advanced back and forth across a 19-gauge or 22-gauge needle are required. Also, to overcome the current limitations of stent migration and tumor overgrowth, the ability to create a permanent fistula between the biliary system and the stomach needs to be explored. The deployment of stents and other therapeutic maneuvers can be challenging when using the oblique-viewing echoendoscope. The role of the prototype forward-viewing echoendoscope for this purpose requires further investigation.

WORKING GROUP RECOMMENDATIONS

There certainly is a need for a less-invasive treatment alternative for patients with obstructive jaundice who had a failed ERCP. Although the data are limited, because of the clinical need and limited treatment alternatives currently available, the working group accords a high priority for fostering clinical research in this area. The work in this area will likely be similar to work in the area of EUS-guided choledochoduodenostomy. Trials aimed at standardizing the procedural technique and comparative studies with EUS-assisted transpapillary rendezvous procedures, EUS-guided choledochoduodenostomy, and PTBD are required. Particular emphasis should be paid to improve the technical success rates and safety profile of the procedure. Until the procedural technique for performing EUS-guided hepaticogastrostomy has been standardized and its clinical efficacy and safety profile is better established, the procedure should ideally be undertaken only at tertiary-referral centers under a research protocol by an endosonographer who is proficient in ERCP or in collaboration with an endosonographer and a therapeutic biliary endoscopist. Also, because the number of patients who would qualify for undergoing EUS-guided hepaticogastrostomy and other related EUS-guided biliary access and stenting techniques is rather large, the working group sets the priority at high for device development in this area.

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