Non-operative Approaches to the Biliary Tree

26

Kevin D. Platt and Ryan J. Law

Introduction

While first-line treatment in patients with biliary disease often involves surgery, there remains a substantial role for less invasive options, particularly with the growing number of medically complex and aging patients who may not be surgical candidates. It is therefore prudent that surgeons be familiar with the available non-operative armamentarium for management of patients with biliary disease, which includes a growing number of percutaneous and endoscopic techniques which can serve as alternative or complimentary approaches to conventional management. Similarly, interventional radiologic and endoscopic interventions have had an expanding role in the management of adverse events from biliary surgery. In this chapter, we will review the most common biliary diseases requiring intervention: cholecystitis, choledocholithiasis, cholangitis, and bile leaks. We will focus on percutaneous and endoscopic techniques and highlight non-operative approaches in patients with surgically-altered gastrointestinal anatomy.

K. D. Platt
Division of Gastroenterology and Hepatology, Department of Medicine, University of Michigan, Ann Arbor, MI, USA
e-mail: plattk@med.umich.edu

R. J. Law (✉)
Division of Gastroenterology and Hepatology, Department of Medicine, Mayo Clinic, Rochester, MN, USA

Section 1: Acute Biliary Disease

Cholecystitis

Acute cholecystitis is an infection of the gallbladder, most commonly (>90%) caused by gallstone disease (calculous) leading to cystic duct obstruction, with the minority of cases being related to bile stasis and hypoperfusion (acalculous) [1]. Overall, treatment consists of antibiotics and either cholecystectomy or non-surgical methods of gallbladder decompression. Please refer Chap. 15 for additional details regarding the clinical presentation, evaluation, and conventional surgical management.

While cholecystectomy remains the standard of care in the management of acute cholecystitis, in patients deemed unfit for surgery due to acute illness and/or significant medical comorbidities, there are a variety of non-operative approaches for consideration, including percutaneous cholecystostomy, transpapillary cystic duct stent placement, or endoscopic ultrasound (EUS)-guided gallbladder drainage. As described below, these approaches may serve as a bridge to future cholecystectomy or may be used as destination therapy.

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Percutaneous Cholecystostomy

Percutaneous cholecystostomy (PC) was first introduced in 1980 [2]. The technique involves using ultrasonographic or computed tomographic guidance to puncture the gallbladder allowing subsequent wire-guided placement of a percutaneous pigtail catheter. This approach effectively resolves acute cholecystitis in approximately 90% of patients [3]. The use of PC has been on the rise, now accounting for nearly 3% of gallbladder procedures performed in the Medicare population [4].

The most frequent reported adverse event of PC is catheter dislodgement (8.6%). Other adverse events include hemorrhage, sepsis, bile leak, bowel perforation, and pneumothorax, occurring overall in <2% of procedures. Intraprocedural mortality is <0.5%. The 30-day mortality ranges from 10% to 15%, likely reflecting the medically complex population who undergo PC [3, 5].

Advantages of PC include a high rate of technical and clinical success. Additionally, the procedure can be performed at the bedside in critically ill patients with no need for general anesthesia, as is typically needed for surgical and advanced endoscopic techniques. The major disadvantage of this approach revolves around the external drainage system. Percutaneous drainage catheters require routine maintenance with catheter exchanges and are often complicated by inadvertent dislodgement and patient discomfort, which can adversely affect quality of life [6, 7].

There is a growing body of literature comparing outcomes of cholecystectomy and PC. The recently completed CHOCOLATE trial by Loozen et al. [8] compared laparoscopic cholecystectomy and PC in severely ill patients with acute calculous cholecystitis. In this study, 142 high operative risk patients (APACHE II score >7) with symptoms of acute cholecystitis were randomly assigned to either laparoscopic cholecystectomy or percutaneous catheter drainage. Mortality at 1-year did not significantly differ between the two cohorts (3% vs. 9%, $p = 0.27$), but the rates of major adverse events (65% vs. 12%, $p < 0.001$), need for re-intervention at 1-year (66% vs. 12%, $p < 0.001$), and recurrent biliary disease at 1-year (53% vs. 4.5%, $p < 0.001$) favored the cholecystectomy approach. While this study favored cholecystectomy, there remain questions of generalizability to real-world scenarios, as only 17% of screened patients were ultimately enrolled in the trial and very high-risk patients (APACHE II scores ≥15) were excluded [9].

PC is often performed to serve as a bridge to definitive surgery; however, available data suggest >50% of patients who undergo percutaneous drainage do *not* ultimately undergo cholecystectomy [3, 10]. The rate of recurrent cholecystitis within 1 year of those patients who do *not* undergo interval cholecystectomy is up to 40% [11]. In patients who remain poor surgical candidates after percutaneous drainage, gallbladder drainage can be internalized via endoscopic techniques using transpapillary cystic duct stent placement [12] or EUS-guided gallbladder drainage [13].

Endoscopic Transpapillary Gallbladder Drainage (ERCP with Cystic Duct Stent Placement)

Transpapillary drainage of the gallbladder was first described in 1990 [14]. During endoscopic retrograde cholangiopancreatography (ERCP), the bile duct is cannulated, and a guidewire is passed into the biliary tree. The guidewire is then manipulated through the cystic duct and ultimately coiled in the gallbladder. A transpapillary double-pigtail plastic stent is then deployed with one pigtail in the gallbladder and the other pigtail in the duodenum, thus facilitating gallbladder decompression into the intestinal lumen (Fig. 26.1a, b). The procedure can be technically challenging as it requires selective guidewire access into the thin, tortuous and often obstructed cystic duct, as well as advancement of a stent through the cystic duct into the gallbladder lumen. Cystic duct patency, as determined by fluoroscopic visualization during contrast injection, is paramount in achieving successful guidewire passage and stent placement into the gallbladder. Lack of fluoroscopic visualization of the cystic duct most commonly occurs due to obstruction by a stone or, less commonly, from malignant

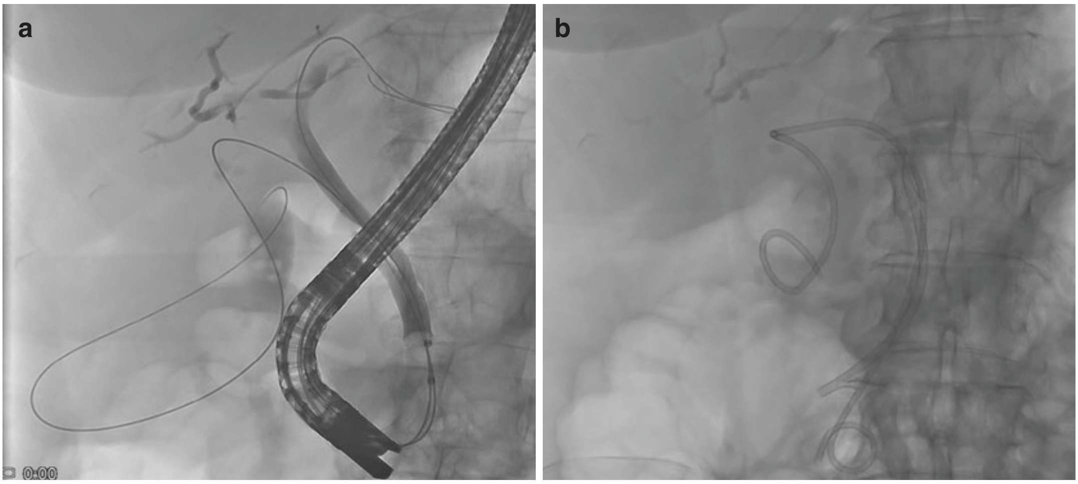


Fig. 26.1 Transpapillary gallbladder stent placement. (**a**) Following selective cannulation of the bile duct, a guidewire is passed into the cystic duct takeoff. The guidewire is manipulated through the Valves of Heister and ultimately coiled in the body of the gallbladder. A second guidewire is seen in the left hepatic duct. (**b**) Over the guidewire, a double-pigtail plastic stent is place with one pigtail in the gallbladder and the other in the duodenal lumen. A second plastic stent is seen in the common bile duct

obstruction. In such circumstances, access to the cystic duct will be extremely difficult, if not impossible [15]. Cholangioscopy using a digital, single operator cholangioscope (Spyglass DS; Boston Scientific, Marlborough, MA) or dedicated direct peroral cholangioscope may be helpful in identification of the cystic duct orifice [16]. Most commonly, double-pigtail plastic stents either 5–7 Fr in diameter and >12 cm in length are used.

When the procedure is technically successful, this method provides effective treatment in 90% of patients with acute cholecystitis [17]. The stent may be left indefinitely or can serve as bridge to surgery with removal prior to cholecystectomy [18]. Cystic duct stents can be left in place indefinitely—compared to common bile duct (CBD) stents—because they act as "wick" whereby bile flows around the stent, and thus patency of the stent is not imperative to maintain bile flow from the gallbladder [19]. As mentioned above, transpapillary cystic duct stents can also be used to facilitate removal of an indwelling PC tube after the tract has matured [12].

Adverse events can be seen in up to 10% of patients, including post-ERCP pancreatitis, stent migration, or post-sphincterotomy bleeding (if biliary sphincterotomy is performed) [18, 20]. In a recent review of 38 patients, technical success of first-attempt transpapillary drainage was observed in 84%, with 76% clinical success [20]. Recurrent cholecystitis was observed in 6 of 32 patients (18%), ranging from 23 to 865 days after the procedure. Recurrent cholecystitis is typically managed with antibiotics, stent exchange, EUS-guided gallbladder drainage, or cholecystectomy, if feasible.

There are advantages of transpapillary gallbladder drainage that make it attractive in certain patient populations, particularly those with advanced liver disease and coagulopathy. The procedure is done endoscopically, with no incisions required externally, and can be done without performing biliary sphincterotomy, thereby minimizing the risk of bleeding in patients with coagulopathy or those receiving systemic anticoagulation [21]. Furthermore, internal drainage is performed while leaving the anatomy untouched, without internal or external fistulous tracts, making transpapillary drainage the procedure of choice in patients with advanced liver disease with ascites and/or awaiting liver transplantation [22, 23].

EUS-Guided Gallbladder Drainage

EUS-guided gallbladder drainage (EUS-GBD) was first described in 2007 [24]. A linear-array therapeutic channel echoendoscope is passed transoral and positioned in the distal gastric antrum or duodenum to identify the gallbladder body. There are several techniques which can be utilized. The conventional method requires puncture of the gallbladder wall with an EUS-FNA needle, followed by bile aspiration and/or cholecystography using water-soluble contrast and fluoroscopy. A guidewire is passed through the needle and coiled within the gallbladder lumen. The tract is then dilated using electrocautery and/or balloon dilation. The stent, either a double-pigtail plastic stent, fully covered self-expandable metal stent (FCSEMS), or lumen-apposing metal stents (LAMS), can then be deployed under endosonographic and fluoroscopic guidance to appose the gallbladder and gastrointestinal lumen [25]. More recently, the gallbladder puncture and stent deployment are done with a LAMS that has an electrocautery tip without the need for guidewire placement and tract dilation (Fig. 26.2a, b). This approach minimizes over-the-wire device exchanges, allowing for a theoretically safer and more efficient procedure [26].

EUS-guided gallbladder drainage is associated with high technical (>90%) and clinical success (>90%) rates. Technical failure may occur due to inability to pass the guidewire, accidental guidewire loss, or stent maldeployment [27]. Adverse events have been reported at a frequency of 7–15% and include bleeding, recurrent cholecystitis, stent migration, stent occlusion, and pneumoperitoneum [28, 29]. When comparing the various stent options for EUS-GBD, data suggest that LAMS have the lowest rate of adverse events [28]. LAMS are specifically designed for transmural drainage, shaped like a barbell with two flanges to appose each luminal surface, thus carrying a very low risk of migration while also allowing for a larger inner lumen diameter than either plastic stents or FCSEMS.

Laparoscopic cholecystectomy may be technically difficult or impossible in certain patients following EUS-guided gallbladder drainage as this procedure creates a permanent fistula between the gallbladder and the adjacent gastrointestinal lumen. EUS-GBD is contraindicated in patients with gallbladder perforation, untreated large-volume ascites, or uncorrectable coagulopathy [30].

Several studies have compared percutaneous cholecystostomy and EUS-GBD [31, 32]. Results have shown no difference in technical or clinical success rates for the treatment of acute cholecystitis; however, these studies have shown statistically significant differences in time to

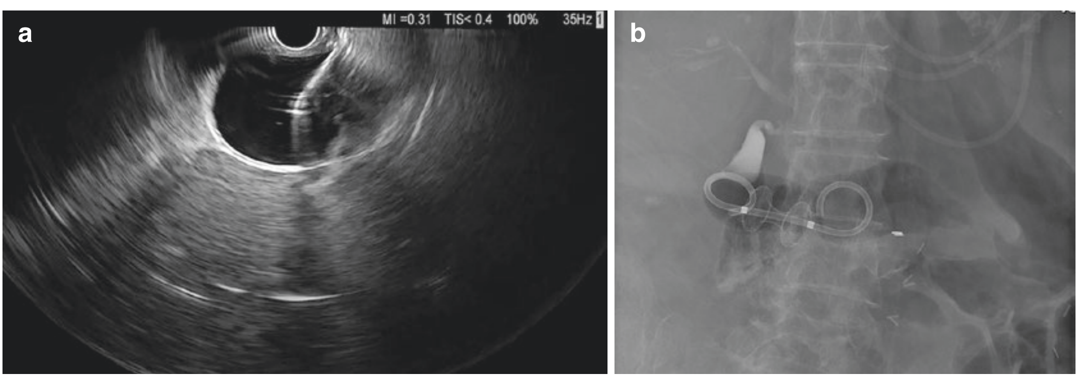


Fig. 26.2 Transmural EUS-guided gallbladder drainage. (**a**) From the antrum of the stomach or the proximal duodenum the gallbladder can be seen endosonographically. A cautery-enhanced catheter housing a lumen-apposing metal stent (LAMS) can then be passed into the gallbladder body. (**b**) The LAMS is then deployed thereby creating an anastomosis between the gallbladder and gastrointestinal lumen. A short double-pigtail stent is placed to minimize mucosal irritation from the stent and prevent stent migration/separation

resolution of cholecystitis, need for re-intervention, mean pain scores, adverse events, and hospital length of stay, favoring EUS-GBD [32]. More recently, a randomized trial (DRAC 1) of 80 patients comparing PC and EUS-GBD demonstrated that EUS-GBD significantly reduced 1-year adverse events, 30-day adverse events, and re-interventions with equivalent technical and clinical success rates [33].

In comparing the endoscopic approaches to manage acute cholecystitis, there are several retrospective studies comparing outcomes between transpapillary (cystic duct stent) and EUS-GBD. These have demonstrated that the EUS-guided approach is associated with better technical and clinical success with a trend toward lower adverse event rates and lower recurrence of cholecystitis [20, 34]. Furthermore, a recent meta-analysis including over 80 studies comparing transpapillary, EUS-guided, and percutaneous drainage found EUS-GBD to have better clinical success, with comparable adverse events between all groups [35].

Choledocholithiasis

Choledocholithiasis, or bile duct stones, generally results from migration of gallstones from the gallbladder into the biliary tree [36]. Less commonly, stones may develop de novo within the CBD. Small bile duct stones may spontaneously pass through the ampulla of Vater and into the duodenum which may cause intermittent symptoms or may result in no clinical symptoms at all. Symptomatic choledocholithiasis typically manifests with characteristic biliary pain with elevated liver enzymes. More serious sequelae of choledocholithiasis include obstruction of bile duct drainage leading to cholangitis and irritation of the pancreatic duct orifice leading to biliary pancreatitis. Choledocholithiasis is typically managed with endoscopic stone extraction, followed by interval cholecystectomy.

Among those with symptomatic cholelithiasis or acute cholecystitis, 10–20% have concomitant choledocholithiasis [37, 38]. The evaluation and management strategy differs depending on the pretest probability of bile duct stones (Table 26.1). The available data clearly support that patients at high risk for choledocholithiasis should undergo ERCP prior to cholecystectomy, while patients at low risk should proceed directly to cholecystectomy. Patients at intermediate risk should be referred for either EUS, magnetic resonance cholangiopancreatography (MRCP), or intraoperative cholangiography (IOC) [39]. All three of these modalities have high sensitivity and specificity for choledocholithiasis and can identify patients in need of endoscopic therapy, with the choice between them often based on local expertise and availability of resources.

ERCP is the first-line therapeutic modality for choledocholithiasis. Endoscopic sphincterotomy

Table 26.1 ASGE risk stratification of choledocholithiasis

Probability	Predictors of choledocholithiasis	Recommended management
High	1. CBD stone visualized on ultrasound or cross-sectional imaging or 2. Total bilirubin >4 mg/dL *and* dilated CBD (>6 or >8 mm in patients who have undergone cholecystectomy) or 3. Ascending cholangitis	ERCP
Intermediate	1. Abnormal liver biochemical tests or 2. Age >55 or 3. Dilated CBD	EUS vs MRCP
Low	None of the above	Cholecystectomy

ASGE Standards of Practice Committee, Buxbaum JL, Abbas Fehmi SM, et al. ASGE guideline on the role of endoscopy in the evaluation and management of choledocholithiasis. Gastrointest Endosc. 2019;89(7):1075–1105.e15 with stone extraction is successful in more than 90% of cases, with an overall adverse event rate of approximately 5%. Adverse events of ERCP of include pancreatitis (2–10%), bleeding (2%), perforation (<1%), and cholangitis (<1%) [40]. During this procedure, a duodenoscope is passed into the second portion of the duodenum where the ampulla can be identified. Selective bile duct cannulation is achieved using a catheter or sphincterotome. Contrast is then injected under fluoroscopy for cholangiography, allowing for delineation of biliary anatomy and identification of stones. A biliary sphincterotomy is performed using electrocautery. This small incision through the sphincter of Oddi enlarges the papillary opening permitting easier stone removal. Stones can then be extracted from the duct using a stone extraction balloon or a wire basket (Fig. 26.3a, b). An alternative technique to endoscopic sphincterotomy is balloon dilation of the intact biliary sphincter (endoscopic balloon sphincteroplasty) to enlarge the biliary orifice using hydrostatic dilating balloons (up to 10 mm). This approach may be best suited for removal of bile duct stones in patients at high risk for post-sphincterotomy bleeding (i.e., routine antithrombotic use) or those with unfavorable or surgically-altered anatomy which may preclude sphincterotomy [41, 42]. While historical data have suggested a higher rate of post-ERCP pancreatitis with endoscopic papillary balloon dilation, this risk appears to be mitigated with the use of larger balloons (>12 mm) held for longer duration (>30 s) [42, 43].

For larger stones (>1 cm), a partial sphincterotomy may be combined with large papillary balloon dilation, using a larger hydrostatic dilating balloon (12–20 mm) to further distend the ampullary orifice (Fig. 26.4) [44]. Alternatively, the stones may need to be fragmented using mechanical or intraductal lithotripsy. During mechanical lithotripsy, a wire basket is used to capture and crush the stone using mechanical force (Fig. 26.5) [45]. Intraductal electrohydraulic or laser lithotripsy can be performed using a cholangioscope, either passed through a duodenoscope into the bile duct (mother-baby system) or by transoral passage of a dedicated small caliber endoscope (direct peroral cholangioscope). An electrohydraulic probe (oscillating shock waves) or pulsed laser (beam of energy) is directed at the stones leading to fragmentation (Fig. 26.6). Fragment clearance can then be performed with standard stone extraction methods. Rarely, extracorporeal shock wave lithotripsy (ESWL) can be used as a last resort [46]. If complete stone removal is not

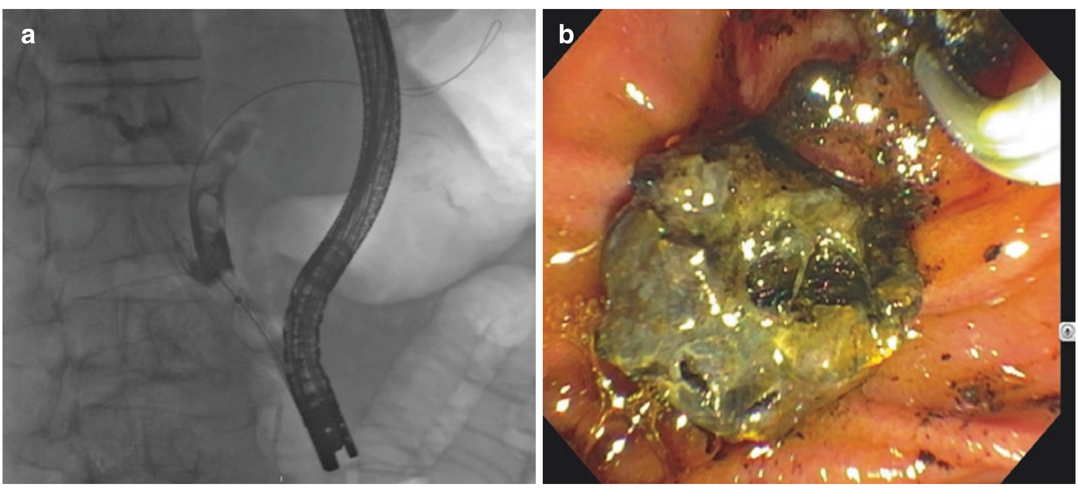


Fig. 26.3 Choledocholithiasis. (**a**) An occlusion cholangiogram demonstrating a large common hepatic duct stone with smaller stones noted in the right and left hepatic ducts. (**b**) Removal of a large bile duct stone into the duodenal lumen using a balloon extraction technique

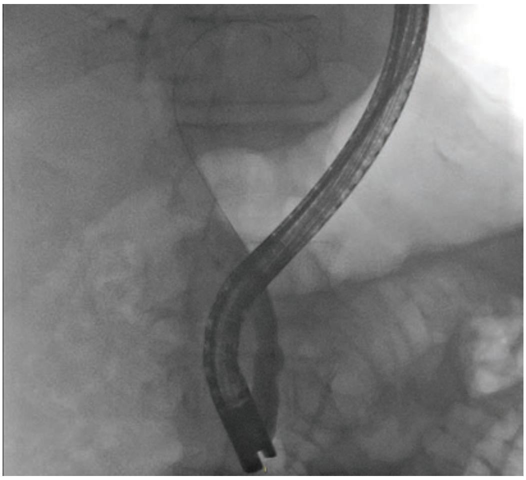


Fig. 26.4 Endoscopic large papillary balloon dilation. Fluoroscopic image of a large (>10 mm) dilating balloon is used to dilate the papillary orifice to aid in extraction of larger common bile duct stones

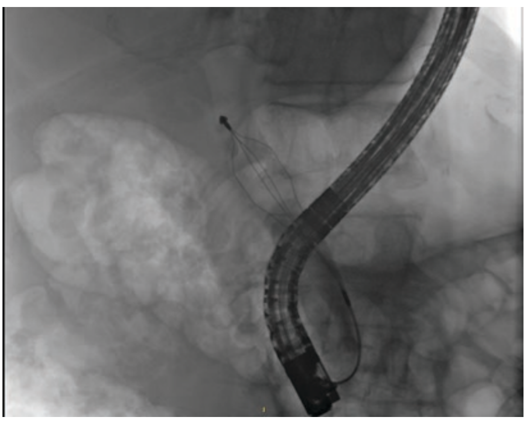


Fig. 26.5 Mechanical lithotripsy. The mechanical lithotripter can be passed into the common bile duct. The lithotripter basket is opened and the basket is used to ensnare large stones. After stones are ensnared, the basket is gradually closed until stones are crushed or fragmented

achieved, a plastic or covered-metal biliary stent should be placed to maintain biliary drainage until repeat ERCP is performed [47].

Interval cholecystectomy should be performed in the vast majority of patients following stone clearance, given the high rate (20%) of recurrent symptoms including cholecystitis, pancreatitis, and recurrent choledocholithiasis [48, 49].

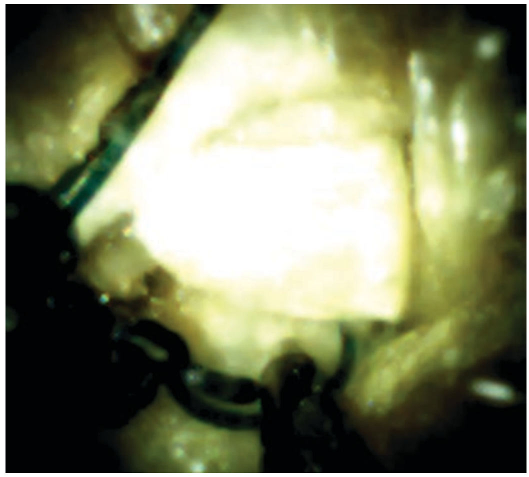


Fig. 26.6 Electrohydraulic lithotripsy. Cholangioscopic images demonstrating intraductal electrohydraulic lithotripsy to fracture a large common bile duct stones which was not amenable to retrieval using conventional methods. Surgical suture can be visualized which served as a nidus for stone formation

Cholangitis

Acute cholangitis, or infection in the bile duct, occurs when biliary obstruction results in cholestasis and infection (Fig. 26.7). This is most often secondary to a bile duct stone, but can also occur in the setting of malignancy, prior biliary instrumentation, biliary strictures secondary to surgery or chronic pancreatitis, or other infectious or auto-immune cholangiopathies [50]. Cholangitis classically presents with Charcot's triad [51], consisting of fever, right upper quadrant pain, and jaundice, or Reynold's pentad [52] (hypotension and altered mentation) if the patient is in shock. Historically, cholangitis carried a high mortality rate, particularly in the elderly [53]. In addition to antibiotics, timely biliary drainage is the cornerstone in management. Endoscopic transpapillary biliary drainage via ERCP is currently the standard of care, with success rates of >90–95% [54]. Reasons for failure of conventional ERCP include ampullary pathology (adenoma/carcinoma), periampullary diverticulum, gastric outlet or duodenal obstruction, or variant anatomy (e.g., Roux-ex-Y) [55]. When ERCP cannot be completed, alternative

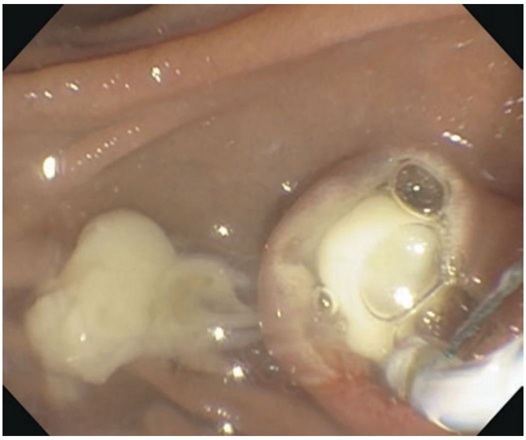


Fig. 26.7 Cholangitis. Pus emanating from the major papilla following endoscopic sphincterotomy

approaches include percutaneous transhepatic biliary drainage (PTBD), or EUS-guided biliary drainage [56].

Endoscopic Transpapillary Biliary Drainage

As noted above, endoscopic transpapillary biliary drainage is first line in the management of cholangitis [40]. ERCP performed within 48 h of presentation is associated with improved outcomes [57]. Patients with overt sepsis and frail, elderly patients who may decompensate quickly should undergo ERCP as soon as it is clinically safe to do so. The technical aspects of the procedure are identical to those used for choledocholithiasis. The primary goal is to establish biliary drainage. In patients with cholangitis secondary to choledocholithiasis, sphincterotomy and stone/sludge extraction are generally sufficient to provide adequate biliary drainage, with stent placement reserved for cases where the stone cannot be easily removed or the patient is too ill to undergo a prolonged procedure. Similarly, in patients with obstruction due to benign or malignant strictures, biliary stent placement with or without stricture dilation is generally needed to provide adequate drainage. The one exception to this approach is in patients with primary sclerosing cholangitis (PSC), whereby stent placement is avoided if possible, with focus on stricture dilation and stone removal to promote biliary drainage.

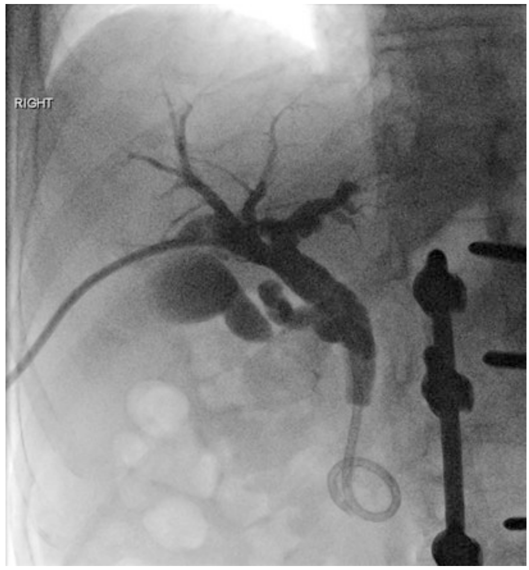


Fig. 26.8 Percutaneous transhepatic biliary drainage. A percutaneous cholangiogram obtained by contrast injection of an internal-external biliary drain

Percutaneous Transhepatic Biliary Drainage (PTBD)

Percutaneous bile duct access was first described in 1937 [58], and ultimately refined for routine clinical use in the 1980s with the advent of specially-designed needle catheters. The technique involves ultrasound-guided identification and percutaneous puncture of an intrahepatic bile duct using an 18–22-gauge needle. After confirming backflow of bile, a guidewire is advanced through the needle into the bile duct. Using fluoroscopic guidance, a 7–10 Fr catheter is advanced into the bile duct over the guidewire. If the guidewire can be passed into the duodenum, the catheter may provide both internal (into duodenal lumen) and external biliary drainage (into external bag) (Fig. 26.8). If the wire cannot reach the duodenum (e.g., obstructed by a stone or stricture), the catheter can be left in the bile duct, facilitating external drainage only.

PTBD has a high success rate (>90%) and can be done without general anesthesia. PTBD is often used to access to the biliary tree when endoscopic approaches are unsuccessful. Similar to percutaneous cholecystostomy, one major disadvantage is the need for an external catheter which may require frequent catheter exchanges and can be associated with catheter dislodgement, patient discomfort, and impaired quality of life [59]. Additional adverse events include sepsis (2.5%), bleeding (2.5%), inflammation/infection (1.2%—including abscess, peritonitis, cholecystitis, pancreatitis), and pneumothorax (0.5%) [60].

EUS-Guided Biliary Drainage

First described in 2001 by Giovannini et al. [61], endoscopic ultrasound-guided biliary drainage (EUS-BD) is a minimally invasive endoscopic option, increasingly offered as an alternative to PTBD for biliary decompression when conventional ERCP fails. In comparison with PTBD, a recent meta-analysis found that EUS-BD had better clinical success, fewer adverse events, and a lower rate of re-intervention [62]. EUS-BD has evolved over the last 20 years and encompasses three main techniques: EUS-guided biliary rendezvous (Fig. 26.9a–d), EUS-guided choledochoduodenostomy (extrahepatic bile duct drainage), and EUS-guided hepaticogastrostomy (intrahepatic bile duct drainage).

To perform EUS-guided biliary rendezvous (EUS-RV), the echoendoscope is advanced to either the duodenum to puncture the extrahepatic

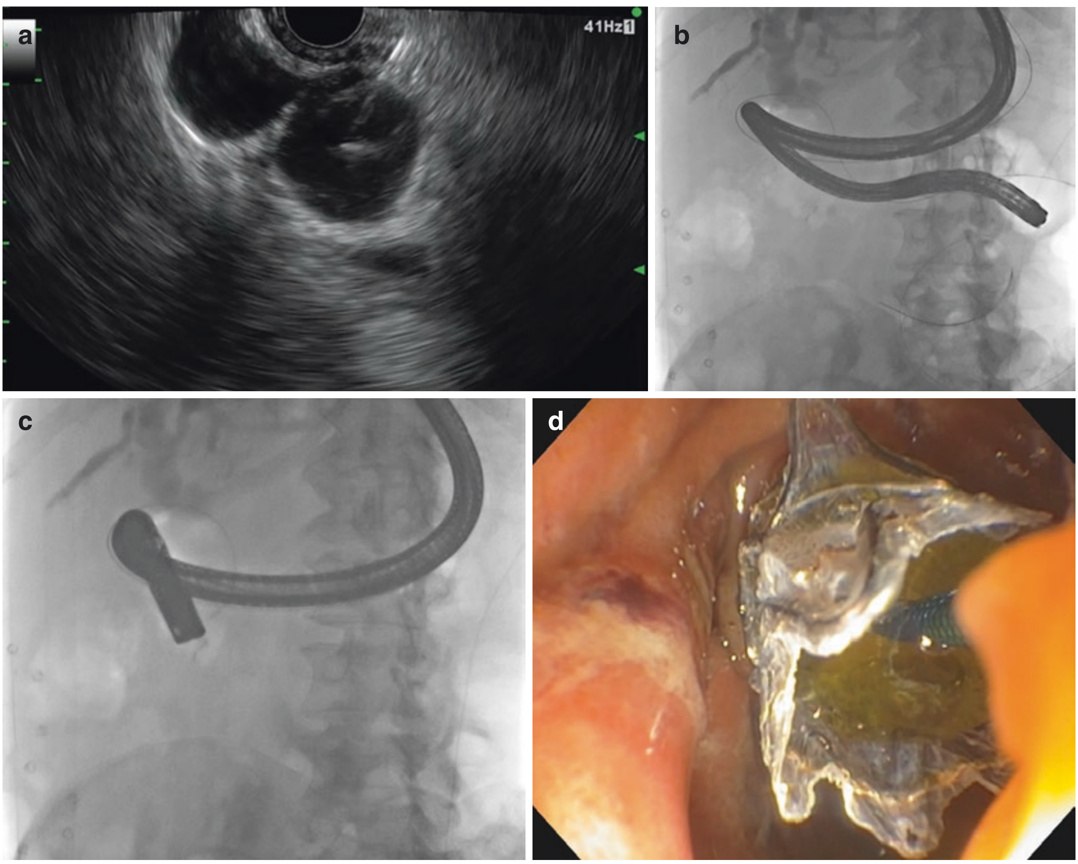


Fig. 26.9 EUS-guided biliary rendezvous procedure. (**a**) The bile duct is identified and punctured under EUS-guidance. Following access, a cholangiogram can be obtained and a guidewire is passed antegrade into the distal bile duct, through the major papilla and ultimately coiled in the duodenum. (**b**) The echoendoscope is exchanged for a duodenoscope. The duodenoscope is passed into the small bowel and the guidewire is located. (**c**) The guidewire is grasped and retrieved through the working channel of the duodenoscope allowing for conventional retrograde interventions. (**d**) Retrograde placement of a fully covered self-expandable metal stent across a benign distal bile duct stricture using the rendezvous technique

biliary duct, or the stomach to puncture a left intrahepatic bile duct. After confirmation of access (i.e., bile aspiration and contrast injection), a guidewire is passed through the EUS-FNA needle into the biliary system with the goal of traversing the ampulla and coiling in the duodenum. Following placement of the "rendezvous" guidewire, the echoendoscope is removed leaving the guidewire in place. A duodenoscope is then passed transorally in parallel to the guidewire and into position within the second portion of the duodenum. The bile duct may then be cannulated alongside the "rendezvous" guidewire, or the guidewire can be grasped and withdrawn through the working channel of the duodenoscope to allow for device/accessory passage over the grasped "rendezvous" guidewire [63].

For EUS-guided choledochoduodenostomy (EUS-CDS), the echoendoscope is positioned in the duodenal bulb and the CBD is punctured with an EUS-FNA needle. After confirmation of needle location, the tract between the duodenum and extrahepatic bile duct is dilated using mechanical dilation (i.e., rigid graduated dilating catheters, dilation balloon) or electrocautery (i.e., electrocautery enhanced LAMS, cystotome) or a combination of the two modalities. Finally, a FCSEMS or LAMS, depending on the chosen approach, is placed to create an anastomosis between the CBD and the duodenum.

For EUS-guided hepaticogastrostomy (EUS-HGS), the echoendoscope is positioned in the stomach to identify a left intrahepatic biliary radicle. An EUS-FNA needle is then used to puncture the bile duct, aspirate bile to confirm location, and inject contrast to obtain a cholangiogram. Similar to choledochoduodenostomy, the tract is dilated using a variety of devices, dependent on the endoscopist's preference. A FCSEMS is placed across the tract, generally not less than 8 cm in length, with the distal flange in the left hepatic duct and the proximal flange in the gastric lumen. Often a plastic double-pigtail stent may be placed to straighten the stent and prevent stent migration/separation of the tract. This EUS-guided approach allows for immediate or future antegrade therapies using conventional ERCP techniques (i.e., balloon dilation or FCSEMS placement across a distal bile duct stricture, stone fragmentation with lithotripsy devices followed by stone removal, etc.). Uncommonly, antegrade therapies may be performed without formal creation of a hepaticogastrostomy tract. This less common technique involves passage of a guidewire into the biliary system followed by over-the-guidewire tract dilation using a rigid graduated catheter or balloon dilator. Antegrade therapy, most commonly a FCSEMS across a distal bile duct stricture, can then be performed without creation of an anastomosis. This idea relies on the premise that bile will flow in the path of least resistance (i.e., through the bile duct stent) and not out the site of puncture/access [64]. The technical success rate for the EUS-antegrade approach (77%) is less than other EUS-guided biliary drainage (EUS-BD) techniques, owing to the difficulty of guidewire passage and stent delivery from an intrahepatic access site to traverse an area of obstruction [56].

Lastly, and less commonly, EUS-guided gallbladder drainage (cholecystoenterostomy) can be used to decompress the biliary system, assuming the cystic duct is patent and above the level of obstruction [65]. This approach is as described above for the non-surgical management of acute cholecystitis. When this technique is used for biliary drainage, it is often in the setting of malignant distal bile duct obstruction with failed ERCP [66].

The cumulative technical success rate of EUS-BD has been reported around 90–95%, with a clinical success rate of 90–95%, and adverse event rate of 15–23% [67, 68]. Adverse events include bleeding (4%), bile leak (4%), pneumoperitoneum (3%), stent migration (2.7%), and cholangitis (2.4%). In terms of comparing the EUS-BD methods, EUS-CDS and EUS-HGS have been found to have equal efficacy and safety, with nearly identical technical success rates [69]. These methods are generally superior to EUS-RV, which has an overall success rate of 80% and adverse event rate of 15% [63]. In the context of currently available literature, there is no optimal EUS-BD approach. Rather, the endoscopist must factor in the clinical circumstance and individual anatomy (e.g., level of obstruction, degree of duct dilation, surgical alteration) as well as the goals of the procedure when choosing the appropriate EUS-BD therapy [70].

Biliary Access in Surgically-Altered Anatomy

Surgically-altered gastrointestinal anatomy may result in anatomic changes that make endoscopic access to the biliary tree technically difficult or impossible. These include gastric resections (e.g., Billroth II gastrectomy), bypass procedures or weight loss operations (e.g., Roux-en-Y gastric bypass [RYGB], loop gastrojejunostomy, duodenal switch with biliopancreatic diversion), pancreatic resections (e.g., Whipple pancreaticoduodenectomy), or biliary drainage surgeries (e.g., Roux-en-Y hepaticojejunostomy or choledochojejunostomy). Depending on the length of the Roux limb in resection surgeries, a duodenoscope or forward-viewing endoscope may be able to reach the major papilla to allow for "conventional" ERCP. However, in patients with RYGB anatomy or a long Roux limb, this is usually not feasible. There are three major endoscopic approaches for biliary interventions in patients with surgically-altered anatomy when conventional accessories cannot be utilized: (1) device-assisted enteroscopy ERCP, (2) laparoscopic-assisted ERCP, and (3) EUS-directed transgastric ERCP.

Device-assisted or "deep" enteroscopy permits advancement of an endoscope deep into the small bowel by "telescoping" the small-bowel over an overtube to bring the target closer, rather than relying on forward propulsion [71]. Devices used in practice include the single-balloon enteroscope, double-balloon enteroscope, and spiral enteroscope. In the context of Roux-en-Y anatomy, the enteroscope must traverse the Roux limb and advance into the pancreaticobiliary limb in order to reach the biliary orifice, at which point ERCP can be performed. This approach has several limitations and has fallen out of favor at many institutions. First, the surgical anastomosis or major papilla may not be reachable. Second, the enteroscope—which is not designed for ERCP—is forward-viewing, lacks an elevator, and is more difficult to maneuver in the region of the papilla, all of which make biliary cannulation technically challenging. Furthermore, accessories for therapeutic interventions are limited because of the long length (200 cm) and small-diameter working channel of the enteroscopes. The success rate varies widely in the literature, with technical success rate ranging from 60–70% at best [72, 73].

Laparoscopic-assisted ERCP requires a surgeon to access the excluded gastric remnant laparoscopically followed by placement of a 15-mm laparoscopic port. The duodenoscope can then be passed through the port and into position for conventional ERCP. Following ERCP, surgical closure of the gastrostomy is performed; however, if repeat ERCP will be required (e.g., removal of stents, stone removal, etc.), a gastrostomy tube can be placed through the tract to maintain patency. Tract dilation may be needed prior to subsequent ERCP to allow scope passage. A major advantage of this approach is that it allows for concomitant cholecystectomy in the same operation. Very high rates of technical success, nearing 100%, have been reported [74]. The most significant limitation of the laparoscopic approach is the need to coordinate logistics between surgical and gastroenterological teams to perform a combined procedure [75].

Most recently, EUS-guided approaches have been described with equally high success rates. One method, EUS-directed transgastric ERCP (EDGE), involves the creation of a gastrogastrostomy between the gastric pouch and gastric remnant in patients with RYGB (Fig. 26.10a–d). To perform this procedure, the gastric remnant is located endosonographically from either the gastric pouch or the blind jejunal pouch of the Roux limb. A 19-gauge needle is used to puncture the gastric remnant, which is then filled with dilute contrast and a coloring agent. Following instillation of ~500 cc of dilute contrast, the gastric remnant is adequately distended and can serve as an endosonographic target. A LAMS is then deployed

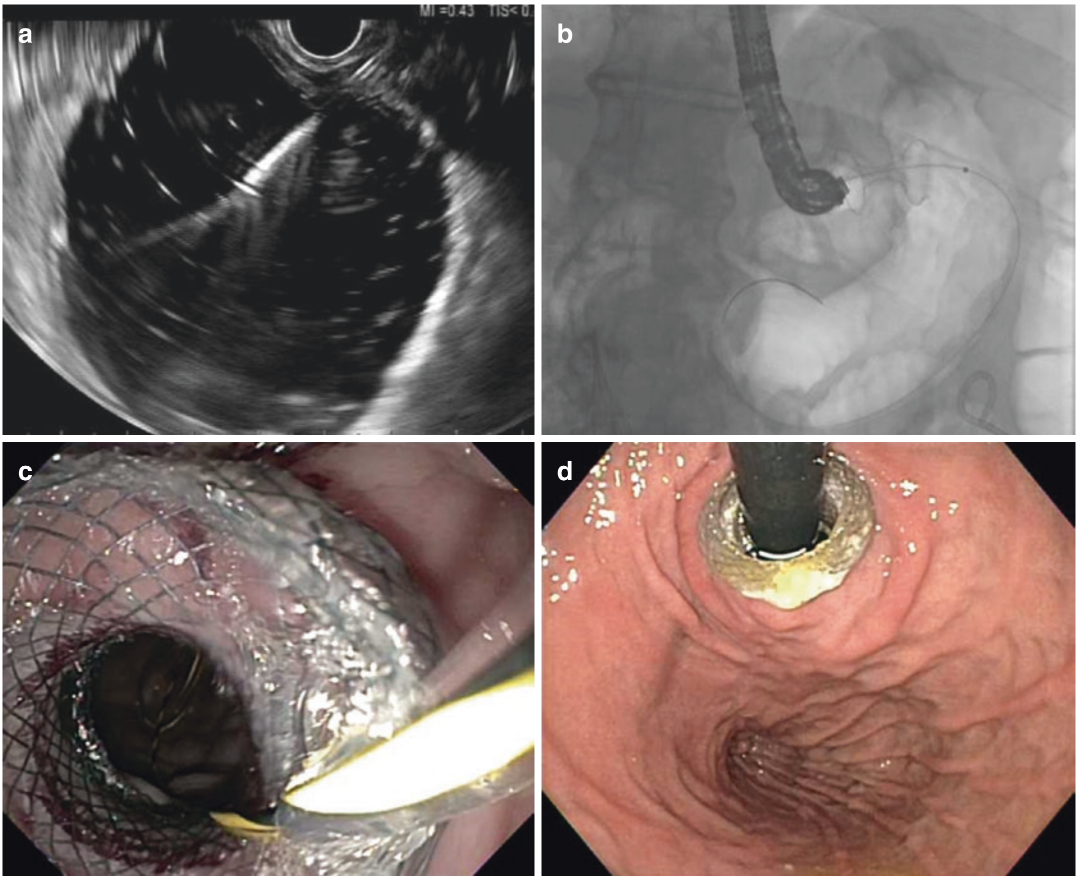


Fig. 26.10 EUS-direct transgastric ERCP (EDGE) procedure. (**a**) The excluded gastric remnant is identified endosonographically and is punctured using a 19-g FNA needle. Dilute contrast is instilled to distend the gastric remnant. (**b**) Fluoroscopic image immediately after deployment of the lumen-apposing metal stent creating the gastrogastric anastomosis. (**c**) Endoscopic confirmation of transgastric access following balloon dilation of the stent lumen. The mucosa of the gastric remnant can be visualized through the stent lumen after dilation. (**d**) Passage of the duodenoscope through the lumen-apposing metal stent to perform conventional ERCP

into the gastric remnant using a cautery-enhanced catheter, either over a guidewire or using a freehand technique, thereby creating a gastrogastric or jejunogastric anastomosis. Subsequently, the LAMS can then be balloon dilated to allow for passage of the duodenoscope into the gastric remnant to complete ERCP during the same session. Alternatively, in stable patients, ERCP can be deferred to a later date (i.e., minimum 2 weeks) to allow tract maturation. It should be noted that the single-session approach carries an increased risk of stent dislodgement during duodenoscope passage [76]. Once interventions are complete, the LAMS is removed at a subsequent procedure, and the tract can be closed via endoscopic suturing or placement of an over-the-scope clip, or left to close without endoscopic closure. Procedural success rates with EDGE are >95% [73, 77]. Serious adverse events occur rarely in expert hands, and include stent migration, perforation, bleeding, and chronic fistulization with risk of weight regain. EDGE is becoming the preferred procedure at centers with expertise in therapeutic EUS and ERCP, as it confers many advantages including high success rates, low rates of serious adverse events, cost-effectiveness, and the ability to use a standard duodenoscope and accessories [78–80].

An alternative EUS-guided approach is EUS-HGS, as described above. Therapeutic interventions can be performed in an antegrade fashion as necessary (i.e., stricture dilation and stent placement, stone removal, etc.). Similar to EDGE, interventions can be performed during the index procedure or in subsequent staged procedures. Recent studies have reported success rates over 90% with an acceptable adverse event rate [81, 82]; however, this approach is limited by the need for a sufficiently dilated intrahepatic duct and the availability of technical expertise.

Finally, percutaneous transhepatic biliary drainage (PTBD), as described above, is also an option; however, this approach requires an external drainage catheter and is associated with the limitations previously mentioned. Ultimately, the procedural approach depends on the clinical scenario and local expertise.

Section 2: Bile Leaks and Bile Duct Injury

Introduction

Bile duct injury (BDI) is a rare and dreaded adverse event of cholecystectomy, which is associated with significant morbidity and mortality. While the incidence of BDI has increased in the laparoscopic era, it remains low at approximately 0.5%, ranging in severity from minor bile leaks to complete bile duct transection [83, 84]. While the majority of BDIs can be treated with endoscopic interventions, some require surgical repair. Prompt recognition of BDI and involvement of a multidisciplinary team including hepatobiliary surgeons, interventional endoscopists, and interventional radiologists is essential to optimize outcomes [85]. In terms of endoscopic management, the most important factor is whether or not there is continuity of the injured bile duct with the CBD. While various classification schemata have been proposed to guide management decisions (Fig. 26.11a–c), the Strasberg system remains the most popular and widely used (Table 26.2) [86].

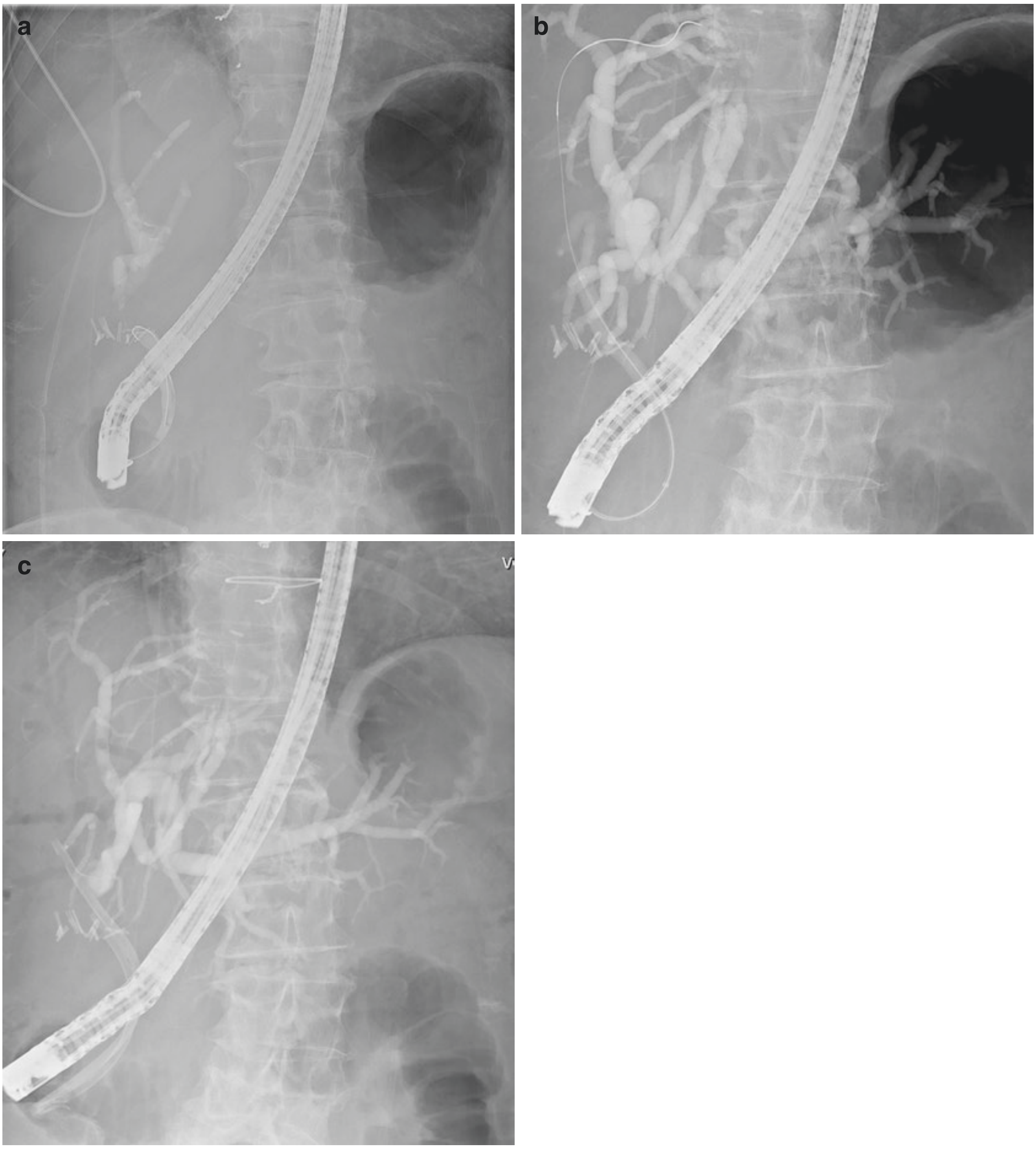
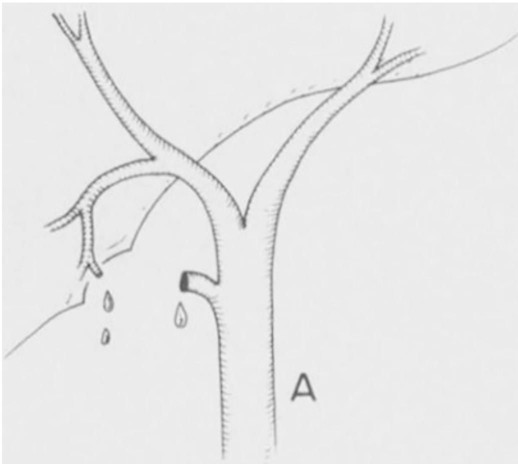
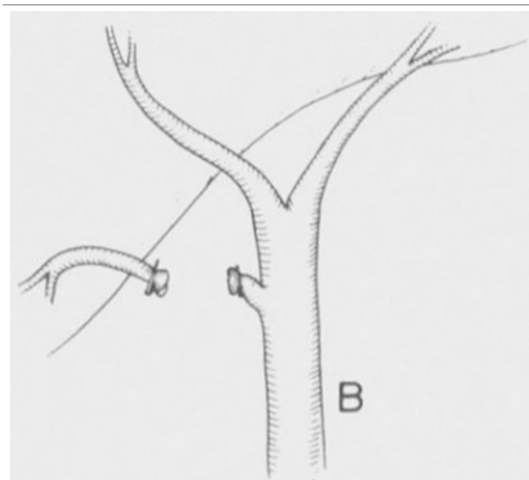
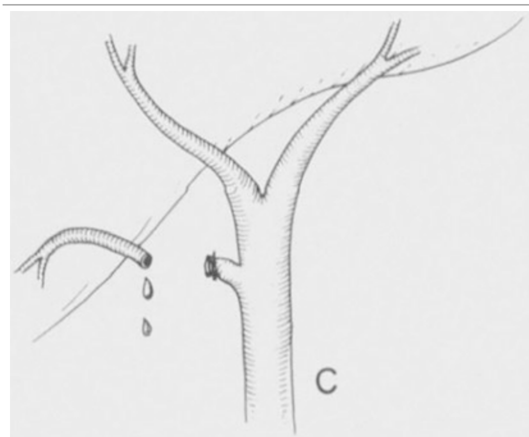


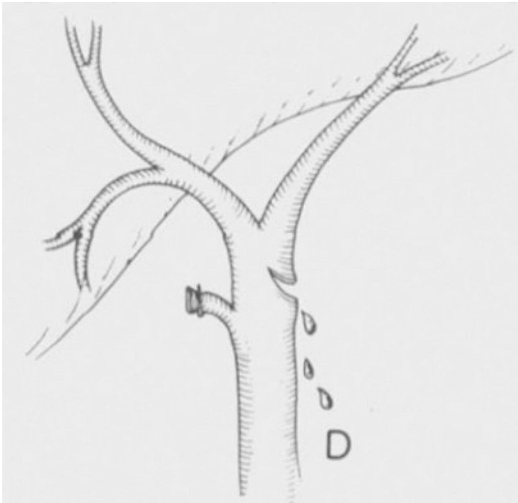
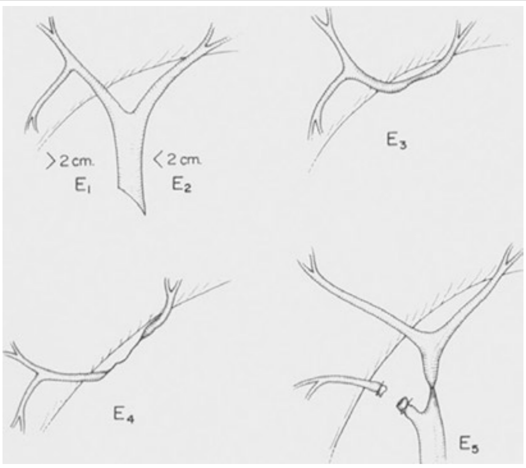
Fig. 26.11 Near-complete bile duct transection. (**a**) Cholangiography demonstrating near-complete clip transection of the common bile duct at the level of the cystic duct insertion. No contrast extravasation is seen and the common hepatic duct and intrahepatics opacify suggesting partial connection to the distal common bile duct. (**b**) Balloon dilation across the site of clip transection. (**c**) Placement of two plastic common bile duct stents to recanalize the bile duct thus promoting antegrade bile drainage and prevent the need for surgical intervention

Table 26.2 Strasberg classification of bile duct injury

Strasberg classification	Definition	Frequency	Treatment
	Leak from the cystic duct or duct of Luschka	45–85% 75% from cystic duct stump 10% from the ducts of Luschka	ERCP
	Ligated sectoral duct	1%	Communication with CBD branches: ERCP No communication with CBD branches: Surgery
	Leak from non-ligated sectoral duct	1%	Communication with CBD branches: ERCP No communication with CBD branches: Surgery

(continued)

Table 26.2 (continued)

Strasberg classification	Definition	Frequency	Treatment
	Side wall injury to the common hepatic duct or CBD	2%	ERCP is the preferred therapy unless there is a significant loss of duct warranting surgical intervention
	Complete bile duct transection or circumferential (>50% of circumference) injury of larger bile duct) E1: Injury >2 cm from junction of the right and left hepatic duct E2: Injury <2 cm from junction of the right and left hepatic duct E3: Stenosis or section at junction of right and left hepatic ducts E4: Stenosis or section A E5: Type C injury plus injury of the main bile duct below the junction of the hepatic ducts	E: 15–49% E1: 15% E2: 18% E3: 7% E4: 8% E5: 1%	Generally surgery, unless continuity is maintained

Strasberg SM, Hertl M, Soper NJ. An analysis of the problem of biliary injury during laparoscopic cholecystectomy. J Am Coll Surg. 1995;180(1):101–125; Pitt HA, Sherman S, Johnson MS, Hollenbeck AN, Lee J, Daum MR, Lillemoe KD, Lehman GA. Improved outcomes of bile duct injuries in the 21st century. Ann Surg. 2013 Sep;258(4):490–9; Abbas A, Sethi S, Brady P, Taunk P. Endoscopic management of postcholecystectomy biliary leak: When and how? A nationwide study. Gastrointest Endosc. 2019 Aug;90(2):233–241

Bile Leak

The majority of biliary leaks are not detected during surgery, with patients typically presenting post-operatively within the first 2 weeks. Typical signs and symptoms include abdominal pain, distention, fever, and jaundice [87, 88]. Patients may be prone to clinical deterioration due to peritonitis and sepsis. While ultrasound or CT scan may depict fluid collections and/or other suggestive findings, these imaging modalities may be unable to identify leaks. Cholescintigraphy (HIDA) has a high accuracy for the detection of bile leaks; however, its utility for locating the site of ductal injury and thus planning treatment is limited by poor spatial resolution. MRCP is the best non-invasive imaging modality as it provides excellent delineation of the biliary anatomy. Cross-sectional imaging can also be helpful in identifying associated vascular injury.

ERCP has become both the preferred diagnostic and treatment modality for clinically significant post-cholecystectomy bile leaks (Fig. 26.12a, b). It can characterize the site of the leak in >95% of cases and leads to effective healing in >90% of cases [89]. Bile leaks may be classified into two grades based on cholangiography. If extravasation is detected *prior* to filling of the intrahepatic ducts, it is classified as high-grade; if the leak is detected *after* filling of the intrahepatic ducts, it is deemed low grade [88].

The goal of therapy is to eliminate the transpapillary pressure gradient, thereby promoting preferential flow of bile into the duodenum and allowing the leak site to heal [90]. This can be achieved through a variety of endoscopic techniques, of which biliary sphincterotomy, biliary stenting, or a combination of both techniques are most commonly used [40]. A recent retrospective review of over 1000 patients suggested that stent

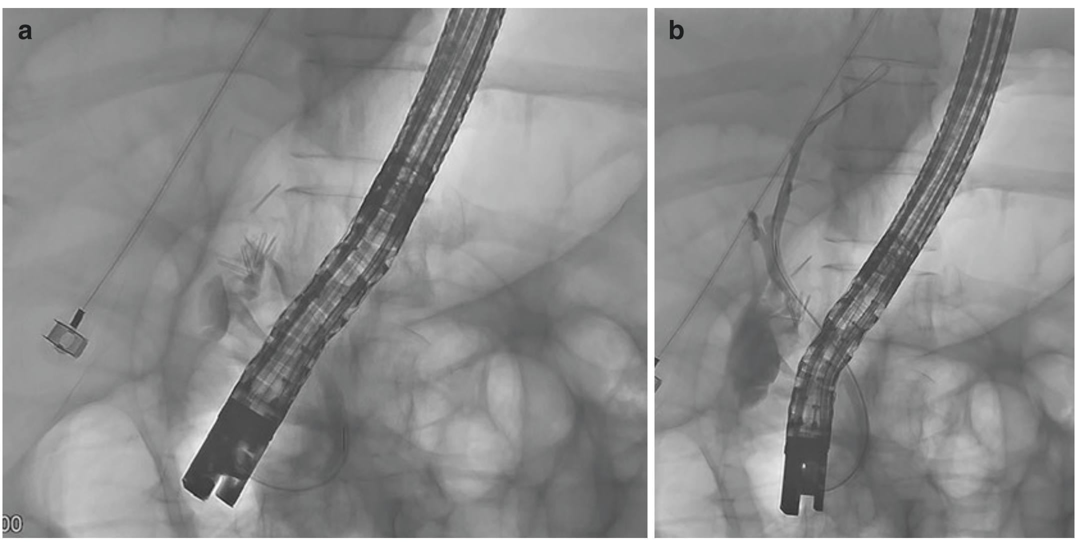


Fig. 26.12 Postcholecystectomy bile leak. (**a**) Extravasation of contrast at the cystic duct stump following cholecystectomy. (**b**) The common hepatic duct and intrahepatics can only be opacified with contrast with injection above the leak site, consistent with a high-grade bile leak

placement alone (failure rate 4%) or combination therapy (failure rate 3%) were superior to sphincterotomy alone (failure rate 11%) [91].

In clinical practice, most endoscopists perform sphincterotomy with placement of a short (i.e., <7 cm) 10 Fr plastic stent. This approach can be applied to most bile leaks. In cases where there is a leak from a branch of the hepatic duct, placement of a longer and possibly smaller caliber stent which traverses the leak site should be considered. Placement of a FCSEMS should be considered for high-grade leaks or leaks secondary to large disruption of the CBD wall [92]. Data are limited regarding the optimal approach, and thus, the choice of endoscopic intervention is often made based on several factors, such as location and grade of the leak, presence of concomitant bile duct stones, and individualized patient considerations (i.e., use of antithrombotic agents, etc.).

Stents are left in place for approximately 4–6 weeks, at which point ERCP is repeated to remove the stent and determine if the leak has resolved. Of note, if a percutaneous drain was placed as part of management of the bile leak, the drain should be removed, or the output should be <10 mL/day, prior to biliary stent removal. In cases of refractory bile leak (i.e., persistent leak on cholangiography or persistent high output percutaneous drainage), rescue endoscopic options include the following: placement of a stent which bridges the leak site, placement of multiple plastic stents, or placement of a FCSEMS, with data suggesting that FCSEMS are superior [92–94].

In the setting of complete transection of the bile duct (Strasberg E), the treatment of choice has traditionally been surgical hepaticojejunostomy, given biliary discontinuity. However, in select cases, recanalization of the bile duct may be feasible with a percutaneous-endoscopic rendezvous procedure [95]. A recent retrospective review of 47 patients undergoing this rendezvous procedure found a primary success rate of 94%, with procedure-related adverse events occurring in 18% of patients, none of which were life-threatening. Rendezvous was the final successful treatment in 55% and served as a bridge to surgery in 30% [96].

Biloma

A bile leak may result in the formation of a biloma. While the majority of bilomas will resolve spontaneously, up to 20% will require drainage due to clinically significant symptoms such as abdominal pain, nausea, vomiting, gastric outlet obstruction, or abscess formation [86]. Percutaneous drainage remains the treatment of choice for most patients [97]; however, if the biloma is close to the gastric or duodenal wall, it may be drained via EUS-guided drainage [98].

Biliary Stricture

Post-operative injuries can result in biliary strictures, which often present much later than biliary leaks (median of 2 months). This delayed presentation is usually a result of ischemic injury with resultant fibrosis [99]. Patients typically present with signs of biliary obstruction, namely jaundice, cholestatic liver biochemistries, and biliary dilation on imaging.

Endoscopic treatment involves stricture dilation and serial placement of multiple plastic stents until stricture resolution (often over 12 months), with exchanges approximately every 3 months [100–102]. Alternatively, FCSEMS appear to have excellent efficacy and require less frequent exchanges (Fig. 26.13a, b) [91]. When using FCSEMS, the stent should be left in place

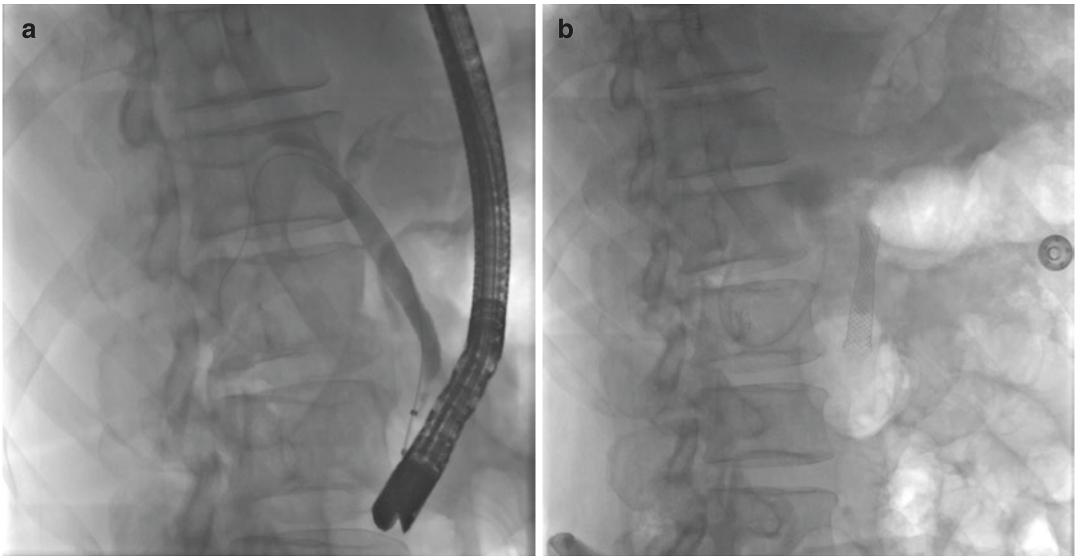


Fig. 26.13 Distal common bile duct stricture. (**a**) Cholangiogram images showing a refractory distal common bile duct stricture in the setting of chronic pancreatitis. (**b**) Placement of a fully covered self-expandable metal stent into the distal bile duct

for a minimum of 3 months to treat the stricture. In rare cases, biliary strictures refractory to endoscopic therapy may require surgical biliary bypass.

Conclusion

Non-operative interventions are valuable tools in the management of biliary diseases and bile duct injuries. In patients unfit for surgery, endoscopic and/or percutaneous procedures may serve as primary treatment modalities or as a bridge to future surgical intervention. Recent advances in endoscopic tools and techniques, particularly EUS-guided interventions, have greatly enhanced the armamentarium. The increasing complexity of patients and therapies alike underscore the importance of multidisciplinary and team-based care.

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Biliary Access in Surgically-Altered Anatomy

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Bile Leaks and Bile Duct Injury

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