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MINIREVIEWS

Endoscopic ultrasonography guided biliary drainage: Summary of consortium meeting, May 7th, 2011, Chicago

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Abstract

Endoscopic retrograde cholangiopancreatography (ERCP) has become the preferred procedure for biliary or pancreatic drainage in various pancreatico-biliary disorders. With a success rate of more than 90%, ERCP may not achieve biliary or pancreatic drainage in cases with altered anatomy or with tumors obstructing access to the duodenum. In the past those failures were typically managed exclusively by percutaneous approaches by interventional radiologists or surgical intervention. The morbidity associated was significant especially in those patients with advanced malignancy, seeking minimally invasive interventions and improved quality of life. With the advent of biliary drainage *via* endoscopic ultrasound (EUS) guidance, EUS guided biliary drainage has been used more frequently within the last decade in different countries. As with any novel advanced endoscopic procedure that encompasses various approaches, advanced endoscopists all over the world have innovated and adopted diverse EUS guided biliary and pancreatic drainage techniques. This diversity has resulted in variations and improvements in EUS Guided biliary and pancreatic drainage; and over the years has led to an extensive nomenclature. The diversity of techniques, nomenclature and recent progress in our instrumentation has led to a dedicated meeting on May 7th, 2011 during Digestive Disease Week 2011. More than 40 advanced endoscopists from United States, Brazil, Mexico, Venezuela, Colombia, Italy, France, Austria, Germany, Spain, Japan, China, South Korea and India attended this pivotal meeting. The meeting covered improved EUS guided biliary access and drainage procedures, terminology, nomenclature, training and credentialing; as well as emerging devices for EUS guided biliary drainage. This paper summarizes the meeting's agenda and the conclusions generated by the creation of this consortium group.

Key words: Endoscopic ultrasound; Biliary drainage; Endosonography-guided cholangiopancreatography; Endoscopic ultrasound guided; Pancreatic drainage; Endoscopic retrograde cholangiopancreatography

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INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is the procedure of choice for biliary drainage in obstructive jaundice resulting from pancreatico-biliary cancer. Although this is successful in more than 90% of the times biliary drainage cannot be achieved *via* ERCP in certain cases[1,2]. This is usually related to a difficult anatomy from prior surgical interventions or due to locally advanced tumors obstructing access to the duodenum[3-5]. Traditionally, such patients underwent percutaneous transhepatic cholangiography[6-8]. However, this method carries a high complication rate and could be associated with fistula formation and recurrent infection[9]. In 1996, Wiersema used endoscopic ultrasound (EUS)-guided cholangiography to define the biliary anatomy, guiding repeat ERCP[10]. The initial report of biliary drainage using EUS guidance was published by Giovannini *et al*[11], and described a bilio-duodenal anastomosis guided by EUS using a single 10 French plastic stent. Shortly after, the same author published a left hepatico-gastrostomy under EUS-Guidance. A self-expandable metal stent (SEMS) was then placed across the fistula created[12]. Later a "rendez-vous" technique was demonstrated in a series by Kahaleh *et al*[13], describing a total of 13 cases undergoing trans-gastric puncture of the left biliary system. With the combination of techniques increasingly available it became obvious that this technique was destined to grow further. Since then many more papers have been published regarding this technique.

TECHNIQUES APPROACHES IN EUS-GUIDED BILIARY DRAINAGE

EUS-guided biliary drainage (EUS-BD) are divided by access route into EUS-guided intrahepatic bile duct drainage, where the intrahepatic bile duct is punctured from a transesophageal, transgastric or transjejunal approach, and EUS-guided extrahepatic bile duct drainage, where the common bile duct (CBD) is punctured from a transduodenal or transgastric approach (usually from the distal antrum). The overall rationale for performing EUS-BD is threefold: (1) logistic advantage (it can be performed in the same session as the originally failed ERCP without further delay); (2) physiologic advantage (it provides immediate internal biliary drainage without the need for external drains); and (3) anatomic advantage (it can be tailored to the individual patient's anatomy; the precise imaging provided by EUS resulting in a potentially less invasive procedure than percutaneous transhepatic biliary drainage.

Extrahepatic approach

In addition to the underlying common rationale for EUS-BD, the extrahepatic approach has its own limitation and advantage. In case of obstruction the common bile duct or common hepatic duct are more easily imaged under EUS than the intrahepatic bile ducts, in contrast to what happens under transabdominal ultrasound. It can therefore potentially be accessed under EUS with minimal risks. The retroperitoneal location of the CBD makes it also an attractive access site for patients with ascites, in whom fluid around the liver makes transhepatic access (whether percutaneous or transgastric under EUS) more difficult and hazardous.

As explained in more detail, antegrade stent insertion from an extrahepatic access site is challenging and has only been reported in a few series[14,15]. The real choice between transmural and transpapillary drainage after extrahepatic bile duct access under EUS therefore lies between EUS-guided choledochoduodenostomy (EUS-CDS) and rendezvous. Proponents of rendezvous argue that it may be less invasive than EUS-CDS, since transmural intervention is usually limited to puncture and guidewire passage, then drainage is accomplished in a retrograde fashion *via* ERCP without the need for puncture tract dilation[16]. However, EUS-BD can fail - even in expert centers - because guidewire passage across the stricture and the papilla can be unsuccessful. The needle does not permit manipulation of the guidewire, across a stricture in the same way as it can be done during ERCP using flexible catheters. EUS-BD by needle-rendezvous may require repeat punctures with different angles often resulting in a prolonged, labor-intensive procedure with the risk of shearing the wire or biliary leakage. The second part of the rendezvous involves exchange of the echoendoscope for a duodenoscope and guidewire retrieval through the duodenoscope. This is also cumbersome and plagued with difficulties. EUS-CDS despite being perhaps more invasive, appears to be a more reproducible approach over transpapillary rendezvous. Nonetheless, both EUS-BD variant approaches can be considered complementary. As we will discuss below, some indications are better suited for one technique versus another. Similarly, even if rendezvous is the intended drainage technique, EUS-CDS can be used as a second line approach to salvage the significant proportion of failed rendezvous cases[17,18]. This open-ended approach to EUS-BD (*i.e.*, inclusive of both rendezvous and EUS-CDS) results in comparatively higher success rates than that of EUS-BD series limiting their approach to just rendezvous[16]. Obviously, future prospective studies comparing EUS-BD with PTBD or surgery are necessary.

TERMINOLOGY

Diagnostic and therapeutic ESCP

EUS-guided access to bile and pancreatic ducts under fluoroscopy in order to obtain diagnostic ductograms was termed "endosonography-guided cholangiopancreatography" and acronymized EGCP in 1996. The alternative acronym ESCP stands for the same name. Within ten years, therapeutic procedures building on the ESCP paradigm were reported in 39 patients to attempt duct drainage (26 biliary and 13 pancreatic). Despite seeming differences in technique and a confusing plethora of terms, the 13 reports originating from 9 different institutions which

Table 1 Variant endosonographic cholangiopancrea-tography approaches (*n*)

	Transpapillary				Transmural	
	Retrograde[1]		Antegrade[2]			
	Institutions	Patients	Institutions	Patients	Institutions	Patients
Pancreatic duct	4	7	1	2	2	4
	Bataille *et al*[19] (1) Mallery *et al*[20] (4) Dewitt *et al*[21] (1) Will *et al*[22] (1)		Kahaleh *et al*[23] (2)		François *et al*[24] (4)	
Intrahepatic bile duct	1	5	1	1	2	3
	Kahaleh *et al*[25] (5)		Püspök *et al*[14] (1)		Burmester *et al*[2] (2) Giovannini *et al*[11] (1)	
Extrahepatic bile duct	2	7	1	1	4	9
	Mallery *et al*[20] (2) Lai *et al*[26] (1) Kahaleh *et al*[27] (4)		Püspök *et al*[14] (1)		Giovannini *et al*[28] (1) Burmester *et al*[2] (2) Püspök *et al*[14] (4) Kahaleh *et al*[27] (1) Kahaleh *et al*[25] (1)[3]	

[1]18 out of 19 retrograde transpapillary endosonographic cholangiopancrea-tography (ESCP) were carried out via rendezvous; [2]None of these four antegrade transpapillary ESCP were "pure" antegrade. Kahaleh *et al*[23] used a single stent bridging both the papilla and the puncture tract, whereas Püspök *et al*[14] used dual stenting: a transmural stent together with a transpapillary stent; [3]Retrograde cannulation of spontaneous bilio-duodenal fistula developing in the setting of postoperative duct injury, after intrahepatic bile duct injection. Similar to the methylene-blue approach, but using contrast material.

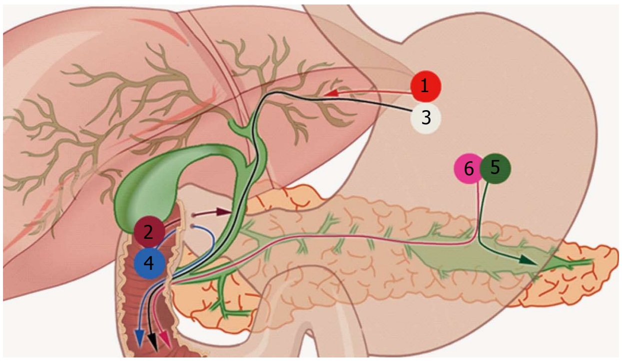

Figure 1 Therapeutic endosonographic cholangiopancreatography: Variant approaches. 1: Transmural drainage, intrahepatic access (hepaticogastrostomy); 2: Transmural drainage, extrahepatic access (choledochoduodenostomy); 3: Transpapillary drainage, intrahepatic access; 4: Transpapillary drainage, extrahepatic access; 5: Transmural drainage, pancreatic access (pancreaticogastrostomy); 6: Transpapillary drainage, pancreatic access. (Reprinted from Perez-Miranda *et al*[41] with permission).

detail these 39 procedures are strikingly consistent (Table 1)[2,14,19-28]. In all of them fluoroscopy-guided intervention through ERCP-based techniques was used to provide drainage following EUS-guided ductal access in complex cases not amenable to ERCP. The substantial anatomic variation in this highly selected patient cohort led to different procedural options, which can be classified into 9 subgroups (3 pancreatic and 6 biliary) based on just two variables, access route and drainage route (Figure 1). Access route can be intrahepatic biliary, extrahepatic biliary or pancreatic, whereas drainage route can be either transmural or transpapillary. Transpapillary drainage can be accomplished either antegradely - most commonly by direct stent insertion across the EUS puncture tract into the duct, the stricture and then the papilla, or retrogradely - most commonly *via* rendezvous ERCP.

Nomenclature problem

Determining the essential elements of a given procedure - the common ground to all its potential variant approaches - and the key variables defining those variant approaches, is of critical relevance to successfully name it. An example of a successful name encapsulating the essence of a complex procedure is ERCP. The acronym ERCP has withstood the test of time over four decades, as the procedure itself metamorphosed from diagnostic to therapeutic, branching out to encompass an ever growing range of interventions. The opposite is true for EUS-guided ductal access and drainage interventions. Not a single one of the 13 early reports replicates the name ESCP. It is significant that 5 of them fail to reference it at all when describing their individual variants of ESCP. However, it is even more significant that most will mention it as just one of the many then developing applications of EUS, overall or on the pancreas. A parent role for ESCP is acknowledged only implicitly and occasionally. This tendency to focus on the uniqueness of each novel variation, losing touch with the prior common ground, has worsened in subsequent reports. With a few hundred cases published, over 120 names and 30 different acronyms have been put in circulation to refer to essentially the same procedure or any of its major variants. Table 2 lists the 22 names and 8 different acronyms proposed for an all-variant encompassing procedure. Further name lists could be produced for just biliary overall (n = 19), pancreatic (n = 14), transmural overall (n = 22), transmural biliary (n = 24) or transpapillary (n = 22) variants.

Key name descriptors

Semantic analysis of names listed in Table 2 under the heading "diagnosis" reveals that descriptors incorporated into the final name include EUS (or endosonography),

Table 2 List of endosonographic cholangiopancreatography names (biliary and panc, *n* = 22)

	Name	Acronym
Diagnosis	Endosonography-guided cholangiopancreatography	EGCP
	Endosonographic cholangiopancreatography	ESCP
	EUS-guided cholangiopancreatography	EUSCP
	EUS-guided cholangiography and pancreaticography	
	EUS-assisted cholangiopancreatography	
	EUS-guided ductography	
	Endo-radio-sono-cholangiopancreatography	ERSCP
	Endoscopic anterograde cholangiopancreatography	EACP
Therapy	EUS-guided cholangio and pancreatic drainage	ECPD
	EUS-guided pancreaticobiliary access and therapy	
	EUS-assisted duct access and drainage	
	EUS-assisted duct opacification and drainage	
	EUS-guided ductal access and drainage	
	EUS-guided ductal cannulation and therapy	
	EUS-guided pancreatic and biliary ductal drainage	EUS-PBDD
	EUS-guided drainage	
	EUS-guided drainage of pancreatico-biliary ducts	
	EUS-guided pancreatobiliary drainage	EUS-PBD
	EUS-guided stent insertion	
	Pancreatobiliary drainage by EUS-FNA	
	Therapeutic EUS-FNA with drainage	
	EUS-guided biliary and pancreatic duct puncture and drainage	

EUS: Endoscopic ultrasound; FNA: Fine needle aspiration.

the ductal component (allowing differentiation between ESCP and related procedures such as EUS-guided pseudocyst drainage), and the presence of fluoroscopy (expressed in the suffix "-graphy"). Names in Table 2 under the heading "therapy" usually omit the critical element of fluoroscopy and often as well the ductal nature of the target pursued under EUS (which, in turn, is what gives fluoroscopy more prominence in ESCP than in, for example, a pseudocyst drainage procedure). The therapeutic intent is variably described, resulting in exceedingly long names. Inconsistent modifiers such as "guided" or "assisted" (sometimes also "directed") introduce another source of variability without much added meaning. A simple way to solve the terminology conundrum would be to follow the ERCP paradigm with ESCP, where the latter refers not only to the ductograms it literally designates but also to therapeutic intervention under fluoroscopy to provide bile and/or pancreatic duct drainage. "Endoscopic" and "retrograde" qualify the way ducts are accessed, as would "endosonographic".

A parent procedure with two major branches

The acronym ESCP could accommodate the term "endosonography-guided cholangiopancreatography" if it proves too ingrained as well as the shorter more specific versions of ESC and ESP, just like ERCP does with ERC and ERP, to designate one ductal system only. ESCP as a manageable acronym would help frame a unifying concept for a procedure distinct from other EUS-guided interventions and from combined EUS-ERCP arrangements, despite the manifold ways in which it can be carried out. Consistently used terms describing individual ESCP approaches, such as hepaticogastrostomy, choledochoduodenostomy or rendezvous, would be bound by a specific umbrella concept and name rather than standing independently among the growing list of EUS-guided interventions.

Dr. Binmoeller proposed the alternative term "EACP": Endoscopic (or EUS-guided) anterograde cholangiopancreatography. He argued that EACP highlights the anterograde route of duct access (relative to the ampulla) in contrast to the retrograde of ERCP, and therefore should be the key distinguishing feature. He noted that "ERCP" does not specify use of a specific imaging modality, in contrast to ESCP. To withstand the test of time, the acronym should be open to imaging modalities that may be used in the future. Choosing an acronym that is familiar will be more likely to achieve adoption, and EACP mirrors ERCP as the anterograde option. Like ERCP, EACP broadly covers a range of diagnostic and therapeutic bilio-pancreatic interventions that will eventually be used under this name. A vote was taken during the conference and the majority favored "ESCP" over "EACP", however, adequate presentation time was not allowed to discuss the pros and cons of the acronyms. It is important to consider the acceptance of this name worldwide and further discourse is planned.

TRAINING IN JAPAN AND IN THE WORLD: DOES ONE SIZE FIT ALL?

Interventional EUS has become popular. In order to perform EUS-guided pancreatico-biliary drainage, experience of not only endosonographer but also ERCP endoscopist is required.

Current situation of EUS instrument in Japan and in the world

Diagnostic EUS using radial model began in 1980s in Japan. Since then, basically radial EUS has been popular in Japan. In contrast, in United States and Europe, although at first radial EUS was performed, EUS-guided fine needle aspiration (EUS-FNA) showed a rapid increase. The ratio of curved linear array (CLA) echoendoscopes to all EUS scopes is 12% in Japan and 40% in United States and Europe[29,30]. One of the reasons is the reimbursement of EUS-FNA procedure. The cost of EUS-FNA in Japan is about less than 200 United States dollars.

Current situation of EUS centers in Japan and in the world

There is no dedicated center for interventional EUS using linear EUS since endosonographers usually perform both radial and linear EUS not only for pancreaticobili-

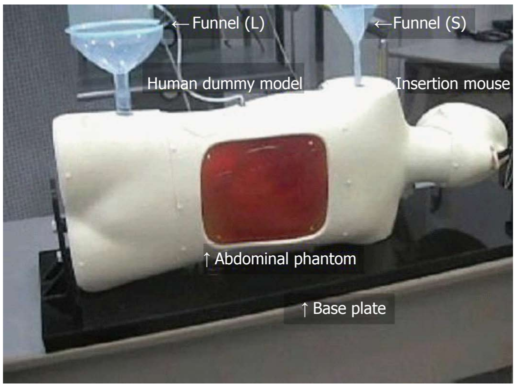

Figure 2 Pancreaticobiliary phantom model (Olympus Medical Systems).

ary diseases but also for gastrointestinal tract diseases, like esophageal or rectal lesions. Most high volume EUS centers have tutorial courses or EUS seminars for endoscopists who want to learn diagnostic EUS, namely EUS imaging including fundamental mode, contrast-enhanced mode and elastography, and EUS-FNA[31].

In Japan, there are more than 30 EUS centers in which conventional therapeutic EUS including pancreatic pseudocyst drainage and celiac plexus neurolysis are performed. Of these centers, only in about 5 EUS centers, EUS-guided biliary drainage and/or pancreatic duct drainage are performed (more than 20 cases). In United States, there are more than 40 therapeutic EUS centers. In Australia, endosonographers perform interventional EUS in more than 17 centers. In South America, therapeutic EUS is performed in more than 10 EUS centers. In Asia including Japan, there are more than 70 EUS centers. In Europe, around 30 EUS centers provide interventional EUS services.

Current status of EUS training

As many endosonographers described, there is no well designed EUS training system. In terms of United States and Europe, the American Society for Gastrointestinal Endoscopy (ASGE) and the European Society of Gastrointestinal Endoscopy sponsored hands-on EUS workshops using a porcine model is regularly held. We can perform not only diagnostic EUS (imaging) but also EUS-FNA (including cyst puncture). Because EUS training on a swine model is recognized to be the more expensive way for EUS teaching, not all trainees in every country can use the model. In contrast, computer-based simulator (EUS mentor; Simbionix, Tel Hashomer, Israel) has been developed for repeat training and shortening the learning phase of EUS. This model is relatively similar to normal anatomy, but it is also expensive. Recently, Olympus Medical Systems made the pancreaticobiliary phantom for both radial and linear EUS training (Figure 2). It includes not only the parenchymal organs but also middle to large vessels. Training system using this kind of phantom and porcine model will probably become mandatory to establish skills in therapeutic EUS.

EMERGING DEVICES FOR EUS-BD

The technique entails three basic steps using various "off-the-shelf" tools in conjunction with a therapeutic CLA echoendoscope.

EUS-guided ductal puncture

Most cases described in the literature use conventional FNA needle (usually 19-gauge to enable passage of a 0.035 inch wire). The continuous stainless steel needle lends excellent visibility on sonographic and fluoroscopic imaging, as well as excellent transfer of force. Drawbacks of the FNA needle are its relative stiffness, which results in a very tangential angle of puncture. An alternative instrument for access is a diathermic needle knife with removable inner needle. Pure cutting current is applied during puncture to penetrate tissue. The advantage of the needle knife is the ability to immediately exchange the inner needle for a guidewire. The outer catheter can then be easily steered in the bile duct, off-axis from the angle that the duct was punctured. The main drawback of the needle knife is the poor visibility of the needle, limited to the catheter tip, on ultrasound and fluoroscopy. A further drawback is the risk of diathermy trauma to tissue, a particular concern should the needle veer off course during puncture. Whereas a continuous stainless steel needle will maintain the predicted trajectory path as it is advanced, the more flexible needle knife catheter may veer off-axis into a neighboring structure, which may be a major vessel.

Dilation of the bilio-enterostomy tract

Tract dilation is required prior to stenting. As in ERCP, graduated bougies and non compliant balloon catheters can be used. Each has pros and cons. Bougies have the advantage of excellent operator control of the dilation force, as the operator can gauge the amount of resistance encountered during advancement of the bougie. However, the dilation force is axial, which can lead to a separation of tissue planes during bougie advancement. Balloons have the advantage that they can be inserted in a compressed state, thereby minimizing the delivery catheter size to around 5 Fr. The dilation force is radial. However, balloons dilate to a fixed diameter in an "all-or-nothing" fashion which increases the risk of perforation, leakage, and bleeding.

If passage of a balloon or bougie across the bowel wall fails after guidewire access, tract dilation can be facilitated with diathermy using a double lumen needle knife catheter. Alternatively, a catheter with a diathermic ring at the tip can be used. Endoscopists in Europe have used a 6 Fr diathermic ring device, (Endoflex, Voerde, Germany). In the United States, only a 10 Fr diathermic ring device (Cystotome CST10; Cook Medical) is Food and Drug Administration cleared. Due to the large size, the Cystotome is a rigid device that is difficult to advance across the oblique exit of the working channel of the therapeutic CLA echoendoscope.

Stent drainage

Again, as in ERCP, a variety of plastic and metal stents can be used. Pigtail stents are a logical choice to minimize the risk of stent migration (especially into the duct), but the pigtail end makes coaxial stent insertion more difficult. An advantage of a straight stent is the ability to retrieve or exchange the stent over the wire without loss of ductal access. Covered SEMS have been used for transenteric drainage, but may migrate, particularly with shortening[32]. The covering may block drainage of a secondary duct (*e.g.*, cystic duct or intrahepatic branch). Uncovered SEMS are unsuited for transenteric drainage due to leakage between the struts. However, an uncovered SEMS can be placed in exchange for a temporary plastic stent after the fistula tract has matured[11].

Current technical challenges

There are three main limitations using current "off-the-shelf" tools. The first is the "step-off" between the wire and device. The device tends to "buckle" where tissue resistance is encountered and may not advance over the wire. The second is the need to exchange multiple devices over-the-wire. This can result in leakage of bile into the periductal space, or leakage of enteric contents into the extraintestinal space. Device exchanges are cumbersome and time consuming, and guidewire access to the bile duct can be lost. The third limitation relates to tubular stents, which are designed for luminal drainage. Whether plastic or metal, tubular stents do not impart the necessary apposition of two nonadherent lumens to prevent leakage. Lacking anchorage, the stent may move or dislocate. The ends of tubular stents may also cause tissue injury.

Compression magnet anastomosis

Jamidar *et al*[33] reported on a novel hinged metalloplastic anastomotic device to create a choledochoduodenostomy. The device resembles a 7 Fr stent, but has a central ferrous metallic component. The devices were inserted into the bile duct of pigs using standard ERCP technique over a 0.035-inch guidewire. A magnet was then endoscopically positioned in the duodenum to mate with the bile duct magnet and exert compressive ischemic force. Anastomoses ranging from 5 to 10 mm were successfully accomplished in all survival animals.

Compression coil anastomosis

Chang *et al*[34] reported on a novel EUS-guided coil technique using a modified compression coil device with "fin-coil" configuration in dogs. The coil delivery device consisted of a 19 gauge needle pre-loaded with stretched coil in the lumen. EUS-guided needle puncture into the CBD was followed by deployment of 50% of the coil into CBD, and remaining 50% stayed within the duodenal bulb to hold the CBD and duodenum walls together with its compressive force. Immediate drainage was successful in 3/4 animals with overall drainage (normalization of bilirubin) successful in 4/4. Creation of a chronic fistula between CBD and duodenum was achieved in all 4 dogs and there was no evidence of bile leak or perforation. All coils dislodged successfully into the duodenum.

Exchange-free lumen-apposing device

Binmoeller *et al*[35] reported on a catheter-based system (AXT System, Xlumena, Mountain View, CA) that delivers multiple tools in a co-axial fashion without the need for device exchange to secure bile duct access, tract dilation and immediate stent placement for drainage. The AXT device locks to the echoendoscope and is designed for single operator - single hand deployment. The exchange-free system is composed of a unique anchor needle that punctures the walls of the gastrointestinal tract and bile duct and maintains continous apposition of the two lumens to prevent leakage of contents during instrumentation. A fully covered lumen-apposing metal stent (AXIOS, Xlumena), previously evaluated in porcine studies[36], is pre-loaded into the AXT System and deployed directly over the anchor needle to maintain tissue apposition and create a tract for drainage. Chronic porcine survival studies were conducted on 3 animals with technical success in creation of a cholecystgastrostomy in all.

CERTIFICATION AND CREDENTIALING

EUS guided biliary drainage is becoming more widely accepted as an alternative to failed ERCP[13,28,37]. Like any other evolving technology in its developing stages, currently there are no defined guidelines as to who should be performing ESCP and what should be the criteria for credentialing someone to perform this procedure. The limitation of this technique resides in its infrequent use with limited number of cases performed and hence formal training dedicated to this specific procedure can be difficult. Further, having a fixed minimum number of cases required as part of training can be even more challenging. Currently ESCP is also limited by the tools available, which are not dedicated for this type of procedure.

National and International organizations also do not have any recommendations or required criteria for training. ASGE has recommendations for number of procedures required for EUS and ERCP credentialing. ASGE recommends 75 mucosal and pancreatico-biliary exams and 50 EUS with FNA[38]. For ERCP the number required is 180 with half being therapeutic[39] . Even these numbers seem suboptimal for comfort of these procedures based on surveys of trainees in advanced training. Definitely the numbers for EUS guided biliary drainage will be much higher based on the significant technical complexity involved. Different variations of the technique with different complexity, are further complicating the credentialing process.

Based on these complexities, in this recent consortium meeting of experts, recommendations on who should be doing ESCP include: (1) Endoscopists routinely performing pancreatico-biliary EUS and FNA; (2) Endoscopists with large ERCP and EUS experience for nearly 4-5 years (at least 200-300 EUS and ERCP each year); (3) Endoscopists with 95%-98% success rate for standard ERCP with normal anatomy; and (4) Location into a center with IR and/or pancreatico-biliary surgery back up.

CODING AND REIMBURSEMENT

Optimal reimbursement of a procedure is dependent on appropriate coding. When developing a code for a procedure, components, which are looked at, are: physician work, practice expense and malpractice expense.

Currently no specific codes exist for ESCP. They are billed with combination of EUS codes and ERCP codes. Some of the interventions done don't fall in the realm of either EUS or ERCP and then surrogate codes are used which is not optimal. Some of the interventions performed, which are unique to ESCP are EUS guided contrast injection, guidewire placement, dilation of the transgastric and transduodenal tracts (balloon/bougie or needle knife) and transmural stent placement[13,37]. CPT specifically states that one should not simply "approximate" coding by using codes that may seem "close enough" but do not accurately describe a service.

The different approaches and drainage routes used make this even more complex. In situations where EUS is used as a mode to access the bile duct (extrahepatic or intrahepatic) and subsequent rendezvous transpapillary ERCP is performed is the simplest situation to code. One can combine EUS with FNA with standard ERCP codes. Even in this case, as there is no specific code for passage of guidewire through the EUS needle, part of the procedure is not clearly defined with currently available codes. Hence the procedure should also be coded with additional *code for unlisted procedure* and *procedure explained in detail.*

The most optimal way for coding these EUS guided bile duct procedures will be to use standard codes for very obvious interventions and along with that use the code for unlisted procedure[40]. Using *code for unlisted procedure* requires additional work. Supporting documentation with each claim has to be submitted separately which should describe the nature, extent and need for the procedure. Time effort and equipment necessary along with complexity of symptoms, final diagnosis, and patient findings are to be described as well. Manual review by payor on case-by-case review is done and many times individual payor has to be contacted to discuss the procedure.

In conclusion, EUS-guided biliary drainage is a novel procedure destined to be incorporated into our therapeutic arsenal. The ability to offer a tailored minimally invasive solution for patients in whom ERCP fails or is not feasible due to various reasons; led to the creation of a dedicated consortium. This consortium aims to create a registry to catalogue the growing number of ESCP techniques and tools, as well as indications. Ultimately, technical advancements will be driven by dedicated research protocols, while nomenclature, training and credentialing will be formalized. Only this will allow to establish EUS-BD as a standard procedure.

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