Indications for ERCP

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Introduction

ERCP was first introduced as a realistic endoscopic procedure in the early 1970s. Since then, the diagnostic and therapeutic clinical applications have changed significantly in parallel with improvements in noninvasive and invasive visualization of the biliary and pancreatic ductal systems. What was once predominantly a combined diagnostic endoscopic and radiographic modality, ERCP has taken on new roles as a more sophisticated diagnostic and therapeutic set of procedures including direct visualization of the ducts, tissue interrogation and sampling, and treatment of a wide variety of biliary and pancreatic disorders (Fig. 2.1a, b, c, d, e, f, g, h and i). In the USA, over 500,000 ERCPs were performed in 2008. In 2009, there were an estimated 1.1–1.3 million cases worldwide. The number of diagnostic ERCPs decreased 6 % while therapeutic ERCPs increased by 12 % up to 2001 [1]. This interventional shift is attributed to the introduction, improvement, and acceptance of other diagnostic modalities such as endoscopic ultrasound (EUS), computed tomography (CT), and magnetic resonance cholangiopancreatography (MRCP). EUS combined with ERCP has become an appropriate alternative to percutaneous radiological access to an obstructed duct when ERCP alone fails or is not possible.

Despite these changes in the role and range of therapeutic possibilities of ERCP, the basic indications have not. These can be divided into three main categories for the evaluation and treatment of:

1. Stone disease (jaundice, biliary pain, cholangitis, biliary pancreatitis, pancreatic duct stones)
2. Ampullary/papillary abnormalities (Sphincter of Oddi dysfunction (SOD), ampullary cancer)
3. Biliary and pancreatic ductal abnormalities (leaks, strictures, malignancies)

As we shall discuss later in this chapter, there are significant complications of ERCP that one must consider before considering this procedure. Therefore, it is of paramount importance to have an appropriate indication for proceeding.

Stone Disease

Choledocholithiasis

This is still the most common reason for undertaking ERCP (Figs. 2.2, 2.3, 2.4, 2.5). Gallstone disease affects approximately 20 million adults in the USA with an estimated annual healthcare cost of $ 5.8 billion [2]. Biliary stone disease is responsible for a spectrum of clinical presentations from asymptomatic (detected by imaging) to biliary obstruction, cholangitis, and acute biliary pancreatitis. Choledocholithiasis is seen in up to 15 % of patients with cholelithiasis, 10–20 % of

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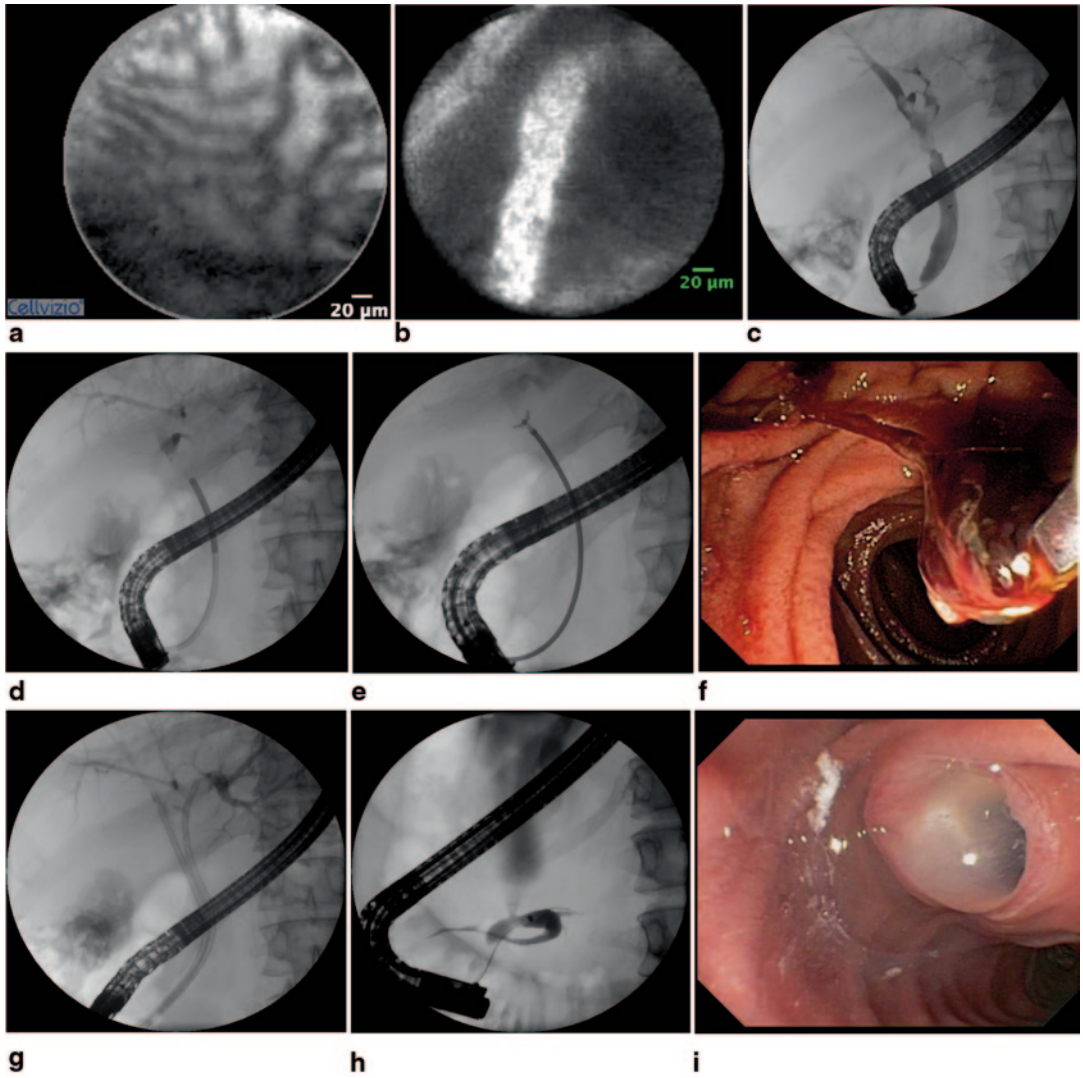

Fig. 2.1 **a** Probe-confocal laser endomicroscopy (*pCLE*) image of normal bile duct with reticular network of *thin dark branching bands* and *light gray* background. **b** pCLE image of bile duct malignancy with *thick dark bands* and *thick white band* (two criteria for malignant stricture). **c** Endoscopic retrograde cholangiography (*ERC*) showing filling defect at the hepatic duct confluence. **d** Fluoroscopy showing cholangioscope advanced to the lesion in **c. e** Biopsy of the lesion in **c. f** Tissue removed with biopsy forceps (*intraluminal cholangiocarcinoma*) from lesion in **c. g** Bilateral plastic stents in the same patient with hilar cholangiocarcinoma. **h** Anomalous union of the bile and pancreatic ducts with type 1 choledochal cyst. **i** Mucus at the papilla in main duct intraductal papillary mucinous neoplasm

those undergoing cholecystectomy, and up to 21% presenting with gallstone pancreatitis [2, 3]. The necessity of expediently diagnosing symptomatic choledocholithiasis is important, as the consequences of failing to do so may result in unfavorable outcomes. Predictors of a high likelihood of choledocholithiasis include jaundice, cholangitis, severe pancreatitis, alkaline phosphatase (AP) more than twice the upper limit of normal (ULN), increased gamma glutamyl transferase (GGT), and increased alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) [4]. One study categorized the likelihood of having ongoing choledocholithiasis as "moderate," "strong" or

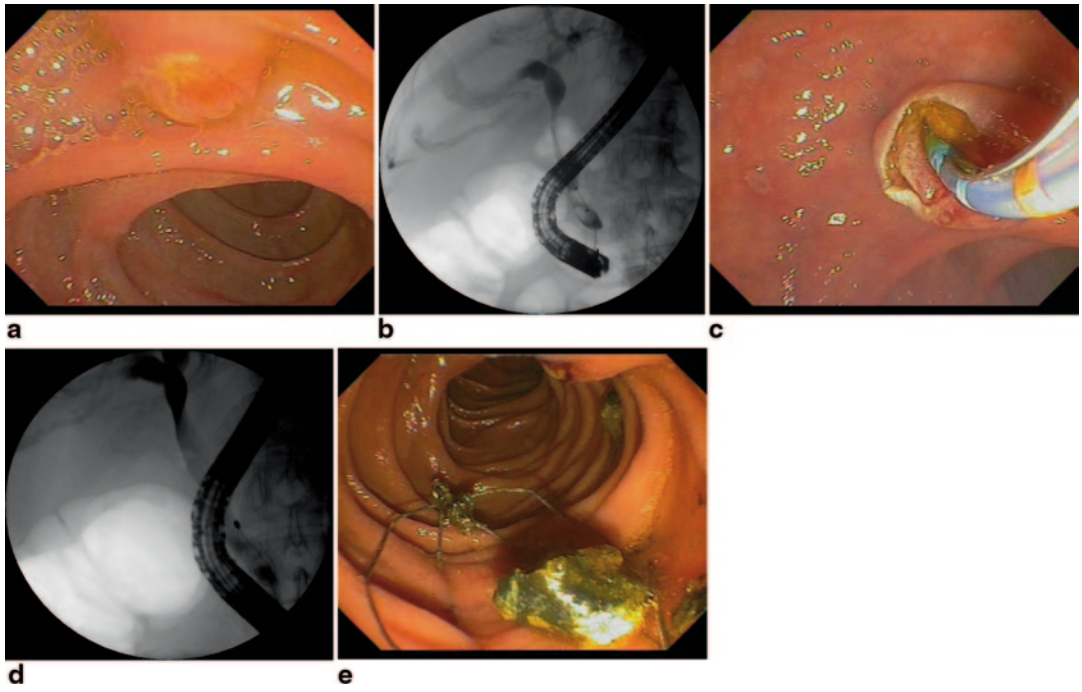

Fig. 2.2 **a** Sequence from normal papilla. **b** ERC with distal CBD stones. **c** Sphincterotomy. **d, e** Basket extraction of stones. *ERC* endoscopic retrograde cholangiography

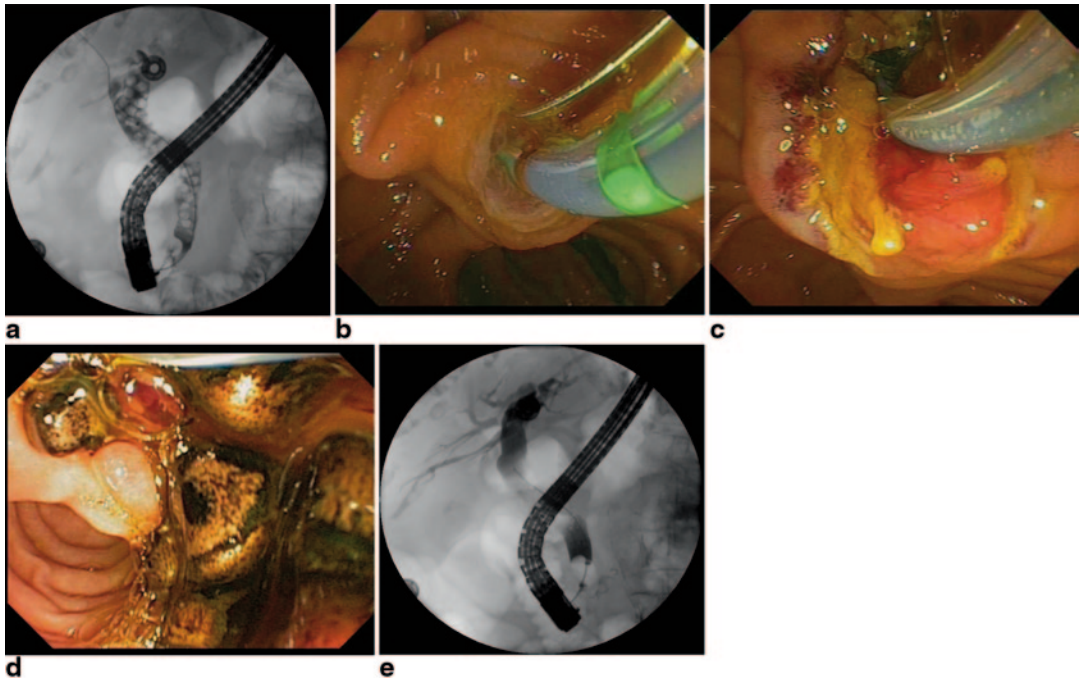

Fig. 2.3 **a** Sequence of ERC showing multiple stones filling extrahepatic bile duct; **b, c** Sphincterotomy in the 11 o'clock direction; **d** balloon extraction; and **e** Occlusion cholangiogram with biliary stone extraction balloon inflated in distal CBD showing no residual stones. *ERC* endoscopic retrograde cholangiography, *CBD* common bile duct

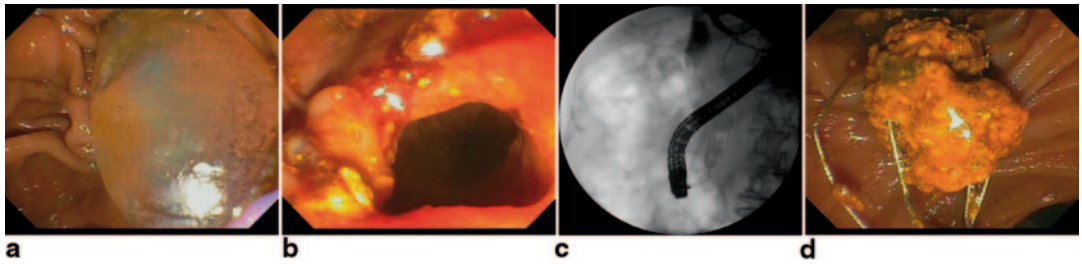

Fig. 2.4 **a, b** Large diameter balloon dilation of the papilla after sphincteromy with **c**, **d** basket extraction of stone material

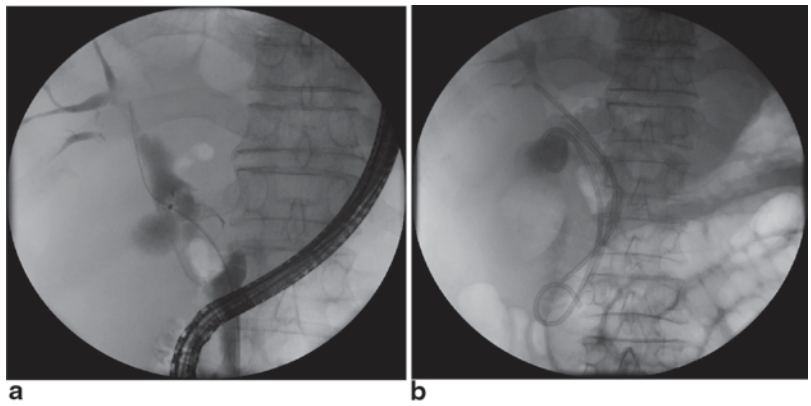

Fig. 2.5 **a** Stone in a cholecystocholedochal fistula, **b** causing biliary obstruction (*Mirizzi syndrome*) treated by CBD and gallbladder stent placement preoperatively. *CBD* common bile duct

"very strong." Those included in the "very strong" category included visualized choledocholithiasis on transabdominal ultrasound, clinical cholangitis, and a total bilirubin >4 mg/dL. "Strong" indicators included a dilated common bile duct (CBD) > 6 mm and total bilirubin between 1.8-4 mg/dL. "Moderate" indicators included abnormal liver tests, age>55, and clinical gallstone pancreatitis [5]. Based on several prospectively supported algorithms, patients can be risk-stratified into "low," "intermediate," or "high" risk for choledocholithiasis [6]. Patients who are "high risk" benefit the most from ERCP as opposed to other noninvasive modalities. In support, the American Society for Gastrointestinal Endoscopy (ASGE) recommends that only patients meeting the criteria for high suspicion undergo an ERCP for choledocholithiasis since it allows for immediate diagnosis and treatment [7]. Sphincterotomy and stone extraction with or without lithotripsy can be performed using the numerous tools now available in order to relieve biliary or pancreatic ductal obstruction caused by stones.

In 1988, Neoptolemos and Carr-Locke et al. were the first to examine the role of early (less than or equal to 72 h) ERCP in gallstone pancreatitis. Prior to this time, ERCP had been considered contraindicated in this setting. The study demonstrated that only patients predicted to have severe disease, by the modified Glasgow criteria, benefited from ERCP. Although mortality was not affected by early ERCP, overall complications were significantly decreased in the ERCP group (24%) compared to those who received conventional supportive treatment (61%) [8]. In 1993, Fan et al from Queen Mary Hospital, Hong Kong, published a study of 195 patients randomized to either early ERCP within 24 h versus conservative treatment. Morbidity in the ERCP group was significantly decreased compared to patients managed by conservative therapy (16 vs. 33%) [9].

The latest American College of Gastroenterology (ACG) guidelines published in 2013 state that patients with acute pancreatitis and concurrent acute cholangitis should undergo ERCP within 24 h of admission. However, the guidelines further state that "ERCP is not needed in most patients with gallstone pancreatitis who lack laboratory or clinical evidence of ongoing biliary obstruction" [10]. Controversy remains in this area concerning the absolute need for concomitant cholangitis and evidence for biliary obstruction, and there is inconsistency in guidelines for and against this inclusion.

Pancreatic Stones

Nearly always in the setting of chronic pancreatitis, pancreatic duct stones are treated in much the same way as bile duct stones and with the same accessories in symptomatic patients. The treatment of asymptomatic nonobstructing pancreatic duct stones is questionable but an argument can be made for removing stones that are causing complete main duct obstruction in order to improve exocrine function although such patients are not truly asymptomatic. There are differences in approach from biliary stones since the pancreatic duct is a more fragile and tortuous structure, may carry strictures as part of the spectrum of chronic pancreatitis, the stone(s) may be located in the duct and may be impacted, all of which renders the successful extraction of pancreatic stones more problematic compared to their biliary counterparts. Extracorporeal shock wave lithotripsy (ESWL) is a useful adjunct and, if not available, may significantly influence the choice of endoscopic, which may need to be sequential, or surgical therapy.

Ampullary/Papillary Abnormalities

Sphincter of Oddi Dysfunction

The modified Milwaukee classification for biliary SOD, used by many for more than two decades, are:

Type I	Biliary-type pain
	Elevated ALT, AST, or AP on one occasion
	Bile duct diameter > 10 mm
Type II	Biliary-type pain
	One of the other two criteria for type I
Type III	Biliary-type pain only

The approximate frequency of abnormal sphincter of Oddi manometry (SOM) is 65–85, 65, and 59 % for type I, II, and III respectively in the post-cholecystectomy patient presenting with presumed biliary pain [11]. Endoscopic biliary sphincterotomy has largely replaced open surgical sphincteroplasty. Regardless of whether SOM is normal or abnormal, 90–95 % of type I SOD patients experience pain relief. Therefore, in type I patients, endoscopic sphincterotomy is indicated. In type II SOD patients, the role of endoscopic sphincterotomy is controversial. In patients with suspected type II SOD with abnormal SOM results, 85 % will have pain relief with sphincterotomy, but in those with normal SOM results, only 35 % will experience pain relief. Regardless, most experienced biliary endoscopists will offer type II SOD a biliary sphincterotomy after discussion of the risks. In type III SOD patients, abnormal SOM has recently been shown not to be predictive of outcome, and empiric sphincterotomy (biliary with or without pancreatic) is not indicated and carries a significant risk. The equivalent pancreatic SOD classification has not been validated as an indication for pancreatic sphincterotomy, but in patients with unexplained recurrent pancreatitis, abnormal pancreatic and/or biliary SOM is often used as an indication for empiric dual sphincterotomy.

Ampullary Cancers/Adenomas

The major duodenal papilla, often interchangeably but erroneously called the ampulla of Vater, can be the source of different types of tumor including adenomas, adenocarcinomas, lipomas, leiomyomas, lymphomas, neuroendocrine tumors, and hamartomas. Adenomas occur sporadically in 0.04–0.12 % of the general population, but in those with hereditary polyposis

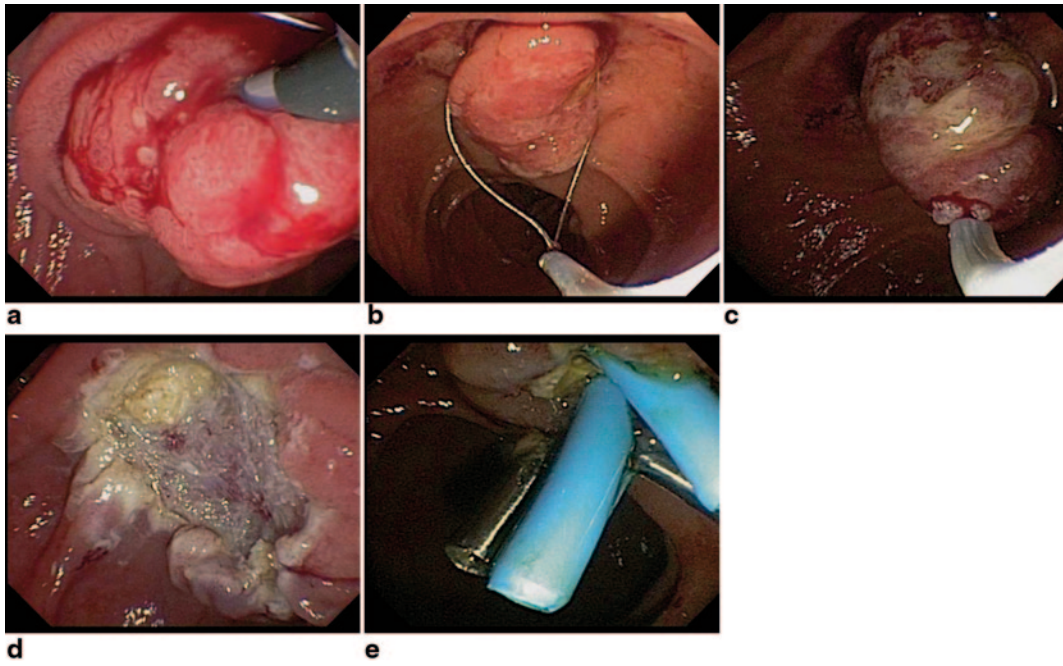

Fig. 2.6 Ampullectomy for adenoma sequence: **a** Cannula injecting pancreatic duct with friable adenoma visible; **b, c** Snare cautery en bloc resection of adenoma; **d** Postresection with biliary orifice visible in *upper left corner* (*yellow stain*); **e** Biliary and pancreatic duct stents inserted with clips visible placed for bleeding

syndromes, the incidence of ampullary adenoma increases to 40–90% [12]. Periampullary adenomas have the potential for malignant transformation into carcinoma at a rate of 30–50% [12] in sporadic cases but the risk in polyposis individuals is also high and this site represents the second highest incidence of cancer after the colon. Two decades ago, the primary treatment of periampullary adenomas was pancreaticoduodenectomy. Due to the increased morbidity and mortality associated with this procedure, especially for a benign disease, the surgery changed to a transduodenal approach with local excision. However, the recurrence rate ranged from 5 to 30% [12]. A review comprising 967 patients undergoing endoscopic ampullectomy reported a recurrence rate of 14% [12]. Endoscopic *en bloc* ampullectomy causes pancreatitis in an unpredictable manner. A prospective randomized controlled trial demonstrated that the placement of a prophylactic pancreatic duct stent conferred a protective benefit against pancreatitis after endoscopic ampullectomy (Fig. 2.6) and should be used in all cases when possible [13].

Cancers in this area can be palliated in the same way as malignant pancreatobiliary strictures (see below) (Fig. 2.7).

Biliary and Pancreatic Ductal Abnormalities

ERCP is of great utility in the diagnosis and management of biliary and pancreatic ductal abnormalities including leaks and strictures. ERCP serves as a platform to access the ductal systems, as it always has, for the purpose of ductography but also to allow sampling by brushing and biopsy. It also permits direct cholangioscopy and pancreatoscopy which further facilitates sampling by directed forceps biopsy and interrogation by confocal laser endomicroscopy and intraductal ultrasound.

Leaks

Leaks from the ductal systems can be treated endoscopically in carefully selected patients.

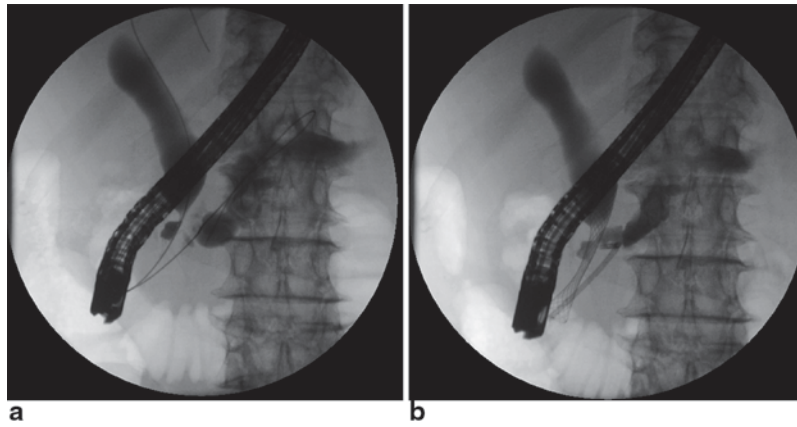

Fig. 2.7 **a** Two wires placed into dilated CBD and PD with distal strictures in patient with ampullary cancer. **b** Metal biliary stent and plastic pancreatic duct stent placed. *CBD* common bile duct, *PD* pancreatic duct

Continuity of the duct to be evaluated and treated is the most important factor determining the feasibility of managing the leak endoscopically [14, 15]. If the bile duct is completely transected or when there is no continuity between the injured segments, endoscopic management is usually not possible. Once duct continuity has been confirmed by cholangiography or pancreatography, the leak can be managed by deploying a stent either across the papilla to reduce intrabiliary pressure in the case of a postoperative biliary leak in an otherwise normal duct, or across the leak itself as in the case of a pancreatic disruption or injury (Fig. 2.8). The types of stent used in these situations continue to evolve as stent technology changes. Two studies performed by Traina et al and Kahaleh et al. reported resolution of the majority of bile leaks after the use of self-expandable metal biliary stents [16, 17]. However, there were instances of stent migration and stricture formation with the use of these metal stents and cost-effectiveness is questionable. It is hypothesized that the success of biliary stenting in the setting of leaks is attributed to the reduction of transpapillary biliary pressure gradient. The reduction in this pressure gradient diverts flow from the leak site to the intact biliary tree and ultimately into the duodenum. Pancreatic duct (PD) leaks are a result of acute or chronic pancreatitis, trauma, malignancy, and surgery. Varadarajulu et al. demonstrated that successful resolution of a PD disruption was dependent on the type of

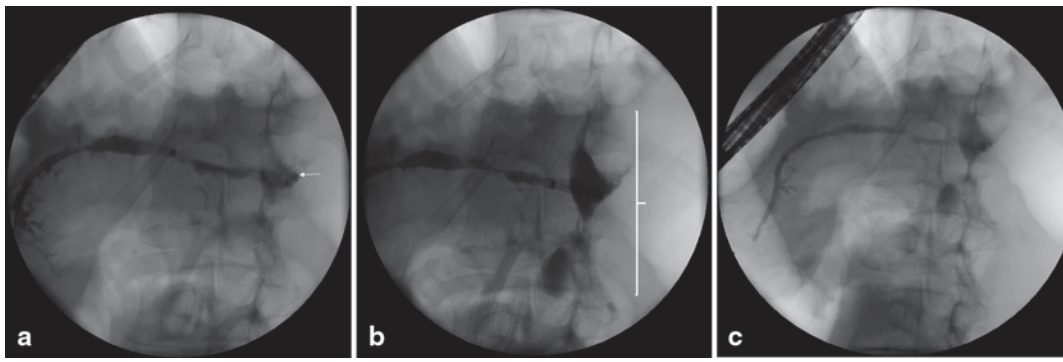

Fig. 2.8 **a, b** PD head stricture and tail disruption (*arrow* and *bracket*) with ascites, **c** treated by stent placement. *PD* pancreatic duct

disruption and the ability to bridge the disruption [18]. A study investigating the role of PD stenting in ductal disruption demonstrated that in 21 out of 28 patients with partial PD disruption who were treated with PD stent alone, the disruption resolved. In six out of eight patients with complete PD disruption, the disruption resolved with PD stenting alone as well [19].

Benign Strictures

The diagnosis of a benign stricture is not always straightforward and usually involves the implementation of the diagnostic sampling tools mentioned above. Once the stricture has been designated as benign and endoscopic therapy chosen as the management plan, either balloon dilation plus stenting or simply stenting alone may be employed. In the case of benign biliary strictures, placement of multiple large bore plastic stents side by side has resulted in good long-term outcomes, [20] but the outcome of self-expandable covered metal stents is being evaluated [21].

Pancreatic duct strictures in the setting of chronic pancreatitis or injury (Fig. 2.9) may also be amenable to endoscopic therapy using the same tools as in biliary applications, but the pancreatic duct does not necessarily respond in the same way and a plan of sequential pancreatic endotherapy needs to be discussed at the outset. Stents specifically designed for use in the pancreatic duct are available.

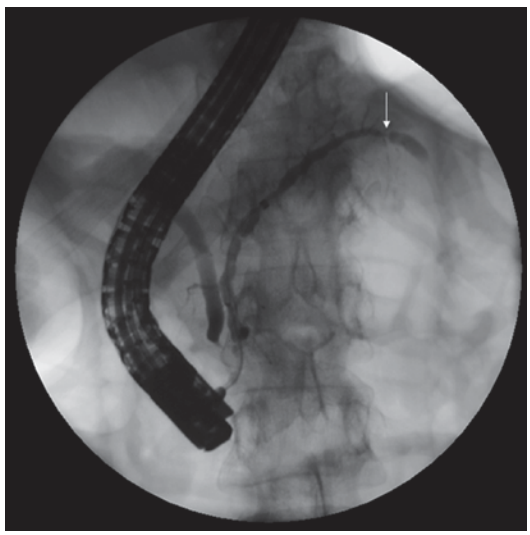

Fig. 2.9 Traumatic PD stricture (*arrow*) from seat belt injury with mild upstream dilation. *PD* pancreatic duct

Malignant Strictures

In the last 30 years, endoscopic decompression through stent deployment has emerged as the therapeutic procedure of choice in the temporary or permanent palliative management of malignant biliary obstruction (Figs. 2.10, 2.11 and 2.12). Lower hospital costs, shorter hospital stays, and lower morbidity when compared to surgical palliation of malignant biliary strictures have been demonstrated [22]. Biliary decompression can palliate the consequences of obstruction including jaundice, weight loss, cholangitis, secondary cirrhosis, and pruritus thus improving quality of life. Biliary stent therapy, however, has not been shown to have significant survival benefit [23, 24]. Although short-term preoperative biliary drainage with plastic stents is not indicated, metal stents may be cost-effective and, in the potentially resectable patient and/or those undergoing neoadjuvant chemoradiation therapy who have a significant delay between diagnosis and surgery, metal stent placement is indicated.

When is ERCP Not Indicated or Contraindicated?

Like any invasive procedure, there are circumstances in which ERCP should not be performed. Relative contraindications include:

1. Portal hypertension with esophageal and/or gastric varices
2. Acute pancreatitis except gallstone pancreatitis (this may change)
3. Recent myocardial infarction and/or severe cardiopulmonary disease unless the procedure is life-saving (e.g., cholangitis)
4. Repeated failed attempts at ERCP therapy when alternatives are available

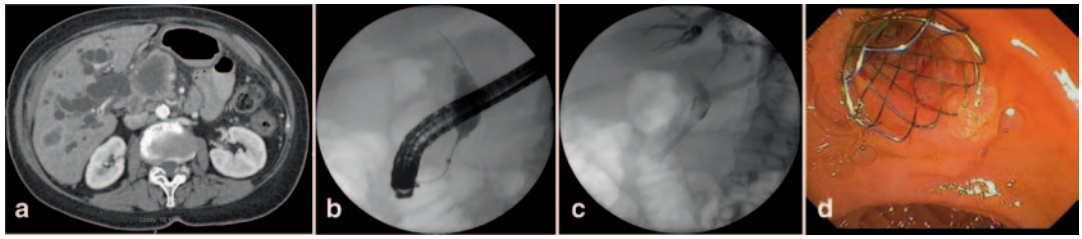

Fig. 2.10 **a** Pancreatic cancer with diffuse intrahepatic biliary dilation on abdominal CT, **b** confirmed by cholangiogram showing distal biliary stricture, **c, d** treated by metal biliary stent placement. *CT* computed tomography

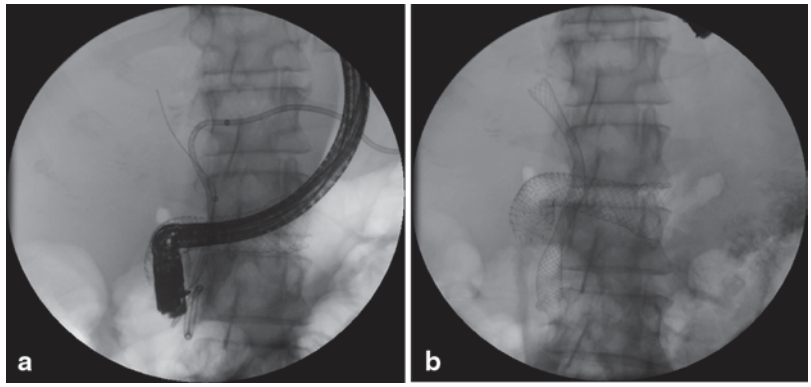

Fig. 2.11 **a** Malignant duodenal stricture treated by metal enteral stent placement and percutaneous biliary drain, **b** exchanged for metal biliary stent

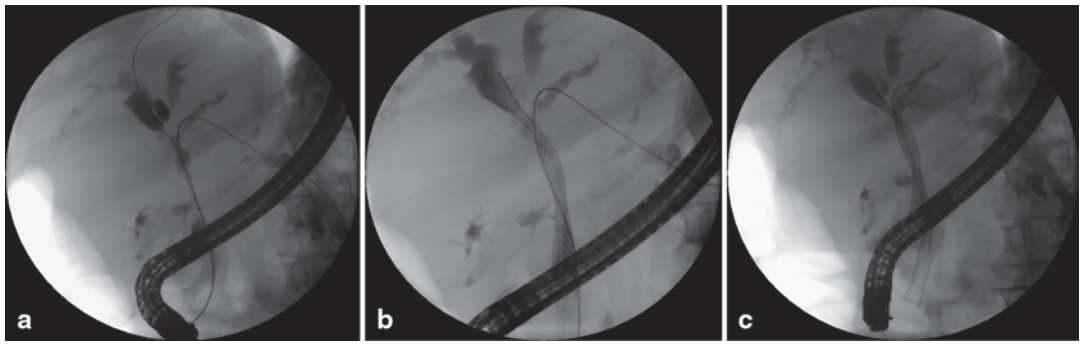

Fig. 2.12 Hilary malignancy treated by bilateral metal biliary stent placement. **a** Two wires advanced into bilateral hepatic ducts. **b** Metal stent placed into right main hepatic duct. **c** Second metal stent placed alongside into left main hepatic duct

5. Patient cannot be adequately sedated.
6. Anaphylactic reaction to radiographic contrast although this usually refers to reactions after intravenous contrast and there is little to no evidence that ERCP carries the same risk. Local policies will guide this.

Absolute contraindications are the following:

1. Pharyngeal or esophageal obstruction (unless these can be treated simultaneously)
2. Severe uncorrected coagulopathy
3. Inadequate indication, e.g., abdominal pain of unknown cause

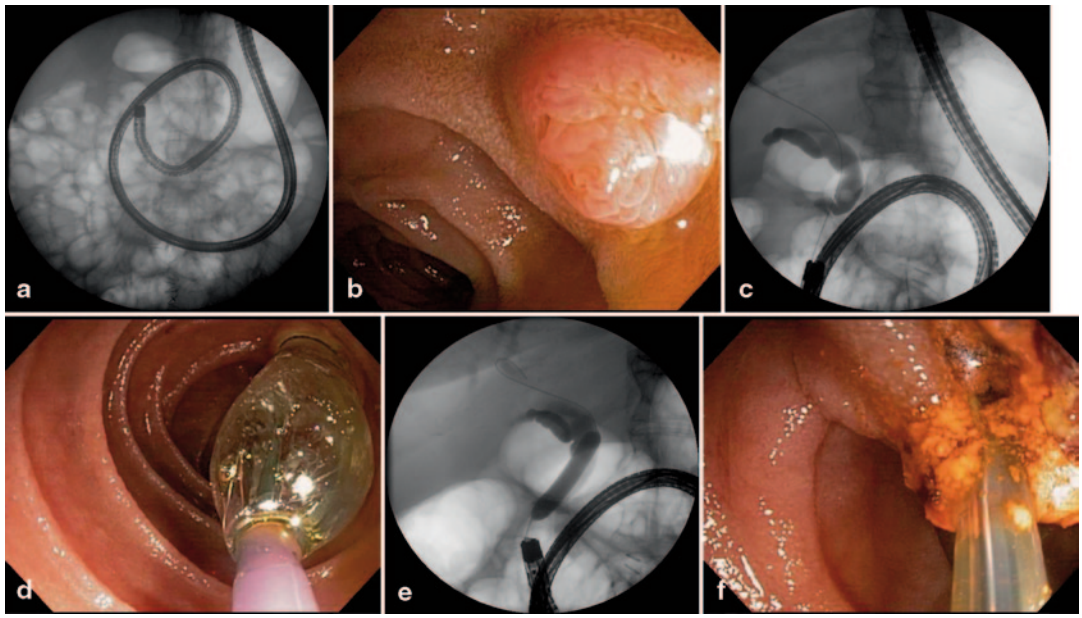

Fig. 2.13 **a** ERC after Roux-en-Y gastric bypass using a colonoscope, **b** showing a normal major papilla, **c** and stone in distal CBD with long guidewire placed. **d, e** Balloon dilation of the papilla performed, **f** followed by stone extraction using a biliary stone extraction balloon

4. Altered anatomy (Roux-en-Y, Billroth II, and pancreaticoduodenectomy) without the necessary skills and tools available (Fig. 2.13)
5. Known or suspected perforation
6. Consent cannot be obtained, unless deemed an emergency
7. The risks of the procedure outweigh the potential benefits

Where Do EUS and MRCP Fit in with ERCP?

EUS and MRCP have emerged as diagnostic modalities to aid, or in many cases, completely replace diagnostic ERCP. Both have become well accepted as less invasive and safer diagnostic procedures compared to ERCP that can provide the same information as ERCP without the risks.

MRCP, first developed in 1991, uses heavily T2-weighted sequences to return a high signal from fluid in the biliary and pancreatic ducts, which have long T2 relaxation times [25]. One of the advantages of MRCP is that there is no use of ionizing radiation nor iodinated contrast material [25]. Another advantage is that MRCP allows for visualization of ductal abnormalities extending into the smaller caliber intrahepatic ducts compared to EUS. Spatial resolution of MRCP compared with ERCP is, however, inferior. Therefore, pathology in nondistended pancreatic side branch or peripheral intrahepatic ducts may be missed [25]. Furthermore, early changes of conditions in chronic pancreatitis and primary sclerosing cholangitis may be missed on MRCP as opposed to ERCP [25].

Where EUS is not readily available, MRCP has become the test of choice in the diagnosis of choledocholithiasis. One study demonstrated that the sensitivity and specificity of diagnosing choledocholithiasis was 100 and 91 % in the EUS group while it was 90 and 100 % in the MRCP group, respectively [4]. Some studies suggest that MRCP is less accurate in detecting smaller diameter stones. For instance, one study reported that the sensitivity of MRCP in the detection of choledocholithiasis decreases from 71 to 33 % as stone diameters fell below 6 mm [2]. Kondo et al. corroborated this by stating that the performance of EUS was superior to

MRCP for detecting common bile duct stones < 5 mm in size [26, 27]. There has been a debate whether the accuracy of MRCP for the detection of choledocholithiasis varies with ductal diameter. This discussion needs further clarification as studies on this topic seem to contradict. For instance, one group concluded that there were no significant differences in the performance of EUS and MRCP in the diagnosis of malignancy and choledocholithiasis in patients with both dilated and nondilated bile ducts [4].

A systematic review of five randomized, prospective trials comparing EUS and MRCP in the diagnosis of pancreatobiliary diseases showed no significant differences in sensitivities, specificities, positive and negative predictive values, and likelihood ratios [28]. When choosing between the two modalities, one should consider other factors including resource availability, experience, costs, and patient requirements. For instance, in high-risk populations such as the elderly or severely ill patients, MRCP would be the better test due to the noninvasive nature of the test [28]. Nevertheless, MRCP is time consuming and requires a high level of patient cooperation. Furthermore, it is not well tolerated in up to 5 % of patients due to claustrophobia [28].

EUS combines both endoscopy and ultrasound to provide images of the pancreatobiliary system in radial or linear array without the interference of bowel air or subcutaneous fat [6]. Literature review comparing EUS to ERCP, intraoperative cholangiography and surgical exploration in the ability to detect choledocholithiasis have varied significantly with sensitivities reported from 71 to 100 % and specificities of 67–100 %. These variations were attributed to factors such as patient selection, operator expertise, and study design [6]. Nine studies including 601 patients have compared EUS to ERCP in the detection of choledocholithiasis. This review demonstrated that EUS was more sensitive and accurate than cholangiography in the detection of stones smaller than 4 mm. The diagnostic limitation of cholangiography in detecting small stones was partly explained by loss of sensitivity in dilated ducts [26, 28, 29]. EUS offers very high-resolution images (0.1 mm), thus allowing the detection of very small diameter stones [6]. In contrast to reports of CT and MRCP, the accuracy of EUS is not diminished in the setting of small stones or a nondilated bile duct [30].

EUS, where available, has become the test of choice in low to moderate suspicion of choledocholithiasis. If stones are detected on EUS, therapeutic ERCP can potentially be performed immediately while the patient is still sedated. This offers a convenient and safe management of these patients who would otherwise have undergone the risks of a diagnostic ERCP or the delay in proceeding to a therapeutic ERCP after a positive MRCP finding. In addition, when MRCP, CT, or ERCP studies are unable to identify the etiology of a bile duct or pancreatic duct stricture, EUS has also been used to exclude an underlying malignancy. If a mass is identified, EUS allows for sampling through fine needle aspiration. Furthermore, EUS is helpful in staging ampullary tumors to ensure that endoscopic ampullectomy is appropriate.

Despite the minimally invasive manner in which EUS provides valuable information for a variety of pancreatobiliary diseases, EUS has several limitations. EUS is not readily available in many community hospital settings, (1) and it is operator-dependent. If the echoendoscope cannot be advanced into the duodenum for reasons including pyloric stenosis, ulcer disease or surgically-altered anatomy, then EUS cannot be effectively considered an option for excluding choledocholithiasis, malignancy, and strictures of the distal CBD and ampulla. Furthermore, like any endoscopic procedure the risk of perforation, albeit small, is still present considering the larger diameter and oblique angle of the endoluminal view.

In addition, EUS has the great potential to provide therapy where ERCP is not possible or fails (Figs. 2.14 and 2.15 and see Chap. 34).

Complications

The best way to prevent or reduce post-ERCP complications is to avoid performance of unnecessary ERCP.

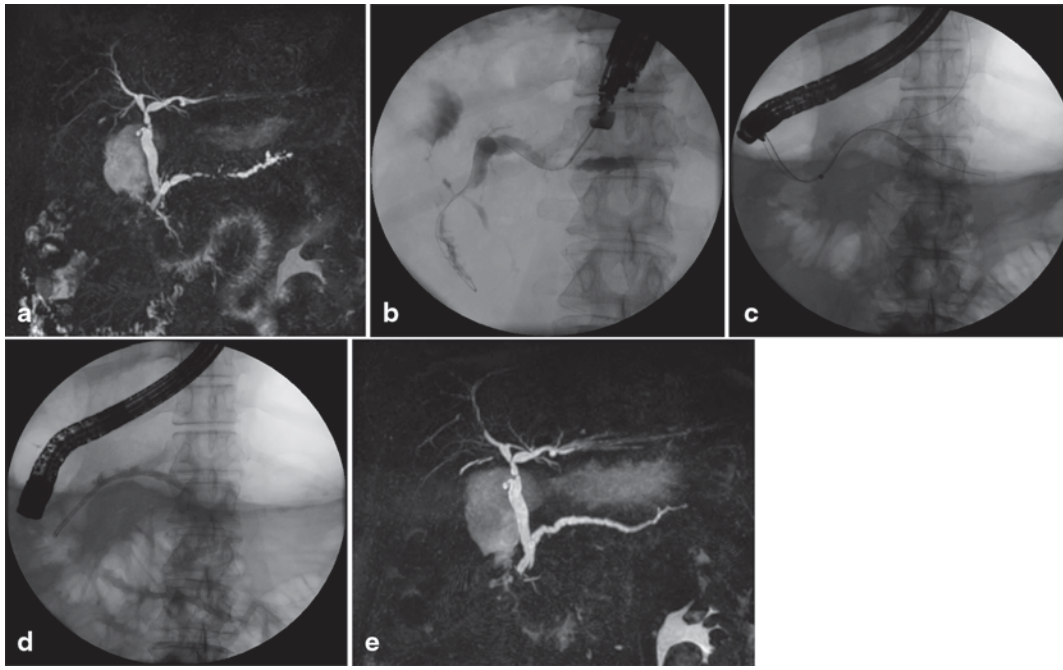

Fig. 2.14 **a** Sequence in a patient with pancreas divisum and postoperative stenosis, **b** showing antegrade access to the PD by EUS using a *19G* needle with guidewire placement, **c** rendezvous ERP, **d** and stent placement, **e** with follow-up MRCP demonstrating resolution of stricture. (Courtesy Dr Petros Benias)

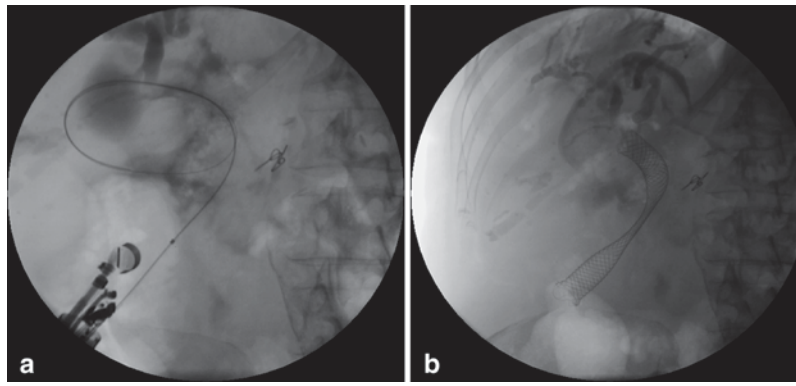

Fig. 2.15 **a** Direct EUS cholangiography through the duodenal bulb, **b** and metal biliary stent placement for malignant biliary obstruction. (Courtesy Dr Petros Benias)

Pre-ERCP Considerations

One of the most important aspects of performing ERCP is patient selection. An anesthesiologist may be the best consultant in this situation as cardiopulmonary depression is the most common complication associated with endoscopy. Up to 50 % of overall complications are associated with sedation [31]. Hypoxic events occurring at an incidence of 7–40 % and aspiration are associated with increased age, chronic illnesses, depressed mental status, supine positioning, and sedation [31].

Questions to ask prior to ERCP include:

1. Is this procedure justified?
2. Is SOD suspected? If so, am I ready to use methods for pancreatitis prophylaxis (pancreatic duct stent, rectal indomethacin)?

3. Is my patient optimized in terms of cardiopulmonary condition?
4. Should I recommend intubation versus conscious sedation?
5. When did the patient last eat and does the patient have a history of gastroparesis or gastric outlet obstruction?
6. What position is safest for the patient?
7. Is the patient of child-bearing age in which pelvic radiation protection must be provided?
8. Is the patient pregnant?
9. Does the patient have any allergies to medications including contrast?
10. Does the patient have any spontaneous or iatrogenic coagulopathies?
11. Does the patient have a history of post-ERCP pancreatitis or other complications?
12. Has this patient undergone a previous ERCP? If so, what were the difficulties and findings?
13. Is all necessary equipment ready to perform the planned ERCP?

Intra- and Post-Procedural Considerations

Complications during these stages include cardiopulmonary events, perforation, bleeding, drug reactions, pancreatitis, hemorrhage, cholangitis, cholecystitis, stent-related complications, and other miscellaneous adverse events. The major adverse events of ERCP are pancreatitis, bleeding, perforation, and infection which are briefly discussed below. See Chap. 3 for an extensive discussion on complications following ERCP. Appropriate management requires recognition of an adverse event, its accurate definition, and its prompt treatment.

Post-ERCP Pancreatitis

The pathophysiology of post-ERCP pancreatitis (PEP) is multifactorial including mechanical, chemical, hydrostatic, enzymatic, and thermal causes [31]. PEP is the most common adverse event with reported rates ranging from 1 to 40% [32]. The most cited rate of PEP is 5%. Multivariate analyses support the following risk factors for PEP: suspected SOD, young age, history of PEP, difficult or failed cannulation, pancreatic duct injection, pancreatic sphincterotomy, balloon dilation of intact biliary sphincter in the West and access papillotomy (precut sphincterotomy). The factors that "may" contribute to PEP include: female sex, normal bilirubin, pancreatic acinarization, absence of CBD stone, low ERCP case volume, and trainee involvement. Factors that do not cause PEP are: small CBD diameter, SOD manometry, and biliary sphincterotomy [32].

An array of technical methods is known to decrease the risk of PEP. A randomized trial showed significant reduction of PEP when a guidewire was used in conjunction with a papillotome compared to papillotome alone [33]. Pancreatic duct stent placement (Fig. 2.16) reduces the risk of PEP significantly and its severity in high-risk ERCPs, such as biliary sphincterotomy for SOD, SOD with normal manometry, pancreatic sphincterotomy, access papillotomy (precut sphincterotomy), ampullectomy, and difficult cannulation [13, 34–36]. Reduction in rate of post-ERCP pancreatitis from 17% in the control group to 9% in the treatment group using rectal indomethacin 100 mg suppositories has also been documented [37].

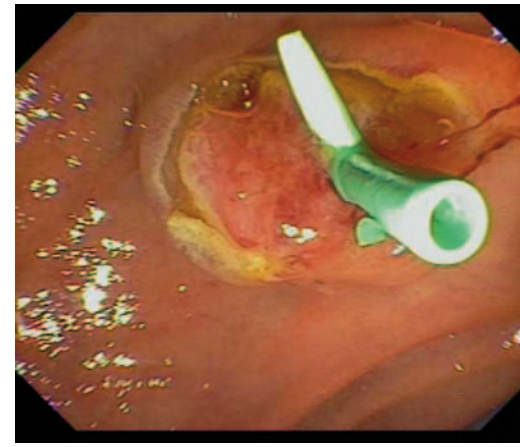

Fig. 2.16 Prophylactic pancreatic stent after sphincterotomy

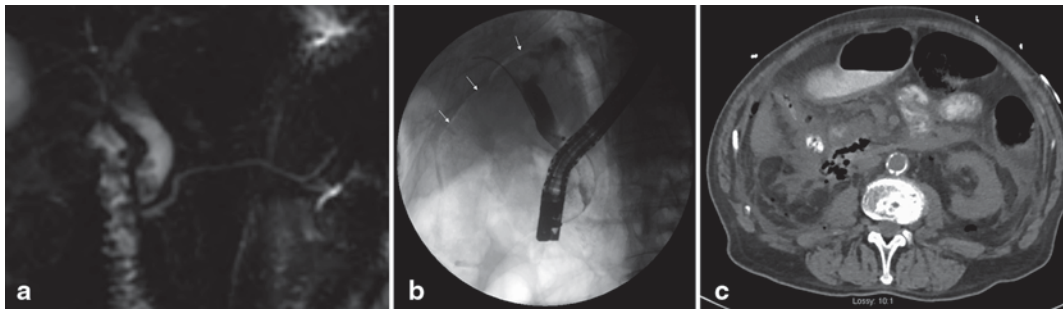

Fig. 2.17 **a** Sequence of MRCP showing multiple distal biliary stones, **b** followed by sphincterotomy and balloon extraction complicated by retroperitoneal perforation seen on fluoroscopy (**b**, *arrows* point to extraluminal air) and **c** abdominal CT scan treated conservatively

Post-ERCP Hemorrhage

Bleeding occurs in approximately 1–2% of patients during or after sphincterotomy [31]. If the bleeding site is visible, address the problem using either injection with epinephrine (1:10,000) and/or clip placement. Alternatively, one can also use balloon tamponade. The need for angiography and emergency surgery has diminished with the improved success of endoscopic management and appropriate patient selection.

Post-ERCP Perforation

Perforation is reported in less than 1% of ERCP and sphincterotomies [38]. Perforations range from micro-perforations after sphincterotomy to frank perforations of the gut and may be retroperitoneal, intraperitoneal, or both. Each perforation must be assessed and managed individually. Risk factors for perforation include: performance of sphincterotomy, presence of altered surgical anatomy, stricture dilation, and long duration of the procedure [39, 40]. The key to managing post-ERCP perforations is early detection and action in parallel with experienced surgical consultation (Fig. 2.17).

Post-ERCP Cholangitis

Adequate pancreatic and biliary drainage of obstructed and contaminated ducts is the key to treatment and avoidance of sepsis. Pre-ERCP planning by MRCP and EUS of obstructed ducts is now routine.

Medico-Legal Issues

The art and practice of medicine are not perfect. The goal of restoring human biology to its original state is often prohibited by adverse events as a consequence of treatment (iatrogenic) as briefly discussed earlier for ERCP. These complications result in decreased quality of life, disabilities, high medical costs, extended hospitalizations and an inability to partake in life's normal activities. Whether these complications are predictable or not, patients may place blame on the physician or facility and seek compensation [41]. Such lawsuits have widespread impact, not only on the accused but also on the criminal justice systems, the community, family members, and public health. The current medico-legal environment has changed the landscape of how we now provide healthcare. Each state has its own laws governing medical malpractice.

The Physician Insurers Association of America (PIAA) database from 1985 to 2005 showed that only 1.8% of claims involved gastroenterologists [41]. In more recent years, a large liability insurer showed that gastroenterologists ranked 5th out of 25 specialties in claims and outcomes [41]. ERCP is one of the more invasive procedures associated with more frequent adverse events. Therefore, it is easy to imagine that ERCP would account for a disproportionate number of legal claims. However, in 1995, the risk of litigation from ERCP was substantially less than other procedures [41]. The relative risk

of litigation from ERCP is less than twice that of simpler procedures including flexible sigmoidoscopy or gastroscopy [42]. In Canada, ERCP is only associated with 6% of GI-related lawsuits whereas in Japan, ERCP is the most common reason for endoscopy-related claims. In Peter Cotton's analysis of 59 ERCP lawsuits, the primary allegations in 32 cases were "marginal indications and poor communication" [43]. Hence it is essential to have firm evidence to justify the risks of performing ERCP as described here earlier.

Aside from having the correct clinical indications for ERCP, the endoscopist should also be properly trained and maintain a level of proficiency to provide the best possible outcome. Undertaking a dedicated advanced endoscopy fellowship has been suggested to decrease the risk of complications during ERCP, but this is controversial. Less than 200 ERCP procedures during training are not considered adequate to attain competence [5]. The ASGE has created guidelines to ensure adequate training. Data suggest that at least 180 to 200 cases is necessary to achieve competence in ERCP [44, 45]. Furthermore, hospitals also take responsibility since they grant privileges to endoscopists who wish to perform ERCP [46, 47].

Conclusion

In summary, when attempting to map out the biliary and pancreatic ductal systems, ERCP, although very sensitive and specific, carries significant risks. When the suspicion for choledocholithiasis is high, proceeding directly to ERCP should not be questioned. In a patient considered high risk with multiple co-morbidities, if she or he demonstrates clinical signs of deterioration secondary to presumed biliary obstruction (cholangitis, gallstone pancreatitis), ERCP can justifiably be undertaken [48]. In the low to moderate risk patient with low to moderate suspicion of choledocholithiasis, the clinician can choose between EUS and MRCP depending on availability followed by ERCP as indicated. For bile and pancreatic duct strictures, ERCP is the diagnostic and therapeutic procedure of choice. However, if ERCP is unable to identify the etiology of the stricture, MRCP and EUS are indicated. If both are available, one must consider what and where the possible pathology may be. If the suspicion is for an intrahepatic duct pathology, an MRCP would be best. If extrahepatic bile duct or pancreatic ductal abnormality is anticipated, EUS confers both diagnostic imaging and sampling benefits. EUS is also beneficial to staging ampullary lesions prior to endoscopic ampullectomy.

Key Points

- Always have a solid indication for performing ERCP and ask yourself: "What if this patient has a serious complication, can I justify what I/we did?"
- Ensure that the therapeutic indication is the best of all alternatives.
- Be familiar with all general and specific risks of ERCP.
- Know your own skill limitations and when to ask for help.
- Be prepared to manage complications as a team.
- Document what you do.
- Be aware that lawsuits mainly arise from situations where the indication was inappropriate or unclear, the consent was not informed, and/or where there was poor communication after the event.
- Utilize EUS and MRCP judiciously to complement ERCP.

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