

Endoscopic ultrasound guided biliary and pancreatic duct interventions

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Abstract

When endoscopic retrograde cholangio-pancreatography fails to decompress the pancreatic or biliary system, alternative interventions are required. In this situation, endosonography guided cholangio-pancreatography (ESCP), percutaneous radiological therapy or surgery can be considered. Small case series reporting the initial experience with ESCP have been superseded by comprehensive reports of large cohorts. Although these reports are predominantly retrospective, they demonstrate that endoscopic ultrasound (EUS) guided biliary and pancreatic interventions are associated with high levels of technical and clinical success. The procedural complication rates are lower than those seen with percutaneous therapy or surgery. This article describes and discusses data published in the last five years relating to EUS-guided biliary and pancreatic intervention.

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Key words: Endoscopic ultrasound; Endoscopic retrograde cholangio-pancreatography; Percutaneous transhepatic cholangiography; Bile duct; Biliary drainage; Pancreatic duct; Pancreatic drainage

Core tip: When endoscopic retrograde cholangiopancreatography fails or is not technically possible, endosonography guided cholangiopancreatography (ESCP) should be considered as the next potential intervention when the technical expertise is available. The increasing volume and quality of literature demonstrates that rendezvous procedures facilitated using ESCP are efficacious and safe. Other interventions are associated with greater complication rates and may be best undertaken only after multi-disciplinary discussion.

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INTRODUCTION

Therapeutic intervention in the common bile duct (CBD) or main pancreatic duct (MPD) is predominantly performed using endoscopic retrograde cholangiopancreatography (ERCP)^[1]. Successful duct access is reported in over 95% of patients with unaltered anatomy^[2-4]. Lower success rates are seen in patients with surgically altered anatomy^[5,6] and neoplastic diseases^[7] due to failure to access the duodenum (*e.g.*, surgical limbs, malignant stenoses) or more difficult duct access (*e.g.*, tumour overgrowth or high grade stricture). Where ERCP fails, alternative approaches for biliary or pancreatic decompression are required.

Radiological [percutaneous transhepatic cholangiography (PTC)] or surgical approaches (hepaticojejunostomy or choledochoduodenostomy) have traditionally facilitated biliary decompression when ERCP fails. However, the complication rates of these procedures are significantly higher than those seen with ERCP^[2-4]. Surgical biliary decompression is associated with morbidity ranging

from 9%-67% and mortality of up to 3% in the post-operative period^[8-11]. PTC is associated with significant complications in over 4% of cases and mortality in 1%-6%, although these figures are lower in patients with dilated biliary systems^[12-16]. In addition, pain, infection, and drain care can lead to significant dissatisfaction after PTC with external drainage^[15,17]. For pancreatic disease, there is no radiological procedure equivalent to PTC in the setting of failed pancreatic duct access. Percutaneous therapies for MPD stenosis^[18], disconnected duct syndrome^[19] and cutaneous pancreatic fistulae^[20] have been described but are not commonly used. Consequently, in the setting of failed pancreatic duct access, management has been symptomatic or surgical.

Within this context, endosonography guided cholangiopancreatography (ESCP) was developed. The technique of endoscopic ultrasound (EUS) guided biliary access was initially described by Wiersema *et al*^[21] who demonstrated a 70% success rate in performing EUS-guided cholangiography after unsuccessful ERCP. EUS guided drainage of the biliary system, using a transduodenal^[22-24] or transhepatic approach^[22,25] was subsequently reported. Similarly, initial descriptions of pancreatography performed using EUS^[26,27] were followed by descriptions of therapeutic interventions^[28,29]. These techniques overcome complications associated with external drains after PTC and/or the recovery time and morbidity associated with surgery.

The past 2 decades have seen numerous small case series reporting these procedures. This article describes large case series published in the last 5 years relating to EUS guided biliary and pancreatic intervention. Where necessary, these articles have been placed in context by referencing earlier studies.

NOMENCLATURE

Numerous terms have been utilized to describe the various techniques of EUS guided biliary or pancreatic intervention. The umbrella term "endosonography guided cholangio-pancreatography" (ESCP) was suggested and agreed upon by the majority of attendees during a recent consortium meeting^[30]. The alternate term "endoscopic antegrade cholangio-pancreatography" was also discussed. The abbreviation ESCP will be used in this manuscript.

While the umbrella term remains to be standardized, only a limited variety of technical outcomes result from EUS-guided intervention^[31]: (1) Biliary transpapillary drainage *via* intrahepatic access (with retrograde or antegrade stent placement); (2) Biliary transpapillary drainage *via* extrahepatic access (with retrograde or antegrade stent placement); (3) Biliary transmural drainage *via* intrahepatic access (hepaticogastrostomy); (4) Biliary transmural drainage *via* extrahepatic access (choledochoduodenostomy); (5) Pancreatic transpapillary drainage *via* pancreatic access; and (6) Pancreatic transmural drainage *via* pancreatic access (pancreaticogastrostomy).

Transmural drainage can be utilised with primary intent or as a salvage procedure where stenoses cannot be traversed to facilitate transpapillary drainage. The placement of a single drain with both transmural and transpapillary aspects is feasible and may reduce the risk of stent migration^[32].

BILIARY INTERVENTION

Access to the biliary tree is required to manage benign and malignant biliary obstruction. ESCP can facilitate biliary decompression where ERCP has failed or is not feasible due to disease-associated pathologies (*e.g.*, malignant ampullary overgrowth, gastric or duodenal obstruction or a disrupted duct), the presence of anatomic variants (*e.g.*, duodenal diverticulum) or surgically altered anatomy (*e.g.*, Billroth II resection or pancreaticoduodenectomy). ESCP is associated with greater technical success than precut papillotomy^[33] and is reported to have similar or better efficacy, similar or fewer complications and, a similar or lower cost than PTC^[34-36]. Furthermore it may be safer than PTC in certain disease processes (*e.g.*, obesity or ascites) or where a delay between PTC guidewire placement and endoscopic rendezvous is foreseen^[37].

Biliary access

Biliary ESCP may be performed using an intrahepatic or extrahepatic approach. However only one point of access is technically feasible in the majority of cases^[31]. Therefore, imaging studies and prior endoscopies should be comprehensively reviewed prior to commencing the procedure. The technical aspects of both approaches have been described comprehensively elsewhere^[32,38-40] but will be described briefly.

Intrahepatic access to the biliary system is approached from the cardia or the lesser curve of the stomach. From these locations, the left lobe of the liver is scanned to identify a dilated bile duct in an orientation which will facilitate both the initial needle puncture as well as the passage a guidewire and other accessories as needed. A fine needle aspiration (FNA) needle is passed into the biliary system and bile aspiration performed to confirm the intraluminal location of the needle tip. A cholangiogram is then performed under fluoroscopy to define the local anatomy and a guidewire then passed into the biliary system.

The extrahepatic approach offers two advantages above the intrahepatic route: (1) access to a dilated CBD or common hepatic duct is often easier in patients with low CBD or ampullary obstruction; and (2) the retroperitoneal location allows safe access in patients with ascites. For an extrahepatic approach the ultrasound transducer is placed in the duodenal bulb or in the second part of the duodenum. Both ultrasound and fluoroscopic assessment are used to identify a point (either intrapancreatic or suprapancreatic) where, after needle puncture of the bile duct, the guidewire is likely to progress in the desired direction. If transpapillary drainage is desired, the echo-

endoscope should be placed in a short-scope position to facilitate passage of the guidewire in an antegrade fashion toward the ampulla^[40,41]. For transmural drainage, the echoendoscope should be in the long-scope position to promote retrograde passage of the guidewire into the intrahepatic system^[42]. An FNA needle is passed into the biliary system and aspiration performed to confirm the intraluminal location of the needle tip. A cholangiogram is then performed under fluoroscopy to define the local anatomy. Under fluoroscopic guidance a guidewire is then passed into the biliary system.

Biliary drainage

Transpapillary: When transpapillary drainage is desired, the guidewire is passed through the site of obstruction and into the duodenum. Advancement of the guidewire to the ampulla may be more difficult during the intrahepatic approach as the wire may pass into other branches of the biliary tree. If a rendezvous procedure^[41,43-45] is desired, a sufficient number of loops of guidewire are left in the small bowel to reduce the risk of wire dislodgement while the echoendoscope is removed from the patient. A standard duodenoscope can be used to complete the procedure in patients with native gastroduodenal anatomy. An extended forward-viewing instrument (colonoscopy or enteroscopy) is needed for patients with an afferent jejunal limb or Roux-en-Y reconstruction following pancreaticoduodenectomy. An alternative strategy is to use the therapeutic echoendoscope to place a transpapillary biliary stent in an antegrade fashion after dilation of the transmural access tract.

Transmural: Where it is not possible to traverse an obstructing biliary lesion, transmural stent placement may be performed for biliary drainage^[46]. This approach may also be deliberately chosen in order to facilitate stent changes where long term drainage is needed (*e.g.*, in patients with altered anatomy or duodenal stenosis). After biliary access is secured with a guidewire, a dilating balloon, dilating catheter, or needle knife is inserted in an antegrade manner, over the guidewire, to dilate the tract. Subsequently, a stent is deployed transmurally with drainage into the stomach or duodenum. As neither the liver nor the common bile duct is adherent to the intestinal wall, transmural drainage carries the risk of bile leak or pneumoperitoneum.

Technical success

Twelve large case-series or prospective trials regarding biliary ESCP have been reported in the last five years (Table 1). The biliary system was successfully accessed in 97%-100% of cases. Where specifically reported, biliary access *via* the intrahepatic and extrahepatic approaches was 100%. Reasons for access failure include failure to access the peripheral hepatic duct^[46], non-dilated hepatic ducts^[47], or surgically altered anatomy^[47].

Successful biliary drainage was reported in 44%-100% of cases; 44%-100% using intrahepatic access, and

81%-100% using extrahepatic access. Drainage was precluded by failure to successfully pass a guidewire through tortuous intrahepatic ducts^[46], failure to traverse a stricture with the guidewire^[41,46] or unsuccessful dilation of the access tract^[48]. A guidewire was passed into the small bowel in 57%-100% of cases through an extrahepatic approach^[46,49], and 44%-94% of cases using an intrahepatic approach^[41,49]. In the series by Maranki *et al*^[46] 13% of intrahepatic approaches were converted to extrahepatic approaches, primarily due to failure to pass the guidewire to the point of obstruction. Once transpapillary placement of a guidewire is achieved, retrograde placement of a transpapillary biliary stent is possible using a rendezvous approach. The alternative antegrade transpapillary or transluminal stent placement requires dilation of the transmural access tract. Intrahepatic access results in a lower success rate of transpapillary drainage^[41,49]. For transmural drainage, technical success rates of over 95% have been reported for both intrahepatic and extrahepatic approaches^[48,50].

Where “real world” approaches have been described, the reported success rates are similar^[47,51,52]. Shah *et al*^[47] reported EUS guided interventions where the desired outcome was rendezvous procedure or antegrade transpapillary stenting when the ampulla was not accessible. Although the final point of access utilized was not specified, the overall success rate for decompression was 85% (58 of 68 patients). As biliary access was achieved in 68 of 70 (97%) of cases, a higher technical success rate was feasible if transmural drainage had also been used. Park *et al*^[51] demonstrated a success rate of 91% (41/45) in a prospective trial utilizing a mixture of rendezvous procedures, antegrade stent placement, transmural drainage or repeat ERCP. In this study 8 of 12 patients in whom the initial procedure failed successfully underwent an alternate ESCP intervention, 2 patients underwent repeat ERCP and 2 patients were referred for PTC. In an earlier trial by the same authors, a 100% technical success rate for extrahepatic drainage was seen when 2 patients who underwent “salvage” rendezvous ERCP were included^[50]. However, in contrast, in a Spanish cohort, where a variety of approaches were used, technical success was reported in only 69% of cases^[52].

Functional success on a per-protocol basis (defined as a > 75% reduction in bilirubin within one month after the successful placement of a stent) was 87% by transmural intrahepatic drainage and 92% by transmural extrahepatic drainage in the prospective series reported by Park *et al*^[50]. Overall functional success rates of > 95% following technical success have been described elsewhere^[51,53].

Procedure related complications

ESCP related complications were reported in 3%-34% of cases (Table 1). The most commonly reported adverse events include infections (cholangitis), pain, pneumoperitoneum, bile leak, and bleeding. Although the choice of transpapillary or transluminal drainage does not appear to

Table 1 Summary of recently published reports of endoscopic ultrasound-guided biliary interventions including > 35 patients

Ref.	n	Access point	Stent placement			Successful drainage n (%)	Complications		Notes
			TP		TM		n (%)	Type	
			RV	AG					
Maranaki <i>et al</i> ^[46] 2009	49	IH	-	26 ^a	3	29/40 (73%)	8/49 (16%) ^b	Pneumoperitoneum (4)	Retrospective Five patients converted from IH to EH and have been included here to demonstrate success <i>via</i> access point (IH n = 40, EH n = 14) Overall technical success of drainage 41/49 patients (84%) ^a Includes one antegrade placement of intra-ductal stent and 1 balloon dilation of stricture (<i>i.e.</i> , the stricture was traversed by the guidewire) ^b Complication rate per patient (IH n = 5, EH n = 3)
		EH	-	8	4	12/14 (86%)		Biliary peritonitis (1) Bleeding (1) Aspiration pneumonia (1) Abdominal pain (1)	
Park <i>et al</i> ^[50] 2011	57	IH	-	-	31	31/31 (100%)	11/57 (19%)	Pneumoperitoneum (7)	Prospective follow up Primary procedural aim was transmural stenting. A rendezvous technique was successfully utilized in 2 patients with malignant disease in whom TM EH stenting was not possible All 6 patients with benign strictures had previously failed an EUS guided rendezvous procedure
		EH	2	-	24	26/26 (100%)		Biliary peritonitis (2) Bleeding (2)	
Vila <i>et al</i> ^[52] 2012	106	NS	NS	NS	NS	73/106 (69%)	24/106 (23%)	NS ^c	Retrospective case series pooling biliary and pancreatic intervention: 19 hospitals, 23 endoscopists, 106 biliary and 19 pancreatic interventions ^c Complications were not specified by procedure type. Of the 29 complications among the biliary and pancreatic interventions 5 were managed endoscopically, 3 with percutaneous intervention and 2 were managed surgically
Shah <i>et al</i> ^[47] 2012	70	NS	39	19	Procedures	58/76 ^{d,e} (76%)	6/76 ^{d,e} (8%)	Pancreatitis (2) Hematoma (1) Bile leak (1) Infection (1)	Retrospective Complications include those from ERCP attempted prior to ESCP ^d In 2 patients intervention was deemed unnecessary after cholangiography. Crossover between antegrade stenting and rendezvous procedure was allowed freely; 6 patients failed rendezvous and were treated successfully by an antegrade EUS intervention, 2 patients failed direct EUS guided therapy and successfully underwent a ESCP rendezvous procedure. Therefore 76 procedures were performed with therapeutic intent ^e Success and complication rates are described on a "per procedure" and "per-patient" basis as some patients had more than one procedure
					Patients	58/68 ^{d,e} (85%)	6/70 ^{d,e} (9%)	Duodenal perforation (1)	
Iwashita <i>et al</i> ^[41] 2012	40	IH	4	-	-	4/9 (44%)	5/40 (13%)	Pancreatitis (2) Abdominal pain (1)	Retrospective Only rendezvous procedures attempted. No transmural drainage or antegrade stenting Overall technical success in 29/40 patients (73%) Technical failure due to inability to pass guidewire to small intestine in 11 patients (27%)
		EH	25	-	-	25/31 (81%)		Pneumoperitoneum (1) Fever, subsequent death (1)	
Dhir <i>et al</i> ^[33] 2012	58	EH	57	-	-	57/58 (98%)	2/58 (3%)	Contrast leakage (2)	Retrospective Only rendezvous procedures attempted. No transmural drainage or antegrade stenting
Dhir <i>et al</i> ^[49] 2013	35	IH	16	-	-	16/17 (94%)	12/35 (34%)	Pain (7) Bile leak (2)	Retrospective Only rendezvous procedures attempted. No transmural drainage or antegrade stenting Overall technical success in 34/35 (97%) Failure due to inability to traverse obstruction with guidewire 11 (of 12 total) complications occurred in the TH cohort
		EH	18	-	-	18/18 (100%)		Pneumoperitoneum (2) Pain (1)	
Park <i>et al</i> ^[51] 2013	45	NS	NS	NS	NS	41/55 ^f (75%)	5/55 ^f (9%)	Pancreatitis (1) Biliary peritonitis (1) Pneumoperitoneum (1)	Prospective observational cohort study Mixture of rendezvous procedures, antegrade stent placement, transmural drainage or repeat attempt at ERCP. Significant crossover during procedures depending on clinical scenario; 10 patients underwent an alternate interventional strategy after the initial procedure failed ^f Success and complication rates are described on a "per procedure" and "per-patient" basis as some patients had more than one procedure
						41/45 ^f (91%)	5/45 ^f (11%)	Stent Migration (1) Biloma (1)	

Khashab <i>et al</i> ^[53] 2013	35	IH	2	-	5 [§]	33/35 (94%)	4/35 (12%)	Pancreatitis (1) Pneumoperitoneum (1) Retained sheared wire (1) Acute cholecystitis (1)	Retrospective An initial attempt using a rendezvous technique was followed by a transluminal approach if rendezvous failed [§] Two patients had trans-esophageal stents placed
		EH	11		15				
Gupta <i>et al</i> ^[80] 2014	240	IH	NS	NS	NS	132/145 (90%)	81/238 (34%)	Bile leak (27) Bleeding (26) Pneumoperitoneum (12) Cholangitis (11) Abdominal pain (5) Stent occlusion (2)	Retrospective Data reported here as they are in the paper; internal consistencies in data reporting without explanation make this data difficult to interpret Overall technical success reported in 87% of patients 52 (of 146, 36%) complications in the IH group and 29 (of 89, 33%) in the EH group
		EH	NS	NS	NS	75/89 (84%)			
Kawakubo <i>et al</i> ^[48] 2014	64	IH	-	-	19	19/20 (95%)	12 (19%)	Bile leakage (5) Stent misplacement (3) Bleeding (2) Pneumoperitoneum (1) Cholangitis (1) Biloma (1) Perforation (1)	Retrospective Only Transmural procedures attempted Transpapillary stent placement had been performed prior to ESCP in 31 (48%) patients Two failures in EH group due to failure to dilate tract. One failure in IH group due to failure to access non-dilated bile duct Six complications were reported in each group. Two stents deployed intra-peritoneally during IH TM drainage. One plastic stent migrated and resulted in perforation
		EH	-	-	42	42/44 (95%)			
Dhir <i>et al</i> ^[54] 2014	68	IH	NS	NS	NS	34/36 (94%)	17/68 (25%)	Cholangitis (5) Bile leak (4) Death (3) Perforation (2) Pneumoperitoneum (2) Bleeding (1)	Retrospective 20 patients underwent rendezvous procedures, 35 underwent direct EUS guided intervention (AG TP or TM). IH approach used in 34 procedures and EH approach in 31 procedures Overall technical success reported in 65/68 (87%) of patients
		EH	NS	NS	NS	31/32 (97%)			

Superscripts refer to specific comments in the "Notes" column. AG: Antegrade; EH: Extrahepatic; ESCP: Endosonography guided cholangio-pancreatography; EUS: Endoscopic ultrasound; IH: Intrahepatic; NS: Not specified; RV: Rendezvous; TM: Transmural; TP: Transpapillary.

affect the complication rate^[54], many reported complications can potentially be attributed to the mural defect associated with ESCP. The intestinal wall is not adherent to either the liver or the CBD. This facilitates the potential leakage of intestinal or biliary luminal contents into the peritoneum or the retro-peritoneal space. The intrahepatic technique is associated with a higher risk of complications^[54]. Consequently, the extrahepatic approach should be considered preferential where a patient's anatomy and disease allow. Covered metal stents may reduce the risk of bile leakage where transmural stenting is performed^[48] but the use of these stents may be precluded by smaller receiving bile ducts. The most significant predictor of complications identified to date is the use of a needle-knife to dilate an access tract during ESCP (odds ratio 12.4)^[50]. Bougie dilators or dilating balloons should be preferentially used where possible. Procedural failure and male patients are associated with a higher risk of complications but these risk factors cannot be altered^[52]. In view of these potential complications, patients should be monitored closely and a low threshold for investigation and intervention adopted. When complications occur, the majority can be managed conservatively.

A 3% mortality associated with biliary ESCP has been reported^[54] and 4% mortality reported in pancreatico-biliary ESCP^[52]. The majority of ESCP associated deaths are associated with biliary, rather than pancreatic, interventions. This may represent publication bias and/or the

proportionally greater number of procedures performed in the biliary tract.

One prospective trial of 25 patients demonstrated that the complication rates of PTC and ESCP appear similar^[34]. A subsequent retrospective report found ESCP to be superior to PTC for both technical success and complications^[35]. The most recent retrospective comparison suggests that functional success rates of ESCP and PTC are similar but that complication rates and cost are lower for ESCP^[36]. No trials have compared EUS-guided intervention to surgery but based on historical data the complication rates of ESCP are lower^[8-11].

Stent dysfunction

Follow up data regarding stent dysfunction (occlusion or migration) is reported in few of the series described in Table 1. Park *et al*^[51] identified no stent dysfunction among 41 successfully placed stents during a mean follow up period of 165 d (range 30-275 d). Khashab *et al*^[53] identified only 2 stent dysfunctions among nine patients followed up for a mean of 276 d (one transluminal metal stent occlusion at 42 d and one transpapillary metal stent migration at 62 d). The remaining 24 patients in this series died as a consequence of their diseases, without stent dysfunction, after a mean of 90 d. In a prospective follow-up study of transmural stenting Park *et al*^[50] estimated mean stent patency for intrahepatic and extrahepatic stents of 132 and 152 d respectively using a Kaplan-

Meier method^[50]. Kawakuba *et al*^[48] similarly reported no significant difference in rate of stent dysfunction between intrahepatic and extrahepatic groups but 25% of the transmural extrahepatic stents and 32% of the transmural intrahepatic stents malfunctioned (mean time to dysfunction of 103 d and 62 d respectively). In all of these studies, a variety of stent types were used but subgroup analyses were infrequently reported. However, in previous smaller studies, with cohorts of three to six patients, similar results have been reported in more homogeneous groups^[55-59].

The heterogeneity of techniques and stents used makes firm conclusions difficult to report. However, for transpapillary stents, either metal or plastic, patency is expected to be similar to those deployed during ERCP for similar indications^[60-63]. Although no prospective comparative studies exist, a metal stent with a larger diameter is expected to offer longer lasting patency than that of a plastic stent in biliary ESCP procedures.

Where dysfunction does occur, stent exchange is required. After tract maturation (estimated to take 2 to 3 wk), the stent can be removed, the fistula re-cannulated and a new stent placed. Where stent malfunction occurs before tract maturation, or where access is more tenuous, a snare-over-the-wire technique can be utilized to safeguard biliary access^[64].

Limitations of data regarding biliary ESCP

ESCP has proven efficacy in successfully treating biliary diseases. Recently published literature (Table 1) describing large case series has refined our understanding of the technical success and complication rates of these procedures. However, significant limitations within the data still exist.

Firstly, the indications for performing ESCP rather than PTC or surgery are not defined. Furthermore, as the reported data represents a heterogeneous mixture of benign and malignant processes, the outcomes by disease type are not clear. However, ESCP to facilitate retrograde access to the biliary system is associated with an acceptable complication rate when considered as an alternative to PTC or surgery. Where short term palliation is needed and transpapillary drainage is not possible, transmural drainage by ESCP (particularly *via* the extrahepatic route) and PTC offer equivalent technical success with shorter hospital stays than surgery^[8-9,34-35,49,65]. However, ESCP offers a single stage procedure which does not require an external biliary drain; factors which may be very important to those with limited life expectancy. Where prolonged decompression of the biliary system is required (*e.g.*, benign conditions refractory to management or malignancy), surgery may be more appropriate than transpapillary stenting as fewer follow up interventions are required^[11,65]. In the absence of trials directly comparing surgery with transmural ESCP for benign and malignant disease, the decision in whom to perform ESCP must be made on an individual basis.

Secondly, there are limited prospective data regarding the “real world” technical success of ESCP. Although

prospective data have demonstrated very high rates of technical success, this reflects the experience of a single operator^[50,51]. Where multicentre retrospective series are described, the success rates are more variable^[48,52]. As second attempt ERCP may be more successful in referral centres when the ampulla is accessible^[3-4], it seems appropriate that ESCP should be performed only in these locations after a second attempt at ERCP has failed. An alternative strategy may be that after a failed second ERCP in local centres, ESCP to facilitate a rendezvous procedure is attempted, followed by referral to a specialist centre if this fails. This approach is supported by two factors: (1) technical success and complication rates do not appear to be associated with the operator’s EUS experience or the location at which the procedure is performed^[48,52]; and (2) second attempt ESCP may be successful where the initial procedure has failed^[66].

Finally, data are lacking regarding the optimal approach to use during ESCP. Extrahepatic approaches and metallic stents are associated with fewer complications but data from well designed prospective randomized controlled studies comparing the long term success of each are lacking. However, as the majority of patients undergo ESCP for malignant disease, a single procedure, achieving functional success for short term palliation, may be sufficient for these patients and offers the advantage of not having to manage an external biliary drain or surgical wounds.

PANCREATIC INTERVENTION

Symptoms associated with chronic pancreatic disease are thought to be associated with MPD pressure^[67,68]. ERCP mediated “decompression” of the MPD has been used to successfully treat recurrent acute pancreatitis, chronic pancreatitis associated with MPD stones or strictures, MPD disruption, pancreatic fluid collections and pancreatico-enteric anastomotic strictures^[1]. ESCP can facilitate pancreatic intervention when ERCP fails. In addition, it provides a non-surgical approach to the management of disconnected duct syndrome.

Pancreatic duct access

The MPD can be visualised throughout its length from the gastric body or the duodenal bulb. The point of access is chosen based on the location of ductal disruption or obstruction. The MPD access point should have minimal intervening pancreatic parenchyma and be orientated to allow needle access, guidewire passage, tract dilation, and stent placement if needed^[69]. After puncture of the MPD using an FNA needle, position is confirmed by contrast injection to obtain a fluoroscopic antegrade pancreatogram. Access to ducts of 1mm diameter is possible and has been used to facilitate rendezvous procedures^[70,71] but for transmural drainage a larger diameter duct is recommended^[72]. In cases where ERCP has failed due to inability to identify the papilla injection of methylene blue with the radio-opaque contrast into the MPD is usually sufficient to allow papillary identification and

successful ERCP^[73]. Where pancreatic intervention failed because of MPD obstruction, a guidewire is advanced under fluoroscopic vision through the MPD and into the duodenum to allow retrograde access to the MPD. Where the guidewire cannot traverse the papilla, transmural intervention may be considered. Transmural interventions require dilation of the access tract.

Technical success

Larger case series from the last five years have demonstrated successful pancreatic duct access in 78%-100% of cases (Table 2). Success rates are lower when the pancreatic duct is of normal calibre (57% *vs* 100% with a dilated MPD)^[73]. Successful passage of a guidewire through the papilla is reported in 33%-88% of cases^[73,74]. Transpapillary guidewire passage may not be possible due to the tendency of the guidewire to pass into pancreatic side branches, difficulty positioning the echoendoscope in an orientation to allow antegrade passage of the guidewire or a high grade stricture^[75]. Pre-procedural assessment of stenotic severity is not a predictor of successful guidewire passage^[71]. In select cases (pancreaticojejunostomy strictures post Whipple's procedure), the use of a needle-knife, passed antegrade through the MPD to the stricture, can increase the success rate of guidewire passage^[75]. However, among the three patients reported in this series, one developed pancreatitis suggesting a possible high rate of complications. Where transpapillary passage of the guidewire fails, the placement of a transmural stent is feasible.

Technical success (*i.e.*, the placement of a stent for pancreatic decompression) has been reported in 45% to 88% of procedures. Series in which either rendezvous or transmural stenting were employed report higher success rates (Table 2). In the largest series reported to date (43 patients), the technical success rate per procedure was 70% for therapeutic intervention^[71]. Although one of the proposed advantages of ESCP is that it can be performed in the same session as failed ERCP, this approach was associated with a lower rate of technical success^[71].

Interestingly, although Kikuyama *et al*^[66] described initial technical success in only 6 of 14 (38%) patients with surgically altered anatomy undergoing EUS guided pancreatic interventions, a repeat attempt resulted in success in another 5 (of 8) patients. This suggests that similar to ERCP, repeat attempts at ESCP may yield higher success rates.

Among those who are successfully stented, the long term success rates are high and durable. Fujii *et al*^[71] demonstrated significant clinical response after 12 mo. Among 29 (of 32) patients available for follow up at median 37 mo (range 12-72 mo), 70% of patients had complete symptom resolution^[71]. Symptoms were better controlled while an MPD stent was in situ (83% complete symptom resolution); during follow up after stent removal (median of 32 mo) symptom recurrence occurred in 4 of 23 patients at a median 14 mo. Benign anastomotic strictures and longer stents were associated with a lower likelihood of a complete symptomatic response in a univariate anal-

ysis. Overall, these data are similar to previously reported pancreatic ESCP data^[29,72,76]. Providing objective evidence for these findings, among patients who have stents successfully placed, the MPD diameter decreases suggesting resolution of MPD hypertension^[29,71,76].

Complications

Complications were reported in 6%-33% of procedures; serious complications are less frequent. In the largest reported series, the complication rate was significantly increased by the inclusion of "abdominal pain" which resolved without any intervention^[71]. Other larger case series have reported serious complication rates of 8%-13%, predominantly pancreatitis^[47,72,76]. Although leakage of pancreatic fluid after tract dilation is a frequently cited technical concern, it was infrequently reported in these cohorts. However, the use of a needle-knife for tract dilation and duct access should be avoided where possible in order to minimize the risk of complications.

Stent patency

Stent occlusion and migration represent the predominant concern during long term follow up. Stent dysfunction is estimated to occur in over 50% of patients with long term stents^[72,76]. The median time until stent dysfunction is estimated to be 5-6 mo^[72,76]. However, it must be noted that this represents reporting of a heterogeneous groups of stents.

Limitations of data regarding pancreatic ESCP

As few percutaneous therapies are available for pancreatic intervention, there is a significant void which ESCP can fill. In patients with surgically altered anatomy, ERCP has high failure rates^[5,77]. When the alternative is surgery, ESCP offers a relatively lower risk therapy for these patients. In situations where the papilla is accessible to ERCP, a pancreatography alone may be sufficient to allow successful pancreatic intervention and should therefore be considered, even without the need for a rendezvous procedure^[73].

However, similar to the biliary ESCP data, heterogeneity among cohorts makes conclusions difficult to draw from the data; chronic pancreatitis with strictures or stones, pancreatic fistulae and disrupted pancreatic ducts are often reported in the same cohorts. Furthermore, many of these series report outcomes per patient rather than outcomes per procedure^[71,76]. As patients may require more than one procedure to achieve technical success, this may bias the technical success rates positively, albeit while increasing the reported complication rate. However, the therapeutic success reported in these studies^[29,71,72,76] is similar to that reported previously after ERCP based intervention^[78]. Yet, for patients with chronic pancreatitis, surgery is frequently required and previous data suggests that it offers better outcomes than endoscopy for both pain and quality of life^[79]. Randomized trials comparing ESCP and surgical intervention will need to be performed to resolve these issues.

Table 2 Summary of recently published reports of endoscopic ultrasound-guided pancreatic interventions including > 9 patients

Pancreatic	Procedures (n)	MPD access	Stent placement		Success Per procedure, n (%) [per patient, n (%)]	Procedure related complications		Notes
			RV	TM		n (%)	Type	
Kinney <i>et al</i> ^[81] 2009	9	7/9 (78%)	4	-	4/9 (45%)	3/9 (33%)	Pancreatitis (1) Retroperitoneal and intraoperative air (1) Fever (1)	Retrospective All patients post Whipple procedure with endoscopic rendezvous attempted <i>via</i> the afferent limb Causes of failures: inability to access the MPD (2) and inability to traverse the pancreaticojejunal anastomosis with the guidewire (3) All patients with successful decompression had good short term clinical relief
Barklay <i>et al</i> ^[73] 2010	21	18/21 (86%)	10 ^a	-	10/21 (48%)	3/21 (14%)	Infection (1) Pancreatitis (1) Shaving of guidewire (1)	Retrospective Among 14 dilated MPDs and 7 normal calibre MPDs, the 3 failed pancreatograms occurred in patients with a normal calibre MPD Unable to pass wire to papilla in 8/12 patients: suboptimal angle (3), tight stricture (5) ^a Four patients successfully underwent rendezvous procedure, six patients successfully underwent repeat ERCP after methylene blue injection into MPD to aid identification of ampulla
Ergun <i>et al</i> ^[76] 2011	24 (20 pts)	20/20 ^b (100%)	5	15	20/24 (83%) [18/20 (90%)]	2/24 (8%) [2/20 (10%)]	Bleeding (1) Perigastric collection (1)	Retrospective The reason for 24 procedures among 20 patients is unclear ^b Successful pancreatography reported in "all 20 patients"
Vila <i>et al</i> ^[52] 2012	19	NS	NS	NS	11/19 (60%)	5/19 (26%)	NS ^c	Retrospective case series pooling biliary and pancreatic intervention: 19 hospitals, 23 endoscopists, 106 biliary and 19 pancreatic interventions ^c Complication type per procedure is not specified. Of the 29 complications among the biliary and pancreatic interventions 5 were managed endoscopically, 3 with percutaneous intervention and 2 were managed surgically
Shah <i>et al</i> ^[47] 2012	30 (25 pts)	25/25 ^d (100%)	9/16	10/14	19/30 (63%) ^e [19/22 (86%) ^d]	4/30 (13%) ^e	Pneumoperitoneum (1) Pancreatitis (3)	Retrospective ^d After pancreatography 3 patients were not felt to warrant intervention ^e 30 therapeutic procedures were attempted (in 22 patients) due to significant crossover during intervention: 6 of 7 failed RV had attempted EUS guided antegrade therapy (5/6 successful); 2 of 3 failed antegrade EUS underwent attempted ERCP (double-balloon guided, 2/2 successful)
Kurahira <i>et al</i> ^[74] 2013	17 (14 pts)	17/17 (100%)	11	3 (4) ^f	15/17 (88%)	1/17 (6%)	Pseudocyst and aneurysm due to PD puncture (1)	Retrospective Two cases did not proceed after pancreatogram; complications during guidewire passage? ^f One patient had a temporary naso-pancreatic drain with subsequent stent insertions
Fujii <i>et al</i> ^[71] 2013	46 (43 pts)	45/46 ^g (98%)	14	18	32/46 ^g (70%) [32/43 (74%)]	16/46 ^g (30%)	Abdominal Pain (13) Pancreatitis (1) Peri-pancreatic abscess (1) Retained guidewire fragment (1)	Retrospective ^g For successful stent placement, three additional procedures were required in two patients

Superscripts refer to specific comments in the "Notes" column. ERCP: Endoscopic retrograde cholangio-pancreatography; EUS: Endoscopic ultrasound; MPD: Main pancreatic duct; Pts: Patients; RV: Rendezvous; TM: Transmural.

CONCLUSION

ESCP is an evolving technique facilitating biliary and

pancreatic intervention where ERCP has failed. Although performed for almost two decades, the last five years have seen a substantial increase in the numbers of procedures

reported in the literature. These publications suggest that ESCP can provide high levels of technical success with acceptable complication rates. Where technical success is achieved, high rates of clinical success follow.

Despite the increase in reported experience with this technique, the cohorts described represent a heterogeneous group of conditions treated using a variety of procedures. Consequently, the optimal management of any specific condition is hard to define with certainty. Rendezvous procedures facilitated by ESCP have the highest reported success rates and lowest complication rates. In the appropriate circumstances, they may be considered as an alternative to precut sphincterotomy or PTC. Antegrade ESCP may be the therapeutic procedure of choice in very specific situations (*e.g.*, symptomatic stenosis of a pancreaticojejunal anastomosis in a patient with altered anatomy where the alternative intervention is surgery). In other clinical scenarios the role of ESCP is less certain.

Complications can be expected when performing these procedures. The majority can be managed conservatively. Where possible, using a trans-duodenal approach and covered metal stents may reduce the risks associated with biliary interventions. A high index of suspicion for complications should be maintained until the patient is clearly fit for discharge.

Although ESCP offers the potential for gastroenterologists to provide definitive care where ERCP has failed, and for patients to avoid surgery, enthusiasm for undertaking these procedures must be tempered with caution for two reasons. Firstly, the reported literature predominantly reflects the experience of a small group of highly skilled interventional endoscopists performing these novel procedures. Lower rates of success, and perhaps higher complication rates, can be expected in clinical practice. Formal training in these emerging techniques, coupled with an appropriate level of personal skill and experience, may be needed to achieve results approaching those reported by the procedural pioneers. To date, no societal guidelines specify the training criteria or experience required of endoscopists prior to undertaking these procedures. Secondly, perhaps with the exception of ESCP facilitated rendezvous procedures, trials evaluating the outcomes of the different subtypes of ESCP, and comparing ESCP to surgery, are required before it can be broadly recommended to patients. In these situations ESCP may be most appropriately considered only where ERCP has failed, after discussion with a multidisciplinary team and, where the technical expertise is available.

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