The role of endoscopy in the management of choledocholithiasis

This is one of a series of statements discussing the use of GI endoscopy in common clinical situations. The Standards of Practice Committee of the American Society for Gastrointestinal Endoscopy (ASGE) prepared this text. In preparing this guideline, a search of the medical literature was performed using PubMed. Additional references were obtained from the bibliographies of the identified articles and from recommendations of expert consultants. When few or no data exist from well-designed prospective trials, emphasis is given to results of large series and reports from recognized experts. Guidelines for appropriate use of endoscopy are based on a critical review of the available data and expert consensus at the time the guidelines are drafted. Further controlled clinical studies may be needed to clarify aspects of this guideline. This guideline may be revised as necessary to account for changes in technology, new data, or other aspects of clinical practice. The recommendations were based on reviewed studies and were graded on the strength of the supporting evidence (Table 1).[1] The strength of individual recommendations is based on both the aggregate evidence quality and an assessment of the anticipated benefits and harms. Weaker recommendations are indicated by phrases such as "we suggest," whereas stronger recommendations are typically stated as "we recommend."

This guideline is intended to be an educational device to provide information that may assist endoscopists in providing care to patients. This guideline is not a rule and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment. Clinical decisions in any particular case involve a complex analysis of the patient's condition and available courses of action. Therefore, clinical considerations may lead an endoscopist to take a course of action that varies from these guidelines.

Gallstone disease affects more than 20 million American adults[2] at an annual cost of $6.2 billion.[3] The incidence of choledocholithiasis ranges from 5% to 10% in those patients undergoing laparoscopic cholecystectomy for symptomatic cholelithiasis[4-7] to 18% to 33% of patients with acute biliary pancreatitis.[8-11] The diagnostic approach to patients with suspected choledocholithiasis is addressed in a separate ASGE practice guideline.[12] This guideline addresses the role of endoscopy in the management of patients with known choledocholithiasis.

Although data regarding the natural history of choledocholithiasis are limited, available studies indicate that 21% to 34% of common bile duct (CBD) stones will spontaneously migrate,[13,14] and migrating stones pose a moderate risk of pancreatitis (25%-36%)[13,14] or cholangitis if they obstruct the distal duct.[15] The natural history of CBD stones incidentally discovered during routine intraoperative cholangiography (IOC) at elective cholecystectomy may be less morbid than symptomatic CBD stones discovered pre-cholecystectomy.[16] However, because biliary pancreatitis and cholangitis may be life-threatening conditions, removal of discovered CBD stones is generally recommended.[17,18]

ENDOSCOPIC RETROGRADE CHOLANGIOGRAPHY (ERC)

Endoscopic retrograde cholangriography (ERC) with endoscopic sphincterotomy (ES) and stone extraction was first described in 1974[19] and has been a first-line management strategy for choledocholithiasis for the past 2 decades. In diverse settings, including community practice, reported success rates for removing CBD stones at ERC have commonly ranged from 87% to 100%,[20-26] with acceptably low rates of morbidity (~5%).[21,27,28]

Timing of ERC and relationship with cholecystectomy

The optimal timing for therapeutic ERC in the management of choledocholithiasis is variable and depends on the specific clinical scenario. Although acute cholangitis should generally lead to an expeditious ERC, the degree of procedure urgency depends on the clinical severity; consensus criteria for defining the severity of acute cholangitis have been proposed.[29] Truly urgent ERC is indicated when obstructing biliary stones are associated with severe acute cholangitis that is not responding to intravenous antibiotics and fluid resuscitation.[29-31] In these instances, biliary drainage is the primary focus of management rather than stone extraction. Early ERC (variably defined, but generally <72 hours) is advocated for patients with moderately severe acute cholangitis who are clinically responding to medical therapy.[29,31] Early ERC has also been advocated for patients with acute biliary pancreatitis and clinical evidence of biliary

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TABLE 1. GRADE system for rating the quality of evidence for guidelines

Quality of evidence	Definition	Symbol
High quality	Further research is very unlikely to change our confidence in the estimate of effect.	⊕⊕⊕⊕
Moderate quality	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.	⊕⊕⊕○
Low quality	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.	⊕⊕○○
Very low quality	Any estimate of effect is very uncertain.	⊕○○○

Adapted from Guyatt et al.[1]

obstruction (yet not cholangitis)[32] and for patients with predicted severe acute biliary pancreatitis,[33-35] as some randomized trials have shown reduced morbidity in these patient groups. However, other trials have not shown a benefit of early ERC in these patient groups,[36,37] and thus uncertainty remains. These data are discussed in more detail in the aforementioned ASGE guideline on the role of endoscopy in the evaluation of suspected choledocholithiasis."[12]

When ERC is selected as a management strategy for CBD stones in the setting of a planned laparoscopic cholecystectomy, several options exist with regard to the sequencing of these procedures. Preoperative ERC for patients with a high likelihood of choledocholithiasis[38,39] or intraoperative[40,41] or postoperative ERC[42,43] for patients with a positive IOC have all been described, without conclusively superior outcomes with any one strategy.[40] A single randomized trial of patients at intermediate risk of choledocholithiasis prospectively compared routine preoperative ERC and selective postoperative ERC; there was no difference in the rates of ductal clearance.[44] However, each ERC-associated strategy is associated with some caveats. With preoperative ERC, there remains a risk of interval migration of additional gallbladder stones before cholecystectomy,[45] and indiscriminant/routine use of preoperative ERC unnecessarily exposes patients to the risks of ERC. Intraoperative ERC is, by definition, on demand and logistically impractical for most gastroenterologists to offer to their surgical colleagues. Centers that have used this approach typically have surgeons capable of performing ERC. Last, the downside to postoperative ERC for stone clearance is the risk of technical failure, potentially requiring reoperation for duct exploration and clearance[1]; as such, this strategy may be optimally used in centers with significant expertise in ERC.

If preoperative ERC is undertaken for choledocholithiasis, laparoscopic cholecystectomy ideally should be performed within 2 weeks because longer delays have been associated with cholecystitis, biliary colic, recurrent choledocholithiasis, gallstone pancreatitis, and a trend toward higher rates of conversion to open cholecystectomy in multiple retrospective analyses.[47-50] Further, in a recent randomized trial of early (<72 hours) versus delayed (6-8 weeks) laparoscopic cholecystectomy in 96 patients status post endoscopic CBD stone clearance, a 36% incidence of recurrent biliary events (mostly biliary colic and acute cholecystitis) was reported in the delayed surgery arm.[51] This was significantly higher morbidity compared with the early surgery group and necessitated emergency surgery in 24% (4/17) of those patients who experienced a recurrent biliary event.

Early reports indicated that recurrent biliary complications after ES and stone clearance developed in a minority (12%) of patients with choledocholithiasis.[52] However, multiple subsequent randomized, controlled trials have addressed the issue of prophylactic cholecystectomy after ERC versus a watch-and-wait approach to the gallbladder. A systematic review of these trials reported higher rates of mortality, jaundice, or cholangitis; recurrent biliary pain; and the need for further cholangiography in those patients assigned to watch-and-wait, of whom 35% eventually required cholecystectomy.[53] As such, cholecystectomy is recommended for most patients with cholelithiasis after ductal clearance by ERC, particularly given the relatively low morbidity of laparoscopic cholecystectomy.

Preparation and cholangiography

In preparation for ERC, antibiotic prophylaxis is unnecessary in the majority of patients with suspected choledocholithiasis, unless cholangitis or immunosuppression is present or biliary drainage is predicted to be incomplete; a relevant ASGE guideline covers this topic in detail.[54] Proper technique for cholangiographic imaging is essential for successful identification of stones at ERC.[55] Despite careful attention to technique, the sensitivity of cholangiography for choledocholithiasis is imperfect (89%-93%)[56,57]; false-negative ERCs usually occur when small stones are present in a dilated duct. When a stone is anticipated, yet not seen on cholangiography, the endoscopist often must decide whether to perform an empirical ES to facilitate duct sweeping. Although empirical ES and sweeping may increase the detection rate of small (<5 mm) stones, it is of uncertain clinical benefit,[58] although perhaps beneficial in the setting of cholangitis.[59] The risks of a missed stone must be weighed against the potential complications of an unnecessary sphincterotomy. This decision will also be influenced by the pretest probability for choledocholithiasis, the quality of fluoroscopy used, and the availability of potentially helpful ancillary techniques such as intraductal US or standard EUS. Various methods for sonographically guided biliary endotherapy using a single echoendoscope have yielded promising early results, but these approaches remain investigational at this time.[60,61]

ES and endoscopic papillary balloon dilation (EPBD)

When 1 or more stones are identified at cholangiography, successful extraction typically requires either ES or EPBD, unless the stones are very small.[62] Endoscopic papillary balloon dilation (EPBD) does not permanently ablate the sphincter choledochus and thus was initially proposed as an alternative to ES with potentially less long-term morbidity.[23] However, multicenter randomized controlled trials,[63] systematic reviews[64,65] and a large prospective ERC series[66] demonstrated a significantly higher risk of pancreatitis with EPBD in addition to poorer technical success for stone clearance and more frequent need for mechanical lithotripsy. As such, primary EPBD is not advocated for routine use, although it may be a reasonable option in select circumstances, eg, coagulopathy, periampullary diverticulum, or surgically altered anatomy that increases the difficulty of ES.[67-69] EPBD after ES is discussed in the following.

ES may be performed using either pure cutting current or blended cutting/coagulation current. Although some trials suggested a reduced frequency of post-ERCP pancreatitis with pure cutting current,[70,71] a recent meta-analysis found no difference in pancreatitis incidence between the 2 modalities, and pure cutting current was associated with a higher risk of bleeding.[72] The appropriate length of the sphincterotomy may be variable depending on papillary anatomy and the size of the stone(s), but should not extend beyond the duodenal transverse fold. Occasionally, a stone will be encountered that is impacted in the ampulla, making traditional biliary cannulation and ES difficult or impossible. In these cases, needle-knife sphincterotomy is frequently effective in disimpacting the stone, and the underlying stone likely adds some margin of safety in protecting the pancreatic sphincter from inadvertent cautery.[73]

Stone extraction and biliary drainage

Extraction of stones may be undertaken using either balloon catheters or wire baskets. Although no data directly compare their efficacy for uncomplicated CBD stones, balloons are typically the first-line device, given the ease of use, utility in occlusion cholangiography, and the lack of risk of becoming entrapped in the duct. Biliary stone extraction devices are the subject of an ASGE technology review.[74] In addition to an adequate ES, surveillance for benign, stone-associated CBD strictures must be undertaken because these strictures must be addressed before stone extraction is possible.[75,76] Multiple stones should be extracted one at a time, starting with the distalmost stone first; attempts to extract multiple stones at once may result in impaction.[77] In cases of incomplete stone extraction or severe acute cholangitis, a biliary endoprosthesis should be placed to ensure adequate biliary drainage. Plastic biliary stents appear to be as effective as nasobiliary drainage catheters in the management of ascending cholangitis.[78-80] In cases of incomplete stone extraction, stent placement may have some therapeutic benefit on the CBD stone(s) in addition to securing drainage; in many instances, difficult biliary stones may be smaller, fragmented, or even absent after a period of stenting.[81-83] However, biliary stenting as a definitive therapy for difficult bile duct stones should be approached with caution. In 4 studies comprising a total of 228 patients, frail and/or elderly patients with CBD stones resistant to endoscopic removal were treated with plastic biliary stent placement.[84-87] Biliary-associated morbidity (mostly cholangitis) rates of 36% to 63% and biliary-associated mortality rates of 6% to 21% were reported during median follow-up times of 20 to 39 months. As such, biliary stenting as a stand-alone therapy for choledocholithiasis should be reserved for highly selected cases (eg, short life expectancy).

Failed biliary access

In a subset of patients with known choledocholithiasis, ERC is unsuccessful because of failure to access the CBD. Although several reasonable options exist for subsequent management, the course of action chosen will depend on several factors including the reason(s) for failure (eg, aberrant anatomy), the presence or absence of cholangitis, the medical stability and performance status of the patient, whether cholecystectomy is planned, and, perhaps most importantly, available expertise. Both a repeat attempt by the same endoscopist on a different day[88] or referral to a tertiary center with significant ERC expertise[89] may be reasonable options and have both been reported to have high rates (88%-96%) of selective cannulation in patients with previous failed ERC. Percutaneous transhepatic cholangiography (PTC) has been used to facilitate ERC via transpapillary guidewire passage, also known as rendezvous procedure, with the ERC performed either at the time of initial PTC[90] or after a few days of percutaneous biliary drainage.[91] PTC has also been used for primary percutaneous therapy of stones after failed ERC, although frequently multiple sessions are required, particularly if large or multiple bile duct stones are encountered.[92] EUS-guided transenteric biliary puncture and a rendezvous procedure have also been described after failed ERC for choledocholithiasis,[93] but the safety profile of this technique is not fully understood, and, at present, it is best reserved for use at tertiary centers with significant experience in EUS and ERC. In medically fit patients with cho-

TABLE 2. Clinical situations associated with difficult bile duct stone extraction

Stones >15 mm[20,98]
Stones that cannot be captured in a basket for extraction or mechanical lithotripsy
Stones associated with complex biliary strictures (eg, primary sclerosing cholangitis, recurrent pyogenic cholangitis), including hepatolithiasis[220,221]
Stones in patients with surgically altered upper gut anatomy (eg, Roux-en-Y gastric bypass, Billroth II gastrojejunostomy)[222,223]
Mirizzi syndrome[224]

ledocholithiasis, surgical intervention is frequently appropriate after failed ERC (or as a primary management approach, discussed in detail in the following), particularly when cholecystectomy is also required. Surgical options include both open and laparoscopic CBD exploration and the so-called laparoendoscopic rendezvous procedure, during which a guidewire is passed via the cystic duct and into the duodenum to facilitate intraoperative ERC.[94]

COMPLICATED BILIARY STONE DISEASE

Approximately 85% to 90% of biliary stones can be removed with a balloon or basket after ES or EPBD.[20,95] Almost by definition, those stones that defy initial efforts represent difficult stones. However, some prespecified clinical factors are associated with increasing procedure difficulty and poorer success rates in the endoscopic management of choledocholithiasis.[20,68,96-98] Table 2 lists clinical scenarios that are considered to be complicated biliary stone disease. Although duodenal diverticula are associated with an increased incidence of choledocholithiasis,[99,100] they have generally not been shown to lower the success rate of biliary cannulation or stone removal,[101-103] although some studies report higher rates of postsphincterotomy bleeding.[104] Other factors, including the degree of angulation of the distal CBD,[104] have been proposed to increase the difficulty of endoscopic stone removal, but not robustly evaluated. Some of the factors that predict difficulty can be identified pre-ERC and thus have implications for consideration of referral to a tertiary center or alternative management approaches. Potential endoscopic management strategies to address these clinical problems are discussed later.

Large bile duct stones

Common bile duct stones larger than 10 mm in diameter[23] and especially stones larger than 15 mm in diameter are associated with a lower success rate of endoscopic extraction and a greater need for some form of lithotripsy to facilitate removal.[20,98] Various techniques have been described to assist in the management of large bile duct stones.

EPBD after ES. EPBD after ES using 12- to 20-mm esophageal or pylorus-type balloons was first described in 2003 as a useful technique to manage large bile duct stones or stones above a tapering distal CBD.[105] Several subsequent reports have described a safety experience that appears comparable to ES alone; the higher pancreatitis rates seen with primary EPBD may be mitigated by the preceding ES with this technique, and rates of bleeding and perforation also do not appear to be increased.[106-111] Although 1 nonrandomized trial found a reduction in fluoroscopy time and less need for mechanical lithotripsy with EPBD after ES compared with ES alone,[112] 2 randomized, controlled trials reported essentially no differences in outcomes between these techniques.[111,113] Although experience remains relatively limited with EPBD after ES, available high-quality data support consideration of this technique as a strategy for managing large bile duct stones.

Mechanical lithotripsy. Mechanical lithotripsy of large CBD stones was first described in 1982[112] and has likely been the most frequently used lithotripsy approach historically, given its minimal expense, ready availability of the required accessories, and lack of the need for cholangioscopy. Classically, mechanical lithotripsy was performed with an external-type (ie, salvage) lithotriptor. Integrated through-the-scope mechanical lithotripsy systems have largely replaced external lithotripsy systems, given their ease of use and ability to capture and crush multiple stones in 1 session.[113]

Mechanical lithotripsy for stones not amenable to conventional extraction has a reported success rate of 79% to 92%.[114-117] The most common reason for failure of mechanical lithotripsy is stone impaction in the CBD,[116,117] and very large stones (>2 cm) have also predicted failure.[117] The reported incidence of complications with mechanical lithotripsy ranes from 6% to 13% in large retrospective series,[116,117] with pancreatitis and bleeding representing the most common adverse events. Technical complications, such as basket impaction and traction wire fracture, may complicate mechanical lithotripsy in as many as 4% of cases.[118] Most technical complications can be managed nonoperatively using an external salvage lithotriptor or an alternative lithotripsy modality.

Alternative lithotripsy approaches. Intraductal shock wave lithotripsy represents an alternative modality for the fragmentation of refractory biliary calculi, allowing subsequent removal. Shock waves may be generated in a fluid medium by a bipolar probe capable of generating a spark in the case of electrohydraulic lithotripsy (EHL) or by pulsed dye laser systems. An ASGE technology status report on biliary and pancreatic lithotripsy devices reviews EHL and laser lithotripsy (LL) in detail.[113] Both EHL and LL are most commonly used with cholangioscopic guidance to allow accurate stone targeting and avoid injury to the duct wall; however, use of "centering" balloons to allow EHL or LL with fluoroscopic guidance alone has been described.[119,120] Given the relative ease of use of integrated mechanical lithotriptors and the propensity of freely mobile stones to avoid EHL/LL fragmentation, these modalities may be best suited for large impacted stones.

The effectiveness of EHL for stone fragmentation ranges from 82% to 98%,[95,121-123] with the majority of patients requiring a single treatment session, although slightly lower rates of stone clearance (74%-95%).[95,121-124] Outcomes with LL are similar to those seen with EHL; bile duct clearance rates of 88% to 97% have been reported.[125-128] Complications with EHL and LL are reported in 3% to 19%,[120-126,128] with cholangitis and bleeding being the most common adverse events.

Extracorporeal shock wave lithotripsy (ESWL). ESWL represents another adjunctive modality in the endoscopic management of difficult CBD stones. Initially used for urolithiasis, ESWL involves the generation of shock waves in a water medium that then travel through the soft tissues of the body (because of their low acoustical impedance). When shock waves arrive at a focus point and impact against a stone, the abrupt change in acoustic impedance generates shearing forces that fragment the stone. Several ESWL systems are commercially available and vary in mechanism for shock-wave generation, focusing, and stone imaging apparatus (generally fluoroscopy, US, or both). Commonly, contrast is instilled via a previously placed nasobiliary catheter to aid in stone visualization, and continuous saline solution irrigation of the bile duct during ESWL has been associated with better outcomes.[129] The newer third-generation lithotriptors do not require an actual water bath and have improved focusing that may reduce collateral tissue damage and patient discomfort, although intravenous sedation is typically used. In most U.S. centers that use biliary ESWL, a collaborative approach with an urologist is typically used.

CBD stone fragmentation rates of 71% to 95% have been reported with ESWL,[121,125,130-132] leading to final ductal clearance rates of 70% to 90%.[121,125,130-135] Most commonly, between 1 and 3 sessions are needed for effective fragmentation, and usually ERC is undertaken within a few days after ESWL to sweep fragments from the duct. Complications have been reported in 10% to 35% of patients undergoing ESWL for choledocholithiasis, including cholangitis, hemobilia, hematuria, and transient arrhythmias.[121,125,129-132]

Three randomized, controlled trials evaluated ESWL compared with EHL[121] or LL.[125,132] In the latter 2 of these trials, LL was associated with a significantly higher rate of ductal clearance than ESWL (83%-97% vs 53%-73%), although no difference in duct clearance rates was seen in the trial comparing EHL and ESWL (74% vs 79%). After crossover to the alternate modality, final duct clearance rates of 91% to 98% were achieved. All 3 trials favored intraductal lithotripsy over ESWL with regard to number of treatment sessions required, whereas no difference in adverse events was seen.

Hepatolithiasis

Hepatolithiasis (ie, intrahepatic lithiasis) typically occurs in conjunction with biliary strictures and is seen in the setting of postoperative biliary strictures, primary sclerosing cholangitis, and recurrent pyogenic cholangitis, among other predisposing conditions.[136-138] Ascending cholangitis is a frequent acute complication associated with hepatolithiasis, although chronic complications include secondary biliary cirrhosis, lobar atrophy, and cholangiocarcinoma. Most studies on the management of hepatolithiasis are composed of patients with recurrent pyogenic cholangitis; limited data exist for other etiologies. Management options for hepatolithiasis include per-oral cholangioscopic lithotripsy (POCSL) (ie, cholangioscopy performed at ERC), percutaneous transhepatic cholangioscopic lithotripsy (PTCSL) (ie, cholangioscopy performed percutaneously via a transhepatic tract or T-tube tract) and surgical resection (ie, hepatectomy). Cholangioscopy with intraductal lithotripsy is usually an integral part of nonoperative approaches for hepatolithiasis because intrahepatic stones are difficult to extract in toto at ERC because of associated strictures or, similarly, via a limited-diameter percutaneous tract without previous fragmentation. In a series of POCSL for hepatolithiasis, the rate of complete stone removal was 23 of 36 (64%)[100]; frequent causes of failure were the inability to access the right posteroinferior and left inferolateral segments because of sharp angulations. PTCSL has attained higher rates of complete stone clearance (80%-85%) and thus is used more commonly.[139-141] However, both POCSL and PTCSL are hindered by high rates of stone recurrence (22%-50% on long-term follow-up), with biliary strictures predicting recurrence.[139-141] Hepatectomy has been associated with stone clearance rates greater than 90%[142,143] and fewer recurrences than nonoperative modalities. Hepatectomy should be considered for patients with acceptable functional status and unilateral stone disease, particularly if biliary strictures and/or lobar atrophy are also present.[144] Commonly, a T tube is inserted to facilitate postoperative cholangiography and PTCSL if needed. A multidisciplinary approach including a hepatobiliary surgeon, interventional radiologist, and gastroenterologist is optimal in the management of these challenging patients.

Surgically altered anatomy of the upper gut

The endoscopic management of choledocholithiasis is frequently more challenging in patients with previous reconstructive surgery of the upper GI tract; ERC in surgically altered anatomy has been reviewed in detail.[102,145,146] Before attempted endoscopic removal of CBD stones, it is prudent to review the surgical report, ensure that required endoscopes and devices are available, and consider and discuss nonendoscopic alternatives with the patient. Selected postsurgical anatomic states and their impact on CBD stone management are reviewed.

Billroth II. Billroth II gastrojejunal reconstructions have been used frequently in the setting of antrectomy for benign or neoplastic gastric disease. Because of the retrograde direction of the endoscopic approach, the orientation of the major papilla is rotated 180 degrees compared with a typical antegrade approach. A duodenoscope or therapeutic gastroscope can traverse the afferent limb and reach the major papilla, and cannulation success rates approximating 90% have been reported with both endoscopes.[101,147] Given the papillary orientation, ES is performed using a specialty papillotome, rotatable papillotome, or, more commonly, using a needle-knife after placement of a biliary stent. EPBD is also an option in these patients to facilitate stone removal; it is technically easier than sphincterotomy and was as effective in a randomized, controlled trial of 34 patients with bile duct stones and Billroth II anatomy, with no difference in complications.[68] Overall, high rates of success (85%-92%) have been reported for endoscopic treatment of CBD stones in Billroth II patients.[68,147,148] However, postsphincterotomy bleeding (reported in as many as 17% of patients[68]) and luminal perforations (reported in as many as 5% of patients [149]) occur more frequently during ERC in Billroth II patients than in patients with native anatomy.[68,149-151]

Roux-en-Y reconstructions. In patients with Roux-en-Y gastrojejunostomy (RYGJ) or Roux-en-Y hepaticojejunostomy (RYHJ) anatomy, a duodenoscope typically lacks the length and maneuverability needed to navigate the Roux limb to reach the papilla or hepaticojejunostomy.[148] As such, pediatric colonoscopes and standard enteroscopes,[152-154] and, more recently, balloon-assisted enteroscopes[155-160] have been used with varying success (62%-100%) for reaching the papilla or hepaticojejunostomy. Biliary cannulation with a forward-viewing colonoscope or enteroscope can be challenging; most operators have reported native papilla cannulation rates of 70% to 80% in this setting, if the papilla can be reached.[155,161,155] Stone removal techniques are similar to those used in Billroth II anatomy, and these patients also share an increased risk (as many as 5%) of perforation.[156]

Patients who have undergone Roux-en-Y gastric bypass (RYGB), which differs from RYGJ and RYHJ reconstructions in 2 regards that are clinically relevant to the performance of biliary endoscopy. First, the creation of the Roux jejunojejunostomy is frequently a greater distance from the stomach, resulting in both longer alimentary (Roux) and biliopancreatic limbs and thus potentially more difficulty in reaching the biliary orifice. However, data are mixed as to whether RYGB anatomy is associated with a lower rate of successful access to the biliary orifice compared with RYGJ or RYHJ when balloon-assisted enteroscopy is used.[155,159]

Second, the intact antroduodenal pathway to the biliary tree makes transgastric endoscopic approaches possible in RYGB patients, which are not options in RYGJ and RYHJ. One option is the creation of a surgical or radiologic gastrostomy into the excluded stomach and subsequent access and dilation of the gastrostomy tract after allowing 3 to 4 weeks for tract maturation.[162,163] Alternatively, laparoscopy-assisted ERCP involves the creation of a laparoscopic gastrotomy and intraoperative passage of a duodenoscope via the newly created gastrotomy. This method has been associated with high rates (90%-100%) of therapeutic success, including CBD stone removal.[164-166] A gastrostomy tube can be placed after ERCP if repeat intervention is anticipated. Complication rates of as high as 13% have been reported with this technique, including perforation/leak at the gastrostomy site and wound infection.[170]

Mirizzi syndrome

Mirizzi syndrome refers to obstruction of the common hepatic duct by a gallstone impacted in the cystic duct or gallbladder neck. It is an uncommon complication of gallstone disease, reported in approximately 0.3% of large series of cholecystectomies.[167,168] Historically, the role of ERC was to diagnose Mirizzi syndrome and relieve biliary obstruction via stenting before definitive surgical management. However, case series also describe successful endoscopic stone removal in Mirizzi syndrome, usually after some form of intraductal lithotripsy or ESWL, both pre- and postoperatively.[103,169,170] Some elderly patients with poor functional status and patients without additional gallbladder stones have been managed with endoscopic stone removal alone.[103,169,170]

NONENDOSCOPIC MODALITIES FOR BILIARY STONE MANAGEMENT

Surgical management

IOC and open CBD exploration for stone removal were frequently performed before the advent of laparoscopic cholecystectomy. In this setting, there was no advantage of preoperative ERC over 1-stage surgical management in randomized, controlled trials.[171] Laparoscopic cholecystectomy has now supplanted open cholecystectomy because of attenuated morbidity and shorter hospital stays. Laparoscopic IOC and transcystic stone removal or removal via laparoscopic choledochotomy (henceforth collectively termed laparoscopic CBD exploration [LCBDE]) are also reasonable treatment options in patients with known or highly suspected choledocholithiasis undergoing cholecystectomy. As an alternative, laparoscopic transcystic antegrade placement of a transpapillary biliary stent to ensure access at postoperative ERC has been described.[172]

Randomized, controlled trials have compared LCBDE at laparoscopic cholecystectomy with both preoperative ERC followed by laparoscopic cholecystectomy for patients at high risk of choledocholithiasis[173-175] as well as postoperative ERC for patients with a positive IOC.[176,177] In general, the primary ductal clearance rates, morbidity, and mortality are similar in ERC and LCBDE in these trials.[174-177] Some trials report a shorter hospital stay for patients treated with LCBDE,[173,177,173] and, not surprisingly, a need for fewer total procedures for those in the 1-step arm than those treated in 2 stages.[175,178,175]

Although LCBDE is an attractive concept for CBD stone management given its similar efficacy and improved efficiency compared with ERC, its adoption has not been widespread.[179-182] Thus, LCBDE is a first-line strategy for choledocholithiasis management, but is limited to centers where appropriate expertise is available.

Percutaneous management

At present, percutaneous management of biliary stones is most commonly used in the setting of hepatolithiasis. However, percutaneous techniques have also been used for extrahepatic biliary stones via a T-tube sinus tract or percutaneous transhepatic tract.[183-186] High rates of successful duct clearance (90%-100%) using a variety of techniques have consistently been reported with percutaneous approaches.[183-191] However, severe bleeding events have been reported in as many as 14% of patients with percutaneous transhepatic approaches, with mortality as high as 8%.[184,188] Given the logistical complexity (percutaneous tracts take time to mature), incidence of severe complications, and available alternatives, percutaneous techniques for managing extrahepatic bile duct stones are not recommended as a first-line strategy. However, removal of small stones via a mature T-tube sinus tract represents a potential exception because excellent results have been achieved in experienced hands.[183]

Dissolution of CBD stones

Bile acids. Data for oral administration of bile salts as a stand-alone therapy for choledocholithiasis are limited and not favorable[192]; this approach is not recommended. Nonrandomized studies of ursodeoxycholic acid (UDCA) as an adjunct to biliary stenting in patients with bile duct stones refractory to endoscopic removal suggested that treatment with 600 mg/day of UDCA for 6 to 9 months is associated with a reduction in stone size and CBD diameter and facilitates subsequent endoscopic duct clearance in 90% to 93% of patients.[193,194] However, a randomized, controlled trial did not support these results. Forty-one patients with large CBD stones in whom endoscopic extraction failed all had a 10F biliary stent placed and were then randomized to 750 mg UDCA/day or placebo for 6 months.[195] At follow-up, there was no difference in stone size or final ductal clearance rates between the 2 groups.

Topical solvents. Topical solvents including monooctanoin and methyl tert-butyl ether were also evaluated in the 1980s for more rapid dissolution of retained cholesterol stones in the CBD. Although effective in 55% to 90% of patients for achieving complete or partial dissolution facilitating endoscopic removal, hepatic and duodenal toxicity of these agents (particularly of methyl tert-butyl ether), frequent adverse effects (eg, vomiting, diarrhea, pain), and cumbersome treatment protocols severely limit the application of these techniques.[196-199]

MANAGEMENT OF RECURRENT STONE FORMATION

Despite apparently complete clearance of bile duct stones at ERC, recurrent CBD stones developed in 3% to 15% of patients in series with long-term (>5 years) follow-up.[200-205] Other than gallbladder in situ, risk factors for stone recurrence generally relate to conditions predisposing to bile stasis, including bile duct dilation greater than 15 mm,[203,204] and anatomic lesions that may impede bile flow (eg, periampullary diverticuli,[203,206] angulation of the CBD,[207] and biliary strictures or papillary stenosis[208]). It should be noted that the vast majority of recurrent or de novo CBD stones are brown pigment stones[204] whose formation is dependent on bacteria (infected bile is nearly ubiquitous in brown pigment stones) and whose composition and pathogenesis differ significantly from those of other types of stones.[209] Fortunately, recurrent CBD stones can be managed at ERC with a high rate of success.[204,210]

In patients with documented CBD stone recurrence, biliary stasis and its predisposing factors may be difficult to definitively correct, and alternative management strategies can be considered. In a small series of 13 patients with 2 or more documented recurrences of CBD stones, a decision to perform annual surveillance ERC for duct sweeping was associated with a reduction in the frequency of ascending cholangitis.[211] The role of UDCA was evaluated in a small trial of 46 patients status post endoscopic clearance of bile duct stones. One of 22 patients who received UDCA 500 mg/day had CBD stone recurrence during approximately 18 months of follow-up compared with 4 of 26 patients receiving placebo.[212] However, data on UDCA in this role remain very limited, and given the different pathogenesis of brown pigment stones compared with cholesterol gallbladder stones, the biological plausibility is not as well established in this setting. Surgical choledochoduodenostomy or related biliary-enteric anastomoses have also been described in the management of recurrent CBD stones.[213-215] However, choledochoduodenostomy has been associated with as much as 5% in-hospital mortality,[216] and a 10% to 28% adverse event rate, including cholangitis, sump syndrome, bile leak, and wound infection.[212,217-219] As such, the role of choledochoduodenostomy is limited to patients with recurrent CBD stones refractory to nonsurgical management.[46]

RECOMMENDATIONS

1. We recommend that CBD stones should be removed if detected unless significant mitigating clinical circumstances are present. ⊕⊕⊕○

2. The optimal timing of endoscopic stone management depends on the clinical scenario. We recommend that urgent ERC is indicated for stones associated with severe acute cholangitis that is not responding to medical treatment. ⊕⊕
3. In the setting of symptomatic cholelithiasis, we suggest that preoperative ERC for patients with a high likelihood of choledocholithiasis or intraoperative or postoperative ERC for patients with a positive IOC are all valid and comparable approaches. ⊕⊕⊕○
4. If preoperative ERC is undertaken for choledocholithiasis, we recommend subsequent cholecystectomy in most cases. ⊕⊕⊕○ We recommend that cholecystectomy be performed within 2 weeks because longer delays have been associated with increased morbidity from recurrent biliary events. ⊕⊕⊕○
5. We suggest that antibiotic prophylaxis is unnecessary in the majority of patients with suspected choledocholithiasis, unless cholangitis or immunosuppression is present or biliary drainage is predicted to be incomplete. ⊕⊕⊕○
6. We recommend against routine use of primary EPBD given the reported risks of severe pancreatitis, although it may be considered in select clinical circumstances that increase the risk or difficulty of ES. ⊕⊕○○
7. We recommend placement of a plastic biliary endoprosthesis to ensure adequate drainage in cases of incomplete stone extraction or severe acute cholangitis. ⊕⊕○○
8. We recommend against the use of plastic biliary stents as a sole therapy for CBD stones refractory to initial endoscopic extraction, given the high frequency of late biliary complications associated with this strategy. ⊕⊕⊕○
9. For large, nonimpacted CBD stones refractory to initial extraction efforts, we suggest that mechanical lithotripsy or EPBD after ES be considered as next steps, given their effectiveness, ease of use, and acceptable safety profiles. ⊕⊕○○
10. We suggest that in patients with large and/or impacted calculi refractory to mechanical lithotripsy, intraductal lithotripsy (EHL or LL) is preferred over ESWL, given the superior rates of ductal clearance. ⊕⊕⊕○
11. Given the increased rate of complications and lower success rate of endoscopic management of CBD stones in patients who have undergone Billroth II or Roux-en-Y reconstructions, we suggest that these patients be referred to biliary centers of excellence. ⊕⊕○○
12. We recommend that LCBDE is an alternative to ERC as a first-line strategy for CBD stone removal in the setting of symptomatic cholelithiasis in centers where surgical expertise is available. ⊕⊕⊕○
13. We recommend against primary percutaneous transhepatic management of CBD stones in patients with native anatomy, given that more expeditious alternatives with similar or better risk profiles exist (eg, ERC, LCBDE). ⊕⊕○○
14. We suggest that UDCA may be considered as an adjunct to biliary stenting in the management of difficult stones. ⊕⊕○○
15. We recommend that recurrent CBD stones may be effectively managed with repeat ERC. ⊕⊕○○ Limited data guide further decision making in these patients, and the use of UDCA, surveillance ERC, or a biliary-enteric bypass must be individualized.

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Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; CBD, common bile duct; EHL, electrohydraulic lithotripsy; EPBD, endoscopic papillary balloon dilation; ERC, endoscopic retrograde cholangiography; ES, endoscopic sphincterotomy; ESWL, extracorporeal shock wave lithotripsy; IOC, intraoperative cholangiography; LCBDE, laparoscopic common bile duct exploration; LL, laser lithotripsy; POCSL, peroral cholangioscopic lithotripsy; PTC, percutaneous transhepatic cholangiography; PTCSL, percutaneous transhepatic cholangioscopic lithotripsy; RYGB, Roux-en-Y gastric bypass; RYGJ, Roux-en-Y gastrojejunostomy; RYHJ, Roux-en-Y hepaticojejunostomy; UDCA, ursodeoxycholic acid.

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