CBD Stones

Cholangioscopy & Lithotripsy
CBD Stones

- The incidence of choledocholithiasis ranges from 5-10% in patients undergoing laparoscopic cholecystectomy for symptomatic choledolithiasis to 18-33% in patients with acute biliary pancreatitis.
- An estimated 21-34% of CBD stones spontaneously migrate and pose a risk of acute biliary pancreatitis or cholangitis if they obstruct the distal duct.
- Because of the life-threatening nature of biliary pancreatitis and cholangitis, removal of discovered common bile duct stones is generally recommended.

CBD Stones

• ERCP with sphincterotomy (ES) is currently the first-line management strategy for choledocholithiasis.

• We use many devices and techniques to facilitate bile duct stone removal, ranging from surgical exploration of the CBD to lithotripsy and SpyGlass® cholangioscopy.

• Overview of the features, techniques, indications, clinical efficacy, safety, and potential complications of various methods of bile duct stone removal.
CBD Stones

• Sensitivity of ERCP for detection of choledocholithiasis is 89-93%.

• Successful extraction of a stone identified at cholangiography, typically requires endoscopic sphincterotomy (ES).

• ES combined with standard endoscopic devices such as balloon catheters and wire baskets has a 90% success rate for bile duct clearance.

• If a stone is anticipated but not identified at cholangiography (e.g., small stone in a duct), an empirical ES can be performed to facilitate duct sweeping.

• Patients with large stones (>12 mm), multiple stones, barrel-shaped stones, or a tapering or tortuous distal common bile duct may require special treatment such as lithotripsy in addition to sphincterotomy to achieve bile duct clearance.

• **ES** when combined with standard endoscopic devices such as balloon catheters and wire baskets has a 90% success rate for bile duct clearance.

• Patients with large stones (>12 mm), multiple stones, barrel-shaped stones, or a tapering or tortuous distal common bile duct may require special treatment such as lithotripsy in addition to sphincterotomy to achieve bile duct clearance.


CBD Stones-Timing of ERCP

- The degree of procedure urgency largely depends on the specific clinical scenario:

- Truly urgent therapeutic ERCP is indicated in cases of severe **acute cholangitis** caused by obstructing biliary stones not responding to medical therapy; biliary drainage, rather than stone removal, is the primary goal of intervention.

- In less severe cases of **acute cholangitis** with clinical response to medical therapy, ERCP can be delayed for 72 hours.

- The benefits of early (<72 hours) ERCP in patients with **acute biliary pancreatitis** have been a subject of controversy: some randomized trials showing reduced morbidity, other trials showing no benefit in the absence of concurrent acute cholangitis or obstructive jaundice.

CBD Stones-Timing of ERCP

• The timing of ERCP for management of CBD stones in relation to a planned laparoscopic cholecystectomy has been the subject of multiple studies.

• Wright et al, 2002: Retrospective study of 67 patients undergoing either a pre-, intra-, or post-operative ERCP for CBD stones. Overall complication rates, hospital length of stay, and total hospital charges were not statistically different among the three groups.

USF:

• Postoperative ERCP – in patients with evidence of choledocholithiasis found during an intraoperative cholangiogram.

• Preoperative ERCP – in patients with a high likelihood of choledocholithiasis.

CBD Stones-ASGE STANDARDS OF PRACTICE COMMITTEE

Risk of choledocholithiasis in patients with symptomatic cholelithiasis.

- **Any Very Strong Predictor:** high likelihood
  - CBD stone on transabdominal US,
  - Clinical ascending cholangitis,
  - Bilirubin >4 mg/dL.

- **Two Strong Predictors:** high likelihood
  - Dilated CBD on US (>6 mm with gallbladder in situ)
  - Bilirubin level 1.8-4 mg/dL.

- **Moderate Predictors:** intermediate likelihood
  - Abnormal liver biochemical test other than bilirubin,
  - Age older than 55y,
  - Clinical gallstone pancreatitis.

- **No predictors present:** low likelihood
CBD Stones-Timing of ERCP

- Multiple retrospective studies:
  
  Delays longer than **two weeks from the time of preoperative ERCP** to lap-chole have been associated with biliary colic, recurrent choledocholithiasis, cholecystitis, gallstone pancreatitis, and a higher rate of conversion to open cholecystectomy.

- Reinders et al, 2010:
  
  A randomized trial of 96 patients status post-endoscopic CBD stone clearance. A 36% incidence of recurrent biliary events, (primarily acute cholecystitis and biliary colic) in the delayed surgery arm (6-8 weeks) compared with 2% in the early group (<72 hours).

  Strong evidence in support of early lap-chole after preoperative ERCP!

Prophylactic Cholecystectomy after ERCP

• In most patients with cholelithiasis who undergo ES for choledocholithiasis, prophylactic cholecystectomy is recommended after ductal clearance by ES.

• A Cochrane Systematic Review, 2007, of multiple randomized controlled trials (662 participants) comparing the outcome of a wait-and-see approach to prophylactic cholecystectomy after ERCP:

The wait-and-see approach carries higher rates of mortality (78% increased risk), recurrent biliary pain, jaundice or cholangitis, and a higher need for repeat ERCP.

35% in the wait-and-see group eventually required cholecystectomy.

ES Technique

- ES - Standard Sphincterotomy requires successful retrograde cannulation of the bile duct. Access is often secured by passing a guidewire into the bile duct and confirmed by injection of radiocontrast material.
- After successful retrograde cannulation of the bile duct, an incision is made in the biliary sphincter by means of electrocautery through a traction-type papillotome with the cutting wire bowed against the roof of the papilla.
- ES - may be performed using either pure cutting current or blended/coagulation current, with no difference in pancreatitis incidence but higher risk of mild bleeding associated with pure cutting current.
- Size of the stone(s) and papillary anatomy are considered in determining an appropriate length of the sphincterotomy.
- The length of the sphincterotomy should not extend beyond the duodenal transverse fold.

ES Technique

• Biliary cannulation is not always possible(e.g. stone impaction in the ampulla).
• Methods that involve dissection of the papilla to expose the bile duct are collectively known as “precut” sphincterotomy.
• The needle-knife precut method - extending a fine cutting wire several millimeters from the catheter tip to unroof the papilla in incremental layers until the bile duct is exposed. In this method, often a small-diameter plastic stent is placed into the pancreatic duct before precutting to protect pancreatic drainage.
• A less common method of precutting involves wedging of a modified traction-type papillotome into the papillary orifice and using it to make incremental incisions until the bile duct is exposed.
• Masci et al,2003 reported in a systematic review of “precut” sphincterotomy to increase the risk of acute pancreatitis.
• Lee et al, 2007 and Testoni et al, 2011 could not identify any risk factors associated with the development of post-ERCP pancreatitis in patients who underwent precut sphincterotomy by skilled endoscopists.

ES - Early Post-Procedure Complications

- The incidence and type of complications after ES is primarily related to the clinical indication and context for the procedure as well as to the technical skill of the endoscopist.

- Two separate large multicenter prospective studies have been performed to investigate complications of ES:

- Complications were observed in 6% of patients at seven academic medical centers, of which two-thirds were considered to be mild (requiring less than three days of hospital stay).

- In a large multicenter prospective study by Freeman et al, 1996 the most frequent complications were pancreatitis (5.4%), hemorrhage (2.0%), cholangitis (1.0%), acute cholecystitis (0.5%), retroperitoneal or bowel wall perforation (0.3%), and other complications (1.1%) such as cardiopulmonary complications, bile leak, intrahepatic bleeding, and ductal perforation.

ES - Early Post-Procedure Complications

• Independent risk factors for post-procedure complications:
  - two patient-related factors (presence of cirrhosis, and suspected sphincter of Oddi dysfunction)
  - three technique-related factors (use of precut sphincterotomy, use of combined percutaneous-endoscopic procedure, and difficult bile duct cannulation).

• The overall risk of complications was not related to the patient’s age, the number of coexisting illnesses, or the diameter of the bile duct.

• Endoscopists who performed more than one sphincterotomy per week were found to have lower rates of all complications including severe complications.

• Rates of complications of ES in patients with bile duct stones or gallstone pancreatitis were similar (8.1% overall) regardless of whether ES was performed before, after, or without cholecystectomy.

ES Complications

• A systematic review of 15 prospective clinical trials identified risk factors for development of post-ERCP pancreatitis.

• Significantly higher risk of acute pancreatitis was seen in patients with suspected sphincter of Oddi dysfunction (RR 4.09), female gender (RR 2.23), and with previous pancreatitis (RR 2.46).

• Two endoscopy-related factors were associated with significantly higher risk of acute pancreatitis:
  - precut sphincterotomy (RR 2.71) and
  - pancreatic injection (RR 2.2).

ES-Long Term Complications

- Long-term complications following ES include recurrent bile duct stones, papillary stenosis, cholangitis, cholecystitis, and liver abscess.
- Long-term followup studies of ES for CBD stones: 4-24% incidence of recurrent biliary problems.
- Stone recurrence risk factors: a dilated bile duct, the presence of periamppullary diverticulum, a gallbladder left in situ, presence of brown pigmented stones at the initial ES, use of a mechanical lithotripter during treatment, the occurrence of pneumobilia after ES.
- Ampullary stenosis and bile duct strictures have been associated with later recurrence of bile duct stones.
- Stone recurrence occurs less frequently in patients with acalculous gallbladders than in patients with calculous gallbladders and in patients who have previously undergone cholecystectomy.

- Routine follow-up is recommended for patients at high risk for stone recurrence.


Endoscopic Papillary Balloon Dilation
Endoscopic Papillary Balloon Dilation

- Endoscopic papillary balloon dilation (EPBD) of the virgin ampulla has been promoted as an alternative to ES for treatment of bile duct stones.
- The primary advantage of EPBD compared to ES lies in longterm preservation of sphincter of Oddi function, as it does not permanently ablate the sphincter.
- Because of significantly higher risk of pancreatitis (15%) and death (2%) as reported in multicenter randomized controlled trials and systematic reviews, EPBD has been abandoned in the US; it is commonly performed in Japan.
- May have a role in patients for whom ES is contraindicated such as those with coagulopathy, periampullary diverticulum, liver cirrhosis, or those with an altered anatomy as in Billroth II gastrectomy patients.


Endoscopic Papillary Balloon Dilation
Endoscopic Papillary Balloon Dilation

- Fujita et al. (2003), large (282 pts) randomized trial of EPBD vs. ES: Comparable complete duct clearance rates, Overall complication rate of 14.5% in the EPBD group, 11.8% in the ES group. Postprocedure pancreatitis rate was significantly higher in the EPBD group (10.9% vs 2.8%), no severe pancreatitis or death was seen in the EPBD group. Hemorrhage was exclusively limited to the ES group.

- Yasuda et al. (2010) followed the 282 pts annually for a median of 6.7 years: Significantly lower rate of recurrent bile duct stones in the EPBD group (17% vs 8%). Significantly lower overall morbidity in the EPBD group (25.0% vs 10.1%).

- 2010 editorial article in GIE raises a serious question as to whether the initial “price” of EPBD is too high (serious pancreatitis, death) to justify the reduced long term biliary complications of EPBD: “Pay me now or pay me later!”


Stone Extraction: Dormia Baskets and Balloon Catheters

Background

- Following an adequate sphincterotomy, most stones <10 mm in diameter will pass spontaneously.
- Failure to ensure stone removal carries a risk of stone impaction and cholangitis.
- The current practice is to remove the bile duct stones at the time of sphincterotomy.
- Balloon catheters and wire baskets, are available to retrieve stones following a successful sphincterotomy.
- Large stones >20 mm in size may be difficult to remove with basket and balloon extraction methods and will require stone fragmentation prior to removal.

Stone Extraction: Dormia Baskets and Balloon Catheters

Background

• The choice of baskets, balloons, or a combination of the two in a single procedure to retrieve biliary stones depends on factors such as the degree of common bile duct dilation and the number, shape, and configuration of stones present.

• Balloons are typically the first-line device due to their ease of use, lack of risk of entrapment in the duct, and their utility in occlusion cholangiography.

• Multiple stones are recommended to be removed one at a time, starting with the distal-most stone first.

• Complete duct clearance is recommended to be documented by performing an occlusion cholangiogram.

Stone Extraction: Dormia Baskets and Balloon Catheters
Stone Extraction: Dormia Baskets and Balloon Catheters
Balloon Catheters

- A deflated balloon catheter is inserted into the CBD through the sphincterotomy site, over a guidewire.
- The deflated balloon catheter is advanced proximally, “above” the targeted stones.
- After inflating the balloon to the size of the bile duct, the balloon catheter is pulled through the scope.
- Once the stone is pulled to the level of ampulla, traction on the balloon catheter while exerting downward deflection on the scope tip allows extraction of the stone.
- When compared to wire baskets, balloon catheters are better suited for removal of small to medium-sized stones and particularly helpful in removal of intrahepatic stones as the narrow caliber of intrahepatic ducts limits the opening of the wire basket.

Raijman, I., Endoscopic management of bile duct stones: Standard techniques and mechanical lithotripsy, in UpToDate, D.S. Basow, Editor 2011, UpToDate: Waltham, MA.
Dormia Wire Basket
Wire Baskets

- Variety of baskets are available in different sizes to capture stones varying from 5-30 mm.
- Stones >20 mm often cannot be extracted intact and require fragmentation prior to removal.
- A Dormia basket, shaped as a 4-wire hexagonal basket made of braided steel or nitinol wires, is the most commonly used type.
- Basket extraction:
  - The closed basket covered by its plastic sheath is inserted into the CBD.
  - Dilute contrast is injected through the basket to localize the stone.
  - The basket is opened above the stone and pulled back/jiggled to engage the stone.
  - Avoid opening of the basket below the stone, it may cause escape of the stone further proximally into the intrahepatic biliary tree.

Wire Baskets

• Once the stone is trapped, the basket is withdrawn to the pre-ampullary level without closing the basket tightly.
• Tight closure of the basket at this time carries the risk of imbedding the basket wires within the stone surface, causing impaction of the basket in the bile duct.
• Traction on the basket catheter allows easy removal of small to medium-sized stones from the CBD.
• Potential complications of basket extraction - impaction of the basket and stone within the bile duct or at the level of the papilla due to a large stone size and/or inadequate sphincterotomy.
• Mechanical lithotripsy may be attempted in such cases to fragment the impacted stone and free the basket.
• Wire baskets provide more effective traction than balloons and are more helpful in removal of medium to large-sized stones.

Stone Extraction: Dormia Baskets and Balloon Catheters
Stone Extraction: Dormia Baskets and Balloon Catheters

Technique Details:

• In many instances, simple pulling of the basket or balloon catheter is sufficient to extract the stone. In some instances, high resistance is encountered as the stone reaches the ampulla. (when the sphincterotomy size is smaller than the stone’s diameter…)

• Gain a larger mechanical force by pushing the scope further in the “long position” while turning the small turning wheel to the right, causing straightening of scope in the bile duct axis.

• Exertion of a traction force along a straight axis in the CBD facilitates the removal of stones while reducing the risk of injury to the papilla or periampullary area.

• Care must be taken to avoid perforation of the opposite duodenal wall by the scope as bending it may push against that wall.

Raijman, I., Endoscopic management of bile duct stones: Standard techniques and mechanical lithotripsy, in UpToDate, D.S. Basow, Editor 2011, UpToDate: Waltham, MA.
Mechanical Lithotripsy

Background

• Over 80% of all common bile duct stones can be removed effectively with ES and conventional stone extraction methods, wire baskets and balloon catheters.

• Large stones >20 mm in size may be difficult to remove with basket and balloon extraction methods alone and require stone fragmentation prior to removal, the reduction of stone size allows easier extraction.

• Mechanical lithotripsy has become the initial procedure of choice with a ductal clearance rate of 80-90%.

• In cases of unsuccessful mechanical lithotripsy we use
  a) Intraductal electrohydraulic lithotripsy (EHL) or laser lithotripsy (LL)
  b) Extraductal shock-wave lithotripsy (ESWL).

Mechanical Lithotripsy

Technique

• Mechanical lithotripsy is accomplished by capturing a stone within a wire basket and crushing it by forceful traction of the basket wires against a metal sheath that is advanced over the basket catheter.

• Several mechanical lithotripters are available including out-of-the-scope lithotripters and through-the-scope lithotripters.

• The out-of-the-scope lithotripters require cutting of the basket handle and removal of the endoscope prior to mechanical lithotripsy. This method is often used on an emergency basis when encountering unexpected impaction of the stone-basket apparatus.
Mechanical Lithotripsy

Out of scope lithotriptor The out of scope lithotriptor is attached to a retrieval basket after the endoscope has been removed from the patient. Cranking of the handle tightens the basket’s wires, causing disruption of the stone. Courtesy of Isaac Raijman, MD
Mechanical Lithotripsy

Technique

• After cutting the basket handle to allow removal of the endoscope, the metal sheath of the mechanical lithotripter is inserted over the basket catheter and advanced all the way up to the stone under fluoroscopic guidance.

• The cut ends of the basket wires are then inserted into the shaft of the crank handle, which is in turn connected to the metal sheath by a Luer lock.

• Slow cranking of the handle of the lithotripter closes and draws the basket into the metal sheath, crushing the stone against the tip of the metal sheath in the process.

• Once the stone is fragmented, the apparatus is removed and conventional methods such as basket or balloon extraction can be used to remove the smaller fragments.
Mechanical Lithotripsy

• The through-the-scope (TTS) lithotripters share the same operative principles but are designed to be used without the need for scope removal. They are used in a more elective setting to remove large, difficult stones or stones located above a stricture.

• Commonly used TTS mechanical lithotripters are the Olympus BML systems and the Trapezoid basket (Microvasive). Some models allow contrast injection to better visualize the stone.

• Both reusable and disposable TTS systems are available.
Mechanical Lithotripsy (ML)

Clinical Efficacy

• Described by Demling et al. in 1982
  Ductal clearance rate of approximately 80-90%.
  20-30% of patients require more than one treatment session.

• Binmoeller et al. (1993)
  - 108 patients with difficult bile duct stones,
    who had failed extraction by ES, Balloons and Dormia baskets.
  - 33/108 patients had stones that could not be extracted
    after entrapment in the Dormia basket.

Stone fragmentation by ML & bile duct clearance was achieved in 100%.

Mechanical Lithotripsy

Clinical Efficacy

- Cipolletta et al. (1997)

  Complete duct clearance using ML in 84% of patients (136 of 162) who had failed stone removal.

  119 patients were cleared during the initial attempt,
  17 patients required multiple sessions.

  Failure of ML was due to inability to capture the stone within the basket.

  Procedure-related morbidity occurred with inadequate biliary drainage: 3 cases of cholangitis (1.8%) and 2 cases of pancreatitis (1.2%).

  No deaths were observed after ML.


Mechanical Lithotripsy

Complications

• Thomas et al. (2007)
• Comprehensive retrospective review of 712 ML cases.
  (643 biliary and 69 pancreatic large or resistant stones)
• A 46-point data questionnaire in 7 tertiary referral centers.
• Trapped and/or broken baskets was documented as the most frequent complication of biliary and pancreatic ML.
• Extension of ES and electrohydraulic lithotripsy were the most frequently utilized treatment options.
Mechanical Lithotripsy

Predictors of Success and Failure

1. Garg et al. (87 patients, prospective)
   The only predictive factor for failure was stone impaction. Stone size was not significant as a predictor for success or failure in the study.

2. Cipolletta et al. (162 patients, retrospective)
   Stone size was the only outcome predictor, with high risk for lithotripsy failure in stones >28 mm.

3. Lee et al. (134 patients, retrospective)
   Predictors of ML failure are
   - Stone impaction,
   - Stone size > 30 mm,
   - Stone size to Bile Duct diameter ratio >1.0

ES and Large Balloon Dilation (LBD)
ES-LBD compared to ML

- Use of large balloon dilation (LBD) with 10-20 mm TTS balloons following ES has been proposed as an alternative to mechanical lithotripsy (ML) following ES in removal of large bile duct stones.

- Ersoz et al. (2003) first reported an 89 - 95 % stone clearance rate and 15.5% complication rate in 58 patients who underwent ES-LBD after failing ES and standard basket/balloon extraction.

- Stefanidis et al. (2011) in a prospective, randomized, controlled trial:
  - Head-to-head comparison between ES-LBD and ES-ML.
  - ES-LBD is equally effective as ES-ML for the removal of large (> 12 mm) bile duct stones and is associated with fewer complications.

- Post-procedure complications were significantly less in patients subjected to ES-LBD at 4.4% compared with 20% in ES-ML.

- Cholangitis developed in none of the patients subjected to ES-LBD compared to 13.3% in ES-ML (p=0.026) group.

- The rates of pancreatitis and post-ERCP hemorrhage were similar between the two groups.

- Dilation balloons greater than 20 mm are not available at this time and ES-ML remains the procedure of choice in patients with stones larger than 20 mm.


## ES-LBD vs. ES-ML

### Outcome of ES–LBD and ES–ML

<table>
<thead>
<tr>
<th></th>
<th>ES–LBD</th>
<th>ES–ML</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complete stone removal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>44</td>
<td>41</td>
<td>NS</td>
</tr>
<tr>
<td>(i) 12–13 mm</td>
<td>17</td>
<td>14</td>
<td>NS</td>
</tr>
<tr>
<td>(ii) 14–16 mm</td>
<td>15</td>
<td>15</td>
<td>NS</td>
</tr>
<tr>
<td>(iii) 17–20 mm</td>
<td>12</td>
<td>12</td>
<td>NS</td>
</tr>
<tr>
<td>Reasons for failure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(i) Tortuous common bile duct</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(ii) Breaking of basket due to a hard stone</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(iii) Inability to capture the stone</td>
<td>3</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Length of hospital stay (days), mean (s.d.)</td>
<td>6 (3)</td>
<td>5 (2)</td>
<td>NS</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Complications</th>
<th>ES–LBD</th>
<th>ES–ML</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-ERCP pancreatitis</td>
<td>1 (2.2%)</td>
<td>1 (2.2%)</td>
<td>NS</td>
</tr>
<tr>
<td>Cholangitis</td>
<td>0 (0.0%)</td>
<td>6 (13.3%)</td>
<td>0.026</td>
</tr>
<tr>
<td>Post-ERCP bleeding</td>
<td>1 (2.2%)</td>
<td>1 (2.2%)</td>
<td>NS</td>
</tr>
<tr>
<td>Perforation</td>
<td>0 (0.0%)</td>
<td>1 (2.2%)</td>
<td>NS</td>
</tr>
<tr>
<td>Total</td>
<td>2 (4.4%)</td>
<td>9 (20.0%)</td>
<td>0.049</td>
</tr>
</tbody>
</table>

Electro-Hydraulic-Lithotripsy (EHL)

Background

- Intracorporeal electrohydraulic lithotripsy (EHL) is a method of stone fragmentation that works by delivering shock waves created by high voltage electric sparks between two isolated electrodes at the tip of a fiber.
- The electric sparks are delivered in short pulses with a high peak pressure, leading to immediate expansion of the surrounding liquid and induction of spherical shock waves.
- Oscillating shock waves are magnified when transmitted through a fluid medium such as saline, creating sufficient pressure to fragment the stone.
- Since shock waves carry a risk of injury to surrounding biliary epithelium, application of EHL is best achieved under direct choledochoscopy and fluoroscopic visualization.
- EHL is used by most endoscopists via the peroral route to fragment large bile duct stones. Additionally, it is used to fragment stones in cases of basket impaction in the bile duct.

Raijman, I. and S. Escalante-Glorsky, Electrohydraulic lithotripsy in the treatment of bile and pancreatic duct stones, in UpToDate, D.S. Basow, Editor 2011, UpToDate: Waltham, MA.
EHL

Technique

• An EHL probe is commonly used in the SpyGlass® system.
• Once the EHL probe is outside the SpyGlass®, visualized endoscopically and fluoroscopically, the tip of the EHL probe is placed against the stone and advanced as close as possible without touching it, avoiding any contact with the wall.
• Firing of the probe tangentially against the center of the stone may allow for better accommodation of the EHL probe in the center of the stone.
• Touching of the stone with the tip of the EHL probe can be done if necessary but is not advised...may reduce the life span of the EHL probe.

Raijman, I. and S. Escalante-Glorsky, Electrohydraulic lithotripsy in the treatment of bile and pancreatic duct stones, in UpToDate, D.S. Basow, Editor 2011, UpToDate: Waltham, MA.
EHL
Technique
• Once the probe is positioned, EHL is delivered in a fluid medium created by continuous saline irrigation according to a preset power wattage (usually in the range of 70 to 100 watts) via 1 to 2-second pulses or continuous pulsations (usually 30/sec).

• Once the EHL is delivered and the stone is fragmented, a cholangiogram is obtained via the water channels of the SpyGlass® catheter to document evidence of stone fragmentation.

• The SpyGlass® is subsequently withdrawn and the stone fragments are removed using standard endoscopic balloons and baskets.

Raijman, I. and S. Escalante-Glorsky, Electrohydraulic lithotripsy in the treatment of bile and pancreatic duct stones, in UpToDate, D.S. Basow, Editor 2011, UpToDate: Waltham, MA.
EHL-Clinical Efficacy and Safety

- Binmoeller (1993) - Among 65 patients receiving EHL, 64 patients had successful bile duct clearance and only one patient failed the treatment due to inability to insert the cholangioscope into the bile duct.
- Adamek (1996) performed a comparison of EHL versus ESWL in a total of 125 patients with CBD stones in whom conventional endoscopic treatment had failed. EHL was 74% successful (34 of 46 patients) in bile duct clearance, compared to ESWL success rate of 78.5% (62 of 79 patients). Combined treatment including ESWL, EHL and LL achieved bile duct clearance in 94% of patients.
- Arya (2004), retrospective review of 111 patients who underwent EHL under direct cholangioscopic control using a “mother-baby” system. Stone fragmentation rate was 96% and a final stone clearance rate was 90%. 76% of patients required only one EHL session, 14% required 2 sessions and 10% required 3 or more sessions. All patients with successful stone fragmentation required post-EHL balloon or basket extraction of fragments.

EHL-Clinical Efficacy and Safety


19 patients with extrahepatic bile duct stones that could not be extracted using standard endoscopic methods (e.g., mechanical lithotripsy).

An EHL probe with a 3.0 F radio-opaque tip was inserted through a balloon catheter. EHL was performed under fluoroscopy until the fragmented stone could be captured in a large basket for ML. Stone fragmentation was 89% successful (17 of 19 patients), and bile duct clearance was 84% (16 of 19 patients). A mean of 1.8 endoscopic sessions was required for complete removal. Additional ML was performed in 56% of the 16 patients. There was no 30-day mortality, Minor complications were noted in 4 patients.
EHL-Clinical Efficacy and Safety

- Moon et al. (2009) evaluated the efficacy and safety of treatment of difficult bile duct stones using EHL or LL under an ultra-slim endoscope designed to be used as a single-operator, peroral cholangioscopy (POCS) system (GIF-XP260N and GIF-N260 from Olympus).
- The following inclusion criteria were applied: failed stone removal using conventional methods (including ML), signs and symptoms of biliary obstruction, dilated common bile duct (>10 mm), and previous complete endoscopic sphincterotomy.
- The overall success rate of bile duct clearance by lithotripsy under direct POCS by a single endoscopist was 88.9%(16 of 18).
- Stone fragmentation under direct POCS was successfully performed in nine patients using EHL and in seven patients using LL.
- The average number of treatment sessions required to complete stone removal was 1.6.
- ML was performed to complete stone removal in 5 of 18 (27.8%) patients.
- Procedure-related complications were not observed.

Peroral Cholangioscopy (POCS)

ERCP and Cholangioscope “Babymother” endoscopes.

No widespread use!

Cost, fragility, limited maneuverability, low optical resolution, requirement of two endoscopists to operate.
SpyGlass® Direct Visualization System

• A “single-use, single-operator” device:

• The SpyScope® Catheter.

• Four lumens:

  - Optic channel through which a SpyGlass® fiber optic probe can pass

  - Two separate irrigation channels

  - A 1.2 mm accessory channel through which the SpyBite® forceps can pass.
SpyGlass® Direct Visualization System

• The SpyScope® catheter is 10 Fr in diameter and features four-way steering capabilities.

• The SpyGlass® fiber optic probe is a fragile “multiple-use” device that can transmit both light and intra-ductal images and measures 231 cm long and 0.77mm in outer diameter.

• The SpyBite® forceps are “single-use” and have a central spike that minimizes the loss of small biopsies.

• The SpyGlass® system is compatible with EHL and laser lithotripsy for stone fragmentation, allowing direct intra-luminal visualization during shock-wave delivery and fragmentation of bile duct stones.
SpyGlass® Direct Visualization System

- The SpyScope® catheter is positioned just below the operating channel of the ERCP scope.
- The endoscopist controls both the tip deflection wheels of the ERCP scope as well as the knobs of the SpyScope® catheter.
- The SpyGlass® system is introduced into the therapeutic channel of the duodenoscope over a guidewire.
SpyGlass® Direct Visualization System

• The bile duct is cannulated by the SpyScope®, after a sphincterotomy, and the SpyGlass® visualization probe is guided into the biliary tree using the SpyScope® catheter.

• The SpyScope® catheter and SpyGlass® probe can be maneuvered to the area of interest within the duct, allowing direct visualization of biliary tract stones while delivering shock-waves using EHL or laser lithotripsy.
SpyGlass®

Clinical Efficacy and Safety

Chen (2007) used a bench simulator to directly compare SpyGlass® to a fiberoptic transendoscopic choledochoscope with two-way deflection. The SpyGlass® system demonstrated statistically significant higher success rates for:

- accessing all quadrants within the simulated bile duct, with and without biopsy forceps.
- accessing biopsy targets and performing simulated biopsies.

SpyGlass®- guided EHL

Chen and Pleskow (2007),
Prospective pilot study of the clinical utility and safety of the SpyGlass® system for diagnostic and therapeutic procedures in 35 patients.

SpyGlass®-directed EHL succeeded in 5 of 5 patients (100%):
3 pts had large stones which had failed ERCP and standard removal methods,
1 patient had an impacted stone,
1 patient had an intrahepatic bile duct stone that was missed at prior ERCP.

Procedure-related complications occurred in 2/35 patients (6%) and resolved uneventfully.

SpyGlass®- guided EHL

Stevens et al. (2007)
SpyGlass® system with EHL in 15 patients with stones that had on average 3 failed stone removal attempts. The mean size of the largest stone per case was 15 mm ± 10 mm.
Stone locations were CBD (8 of 15), cystic duct (2 of 15), CHD (3 of 15), and IHD (2 of 15).

Stone clearance was achieved in 73% of cases (11 of 15).
53% (8 of 15) of cases cleared with one EHL treatment,
20% (3 of 15) of cases cleared with two EHL treatments.

7% (1 of 15) case failed because an excessive sludge could not be cleared for the EHL procedure.
7% (1 of 15) case was lost to f/u.

The mean number of EHL probes needed to complete the stone extraction was one (range 1-2).

No complications were reported.

SpyGlass® cholangioscopy provides a safe and effective method for biliary EHL.

SpyGlass®- guided EHL

Loren et al. (2008)

100% complete duct clearance using SpyGlass®-guided EHL or LL in 9 patients with biliary(8) or pancreatic(1) stones.

Complete duct clearance in a single session - achieved in 8/9 pts

One patient with a heavy stone burden - additional sessions.

Safety: the nature and frequency of complications were within the spectrum of those reported with other interventional pancreaticobiliary procedures.

SpyGlass®- guided EHL

Fishman et al. (2009),
Multicenter retrospective analysis of the feasibility, and safety of the SpyGlass® in Texas.

41 patients for biliary stone disease (used perorally in 35 patients, percutaneously in 6).
EHL was used in 38 patients and holmium LL in 3 patients.

Lithotripsy was successful in 90.2% of patients (37 of 41).

Technical aspects
- In 5 patients, the EHL probe could not be advanced through the SpyScope at the tip of the ERCP scope.
- In 7 patients, the EHL probe could not be oriented to fully target the stone;
  it produced enough fragmentation to remove the stone.

In 87.1% of cases (36/41) therapy for stones was completed in one session.
In 5 patients successful ductal clearance took two sessions.

SpyGlass®- guided EHL

Draganov et al. (2011),
Prospective cohort study of the efficacy and safety of the SpyGlass® system.

• Complete stone clearance was achieved in 92.3% of patients (24 of 26).
• It was achieved in one session in 84.6% of cases (22 of 26).

• 2 patients required more than one SpyGlass® procedure to achieve bile duct clearance:
  - One patient had Mirizzi syndrome and required two SpyGlass® sessions to fragment and extract a 10-mm stone impacted in the cystic duct.
  - One patient, had two EHL treatments that failed to fragment a hard stone; Holmium LL in the SpyGlass® was successful.

• One patient (3.9%) required mechanical lithotripsy in addition to cholangioscopy-guided lithotripsy.

SpyGlass®

Draganov et al. (2011),

• Two failed cases:
  - One had Mirizzi syndrome, had surgical removal of the stone after failing SpyGlass®-guided EHL due to inability to target the stone with the EHL probe.
  - One patient had successful initial fragmentation of 25 mm stone with EHL but was lost to follow-up...

• Four adverse events (4.8%):
  - 3 patients had mild post-ERCP pancreatitis with uneventful recovery;
  - 1 patient had a periampullary perforation caused by sphincterotomy and recovered with conservative management.

**ERCP guided SpyGlass® cholangioscopy is technically feasible and can safely achieve bile duct clearance in most patients with difficult biliary stones that have failed prior extraction methods.**

SpyGlass® in Altered Anatomy

The long catheter length of 230 cm provided by the SpyScope® allows passage of the SpyGlass® system through the therapeutic channel of a colonoscope:

Baron and Saleem (2010),

a case report of successful hepatic duct stone removal by using the SpyGlass® cholangioscope through a colonoscope to perform EHL under direct endoscopic visualization in a patient with a Roux en-Y Hepaticojejunostomy.

Mou et al. (2010),

a case of peroral cholangioscopy for biopsy in a Roux-en-Y Hepaticojejunostomy achieved by using the SpyGlass® system and a standard colonoscope.


Altered Anatomy ERCP
SpyGlass®

Anecdotal Case Reports:

1. The Spyglass® system was used to cannulate and stent the cystic duct in a surgically high-risk patients in whom decompression of the gallbladder could not be performed by percutaneous transhepatic gallbladder drainage or aspiration.

2. The SpyGlass® system with EHL was used to fragment gallbladder stones and flush out the remaining small fragments in the gallbladder of a patient with symptomatic gallstone disease/multiple gallstones on transabdominal ultrasound, and Child’s Class C cirrhosis that precluded the possibility of cholecystectomy.


Summary

• In the treatment of choledocholithiasis, endoscopic sphincterotomy (ES) serves as the standard treatment and the prerequisite for basket and balloon extraction as well as mechanical, electrohydraulic, and laser lithotripsy.

• While most stones <10 mm in size pass spontaneously following endoscopic sphincterotomy, it is current standard practice to attempt stone extraction and clear the bile duct to avoid stone impaction and subsequent risk of cholangitis.

• For extraction of stones >12 mm in size, mechanical lithotripsy is 80-90% successful, although repeated treatment sessions may be needed in 20-30% of cases to achieve complete bile duct clearance.

• In cases of unsuccessful mechanical lithotripsy additional methods of lithotripsy are available.

• Intracorporeal electrohydraulic lithotripsy or laser lithotripsy can be attempted under direct choledochoscopic visualization. The laser lithotripters are far too expensive to encourage widespread implementation, and therefore electrohydraulic lithotripsy has been used more frequently.
Summary

Several techniques and devices are evolving as new treatment options for choledocholithiasis:

• Use of large balloon dilation followingsphincterotomy (ES-LBD) has been shown as a viable and efficient alternative with fewer complications compared to mechanical lithotripsy (ML) following ES in removal of large bile duct stones.

• Recent data showed lower rate of overall morbidity and recurrent bile duct stones of papillary balloon dilation (EPBD) compared to endoscopic sphincterotomy (ES), the jury is still out on whether can safely substitute for endoscopic sphincterotomy in treatment of choledocholithiasis.

• The therapeutic capabilities offered by the utilization of the SpyGlass® system have reached impressive results. Hopefully the sub-optimal image quality and fragility will improve!

