18 Endoluminal Therapy for Choledocholithiasis and Cholangitis

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Introduction

Choledocholithiasis is the presence of stones within the bile ducts. They can be classified into either primary, which develop de novo in the bile ducts, or secondary from the passage of gallstones from the gallbladder. About 85% of choledocholithiasis is secondary to passage of gallstones from the gallbladder into the common bile duct (CBD). Gallstones represent a failure to maintain a balance of biliary solutes (cholesterol, calcium salts, bile acids) leading to either cholesterol stones (70–80%) or pigment stones consisting of unconjugated bilirubin. The pigment stones are primarily black (20–30% of all stones) and are formed due to deposition of bilirubin as polymers of calcium bilirubinate. Brown pigment stones are formed due to bacterial infection or overgrowth from stasis leading to deconjugation of bilirubin and subsequent precipitation and represent about 30–90% of gallstones in Asian populations. The formation of primary stones in the CBD is mostly due to bile stasis from diseases such as benign biliary strictures, choledochal cysts, cystic fibrosis, or peri-ampullary diverticula (Fig. 18.1). Recurrent or persistent infections from primary sclerosing cholangitis or recurrent pyogenic cholangiohepatitis seen in the East Asian population (termed "oriental cholangitis") can also lead to intraductal stone formation as well [1].

Obstruction of the bile duct can lead to an infection of biliary tree (acute cholangitis), primarily by translocation of bacteria from the duodenum and rarely from the portal venous system [2]. In addition to an obstructing stone, other causes of biliary obstruction leading to

Fig. 18.1 Peri-ampullary diverticulum (arrows)

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R. Lim (ed.), *Multidisciplinary Approaches to Common Surgical Problems*,
https://doi.org/10.1007/978-3-030-12823-4_18

cholangitis may include biliary stricture, pancreatic head mass, or extrinsic compression on the bile duct (Mirizzi syndrome or bulky lymphadenopathy).

Clinical Presentation

The typical presentation of choledocholithiasis is usually biliary colic, where the patient reports epigastric and/or right upper quadrant (RUQ) abdominal pain. The pain radiates to the back and is associated with autonomic symptoms of nausea and non-bloody emesis that may resolve after 1–2 hours. Tenderness may or may not be elicited in the RUQ [1, 3, 4]. A typical cholestatic pattern is seen in the liver chemistries with elevation in alkaline phosphatase (ALP), gamma-glutamyl transferase (GGT), and bilirubin (conjugated predominant), far exceeding a rise in aspartate transaminase (AST) and alanine transaminase (ALT) [1, 5–7]. Charcot's triad is the combination of a fever (>100.4 °F), persistent RUQ pain, and clinical jaundice; and it raises the suspicion of acute cholangitis. Often there will be a significant elevation of ALP, GGT, and bilirubin (conjugated predominant) as well as elevation of the WBC and a leftward shift in the granulocytes in the setting of acute cholangitis. If underlying sepsis becomes severe with development of encephalopathy and hypotension, Reynaud's pentad for acute cholangitis is met, which reflects the severe and systemic manifestation of acute suppurative cholangitis [1, 8–10]. Rarely, AST and ALT can be elevated to >1000 when there is associated hepatocyte necrosis due to spread of infection into the liver parenchyma, leading to microabscesses [10]. In the setting of choledocholithiasis, patients may also develop pancreatitis due to obstruction of the pancreatic duct by a stone at the level of the ampulla, leading to elevation of lipase greater than three times the upper limit of normal as well as elevation of ALT greater than three times upper limit of normal [1, 10–13]. An ALT greater than three times the upper limit of normal is the most specific laboratory abnormality found in acute biliary pancreatitis [14].

Diagnosis

Ultrasound (US) of the abdomen is usually the first diagnostic study that is undertaken to assess the biliary tree and gallbladder, although it is operator-dependent and has varied sensitivity and specificity [15–17]. Based on the clinical presentation, laboratory data, and the transabdominal US, the American Society for Gastrointestinal Endoscopy (ASGE) has proposed a set of guidelines in 2010 to stratify the risk of a patient with symptomatic cholelithiasis of having choledocholithiasis and to determine the next step in management (Table 18.1) [18].

Based on the risk assessment, an algorithm for the management of symptomatic cholelithiasis with regard to the likelihood of choledocholithiasis has been proposed (Fig. 18.2, modified from Tse et al. [19]).

In regard to the choice of imaging, meta-analyses have found that endoscopic ultrasound (EUS) has a 94% sensitivity and a 95% specificity for detecting choledocholithiasis [13, 20, 21], while systematic reviews have shown that magnetic resonance cholangiopancreatography

Table 18.1 ASGE 2010 Guidelines in determining the likelihood for choledocholithiasis based on clinical, laboratory, and imaging predictors

Very strong predictors
CBD stone on transabdominal US Ascending cholangitis (Charcot's triad or Raynaud's pentad) Total bilirubin > 4 mg/dL
Strong predictors
CBD diameter > 6 mm on transabdominal US with GB in situ Total bilirubin 1.8–4 mg/dL
Moderate predictors
Abnormal liver chemistries (AST, ALT, ALP) other than bilirubin Age > 55 years Gallstone pancreatitis
High likelihood of choledocholithiasis
Any one very strong predictor Two strong predictors
Low likelihood of choledocholithiasis
No predictors
Intermediate likelihood of choledocholithiasis
All others

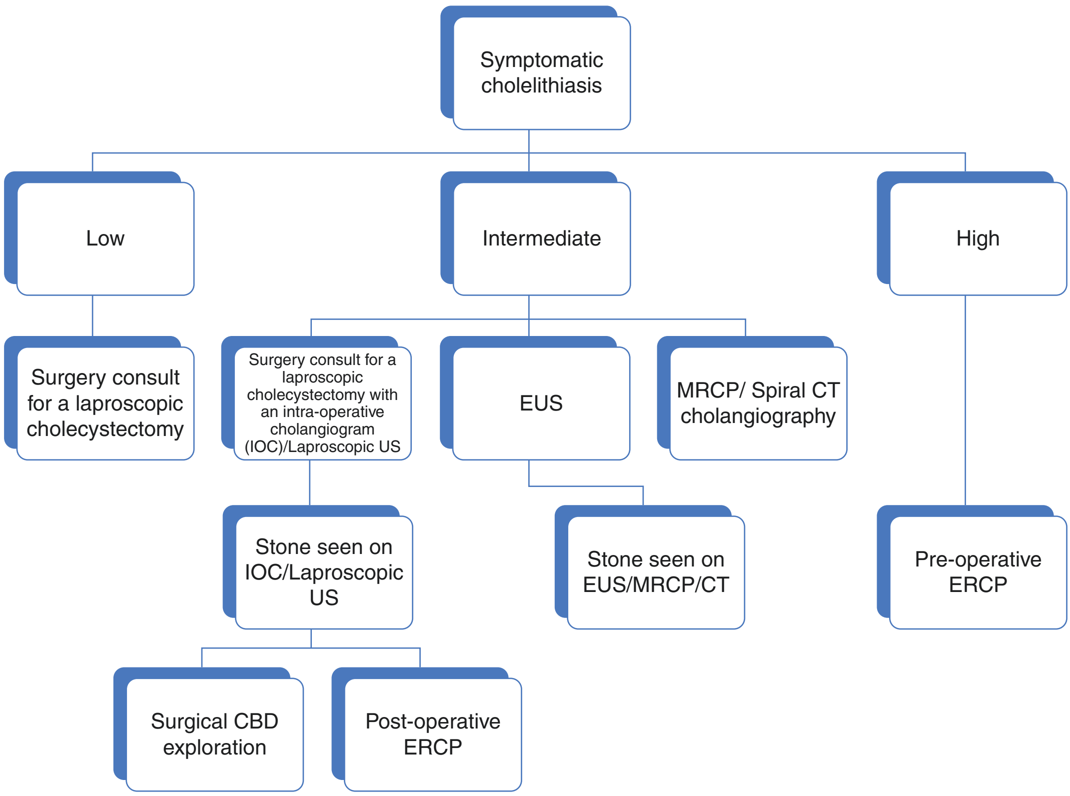

Fig. 18.2 Algorithm for the management of symptomatic cholelithiasis based on the likelihood of choledocholithiasis

(MRCP) has a 93% sensitivity and a 94% specificity [22]. Systematic reviews of studies comparing EUS and MRCP show no significant difference in the accuracy of the two modalities to detect choledocholithiasis [23–25]. However, the accuracy of MRCP to detect stones <6 mm in size may be slightly inferior [26].

EUS has the benefit of a subsequent endoscopic retrograde cholangiopancreatography (ERCP) in tandem during the same procedure, if a stone is detected. But this service is not available at all institutions and is dependent of the availability and expertise of the operator.

Literature suggests the presence of CBD stones in 9–11% of patient undergoing cholecystectomy with intraoperative cholangiogram (IOC). IOC technical success rate has been previously described to be 88–100%, with a sensitivity of 68–100% and a specificity of 92–100% [27, 28]. An alternative approach is an intraoperative US, which has a sensitivity of 90% and does not have the small risk of bile duct injury that an IOC carries, as there is no cannulation of the bile duct [27, 29, 30]. This is not a skill, however, that most general surgeons have.

Diagnostic ERCP to detect bile duct stones in patients with a low or intermediate likelihood of choledocholithiasis is rarely undertaken due to the higher risk of this procedure and the availability of other diagnostic modalities with a reasonably high level of accuracy [31, 32]. For patients with low or intermediate likelihood of having choledocholithiasis, studies have indicated that an EUS-first approach, when available, carries a high negative predictive value with a very small number of patients subsequently developing pancreatobiliary symptoms from choledocholithiasis on follow-up, without the associated mortality and morbidity associated with ERCP. It has also been found to be a cost-effective approach [33–36].

Treatment

The definitive treatment of choledocholithiasis is extraction of the stone – either with an endoscopic approach using an ERCP, via percutaneous transhepatic cholangiography (PTHC), or via surgical exploration of the CBD at the time of cholecystectomy. Studies have suggested that it is not emergent to relieve obstruction from choledocholithiasis and can be done electively in the absence of cholangitis [37–39]. However, if the patient manifests signs of acute cholangitis, achieving source control and removal of the obstruction via an ERCP within 48 hours has been shown to improve mortality and to decrease the length of hospital stay [40–42]. Generally, in the patient with suspected cholangitis, we recommend ERCP promptly as soon as the patient has achieved clinical stability after initial resuscitation after presentation (within the first 48 hours). If the patient is actively clinically decompensating despite optimal resuscitation in an intensive care unit and may not tolerate anesthesia for an ERCP, then drainage via PTHC is required to stabilize the patient prior to undergoing definitive management with ERCP.

As with any cause of sepsis, obtaining blood cultures, fluid resuscitation, and initiation of antibiotics to cover gram-negative enteric organisms as well as enterococcus species is of paramount importance, with a plan for an ERCP once resuscitation and a reasonable level of hemodynamic stability have been achieved [43–45].

Most often, extraction of choledocholithiasis is achieved with ERCP. A number of ERCP approaches can be utilized for biliary access and stone extraction. Following cannulation of the major papilla, a cholangiogram is performed by injecting a contrast agent into the biliary tree, thereby facilitating identification of choledocholithiasis (Fig. 18.3a, b). If cholangitis is suspected, often injection is limited to minimize the intraductal pressure and risk of disseminating infection retrograde into the liver. In this case, aspiration of biliary contents can confirm biliary location and enable the bile to be sent for culture and sensitivity testing. Once cholangitis or a biliary stone is identified, an endoscopic biliary sphincterotomy is usually performed to help relieve the resistance offered by the sphincter of Oddi and enable stone extraction (Fig. 18.4). Rarely, the biliary tree is unable to be cannulated, sometimes due to impaction of the stone at the ampulla. In this case, a "precut" papillotomy may be performed using a freehand technique or over a pancreatic duct stent, to gain access into the biliary tree (Fig. 18.5a–c) [46]. After biliary sphincterotomy, most CBD stones < 15 mm in size can be extracted with either a stone extraction balloon or a stone extraction basket (Fig. 18.6).

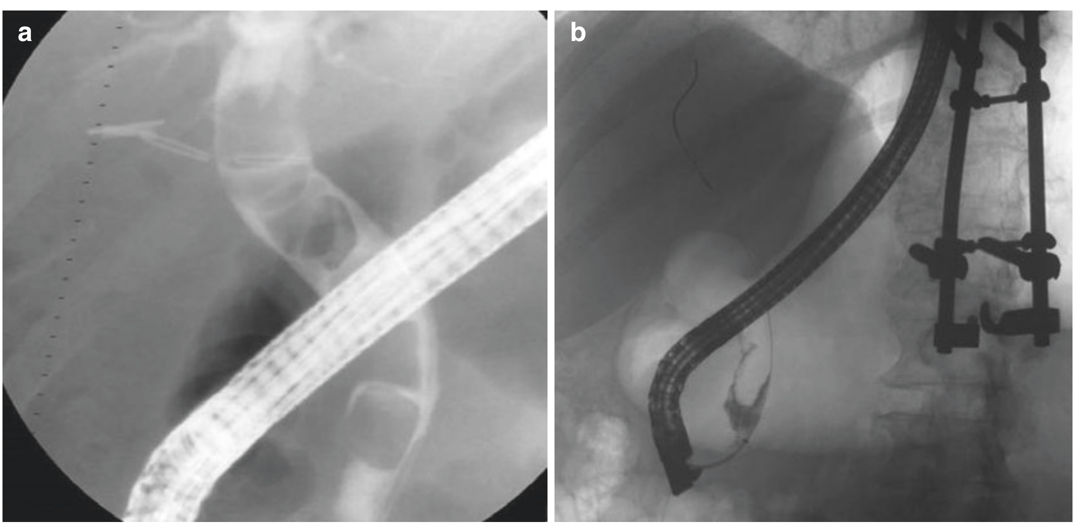

Fig. 18.3 (**a**) Multiple stacked stones identified at time of ERCP in the CBD and common hepatic duct. (**b**) Single large stone identified at time of ERCP in the CBD

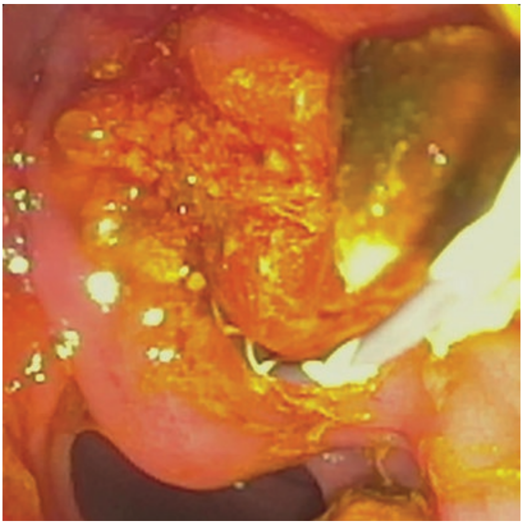

Fig. 18.4 Extraction of stones after conventional biliary sphincterotomy

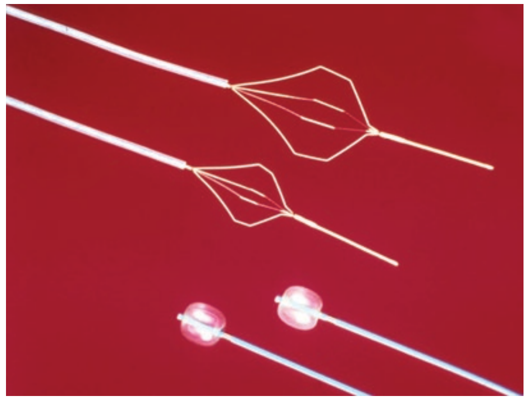

Fig. 18.6 Endoscopic stone extraction balloons and baskets

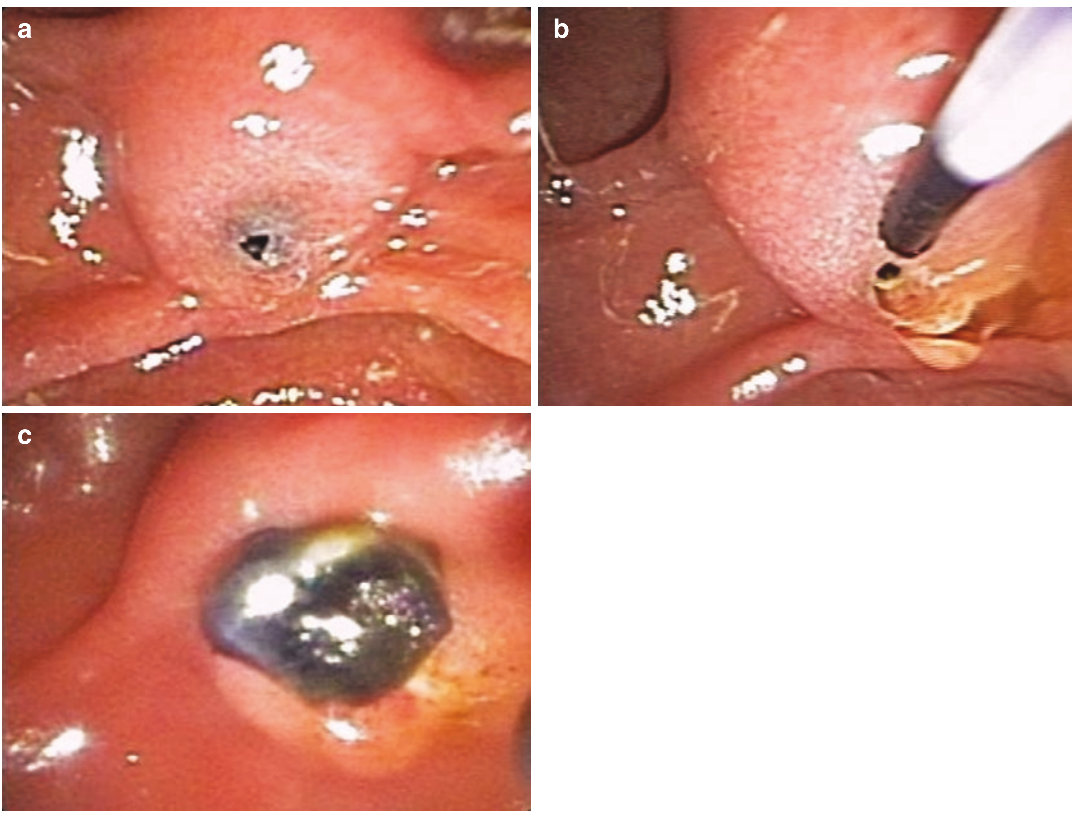

Fig. 18.5 (**a**) Stone apparent at the biliary orifice of the major papilla. (**b**) Precut biliary access using freehand needle-knife technique. (**c**) Extraction of stone after precut sphincterotomy

ERCP with sphincterotomy in the setting of choledocholithiasis is associated with periprocedural (<30 days) complications of approximately 10% that include bleeding (1%), pancreatitis (5%), perforation (1%), and cholangitis (1%), with a mortality rate of 0.1% [47–50]. Certain factors, such as pain during the procedure, indication of the procedure, and procedural factors, increase the risk of immediate complications [51]. The peri-procedure administration of rectal indomethacin and/or protective pancreatic duct stenting have been shown to reduce the risk of pancreatitis in selected patients [52]. Long-term complications from sphincterotomy include development of papillary stenosis in about 6–24%, leading to recurrence of stone formation and cholangitis rarely, with no evidence of increased risk of cholangiocarcinoma [53–57].

If a sphincterotomy is contraindicated due to presence of anticoagulants and/or antiplatelet agents or due to abnormal anatomy, a balloon sphincteroplasty can be performed using a dilation balloon to dilate the biliary orifice [58]. A Cochrane review [59] of available literature suggests that a balloon sphincteroplasty is less efficacious in extracting a CBD stone compared to a sphincterotomy (90% vs 95%); and it required more frequent use of repeat procedures and mechanical lithotripsy for stone clearance. Balloon sphincteroplasty without sphincterotomy is also associated with a higher risk of post-ERCP pancreatitis (8.6% vs 4.3%). However, there was no increase in mortality related to pancreatitis. The sphincteroplasty method, however, was associated with a lower risk of short-term (2.5% vs 5.0%) and long-term infections (2.4% vs 5.8%), as well as a lower risk of bleeding (0.1% vs 4.8%). Overall, there was no difference in the rates of perforation and overall mortality [59].

In the case of large stones and a tapering distal CBD, where conventional extraction maneuvers may fail, a combination technique such as dilation-assisted stone extraction (DASE), which incorporates balloon dilation of the sphincter orifice after a biliary sphincterotomy is performed, has shown to be more effective than a sphincterotomy alone, particularly with a decreased need for lithotripsy and no increased risk of ERCP-related short-term or long-term complications [60, 61].

In 10–15% of cases, stones cannot be removed with standard ERCP techniques described above. This generally occurs if the stone is >15 mm, located above a stricture, or is impacted [1]. In this case, more complex endoscopic interventions such as laser lithotripsy (LL), electrohydraulic lithotripsy (EHL), or mechanical lithotripsy can be employed to fracture the stone into fragments and subsequently extract them. In the case of mechanical lithotripsy, through-the-scope lithotripters are available to grasp the stone at any level in the biliary tree and crush into fragments with mechanical force. A mechanical winch attached to the device increases the pressure within the lithotripter [62–66]. LL or EHL is used predominantly to fragment large stones in the common duct or impacted intrahepatic stones. The lithotripsy probes are advanced under fluoroscopic guidance and direct visualization using a digital single-operator cholangioscope (D-SOC) [67] (Figs. 18.7 and 18.8a–c). EHL consists of a bipolar lithotripsy catheter probe that discharges high-pressure hydraulic pressure waves in an aqueous medium with the tip of the probe positioned within 2 mm of the stone. The energy is delivered in pulses over 1–2 s and continued until stone fragmentation is

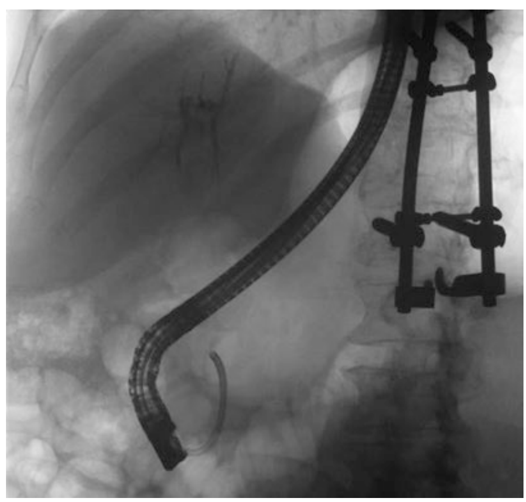

Fig. 18.7 Digital single-operator cholangioscope visualized under fluoroscopy

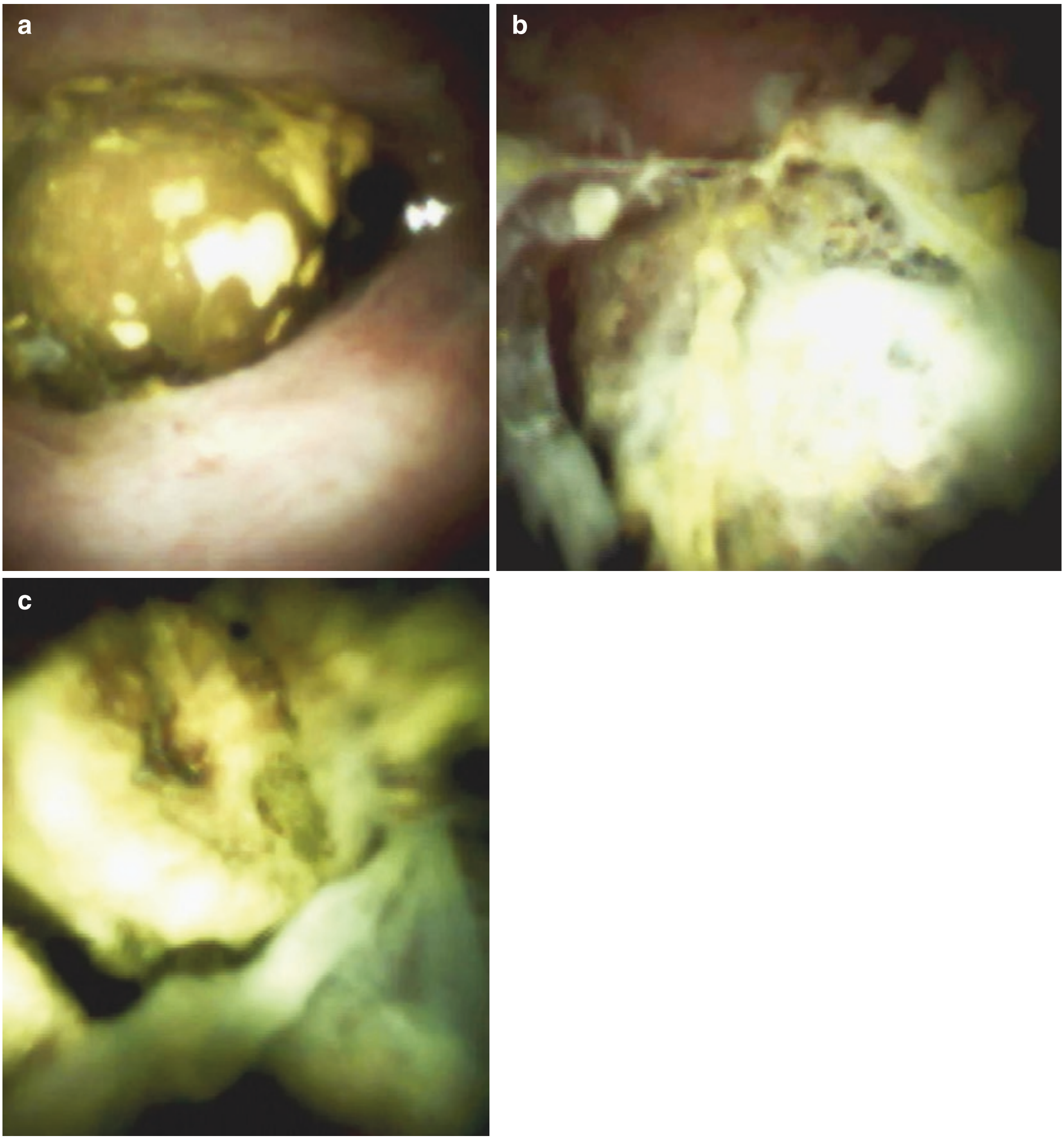

Fig. 18.8 (**a**) Pigmented CBD stone visualized with digital single-operator cholangioscope. (**b**) CBD stone visualized with digital single-operator cholangioscope. (**c**) CBD stone visualized with digital single-operator cholangioscope

achieved, with subsequent extraction of the fragments using conventional techniques (Fig. 18.9a, b) [68]. It has a demonstrated success rate greater than 97% in the fragmentation and extraction of stones over 1–4 sessions, with most requiring just one session (77%) [68–72]. In the case of LL, YAG laser-induced pulsed shock waves are directed precisely to target the biliary stones without damaging the biliary epithelium under direct visualization using a single-operator cholangioscopy (SOC) and further assisted by a radiopaque marker for fluoroscopic control. It is reported to have a similar efficacy to EHL but with a shorter procedure time (73.9 ± 33.5 min vs 49.9 ± 32.4 min). It does, however, require the practitioner to undergo special training to utilize the therapeutic laser. The risk of adverse events for EHL/LL is similar to

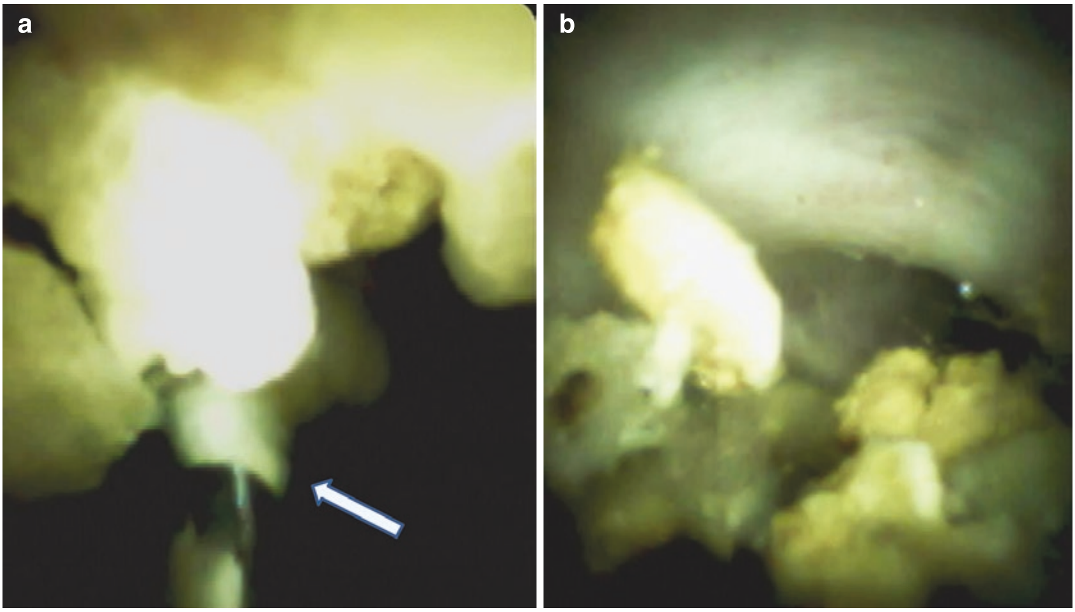

Fig. 18.9 (**a**) EHL probe (arrow) directed fragmentation of a CBD stone under direct visualization with a digital single-operator cholangioscope. (**b**) Fragments of CBD stone after EHL probe under direct visualization with a digital single-operator cholangioscope

conventional ERCP, with technical failure related to failure of cannulation of the CBD [68, 73–75].

In the setting of suspected cholangitis, we recommend aspiration of bile at the time of ERCP to evaluate the bile for presence of microorganisms. If the cultures are positive, they should be sent for microbial antibiotic sensitivity to help direct clinical care of the infection [44, 76]. If there is significant purulence seen in the bile duct following cannulation (Fig. 18.10a, b), to reduce the risk of spreading the infection retrograde to the liver, forceful biliary injection of contrast is not recommended. Once the obstruction is identified, a biliary stent traversing the obstruction should be placed [77], with or without a biliary sphincterotomy or sphincteroplasty. After adequate treatment with antibiotics and aforementioned biliary drainage, a subsequent ERCP can then be performed to treat the obstruction stone or lesion definitively.

Furthermore, with postsurgical anatomy or in the rare case that ERCP fails in the setting of choledocholithiasis or cholangitis, an EUS-guided rendezvous technique can be employed, a percutaneous transhepatic biliary drain (and subsequent therapy) can be attempted by interventional radiology, or a surgical common bile duct exploration and clearance may be pursued [78].

After removal of choledocholithiasis, a cholecystectomy is recommended in surgical candidates, to reduce the risk of recurrence of choledocholithiasis, cholangitis, or gallstone pancreatitis. Studies show an increased risk of recurrent pancreatobiliary events in those who were managed expectantly without cholecystectomy, which is higher when compared to groups who had a cholecystectomy – with the recurrence as high as 47% [79]. Also, patients who underwent early cholecystectomy within 72 hours of presentation had a lower rate of recurrent biliary events compared with those who delayed cholecystectomy up to 6–8 weeks (2% vs 36%) [80]. On the other hand, a systematic review of studies which included patients of both Asian and Western populations that were at a high risk of surgical complications from cholecystectomy (e.g., elderly patients, patients with cardiopulmonary comorbidities, cancer, or cirrhosis) showed an

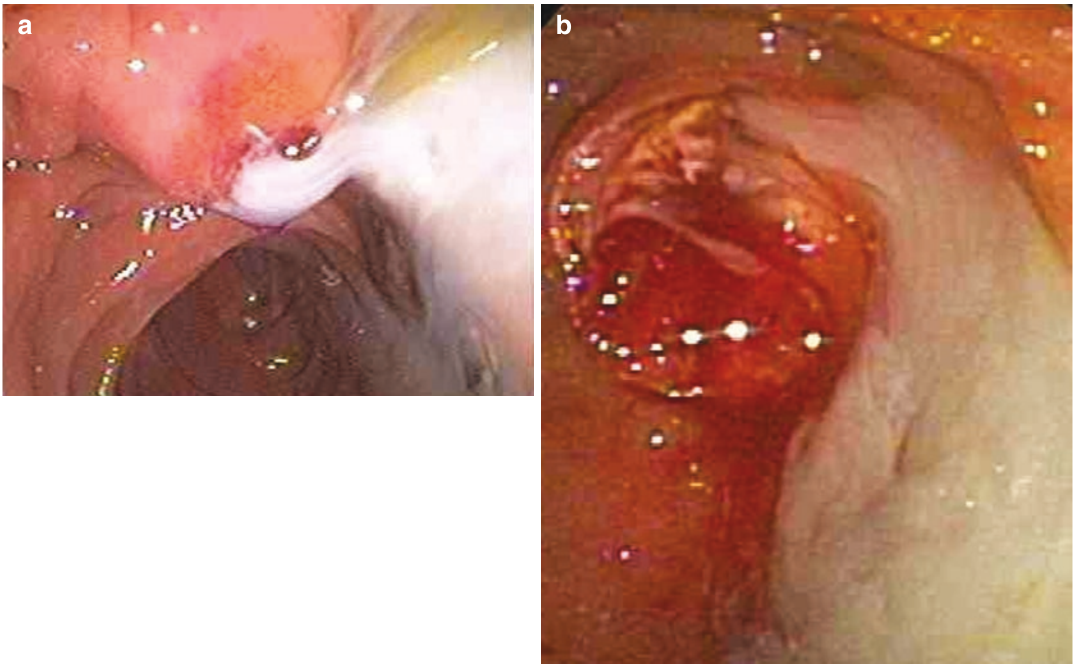

Fig. 18.10 (**a**) Purulent material exiting biliary orifice . (**b**) Purulent material exiting biliary orifice status post-biliary sphincterotomy

increased risk of biliary events but no difference in mortality with expectant management of choledocholithiasis after a biliary sphincterotomy when compared to receiving a subsequent cholecystectomy [81]. These findings are corroborated by a recent retrospective [82] and outcome study [83]. Ultimately, however, the determination of risk versus benefit of subsequent cholecystectomy of high-risk patients should be determined by the surgeon and the patient. It is not unreasonable for high-risk patients with underlying chronic disease such as cardiopulmonary disease or cirrhosis to be referred to a tertiary care center for multidisciplinary consultation.

Conclusion

ERCP is the first-line treatment for choledocholithiasis and should be performed within 48 hours in patients who are suspected of having cholangitis or pancreatitis. Consideration should be made for even earlier intervention in patients who present with septic shock due to the cholangitis. There are several techniques available for the endoscopist who has advanced endoscopic skills, all with similar outcomes and risks. In general, successful stone extraction should be followed by cholecystectomy within 72 hours. For the frail patient who is high risk for general anesthesia, consideration can be made for sphincterotomy alone with expectant management for any future biliary-pancreatic symptoms.

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