III

Chapter 43

Choledocholithiasis

James Y.W. Lau, Yuk Tong Lee, and Joseph Sung

Gallstone disease is a common condition. It is estimated that in the United States between 500,000 and 700,000 cholecystectomies are performed per year. In a U.S. National Health and Nutrition Examination Survey 14,228 participants between the ages of 20 and 74 underwent gallbladder ultrasonography. The prevalence of gallstones was 7.1% and the cholecystectomy rate was 5.3%.[1] However, the true prevalence in the general population is probably higher if more elderly subjects are included.

The prevalence of bile duct stones is less well defined. In Western countries bile duct stones typically originate from the gallbladder. These stones are often mixed or cholesterol stones. In the East, stones often arise de novo within the bile duct. These are brown in color, soft, and muddy pigmented stones. The mechanism of primary stones is bile duct infection and stasis. Approximately 10% to 15% of patients with gallbladder stones develop adverse events of biliary colic, cholangitis, or pancreatitis, with some overlap among these clinical presentations. In surgical series of cholecystectomy for uncomplicated gallstone disease, the incidence of bile duct stones is less than 5%,[2] though the proportion of bile duct stones can be as high as 47% in patients with acute biliary pancreatitis who undergo early endoscopic retrograde cholangiopancreatography (ERCP).[3] Those with acute cholangitis are expected to have a high rate of bile duct stones as well.

The natural history of bile duct stones is not well understood. In a study[4] that compared findings of endoscopic ultrasound (EUS) and subsequent ERCP, 21% of 92 patients with bile duct stones on EUS had passed them within 1 month. Stone size <5 mm was an independent predictive factor of passage. In another study[2] Collins et al. performed sequential cholangiography using a transcystic catheter placed at the time of laparoscopic cholecystectomy. The rate of bile duct stones in patients on cholangiography was 3.4%. In more than one third of cases, calculi passed spontaneously at 6 weeks. Smaller stones may therefore pass spontaneously into the duodenum without causing symptoms. On the other hand, stone passage through the ampulla of Vater may cause bile reflux into the pancreatic duct with resultant acute pancreatitis. Larger stones can also be impacted at the distal bile duct causing biliary colic and cholangitis. Chronic obstruction, though uncommonly due to stones, can lead to secondary biliary cirrhosis and portal hypertension. In general, these adverse events are serious and can be life threatening. Patients with suspected bile duct stones should therefore be investigated and if stones are identified, these should be extracted.

Evaluation of Patients with Suspected Choledocholithiasis

Initial investigations in someone suspected to have bile duct stones should include liver biochemical tests and transabdominal ultrasonography (TUS) (see Chapter 33).

Normal liver function and biochemical tests are useful in excluding the presence of bile duct stones. In 1002 patients undergoing laparoscopic cholecystectomy, normal liver function tests accurately predicted the absence of bile duct stones. The negative predictive values of biochemical parameters of gamma-glutamyl transferase (GGT), alkaline phosphatase, total bilirubin, alanine, and aspartate aminotransferase were all high and ranged between 94.7% and 97.9%. Unfortunately the positive predictive value of only one abnormal liver function test is just 15%.

TUS has a sensitivity of <50% in diagnosing bile duct stones. A bile duct stone seen during TUS is highly specific for stones found at ERCP and surgery. TUS is sensitive in detection of bile duct dilation (>6 mm in diameter), which is associated with the presence of bile duct stones. Mild biliary ductal dilation is seen in elderly patients and in those with prior cholecystectomy. A TUS finding of a normal-sized bile duct has a 95% negative predictive value of finding bile duct stones at ERCP.[5,6] TUS findings of gallstones may also have implications for patient management. Patients with pancreatitis or jaundice often have smaller gallbladder stones on TUS (3 to 4 mm) when compared to those with cholecystitis or uncomplicated bile duct stones. Multiple small gallbladder stones are more likely to migrate in the bile duct and become clinically important.[7]

No single parameter accurately predicts the occurrence of bile duct stones in patients with gallstones. Most predictive models are based on a combination of clinical, biochemical, and TUS findings. For example, a patient older than 55 years who has a serum bilirubin >30 µmol/L (1.8 mg/dL) and a dilated bile duct on TUS has a 72% probability of finding bile duct stones at ERCP.[8] The American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee proposes a scheme to stratify patients with gallbladder stones into those at low (<10%), intermediate (10% to 50%), or high (>50%) risk of harboring bile duct stones. Other very strong predictors include clinical cholangitis and bilirubin >4 mg/dL. Strong clinical predictors are a dilated bile duct on TUS (>6 mm with an intact gallbladder) and a serum bilirubin of 1.8 to 4 mg/dL. The presence of one very strong predictor or both strong predictors categorizes a patient as being at high risk of having a bile duct stone. Age greater than 55 years, clinical gallstone pancreatitis, and abnormal liver function tests other than a raised serum bilirubin are associated with an intermediate risk of choledocholithiasis. The absence of any of these predictors is considered low risk.[9]

The ASGE Standards of Practice Committee proposes a risk-stratified scheme in the evaluation of patients with symptomatic gallstones and possible concomitant bile duct stones. It is suggested that patients at "low risk" as defined above should undergo cholecystectomy without further investigation. Patients at intermediate risk should be offered preoperative imaging such as EUS or magnetic resonance cholangiography (MRC). Those at high risk of harboring a bile duct stone should undergo preoperative ERCP and stone extraction.

MRC, EUS, and Other Imaging Modalities in the Diagnosis of Choledocholithiasis

Two systematic reviews found both a high sensitivity (85% to 92%) and a high specificity (93% to 97%) in the detection of bile duct stones with MRC.[10,11] The sensitivity of MRC appears to be related to stone size. In one study the sensitivity was 100% in stones around 1 cm in diameter and decreased to 71% for stones <5 mm in diameter. False positives can also occur[12] and are mostly related to air bubbles or bilioenteric anastomosis such as a choledochoduodenostomy. MRC has the distinct advantage of being entirely noninvasive.

Because of the proximity of the extrahepatic bile duct to the duodenum, an echoendoscope can obtain excellent images of the bile duct (**Fig. 43.1**; see Chapter 31). With the patient in the lateral decubitus position and the transducer in the second portion of the duodenum and ampullary region, the distal bile duct and its intraduodenal portion can be well visualized. The common bile duct and common hepatic duct can be examined in longitudinal sections with the transducer wedged in the region of the duodenal bulb. Both radial and linear EUS have a high sensitivity (93%) and specificity (>95%) for the diagnosis of bile duct stones. Importantly, sensitivity does not seem to be affected by stone size or bile duct diameter.[13]

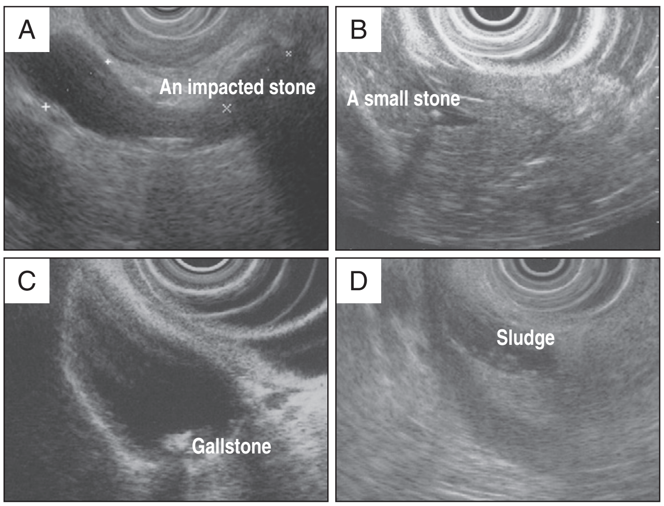

Fig. 43.1 Endoscopic ultrasound (EUS) showing **(A)** an impacted stone at the distal bile duct, **(B)** a small stone at the bile duct, **(C)** a gallstone, and **(D)** sludge. EUS is more sensitive than magnetic resonance cholangiography in the diagnosis of small bile duct stones and biliary sludge.

In a systematic review of five prospective blind studies with 301 patients comparing MRC and EUS, both modalities were found to have a high diagnostic performance for bile duct stones. The pooled sensitivity and specificity were marginally higher, though statistically insignificant, for EUS (0.93 versus 0.85 and 0.96 versus 0.93, respectively). For small stones and biliary sludge, EUS is likely to be more sensitive. The choice between MRC and EUS is often determined by resource availability and patient preference.[11]

Both MRC and EUS reliably replace diagnostic ERCP. ERCP is associated with procedural-related morbidity, mostly in the form of pancreatitis. Thus ERCP should be reserved for therapeutic purposes. In patients at intermediate or low suspicion of bile duct stones, it is logical to perform EUS before undertaking ERCP. Using EUS as the first approach reduces unnecessary ERCP and associated risks. Several randomized trials comparing EUS and ERCP as the initial approach in patients at intermediate to high risk of harboring bile duct stones[14–18] showed that 27% to 40% of patients who underwent EUS were found to have bile duct stones. The negative predictive value of EUS in detecting stones was high. On follow-up only 0% to 4% of patients without EUS evidence of stones had recurrent symptoms. In a pooled analysis of 4 trials that compared ERCP and EUS first approach in 213 patients, ERCP was avoided in 143 patients (67.1%). The use of EUS reduced the risk of overall adverse events (relative risk [RR] 0.35, 95% confidence interval [CI] 0.2 to 0.62) and specifically post-ERCP pancreatitis (RR 0.21, 95% CI 0.06 to 0.83).[19] With reduced adverse events, diagnostic EUS followed by selective ERCP is likely to be more cost-effective for patients with an intermediate probability of choledocholithiasis. The cost saving may in fact be higher if EUS and ERCP are performed during one session.

Technique of ERCP in Extraction of Bile Duct Stones

ERCP with endoscopic sphincterotomy (ES) and stone extraction is a time-honored technique with a high success rate (87% to 100%) and an acceptable rate of morbidity (around 5%). Before offering ERCP the clinician should be confident that an intervention is required and avoid unnecessary ERCP, especially in those at high risk for post-ERCP adverse events (e.g., young female patients with a normal bile duct). ERCP should be the first-line treatment for most patients with bile duct stones, especially those with cholangitis and severe biliary pancreatitis.

Patient Preparation (see also Chapter 9)

Patients undergoing ERCP and ES for stone extraction should have a complete blood count, prothrombin time, and activated partial thromboplastin time (APTT) checked before the procedure. The ASGE guidelines on periprocedural management of anticoagulation[20] suggest that ES is probably safe in patients on aspirin or nonsteroidal antiinflammatory drug (NSAID) agents. Patients on clopidogrel should have the drug stopped 7 to 10 days prior to an elective procedure. Warfarin should be stopped several days prior to ES, and a heparin bridge should be used in selected patients at high risk for thromboembolic adverse events. In patients with sepsis mandating urgent ERCP, the use of anticoagulation should not defer the procedure. A short length biliary stent can be inserted for drainage as an alternative to ES.

The ASGE guidelines recommend the use of antibiotics in patients with biliary obstruction and clinical ascending cholangitis and in whom incomplete biliary drainage is anticipated (multiple stones and those with complex strictures) and the continuation of antibiotics after the procedure. It has not been shown conclusively that the use of preprocedural antibiotics decreases post-ERCP cholangitis in those with biliary obstruction in the absence of cholangitis and in whom complete biliary drainage is likely after ERCP.[21] We recommend the routine use of antibiotics in immunocompromised patients.

We prefer to perform ERCP with the use of anesthesia-administered propofol. Patients with sepsis who have unstable hemodynamics or potential airway problems should be endotracheally intubated for the procedure (see Chapter 5). Prior to ERCP a short period of resuscitation is often desirable in patients with sepsis and hypotension. The patient is usually placed prone. Increasingly we perform ERCP with patients in the left lateral decubitus position. A duodenoscope with a 4.2-mm instrument is used in anticipation of large stones, the use of mechanical lithotripsy, and insertion of a 10 Fr stent.

Biliary Cannulation, Cholangiography and Sphincterotomy

We recommend wire-guided biliary cannulation since injection of contrast can increase hydrostatic pressure and cause mechanical trauma to the pancreatic duct (see Chapter 18). In a pooled analysis of controlled trials that compared contrast and wire-guided techniques of biliary cannulation,[22] a significantly lower rate of pancreatitis was seen with wire-guided cannulation.

We use a pull-type sphincterotome, typically with a 25-mm cutting wire preloaded with a 0.025- or 0.035-in guidewire that has a hydrophilic terminal portion. Flexing of the sphincterotome provides additional angle for cannulation. Upon deep cannulation of the bile duct, the sphincterotome is advanced above the cystic duct junction. Injection of contrast with the catheter positioned at the distal bile duct can cause a small stone to pass into intrahepatic ducts, making subsequent extraction difficult. Bile is first aspirated and exchanged with contrast. We avoid overdistension of the bile duct, as an increase in biliary pressure can induce bacteremia in patients with cholangitis. In patients with cholangitis, especially suppurative cholangitis, the primary aim is to provide biliary drainage. This can be accomplished by insertion of a 7 Fr nasobiliary drain or a short stent to prevent calculous impaction. There are several randomized controlled trials comparing placement of a nasobiliary drain and a stent; no difference in biliary drainage and adverse events was seen. We prefer the use of a short stent, as a nasobiliary drain can kink at the back of the oropharynx; is prone to accidental dislodgement, particularly in delirious or elderly patients; and can be a source of discomfort.[23–25]

The technique of optimizing cholangiography during ERCP has been reviewed (see Chapter 3).[26] A scout film should be obtained prior to insertion of the endoscope. Devices for cannulation should be prefilled with contrast to avoid injecting air into the bile duct. We use half-strength contrast for better visualization of stones. When compared to air bubbles, stones are often faceted. To visualize segments of the bile duct behind the duodenoscope, one can gently push the endoscope into a semilong position. With the patient in a prone position, the left lobar ducts are more dependent. Small stones in the left lobar ducts may therefore migrate into the bile duct as the patient is rolled to a lateral or supine position. Despite position change the sensitivity of cholangiography is imperfect and varies between 89% and 93% in diagnosing bile duct stones. Small stones can still be missed in a spacious and dilated bile duct.

When a cholangiogram is obtained and no apparent stones are identified, the decision to perform an empirical ES is influenced by the likelihood of finding a stone based on clinical parameters prior to ERCP. In cases where there is strong clinical suspicion of a stone (stone seen on TUS or a patient with clinical cholangitis), we advocate a more liberal policy in performing empiric ES. An ES enables a more thorough ductal evaluation. With this approach, more small stones and sludge are detected more often. In a randomized study of ES or no endoscopic treatment, patients with cholangitis and cholelithiasis but without bile duct stones seen on ERCP who underwent ES had a reduction in recurrent stones and sepsis at a mean follow-up period of 22 months.[27] In most circumstances the risk of missing a bile duct stone outweighs that of an unnecessary ES. When expertise is available, EUS and intraductal ultrasonography are ancillary techniques that may aid in resolving the dilemma.

ES is performed with the distal portion of the cutting wire in the duct and with minimal wire tension (see Chapter 16). The incision proceeds in a stepwise manner. If an uncontrolled electrosurgical generator is used, excessive tension on the cutting wire and tissue contact during ES can result in a "zipper cut" with coagulated tissue being forced open, resulting in perforation and bleeding. We prefer the use of a blended current in a pulsed mode or an "ENDOCUT" mode. It was initially suggested that a continuous pure cutting current minimizes coagulation injury around the papillary orifice and reduces the risk of post-ERCP pancreatitis. However, subsequent studies have shown that the use of pure cutting current increases intraprocedural bleeding without reducing pancreatitis.[28]

It is often difficult to define the upper limits of a biliary sphincterotomy. The size of the ES varies with the size and configuration of the distal bile duct. In patients with a narrow, tapering distal bile duct, only a limited ES can be made. In the presence of a dilated bile duct with a flat and square distal end, a more generous ES is possible. Often a transverse fold is seen above the papilla. One can often cut to the top of the fold and the intraduodenal portion of the ampulla and the duodenal wall. As muscle fibers to the biliary sphincter are severed, one can see free bile flow. Another sign of an adequate sphincterotomy is free passage of a fully bowed sphincterotome with a 25-mm cutting wire through the sphincterotomy orifice (**Fig. 43.2**).

The use of needle-knife precut sphincterotomy has consistently been identified as a risk factor for adverse events. It is often debated whether the high rate of adverse events is consequent to protracted attempts at cannulation or to

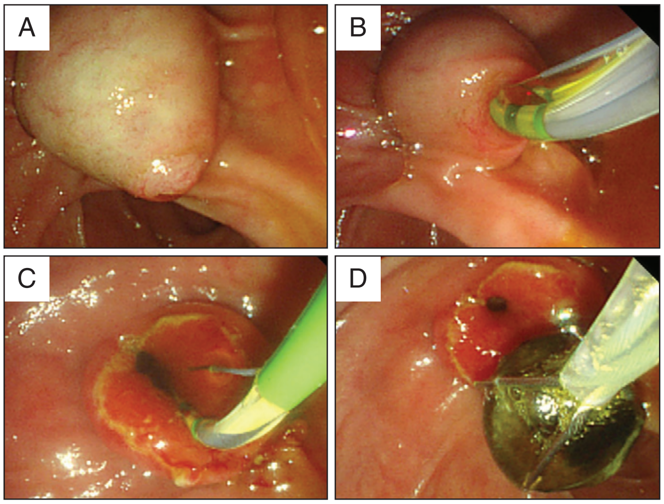

Fig. 43.2 **A,** An impacted stone at the ampulla. **B,** The stone disimpacted on cannulation. **C,** A complete biliary sphincterotomy. **D,** Stone removal using a Dormia basket.

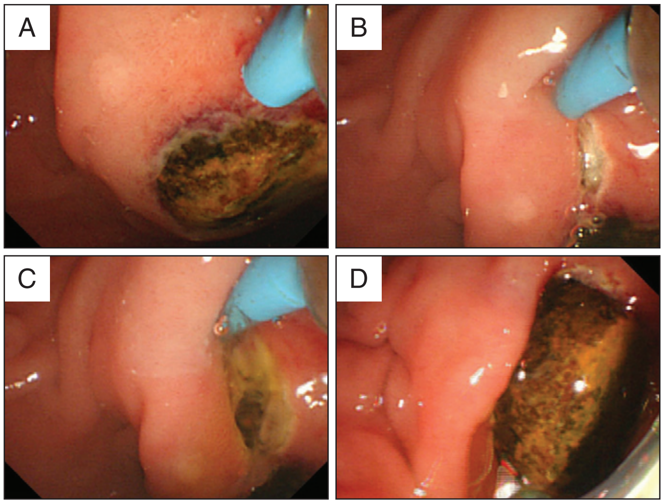

Fig. 43.3 **A,** An impacted stone at the ampulla. **B,** Incision to the ampulla using a needle knife. **C,** The sphincterotomy is extended. **D,** The stone is disimpacted.

needle-knife sphincterotomy itself. Many experts advocate early precutting after initial attempts at cannulation fail. In patients with bile duct stones, the intrabiliary pressure is usually high from obstructing stones. Cannulation of the biliary sphincter is often easy. In the situation of an impacted stone at the ampulla, incision onto the bulging ampulla with a needle knife is safe, as the stone protects the pancreatic orifice (**Fig. 43.3**). Needle-knife sphincterotomy often disimpacts the stone and relief of obstruction is often dramatic. A full discussion of the use of needle-knife sphincterotomy is provided in Chapter 14. There should be a clear indication for access to the bile duct. The endoscopist must be aware of inherent risks in the particular patient. After multiple pancreatic duct injections or wire passages, placement of a short 5 Fr pancreatic duct can reduce post-ERC pancreatitis.[29] After pancreatic stent placement the appropriate bile duct axis for precut can be determined.

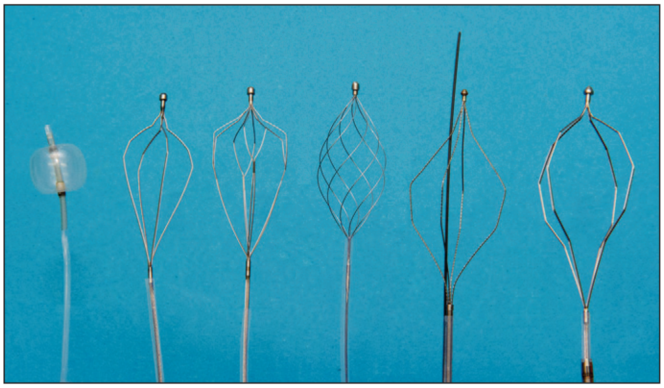

Fig. 43.4 Stone extraction devices. Starting from the left, soft extraction balloon for standard Dormia-type basket; flower and spiral baskets for smaller stones and fragments; and lithotriptor baskets including Trapezoid basket (Boston Scientific, Natick, Mass.), which can be passed over a wire, and through-the-scope mechanical lithotriptor basket (Olympus, Tokyo).

Techniques and Devices in Stone Extraction and Biliary Drainage

The choice of extraction devices is dependent on the size and type of stones (**Fig. 43.4**).[30] An estimate of stone size can be made by comparing the measured stone to the width of the duodenoscope. The devices available include soft Fogarty-type extraction balloons, wire baskets, and mechanical lithotriptors. A duodenoscope with a 4.2-mm instrument channel is required for use of through-the-scope mechanical lithotriptor baskets. It is imperative that an ES commensurate with the size of the stone is made before attempted removal. For large stones we perform balloon dilation in addition to ES. Consideration should be given to the configuration of the distal bile duct in choosing the extraction device and technique.

For small stones (<10 mm) a soft retrieval balloon is used. Many extraction balloons are triple-lumen devices that allow for contrast injection and passage over a guidewire. The balloons are inflated with air to preset sizes or to the size of the bile duct as judged on the cholangiogram. The use of soft balloons is least traumatic to the bile duct and avoids the risk of stone and device entrapment in the distal bile duct. The soft balloon can also be used to gauge the size of ES. An occlusion cholangiogram can be obtained with the use of the same balloon at the end of the procedure.

Stones can also be removed using a wire basket. The shaft of a wire basket is stiffer. The maneuver to advance a wire basket is called the “kissing” technique. The tip of the basket is first impacted against the roof of the ES opening. An upward angle deflection followed by a slight forward advancement of the duodenoscope then aligns the shaft of the basket with the bile duct axis. The basket should be opened above the stone. Contrast is then injected to outline the stone. Ideally the stone should be trapped within the wire mesh in a more dilated portion of the bile duct. This can be accomplished with a jiggling movement of the basket by gentle wrist rotation or a slight in-and-out movement of the catheter. A Dormia basket is made of four wires and opens to the shape of two perpendicular hexagons. For smaller stones and stone fragments, the use of either spiral or flower baskets is advised. They are made of eight wires with closer mesh for better engagement of small stones. These devices can also be rotated within the bile duct. In the event of multiple stones, they should be removed one at a time starting with the most distal stone. A common reason for basket entrapment is the presence of stones and debris below a basket with an engaged stone. A wire basket should be closed just enough to trap the stone. Excessive closure may result in the wire grinding into the stone. Should the stone fail to be removed, it becomes difficult to disengage the stone from the basket. The technique of stone extraction is a downward deflection of the tip of the scope with the scope gently pushed forward in line with the axis of the bile duct. If the engaged stone is not easily withdrawn, the basket should be returned to mid bile duct and the stone disengaged. The situation should then be reassessed. Often extension of the sphincterotomy, balloon dilation, or use of mechanical lithotripsy is required. Forceful traction of the basket in an axis perpendicular to that of the bile duct can result in avulsion of the pancreatic head and should never be practiced. Baskets compatible with lithotriptor devices are available. In anticipated difficult stone extraction (e.g., narrowed distal bile duct) such a basket can be considered or, better still, a through-the-scope mechanical lithotriptor basket is used at the outset. Alternatively, balloon dilation of the distal bile duct and sphincterotomy site can be performed.

Large bile duct stones (>15 mm) are difficult to extract. Often mechanical lithotripsy is required. As mentioned, we ensure that the sphincter opening is sufficiently large and often perform sphincter dilation in addition to ES. There are several available mechanical lithotriptor devices and the ASGE has provided a comprehensive review of these devices. Typically a through-the-scope lithotripsy basket is used (e.g., BML lithotripsy baskets, Olympus, Tokyo). The lithotriptor consists of three layers: a basket with four braided wires, a Teflon catheter, and a metal sheath. The device is first introduced into the bile duct using the Teflon catheter with the basket closed. Opening the basket within the bile duct advances the device deep into the bile duct. With the basket opened, contrast can be injected through the tip of the Telfon catheter to outline the stone. The stone is then engaged and the wire closed over it. The metal sheath is then advanced over the Teflon catheter. The wires are pulled and the stone is crushed against the tip of the metal sheath by turning the control knob at the crank handle. This has to be done slowly, allowing for gradual grinding of wires into the stone. Otherwise a very hard stone can slip through the wire mesh (**Fig. 43.5**). The Trapezoid RX basket (Boston Scientific, Natick, Mass.) has an emergency release feature to avoid basket entrapment.

In the event of stone and basket entrapment with the use of a standard basket, a Soehendra lithotriptor can be used as a rescue device (**Fig. 43.6**). The handle of the wire basket is cut, the duodenoscope is removed, and the plastic sheath surrounding the basket wires is then removed. A metal sheath is passed over the wires and is then attached to a crank handle. The ends of the basket wires are tied to the handle. By turning the crank handle, the metal sheath is advanced over the wire and onto the stone under fluoroscopic guidance.

It is important that adequate biliary drainage is provided at the end of ERCP. In patients with multiple stones or large bile duct stones that remain after fragmentation, complete removal cannot be assured. The insertion of a short stent or a nasobiliary drain prevents impaction of residual fragments and subsequent cholangitis.

Balloon Sphincter Dilation

Balloon dilation to the biliary sphincter has been proposed as an alternative to ES in patients undergoing stone extraction

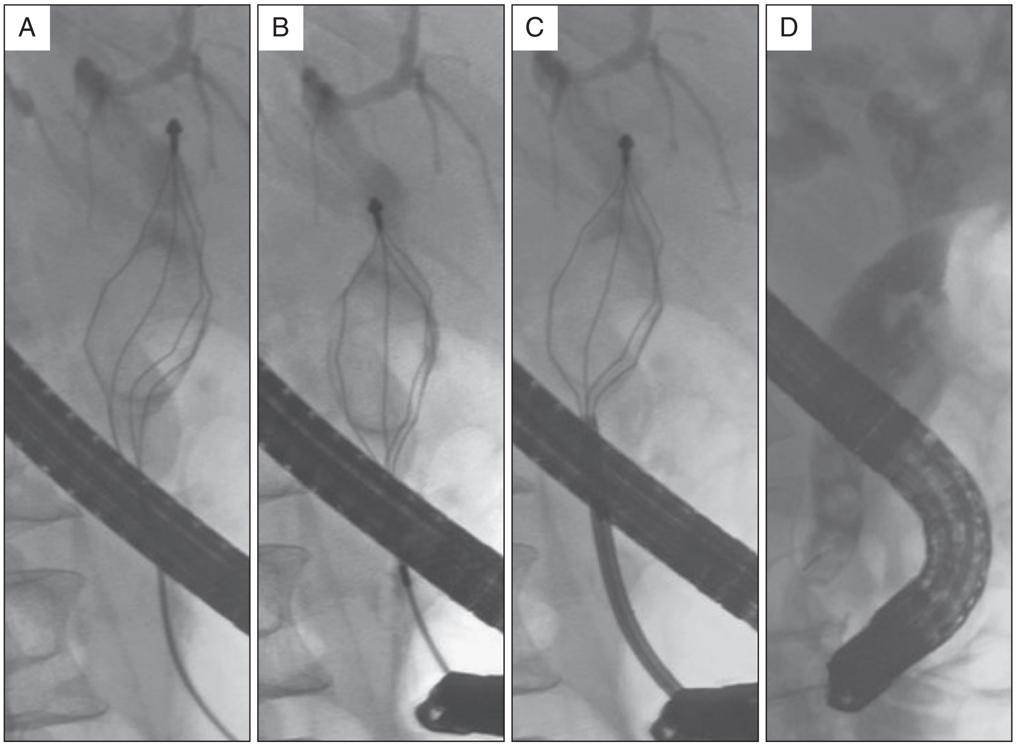

Fig. 43.5 Basket mechanical lithotripsy. **A,** A large stone is first trapped with a basket. **B** to **D,** A metal sheath is then advanced over the Teflon sheath and the stone is slowly crushed, leaving multiple fragments in the mid bile duct.

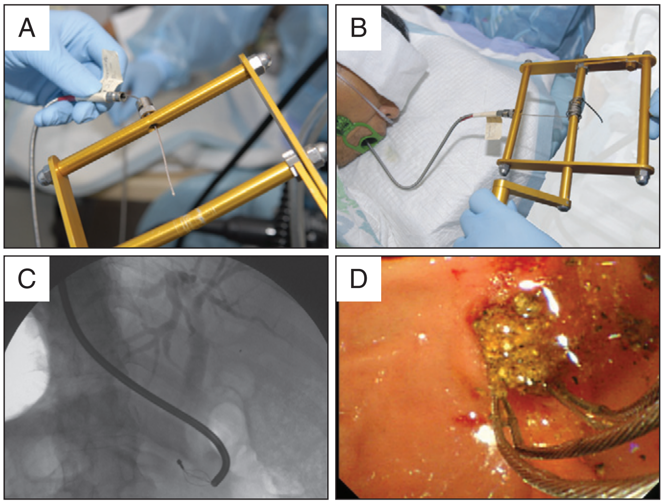

Fig. 43.6 Soehendra lithotriptor as a rescue device for an entrapped basket with a stone. **A,** The basket wires are first cut at the handle, the plastic sheath is removed, and the wires are then passed through a metal sheath and cranking device. **B,** The end of the wire is attached to the handle. **C,** With rotation of the handle the metal sheath is advanced under fluoroscopy onto the entrapped basket with stone. **D,** The stone is crushed and fragments are removed using standard baskets or through-the-scope basket mechanical lithotripsy.

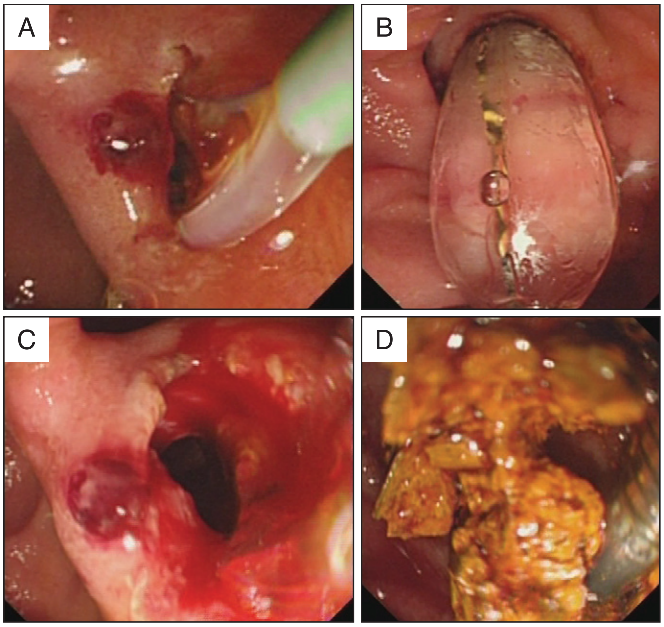

Fig. 43.7 The technique of large balloon sphincteroplasty after an initial endoscopic sphincterotomy. **A** and **B,** A CRE balloon (Boston Scientific, Natick, Mass.) 15 mm in maximal diameter and 5.5 cm in length is inflated across the sphincter opening under fluoroscopy. Following the disappearance of the "waist," it remains inflated for around 30 seconds. **C,** A large opening is seen endoscopically following sphincteroplasty. **D,** Stones are extracted using standard techniques.

(see Chapter 17). There are advantages to the technique over ES. The bleeding risk associated with sphincter dilation is less. The technique may be useful in specific situations such as patients with cirrhosis and coagulopathy and those with a difficult bile duct orientation as seen after Billroth II gastrectomy (**Fig. 43.7**).[31,32] Preservation of the muscular sphincter complex reduces reflux and possibly ascending bile duct infection. In one trial that compared sphincter dilation using an 8-mm balloon to sphincterotomy, the rate of cholecystitis at 6 months following sphincterotomy was 10% and was significantly higher than in patients who received sphincter dilation alone.[33] The immediate risk of severe post-ERCP pancreatitis is much higher after balloon dilation when compared to ES.[34–36] In a multicenter U.S. study, the rate of pancreatitis was 15.4% in 117 patients following sphincter dilation, with two fatal outcomes.[34] In the majority of patients, extraction of bile duct stones using sphincter dilation should be avoided.

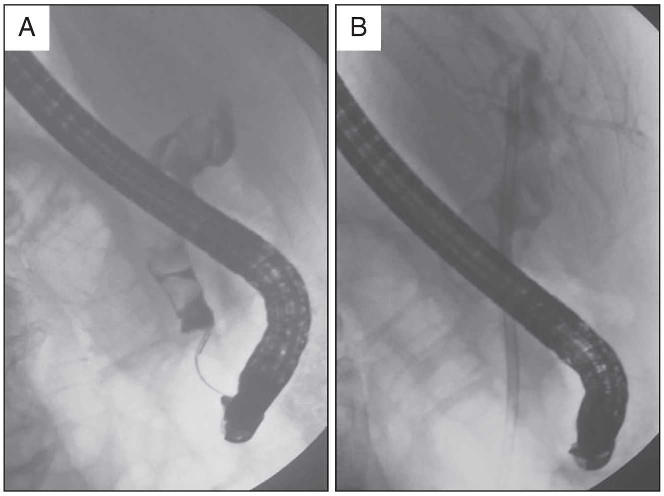

Fig. 43.8 Multiple bile duct stones and endoscopic insertion of a 10 Fr stent.

Sphincterotomy versus Sphincterotomy and Large Balloon Sphincteroplasty (see also Chapter 17)

Ersoz et al. first reported the technique of large balloon dilation (12 to 20 mm) following ES in managing large bile duct stones.[37] After ES, a balloon catheter (CRE Esophageal/Pyloric, maximum diameter 15, 18, or 20 mm; length 5 cm, Boston Scientific) is passed over a guidewire with its midpoint positioned across the sphincterotomy. The balloon is then filled with half-strength contrast under fluoroscopy and endoscopy guidance. A waist over the balloon is observed, which should disappear following gradual inflation of the balloon. The balloon inflation time varies across reports. Most leave the balloon inflated for up to 30 seconds (**Fig. 43.8**). Mucosal bleeding from the edge of the papillary orifice is commonly observed after balloon dilation and usually stops without need for intervention. The combined technique does not increase adverse events when compared to ES alone.[38–40] In one trial the use of combined ES and balloon sphincteroplasty reduced the need for mechanical lithotripsy and fluoroscopy time.[39] In another trial the combined technique also reduced post-ERCP cholangitis when compared to ES and mechanical lithotripsy.[40] This may be related to improved drainage from a larger sphincter opening. Initial ES separates the pancreatic orifice and controls the direction of muscle disruption in subsequent balloon dilation. This may explain the lower rate of pancreatitis when compared to that associated with primary biliary sphincter dilation.

There are several caveats to performing the technique of ES and balloon dilation; the balloon size should not exceed the size of the distal bile duct. Reports of bile duct perforation have occurred exclusively with dilating balloons >15 mm in size. For this reason, we seldom use a balloon >15 mm in diameter. We also caution against large balloon dilation in patients with portal hypertensive bilopathy. Massive hemobilia can occur through rupture of anomalous varices around the bile duct.

The Role of Biliary Stents

In patients with cholangitis, especially those with suppurative cholangitis, it is reasonable to insert a short biliary stent as a temporizing procedure. This allows time for sepsis to resolve and the patient's condition to be optimized while definitive treatment is planned. The purpose of stent placement is to prevent calculous impaction in the distal bile duct. A 10 Fr, 5-cm–long stent is often used (see **Fig. 43.8**). A biliary stent has been advocated as a definitive treatment in elderly or debilitated patients with bile duct stones. There is also evidence to suggest that stones may become smaller with a period of stenting.[41] This is probably due to friction of the stones onto the stent itself or improved biliary drainage, especially in the case of pigmented stones. It is probably reasonable to defer stone extraction for several weeks after stent placement in those patients with large stones. The use of biliary stenting as a definitive or long-term treatment should, however, be discouraged.[42] In one series of 117 patients,[43] 40% of patients developed recurrent cholangitis due to stent clogging and migration after a median follow-up of 40 months. The rate of adverse events is higher in those with gallbladder in situ. Long-term stenting should be restricted to very select patients who are debilitated from other illnesses and have a limited lifespan.

Difficult Bile Duct Stones

Clinical Scenarios

In a subset of patients (5% to 10%), ERCP is unsuccessful in removing bile duct stones. These stones fall into the category of "difficult" bile duct stones. Unsuccessful ERCP may be due to several reasons. The route to the ampulla may have been altered, such as after a Billroth II gastrectomy or a Roux-en-Y jejunal limb reconstruction. The ampulla may be hidden within a periampullary diverticulum, which is associated with stone disease and commonly seen in elderly patients. A stone cannot be captured with a basket mechanical lithotriptor (BML) due to its size or shape or the lack of room in a narrow bile duct, such as in the case of Mirizzi syndrome. Presence of biliary strictures may prevent stone access, a feature often seen in recurrent pyogenic cholangitis.

The next course of action in this group of patients depends on the reason for failed ERCP. In a medically fit patient without cholangitis in need of cholecystectomy for gallstones, it is reasonable to refer the patient for laparoscopic cholecystectomy and bile duct exploration. In patients with failed attempts at cannulation, a second ERCP by the same endoscopist or someone with more experience in the same institution or a tertiary referral center can often be successful. In patients with failed cannulation and cholangitis, biliary drainage with a percutaneous transhepatic cholangiography (PTC) is indicated. Following a few days of drainage, a guidewire can be passed antegrade through the papilla. An ERCP can be completed by ensnaring the wire through the instrument channel (a rendezvous procedure). In centers where there is close collaboration between surgeons and endoscopists, a transpapillary wire can be passed via the cystic duct during laparoscopic cholecystectomy for intraoperative ERCP. EUS-guided transduodenal puncture of the bile duct (or transgastric through the left intrahepatic duct) and rendezvous procedure have also been described. The true rate of adverse events is unknown until more case series are conducted and preferably until comparative data become available.

Extra or Intracorporeal Lithotripsy

Shock wave lithotripsy can be delivered extracorporeally (ESWL) or intracorporeally, generally with the guidance of direct cholangioscopy (see Chapter 26). ESWL is performed with a prior endoscopically placed nasobiliary drain through which irrigation and normal saline and contrast injection for stone visualization are possible. Sedation is required in most patients. Under fluoroscopy, the stone is targeted. A stone fragmentation rate of up to 95% has been reported, leading to complete duct clearance in 90% of patients. Often 2 or 3 sessions are required. A final ERCP is often carried out to clear all fragments. Adverse events include hemobilia, cholangitis, and hematuria in up to 35% of patients. Intraductal lithotripsy is delivered with the use of direct cholangioscopy (**Fig. 43.9**). Stones are fragmented under direct vision to avoid ductal injury. Holmium laser fiber or electrohydraulic laser fibers are preloaded into a cholangioscope. Normal saline is infused using a three-way stopcock or via a nasobiliary drain.

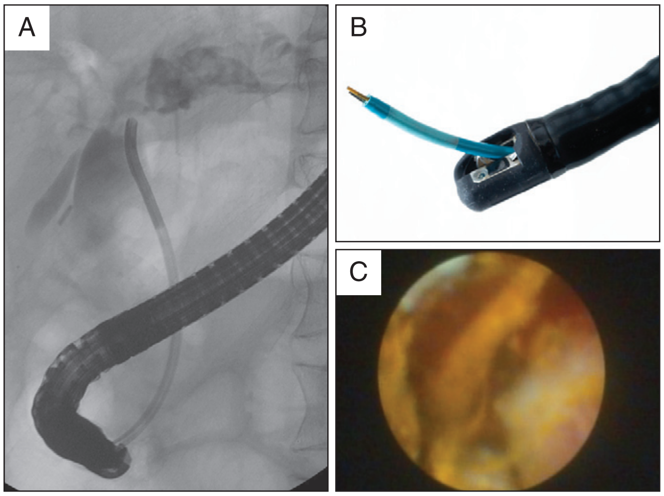

Fig. 43.9 Intraductal lithotripsy in a patient with recurrent pyogenic cholangitis. **A,** The cholangiogram shows a left intrahepatic duct stricture with proximal dilation and multiple stones. **B,** The SpyScope (Boston Scientific, Natick, Mass.) is passed loaded with an optical fiber for viewing and an electrohydraulic lithotripsy fiber for stone fragmentation. **C,** A view through the SpyScope showing multiple stone fragments.

Electrohydraulic lithotripsy (EHL) or laser lithotripsy is effective in fragmenting large bile duct stones, and stone clearance is usually accomplished in one session.

The number of sessions required for stone clearance is less with intraductal lithotripsy when compared to extracorporeal lithotripsy.[44] Rates of adverse events are similar with either approach. Most endoscopists favor the use of intraductal lithotripsy. Intraductal lithotripsy is useful in patients with Mirizzi syndrome when a large stone has eroded through the gallbladder neck into the bile duct. In these cases the distal bile duct is often small and the stone is too big to be engaged with a mechanical lithotripsy basket.

Percutaneous Management

The percutaneous approach is used mostly in patients with hepaticolithiasis, who often have intrahepatic duct strictures (see Chapter 47). The percutaneous tract is serially dilated up to 18 to 20 Fr in diameter. The dilation process and externally protruding drain is often uncomfortable. The percutaneous tract matures in approximately 10 days. The tube is removed and a cholangioscope is passed through the tract. Stones are grasped and withdrawn using baskets or pushed into the duodenum. A percutaneous approach is also used through the T-tube tract in patients with retained stones after an operative bile duct exploration several weeks after surgery after the tract has matured. Minimal dilation is required, as T-tubes are usually ≥14 Fr in diameter.

Stricture Disease and Hepaticolithiasis

Intrahepatic ductal stones are prevalent in Southeast Asia. Hepaticolithiasis is frequently associated with stricture disease from different etiologies, including recurrent pyogenic cholangitis, sclerosing cholangitis, and postoperative strictures. It is technically challenging to treat. The management should be multidisciplinary, as recurrences are common, especially in patients with intrahepatic ductal strictures. Outcome following endoscopic treatment is often suboptimal. Strictures need to be evaluated, as cholangiocarcinoma can coexist. There have been reported series on the use of PTC and intraductal EHL with a high initial success rate, but stone recurrence with cholangitis occurs frequently.[45,46] Hepatic resection is appropriate in cases with frequent recurrences, especially if strictures and stones are confined to one liver segment or lobe and when the involved liver has become atrophic.

Surgically Altered Anatomy of the Upper Gastrointestinal Tract

It is crucial that endoscopists have knowledge of the surgical anatomy or type of reconstruction when planning endoscopic extraction (see Chapter 29). This often involves discussion with a surgeon and thorough review of the operative record. Patients should also be informed of options other than endoscopy and the high rate of adverse events associated with an endoscopic approach. Endoscopists should have experience in managing such patients, including the use of balloon-assisted enteroscopy in Roux-en-Y jejunal limb reconstructions.

A Billroth II–type gastrojejunostomy is typically performed after an antrectomy often for peptic ulcer disease. In an isoperistaltic reconstruction, the afferent limb is anastomosed to the lesser curvature of the stomach. Ironically the afferent limb is the more difficult one to enter. It is often easier with the patient in the left lateral decubitus position. As the endoscope is advanced into the afferent limb, it forms a "hockey stick" configuration and backs away from the limb itself. The afferent limb opening is first engaged with the scope tip. Intubation is often successful with a downward deflection and right turn of the endoscope tip. At the fixed retroperitoneal portions (third and fourth) of the duodenum, passage of the endoscope is risky and may result in perforation, especially when the endoscope is advanced forcefully. In one series, the rate of small bowel perforation was as high as 6%.[47] When a side-viewing endoscope meets resistance, we often change to an end-viewing endoscope with a short transparent cap at its tip. However, biliary cannulation using a duodenoscope is easier. We recommend the use of a straight ball-tip cannula with a preloaded hydrophilic wire. To adjust for the correct axis for bile duct cannulation, the scope is often pulled back (**Fig. 43.10**). A rotatable sphincterotome (Autotome, Boston Scientific) can also be useful. Upon deep cannulation of the bile duct a short stent is inserted and a needle knife is used to incise over the stent (**Fig. 43.11**).

In patients with either Roux-en-Y gastrojejunostomy or hepaticojejunostomy, a standard endoscope is often not long enough to reach the papilla. Balloon-assisted enteroscopes are increasingly used in such circumstances with variable rates of success (68% to 100%).[48–52]

In a large series of ERCP using double balloon–assisted enteroscopy, perforations for Roux-en-Y reconstruction occurred in 5 of 55 patients.[51]

Baron and Vickers first reported performance of a surgical gastrotomy as access for ERCP,[53] which subsequently has been reported in small series of patients after Roux-en-Y gastric bypass.[54] The prerequisite for this procedure is an intact antropyloric channel, although it is possible to introduce the

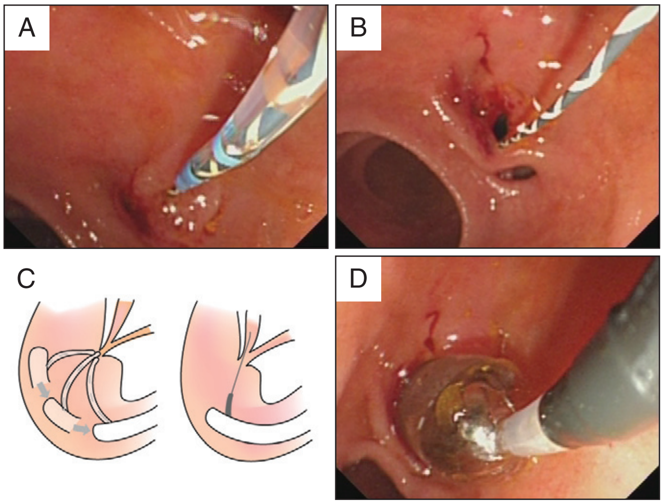

Fig. 43.10 Billroth II anatomy. **A,** The papilla is seen face down with the bile duct axis at around the 7 o'clock position. **B,** For bile duct cannulation, a straight cannula is often used with a hydrophilic tip guidewire. The guidewire or tip of the cannula is first impacted at the common channel. **C,** To align with the bile duct axis for cannulation, the scope can be pulled back for adjustment as shown in the diagram. **D,** Primary sphincter dilation using a balloon can be performed instead of sphincterotomy.

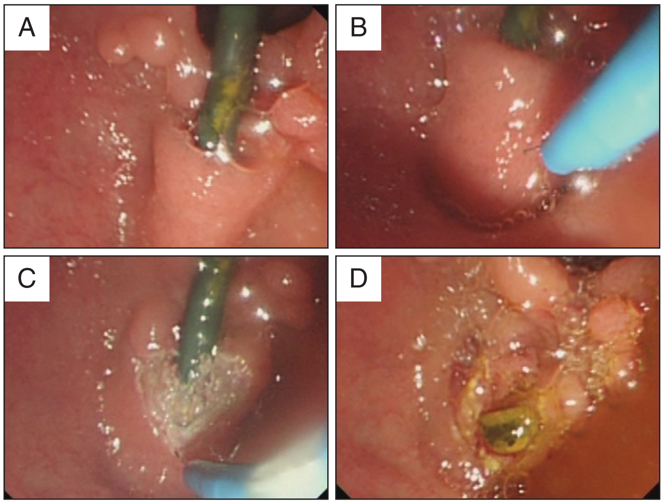

Fig. 43.11 The technique of sphincterotomy in Billroth II anatomy. A, A short stent is first inserted followed by the use of a needle-knife incising over the stent. B, A needle knife is then used to incise over the stent. C, Sphincter muscle is exposed. D, Final result with stones removed.

duodenoscope through a jejunostomy under laparoscopic assistance. After a gastrostomy a feeding tube can be left through the opening at the end of the procedure. ERCP can be repeated in several weeks following maturation of the gastrostomy tract.

Conclusion

MRC and EUS have replaced diagnostic ERCP. In the majority of bile duct stones, ERCP and ES allow for their complete extraction. In the management of "difficult" stones due to access or stone size, more advanced techniques are now available. It is becoming exceedingly rare not to be able to clear all bile duct stones by endoscopic means.

The complete reference list for this chapter can be found online at www.expertconsult.com.

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