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Review Article

Recent development of endoscopic ultrasound-guided biliary drainage

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ABSTRACT

Endoscopic ultrasound (EUS)-guided drainage of bile ducts is experiencing widespread introduction into clinical algorithms and utilization of its benefits on regular basis. Various types of procedures, including EUS-guided choledochoduodenostomy, EUS-guided hepaticogastrostomy, EUS-guided antegrade drainage facilitate biliary interventions particularly in those cases when endoscopic retrograde cholangiopancreatography fails or is not possible at all, for example in cases with surgically altered anatomy. Available clinical data are encouraging, but prospective and randomized controlled trials are warranted. The need for development of special tools and accessories seems to be essential for safer spreading of these procedures into algorithms of clinical care.

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Keywords: Endoscopic ultrasound; Endoscopic ultrasound-guided antegrade drainage; Endoscopic ultrasound-guided biliary drainage; Endoscopic ultrasound-guided choledochoduodenostomy; Endoscopic ultrasound-guided hepaticogastrostomy

Introduction

It has been more than 40 years since Hisanaga et al^{1,2} from Japan reported on the first use of ultrasound scanning through the digestive tract, followed shortly afterwards by reports and papers of DiMagno et al³ and Strohm et al⁴ exploring further utilization of endoscopic ultrasound in this area. Endoscopic ultrasound has undergone tremendous development in the following decades in technology and image resolution, thus providing a reliable diagnostic tool for numerous pathologies. Development in interventional part has been rather limited, despite continuous and steady improvements, to tissue sampling, drainage of fluid collections and endoscopic ultrasound (EUS)-guided treatment targeting plexus coeliacus.

Even though many other EUS-interventions have been described and occasionally used in clinical practice, their further widespread was mostly limited due to missing dedicated and specially developed instruments and accessories. For the vast majority of these procedures, other tools, usually adopted from endoscopic retrograde cholangiopancreatography (ERCP) techniques and procedures, were utilized. EUS-guided biliary drainage

(EUS-BD) as EUS-guided choledochoduodenostomy (EUS-CDS) has been first described and the case reported by Giovannini et al⁵ in 2001. Needle-knife sphincterotome, 0.035 guidewire, bougie dilator and 10Fr -plastic stent were used in case of a jaundiced patient with pancreatic head cancer and after failed cannulation of papilla Vateri.

The technique was used since then in various modifications in many institutions providing advanced endoscopic treatment and having access and quality to both, ERCP and EUS. Various access strategies were applied with the use of needle-knives, EUS needles, bougie or balloon dilators, and both plastic and self-expandable metal stents were used. Nevertheless, the complexity and lack of standardization of the procedure, as well as lack of dedicated accessories, prevented its full implementation in the clinical practice and routine protocols of clinical care. Despite very high overall procedure success rate of 94% (range, 50%–100%) in 30 reviewed studies on EUS-CDS, published in between 2001 and 2014, the reported complication rate was 19%. With numerous severe adverse events including peritonitis, cholangitis, hemobilia, bile leak, pancreatitis, hemoperitoneum, stent migration, etc.⁶

However, in the last decade, we can see widespread of EUS-

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BD, especially related to improved EUS and ERCP tools, as well as and mainly due to introduction of devices and accessories fully dedicated and developed for EUS-BD. This improvement of our armamentarium has allowed us to incorporate EUS-BD into clinical practice as a routine procedure, mainly in those cases when transpapillary cannulation fails or is not an option, for example in cases of surgically altered anatomy.

All these techniques and their understanding are equally important as they often complement each other and do not present as directly competing approaches. Different techniques can be also used in the same patient and in the period of time in his or her treatment and as the patient disease progresses. It is therefore important and essential for the biliopancreatic endoscopist to understand all these procedures, their indications and limitations, and if possible, to command the safe performance these techniques.

Despite there is this substantial gap in missing prospective and randomized controlled data, provided evidence based mostly on retrospective studies is encouraging enough for safe and effective clinical applications.

Main or Primary Indications for EUS-Guided Biliary Drainage

Failed ERCP still represents the main challenge in hepatopancreatobiliary endoscopy. Since ERCP has shifted to an almost purely therapeutic procedure already about 30 years ago, failure to perform these interventions imposes significant consequences.

There are two major and distinctive situations when ERCP fails. In the first one, the papilla is reached but cannot be cannulated (e.g. due to pathology on papilla, juxtapapillary diverticulum, anatomic variations, failure of passing the guidewire through the stricture or simply due to lack of experience of the endoscopist) or papilla is inaccessible (e.g. cannot be reached due to gastric outlet obstruction or surgically altered anatomy).

If papilla can be reached, so-called EUS-assisted ERCP may be performed. It allows inserting guidewire transpapillary in the antegrade fashion, either from duodenum or stomach (transhepatically), followed by the exchange of echoendoscope to therapeutic duodenoscope. Therefore EUS-assisted approach is essentially two endoscope procedure where EUS only facilitates access. This is known as the so-called EUS rendez-vous (EUS-RV) procedure or access.

If papilla is inaccessible, this principle obviously cannot be applied and direct EUS-BD needs to be performed. Echoendoscope is in such case the only endoscope engaged in this type of drainage.

EUS-RV has reported may be also quite technically challenging and overall reported success rate is only above 82% with 10% complication rate.⁶ Thus, it is indeed an option to apply strategy and use EUS-BD approach, even in those cases when papilla Vateri is accessible.

Types of EUS-Guided Biliary Drainage

There are two main points of access to bile ducts in terms of EUS-BD. Transduodenal or transgastric. In rare cases, especially of surgically altered anatomy, we can also gain access as transenteric, transcolonic, etc.

These accesses allow us to create either downstream or upstream drainage. In case of downstream drainage, stenting is performed across the obstruction, papilla or anastomosis. Upstream drainage is created above the obstruction transhepatically (usually, from the stomach), transduodenally or transjejunally.

Understanding the anatomy, bile flow dynamics and pressure gradients are key elements for clinically successful and effective EUS-BD.

EUS-BD can be created as anastomosis on extrahepatic bile ducts or as a transhepatic anastomosis.

EUS-CDS is the most frequent type of extrahepatic bile duct anastomosis. Usually, it is created as a retroperitoneal anastomosis, directly in between duodenum and distal common bile duct (CBD). This has importance in understanding the safety and risk of the procedure, respectively.

Far less frequent variations of extrahepatic EUS-BD are hepaticoduodenostomy, depending on the patient's anatomy of hepatocholedochus and its angulation towards duodenum, and choledochogastrostomy, in rare cases when the transduodenal approach is not feasible.

A transhepatic anastomosis is performed typically as EUS-guided hepaticogastrostomy (EUS-HGS).

EUS-Guided Choledochoduodenostomy

As mentioned already above, the initial studies and reports of 300 patients indicated a high overall procedure success rate of 94% in 30 reviewed studies on EUS-CDS, however, the reported complication rate was 19%. With numerous severe adverse events.⁶

Development and introduction of lumen-apposing metal stents (LAMS) provided a new and dedicated tool for EUS-guided interventions, including EUS-BD and in this case EUS-CDS. In Europe, LAMS are used on-label in this indication. Many others use them off-label if approved and indicated.

So-called cold devices, requiring gaining initial access to the bile duct with the following dilation of the fistula tract were replaced later on with electrocautery enhanced "hot" devices, which allows introducer to gain access and deploy LAMS without need to use additional puncture device. Electrocautery enhanced devices also allow potentially to be used in the "freestyle" technique, where access and LAMS release is done directly without need of the over-the-wire procedure.⁷ Such approach may require a bit of experience and skills while deployment is performed in moderately dilated ducts, but the technique is feasible and safe and eliminates the potential risk of error while manipulating and exchanging other accessories over the wire, and makes also performance faster.

Retrospective studies have shown very high technical success rates of 98.2% and 93.5%, with clinical success of 96.4% and 97.7%, and adverse events in 7% and 11.6%, respectively.^{8,9}

It has been suggested that EUS-CDS performed by LAMS may replace percutaneous transhepatic biliary drainage (PTBD) in cases of failed ERCP and thus complement to other biliary endoscopic procedures (e.g. ERCP, EUS-assisted ERCP, etc.).^{8,10,11}

A meta-analysis of seven studies on EUS-CDS by LAMS (284 patients) has shown a 95.7% technical success rate and a 95.9% clinical success rate, with postprocedural adverse events in 5.2%. Subgroup analysis on using electrocautery-enhanced LAMS included 201 patients from five studies with 93.8% technical success rate and a 95.9% clinical success rate, with postprocedural adverse events in 5.6%.¹²

Major advantages of EUS-CDS performed by LAMS in comparison to PTBD, surgery and ERCP are that EUS-CDS can be performed in the very same session as failed ERCP as one-session procedures, usually requires only conscious sedation as the procedure is not painful, can be carried out as out-patient procedure, which is also short in time, eliminates the risk of post-ERCP pan-

creatitis, no external drainage is established and thus drain care and bile loss are also eliminated, and the procedure is not limited by obesity and ascites. This all factors underline the final positive impact on patient's quality of life.⁸

In our initial five-year experience of 251 consecutive cases of EUS-CDS, in between January 2013 and July 2018, we have technically succeeded achieved drainage in all 100% of cases. It was effective for 97.2% (244/251) of patients. Adverse events were observed in 4.4% (11/251) of patients. With the median procedure time of 7 minutes. All at a median follow-up of 306 days. In 96.4% (242/251) was papilla inaccessible due to gastric outlet obstruction and only in 3.6% (9/251) of cases the reason for EUS-CDS was failed cannulation. Adverse events were mainly represented by sump syndrome typically presented in cases when patient survival was longer than 12 months. By EUS-CDS side-to-side anastomosis is created. This type of anastomosis has been abandoned by surgery decades ago, due to sump syndrome in the group of surviving patients. This initial experience has shown favorable results in comparison to PTBD and we have implemented EUS-CDS fully into our therapeutic algorithms in order provide procedures in the same session as failed ERCP, with a positive impact on patient flow, length of hospital stay and quality of life.¹³

For this particular procedure, we do prefer the use of forward-viewing therapeutic echoendoscope (TGF-UC180J; Olympus Corp., Tokyo, Japan) which is, however, not frequently used and widely available echoendoscope. EUS-CDS is typically performed in the long scope position when the tip of the echoendoscope is directed towards the midline. While using conventional linear echoendoscopes with oblique optics, the axis of the working channel usually directs towards liver hilum. This position may limit options for the potential to maneuver depending on patient anatomy, angulation of extrahepatic bile duct towards the upper edge of the duodenum as well as with the respect to the diameter of the bile duct. Changing the direction of this axis caudally require a short-

ened position of the echoendoscope which might be very difficult and even impossible. For these reasons, forward-viewing therapeutic echoendoscope seems to be a better option, as the axis of the working channel is usually perpendicular towards hepatobiliary duct and selective targeting of both, proximal extrahepatic bile duct as well as distal CBD seems to be much easier, by small position adjustments of echoendoscope's tip and its angulation. This approach allows us to safely drain by LAMS bile ducts with a diameter over 8mm, while still using the "freestyle" technique. Otherwise, typically EUS-CDS by LAMS typically recommends when distal CBD is dilated at least to 12 or 15 mm.

We typically use 6 mm × 8 mm LAMS which creates good and persisting flow, without significant risk of food impaction (Fig. 1; Supplementary Video 1).

In cases when intraductal intervention is anticipated and EUS-CDS serves also as an access anastomosis, usually 10 mm LAMS is inserted, allowing comfortable intubation by cholangioscope and/or therapeutic accessories. We apply this approach for example in cases when lithotripsy under cholangioscopic guidance should be performed or when cholangioscopic evaluation and tissue sampling is supposed to be done.

EUS-Guided Hepaticogastrostomy

EUS-HGS represents an alternative approach to bile duct drainage. It may supplement other alternatives and but in certain circumstances, it may be also the only option. Particularly, in cases of surgically altered anatomy or duodenal obstruction involving also duodenal bulb, when EUS-CDS is not a feasible approach.

It has been first described by the German group from Lübeck by Burmester et al¹⁴ in 2003.

Techniques have evolved since, with overall technical success rate of 96%, the clinical success rate of 90% and adverse event

Fig. 1. (A) Dilated distal common bile duct due to pancreatic head cancer while "freestyle" puncture with lumen-apposing stent introducer is performed under endoscopic ultrasound (EUS)-guidance using forward viewing therapeutic echoendoscope Olympus TGF-UC180J. (B) EUS-guided choledochoduodenostomy (EUS-CDS) with lumen apposing metal stent. (C) Fluoroscopic view of deployed lumen-apposing metal stent in EUS-CDS performed by forward viewing therapeutic echoendoscope Olympus TGF-UC180J. (D) Combined iodine contrast cholangiogram and pneumocholangiogram by carbondioxide after EUS-CDS is created.

Fig. 2. (A) Endoscopic ultrasound (EUS)-guided hepaticogastrostomy – transgastric puncture of dilated left intrahepatic ducts by 19G EUS needle. (B) Antegrade cholangiogram obtained by transgastric puncture of left intrahepatic bile ducts. Hilar cholangiocarcinoma Bismuth-Corlette II. (C) Deployment of semicovered self-expandable metal stent and creation of EUS-guided hepaticogastrostomy. (D) Semi-covered self expandable metal stent in EUS-guided hepaticogastrostomy.

rate of 18% while considering data from studies and reports of 810 patients in between 2003 and 2018.¹⁵

Evolution of technique for EUS-HGS has been similar to EUS-CDS when various accessories, including needle knives, bougies, dilation balloons and cystotomes have been used. Lately, we can see the development of special stents which are either fully of semicovered and also having larger flanges in order to reduce the risk of migration once the stomach is deflated after transgastric placement of the stent into the intrahepatic bile ducts.

A semicovered stent may be particularly useful when we would like to avoid drainage of side branches in the left liver lobe to be blocked by the stent coating. The covered part provides a safe healing environment for the creation of fistula in between stomach, liver capsule and liver parenchyma into intrahepatic bile ducts, while reducing the risk of leak of bile or stomach content as the stent transverses peritoneal cavity.

EUS-HGS may represent also access for further antegrade intrahepatic treatment, interventions on the level of extrahepatic bile ducts and liver hilum as well as transpapillary interventions. In cases when such antegrade procedures and interventions are anticipated, it is preferred to drain through the liver segment 2, otherwise for left-sided EUS-HGS approach through segment 3 is also acceptable.

We prefer to avoid use of electrocautery while creating and dilating puncture fistula tract, order to avoid immediate or delayed thermal injury of concomitant vessels to bile duct in the liver parenchyma. Instead, small diameter balloon dilation is used in order to facilitate stent insertion. Similar to the technique as described by Ogura et al.¹⁶

Novel devices may address this issue while using all-in-one introduction system, allowing stent insertion and deployment without prior dilation of the fistula tract.¹⁷

In five-year span we have performed 145 procedures with the technical success of 96%, the clinical success of 5.8% adverse events in only 5.8% (Fig. 2; Supplementary Video 2).¹³

EUS-Guided Antegrade Stenting

EUS-guided puncture of the bile duct, either from duodenum, stomach or even jejunum, and successful guidewire placement across the stricture and/or across papilla, may not only be used for EUS-assisted approach for the rendez-vous technique as described above but may also be used for antegrade placement of the stent, eventually also with other antegrade interventions. This type of approach should be particularly considered in those situations where downstream drainage might be potentially superior over upstream drainage. The technique might be sometimes challenging due to limited maneuverability of the guidewire. Nevertheless, still providing high technical success rates and relatively low risk of adverse events.^{18–21}

Place of EUS-Guided Biliary Drainage in the Treatment Algorithms

Some randomized control trials have recently looked at the comparison of ERCP to EUS-BD, suggesting that success rates are similar for both techniques, respectively, but adverse events and reintervention rates might be lower for EUS-BD, and thus justifying the use of EUS-BD as the primary approach particularly in specific and challenging situations.^{22–24}

Systematic review and meta-analysis also suggest that in cases if palliative drainage of distal malignant biliary obstruction, EUS-BD and ERCP present similar rates of technical success, adverse events and stent patency. The rates of stent dysfunction appear to be lower for stents placed under EUS guidance.²⁵

Systematic review and meta-analysis comparing EUS-CDS and EUS-HGS, including 10 studies and 434 patients, found equal efficacy and safety, where both techniques are associated with very high technical and clinical success. There is no difference in adverse events and EUS-CDS is slightly faster. The choice of approach may be selected based on patient anatomy.²⁶

Fig. 3. Algorithm for EUS-BD. Cited from the article of Kunda et al (Proceedings from 87th Congress of the Japan Gastroenterological Endoscopy Society, 2014; Fukuoka, Abstract 030-07)²⁷ with original copyright holder's permission. ERCP, endoscopic retrograde cholangiopancreatography; EUS, endoscopic ultrasound; EUS-BD, EUS-guided biliary drainage; CBD, common bile duct; EUS-CDS, EUS-guided choledochoduodenostomy; EUS-HGS, EUS-guided hepaticogastrostomy; ?, in selected and limited number of cases.

At Aarhus University Hospital in Aarhus, Denmark and then also at Universitair Ziekenhuis Brussel, Brussels, Belgium, we have introduced already since 2014 an algorithm reflecting the role of EUS-BD and its different types in various anatomical situations as well as feasibility to perform successful ERCP (Fig. 3).²⁷

The strong belief and emphasis have been placed also on the fact that EUS-BD should be performed in the very same session as failed ERCP. Thus, enhancing patient flow, reducing the length of hospital stay and providing better satisfaction and quality of life for patients. The patient is providing the informed consent for both procedures at the same time, especially in those cases when the engagement of EUS-BD is anticipated and likely.

All techniques are considered to be complementary rather than competing and interventional endoscopist should command all of them, if possible, in order to provide the best possible solution. It is needless to be said that some approaches may not be feasible, e.g. EUS-CDS is standardly impossible in cases following gastric bypass surgery or some gastric resections and EUS-HGS may be challenging or impossible following some liver resections, especially in early postoperative periods, respectively.

The emphasis is also given to choices for various approaches based on the location of stricture in order to provide sufficient pressure gradients for effective bile flows and reducing the risk of sump syndrome as well as longer “stumps” of rather stagnating bile content.

Despite the fact that EUS-BD is traditionally not an approach of choice for Bismuth-Corlette IIIa and IV patients, as it is considered often as technically impossible, we are focusing also on cases, where hilar obstruction can be traversed from the left side to the right side, either from the junction of both hepatic ducts or even through the liver parenchyma.

Various EUS-BD techniques provide us also additional options to solve recurring or even newly developed bile duct obstructions as the disease progresses in the time and initial drainage is not efficient enough, regardless if it was primarily done as ERCP, EUS-CDS or EUS-HGS. It means that techniques complement also in the time of the disease evolution.

Conclusion

Bile duct interventions and drainages, including surgical, radiological and endoscopic approaches, have been redefined and also reinvented by more widespread and somewhat standardized approach introduced by interventional EUS and EUS-BD.

Techniques should be considered as complementary to ERCP, and not competing, for the time being.

However, EUS-BD is highly beneficial in cases of surgically altered anatomy, where otherwise endoscopic (and sometimes even surgical or radiological) approach would be challenging or yielding high risk of adverse events or even impossible.

Some of these extraluminal techniques represent a completely new approach. All these procedures complement current therapeutic portfolio, while preserving minimal invasiveness with all its known benefits. Potentially, in the future, they may replace some other minimally invasive procedures. EUS-BD facilitates in some cases also a performance as fluoroscopy type of intervention.

As interventional EUS and its procedures are representing approach reaching across multiple specialties, it is essential to apply multidisciplinary approach (involving mainly all relevant surgical specialties, gastroenterologists, radiologists, interventional endoscopists, etc.) while creating the effective standards of treatment and algorithms for routine and safe use of EUS-BD.

Further prospective and randomized controlled trials are warranted. As well, development of new tools directly designed and created for EUS-BD, including special steerable access needles, novel types of stents, accessories for effectively and safely achieving all liver segments to be drained and many more.

Conflicts of Interest

Prof. Rastislav Kunda is consultant for Boston Scientific (Marlborough, MA, USA), Olympus Corp. (Tokyo, Japan), BCM (Seoul, Korea), Omega Medical Imaging (Sanford, FL, USA), Apollo Endo-Surgery (Austin, TX, USA), and Ambu (Ballerup, Denmark).

Supplementary Materials

Supplementary data is available at <https://doi.org/10.18528/ijgii200047>.

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