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PANCREAS AND BILIARY TRACT (O HALUSZKA, SECTION EDITOR)

Endoscopic Management of Difficult Bile Duct Stones

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Abstract

Purpose of Review In 10–15% of the cases, conventional methods for removing bile duct stones by ERCP/balloon-basket extraction fail. The purpose of this review is to describe endoscopic techniques in managing these "difficult bile duct stones."

Recent Findings Endoscopic papillary large balloon dilation with balloon extraction ± mechanical lithotripsy is the initial approach used to retrieve large bile duct stones. With advent of digital cholangioscopy, electrohydraulic and laser lithotripsy are gaining popularity. Enteroscopy-assisted or laparoscopic-assisted approaches can be used for those with gastric bypass anatomy.

Summary Difficulties in removing bile duct stones can be related to stone-related factors such as the size and location of the stone or to altered anatomy such as stricture in the bile duct or Roux-en-Y anatomy. Several endoscopy approaches and techniques have described in the recent past that have greatly enhanced our ability to remove these "difficult" bile duct stones.

Keywords Bile duct stones · Endoscopic papillary large balloon dilation · Digital cholangioscopy · Lithotripsy

Acronyms

CBD	Common bile duct
DPOC	Direct per-oral cholangioscopy
ERCP	Endoscopic retrograde cholangiopancreatography
EPLBD	Endoscopic papillary large balloon dilation
EHL	Electrohydraulic lithotripsy
EST	Endoscopic sphincterotomy
EUS	Endoscopic ultrasound
LL	Laser lithotripsy
ML	Mechanical lithotripsy

Introduction

More than 500,000 endoscopic retrograde cholangiopancreatography (ERCP) cases are performed annually in the USA. Over 50% of ERCPs are done for biliary indications, predominantly for common bile duct stone extraction [1]. Since its introduction in 1974, ERCP became the standard method of choice for removing bile duct stones which involves endoscopic sphincterotomy (EST) with balloon or basket-assisted stone extraction [2]. The success rate of removing stones using this approach is around 90% [3, 4]. Balloons generate an axial and an oblique force on the stone in relation to the long axis of the bile duct and hence can slip past the stone. If the stone size is large and the stone gets impacted in the bile duct, the balloon can be deflated and removed. On the other hand, a standard basket exerts an axial force and can be more effective than balloons for stone extraction. However, if the stone with the basket gets impacted in the bile duct, then removing the basket can become difficult as it cannot be re-opened easily. An impacted basket may require rescue lithotripsy as described below.

When the above conventional methods for extracting bile duct stones fail, these stones can be considered as "difficult bile duct stones." They may require additional techniques and tools for extraction [4, 5].

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Difficult Bile Duct Stone

Although there is no general consensus on the definition of difficult bile duct stones, factors that contribute to the difficulty in extracting stones can be classified into three major categories: (1) *Stone characteristic*, as in stones larger than 15 mm in size, shape of stones (barrel or square-shaped stones), multiple stones, and the consistency of stone (hard stones). (2) *Anatomical variations* which makes accessibility to the papilla challenging such as the presence of periampullary diverticulum, Roux-en-Y gastric bypass, Billroth-II anatomy, duodenal stricture, bile duct stricture, or intrahepatic stones, and (3) *Patient's general condition* as in bleeding diathesis, on antithrombotic, and age > 65 years [6–9, 10••].

Techniques

Endoscopic Papillary Large Balloon Dilation

Stones that are less ≤ 10 mm in size can be successfully retrieved by conventional approach of EST and balloon/basket extraction in 90% of the cases [3, 4]. However, EST alone may not be sufficient to retrieve stones that are ≥ 15mm [11, 12]. Dilating the papilla with a large diameter balloon without a prior EST can be associated with high incidence of pancreatitis most likely due to the balloon traumatizing the pancreatic sphincter with an intact common channel. On the other hand, large EST can result in bleeding or retroduodenal perforation, especially when the sphincterotomy is extended to near the duodenal wall. Hence, conceptually speaking, if a small EST is performed to cut the common channel to separate the pancreatic orifice from the biliary opening without risking bleeding or perforation, a large balloon dilatation can be safely performed to remove large bile duct stones without a significant risk of pancreatitis or EST-related bleeding/perforation. Balloon dilatation will also dilate any extra-duodenal component of the biliary sphincter that cannot be cut by EST without risking a perforation.

Endoscopic papillary large (12–20-mm diameter) balloon dilation (EPLBD, also referred to as dilatation-assisted stone extraction or DASE) has been utilized to dilate the papillary orifice immediately following partial biliary sphincterotomy in order to facilitate large stone extraction (Fig. 1) [10••, 12–15]. Since biliary dilatation balloons are at maximum 10 mm in diameter, for EPLBD, Controlled Radial Expansion balloon (CRE, Boston Scientific, Marlborough, MA) or other similar esophageal balloons are used, preferably those that are wire-guided. Following a small (4–6 mm) EST, the balloon is positioned across the EST site and inflated to 1 atm at a time with dilute contrast till the "waist" at the ampullary seen on fluoroscopy obliterates. Rapid inflation will either pull or push the balloon in or out respectively or can lead to perforation. Since esophageal balloons are relatively longer in length compared to biliary dilation balloons, when used for the bile duct, it is important that the guidewire is not in the cystic duct and that majority of the balloon lie in the duodenum rather than within the bile duct. The diameter selected for inflation should be not more than the diameter of the dilated upstream bile duct (generally up to 12–15 mm). It is also important to ensure that stone is above the balloon in order not to sandwich the stone between the bile duct wall and inflated balloon which can lead to bile duct perforation.

EPLBD was first described by Ersoz et al., using an esophageal dilatation balloon of 12–20-mm diameter. They reported an outstanding success rate of 90% in retrieving large stones after one session with self-limited complication rate of 16% that included mild pancreatitis and bleeding [10••]. EPLBD has launched a new era in the management of large stones with or without mechanical lithotripsy (ML) with a success rate of 88–100% and an acceptable complication rate of 0–16% [16–19].

Although EPLBD following a small EST is effective in extracting large CBD stones, the length of EST is not yet standardized. Many studies showed that the rate of immediate or delayed bleeding at sphincterotomy site following EPLLBD range from 0 to 8% [15, 17, 20]. Park et al. had shown in a large multicenter study that included 946 patients with large stones, the rate of bleeding was 6% with one death due to massive bleeding and three fatalities due to bile duct and duodenal perforation. On multivariate analysis cirrhosis (OR 8.00, $p = 0.003$), full length EST (OR 6.22, $p < 0.001$) and stone size ≥ 16 mm (OR 4.00, $p < 0.001$) were associated with increased risk of bleeding [21•]. In a study by Maydeo et al., 60 patients underwent full-length sphincterotomy prior to EPLBD for large CBD stones (mean size of 16 mm). Their success rate in clearing the duct was 95% in one session, and

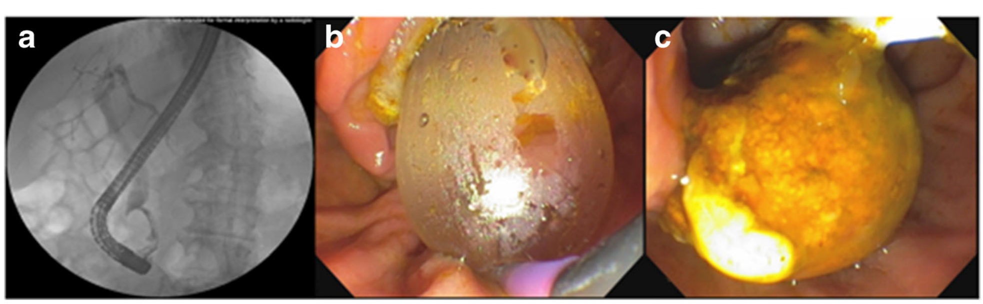

Fig. 1 Endoscopic papillary large balloon dilation (EPLBD). **a** Large distal bile duct stone. **b** Large-balloon dilation (15 mm). **c** Extracted stone.

8% of patients had self-limiting bleeding at the sphincterotomy site. Although there are no guidelines to determine the recommend length of EST, it seems logical to avoid full-length EST since it carries higher risks for bleeding and does not add to better rates of stone clearance compared to limited sphincterotomy [22].

It is unclear if endoscopic papillary balloon dilation without EST is sufficient enough to retrieve large stones. The advantages of endoscopic papillary balloon dilation over EST are less post-procedural bleeding and preservation of sphincter function [23]. This technique may carry a substantial risk of pancreatitis although the results are conflicting [24••, 25]. Disario et al. evaluated the outcomes of balloon dilation to standard EST for extracting bile duct stones. The study was terminated at after an interim analysis due to two deaths related to post-procedure pancreatitis [24••]. On the other hand, Park et al. enrolled 128 patients with large bile duct stones and reported complete stone removal rate of 95% using balloon dilatation without EST. Although 14% of patients required mechanical lithotripsy (ML), 83% of the patients achieved stone clearance in one endoscopic session with overall complication rate of pancreatitis and minor bleeding of 1% [23]. These findings were replicated by Omuta et al. In their study, they enrolled 41 patients with a mean stone diameter of 13 mm who underwent EPLBD without preceding EST. Stone removal was successful in 98% of the patients with a mean number of required endoscopic session of 1.2 per patient [26]. In a recent meta-analysis of five randomized controlled trial comparing the efficacy and safety of EPLBD to EST in extracting stones ≥ 10 mm, a total of 621 patients were included. Both methods had similar outcomes in stone removal rate (94 vs 93%) and ductal clearance in one session (82 vs 77%) with no differences in overall adverse events including post-ERCP pancreatitis, bleeding, and perforation [27]. Based on the above evidence, EPLBD could be used as a sole method in clearing large bile duct stones obviating the need for EST especially in a subset of patients with underlying coagulopathy [28, 29].

Mechanical Lithotripsy

Mechanical lithotripsy (ML) is done for crushing stones into smaller fragments. With the advent of EPLBD, the indications for ML are diminishing. ML may be required if the stone is too large to extract even after EPLBD, or there is a bile duct stricture below the stone, or a traditional basket is impacted in the bile duct with a stone [30]. Traditional baskets cannot crush hard stones as the basket wires are thinner and they close against a collapsible outer plastic sheet. ML baskets are made of reinforced wires that close against an outer sheet made of metal coil (Fig. 2). There are two types of mechanical lithotripters: baskets attached to a cranking handle as an integrated device (wire- or non-wire guided) and the other type that is used to crush a stone caught in a traditional basket impacted in the bile duct; "salvage or rescue ML device" [31].

The role of ML for crushing and clearing large bile duct stones has been evaluated in many studies with a reported success rate of 79–96% [32–34, 35•] . However, this rate dropped significantly for stones ≥ 20 mm [36]. Lee et al. evaluated the predictors ML failure in 102 patients. Stone size ≥ 30 mm, impacted stone, and stone size: bile duct diameter ratio of > 1 were predictors of ML failure with odds ratios of 4.32, 17.8, and 5.47, respectively [37]. In a large single-center study that involved 592 patients, ML was successful in clearing stones in 96% of patients with impacted stones, and 96% of stones more than 20 mm in diameter. However, ML was also associated with high complication rates that included basket impaction, hemorrhage, pancreatitis, and cholangitis compared to patients with smaller stones [38]. Although these studies showed that the stone size matters and can negatively affect bile duct clearance rate, Garg et al. showed that stone impaction in the bile duct is the only important predictor for failure and not stone size itself. This is related to the inability to pass the basket proximal to the stone or the failure to fully open the basket to encircle and grasp the stone [35•].

Despite the various types of ML baskets that are used to crush difficult stones, this technique is considered cumbersome and ineffective in 10% of patients and may require multiple endoscopic sessions [39]. In such clinical setting or as an

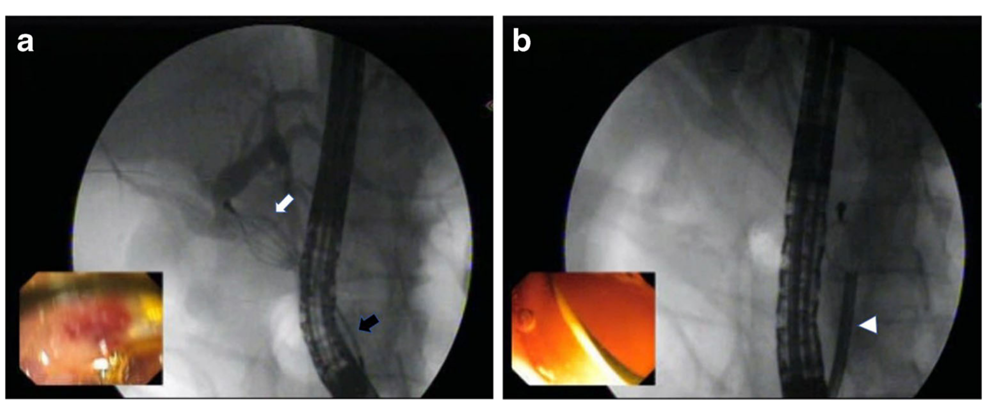

Fig. 2 Mechanical lithotripsy. **a** Large bile duct stone captured in the wire basket (white arrow). The stone cannot be crushed against a plastic catheter (black arrow). **b** After advancing the metal sheath over the plastic catheter (arrowhead), the basket was closed against the sheath to crush the stone

initial approach after failed EPLBD, one can proceed to digital cholangioscopy with electrohydraulic or laser lithotripsy to fragment large stones.

Cholangioscopy-Guided Lithotripsy

In certain situations, the ability to extract large stones using EPLBD or ML cannot be successfully achieved due to impaction of the stone in the bile duct, size of the stone > 2 cm, and/or the location of the stone above a stricture [40, 41]. In these situations, electrohydraulic lithotripsy (EHL) and laser lithotripsy (LL) are useful tools that can fragment large stones inside the bile duct and facilitate their extraction.

EHL system is composed of a bipolar probe that is connected to a charge generator. The probe can be passed through the accessory channel of a cholangioscope. Using a setting of 75–90 V and 5–6 shocks per second, a charge is conducted across the electrodes at the tip of the probe generating a spark underwater. This leads to hydraulic pressure waves that transmit energy to the stone leading to its fragmentation [41, 42]. On the other hand, LL uses laser, focusing its high-power density light on the surface of the stone creating an oscillating plasma bubbles that fragment the stone [31]. Both of these methods require the EHL/LL probe to be in close proximity to the stone to achieve best results. Traditionally, per oral cholangioscopy using "mother–daughter" system was utilized where the cholangioscope is inserted through the therapeutic channel of the duodenoscope. This process is cumbersome, requiring complex equipment, the coordination between two experienced endoscopists in addition to the limited steerability and maneuverability of the cholangioscope leading to limited field visualization. The SpyGlass Direct Visualization System (Boston, Scientific, Natick, MA) is designed for a single operator, has a four-way steering capability, and has a dedicated channel for irrigation and EHL/LL probes. This system has been recently upgraded to enhanced digital imaging quality with 120^0 field of visualization (SpyGlass-DS) (Fig. 3) [43].

Fig. 3 Digital cholangioscopy

In a multicenter study, using EHL with the mother–daughter cholangioscope, Arya et al. reported success rate of 94% for fragmenting large bile duct stones (> 2 cm) with overall ductal clearance rate of 90% [41]. The majority of patients (76%) required one EHL session. Eighteen percent of patients had post-procedural complications which included cholangitis, hemobilia, and bile leak. In a recent prospective study by Ogura et al. evaluating the diagnostic and therapeutic benefit of SpyGlass-DS, 55 patients were enrolled of which 13 patients had difficult bile duct stones. All these patients underwent EHL therapy with 100% technical success with no adverse events. That study highlighted the advantages of a single-operator SpyGlass-DS and the ease of performing therapeutic interventions in patients with complex bile duct stone [44].

Similar to EHL, studies have shown laser lithotripsy (LL) to be equally effective with a success rate of 89–100% in fragmenting and clearing the bile duct of large stones with or without ML [43, 45–47]. In a recent prospective study by Wong et al., 17 patients with a median size of bile duct stones of 2 cm who failed conventional treatment with ML underwent ERCP and SpyGlass-DS. Using LL, stones were successfully cleared in 94% of the patients over a median of one endoscopic session. However, overall complication rate was 18% including two cases of cholangitis and one case of respiratory distress post-procedure that responded to conservative management [45]. In a multicenter study on 31 patients using SpyGlass-DS with LL, stone fragmentation and extraction was successful in all patients. Eighty-seven percent of patients achieved duct clearance in one session. This high success rate was attributed to the feasibility and accessibility to the targeted stone through using SpyGlass-DS and enhanced image quality [48•]. Biliary complications as in hemobilia, bile duct perforation, and cholangitis remain a concern especially if this procedure is done with inexperienced operators [49–51].

Direct peroral cholangioscopy (DPOC) can also be accomplished using the ultraslim upper endoscope. The main advantages of the ultraslim endoscope are allowing direct visualization of the CBD stones through its high-resolution optics in addition to its 2.0 mm working channel which can facilitate different therapeutic and diagnostic intervention for malignant strictures or impacted common bile duct stones (CBD) using different accessories that cannot pass through other cholangioscopes [47, 52, 53]. A major obstacle in using the ultraslim endoscope is the difficultly to maneuver its flexible shaft from the duodenum up into the biliary tract related to looping of the endoscope in the stomach or in the duodenum. To facilitate bile duct intubation, Moon et al. used a novel 5F balloon catheter that was advanced into the bile duct via the accessory channel of the endoscope. Inflating the balloon in the bile duct provided anchorage to allow the endoscope to be advanced into the bile duct [47, 54]. In their study, 18 patients with difficult bile duct stones who failed ML underwent EHL or LL using an ultraslim endoscope. Overall success rate was 89% with an average endoscopic session of 1.6 per patient. Despite a high success rate of this method in extracting difficult stones [55], air embolism is one of the feared adverse outcomes which can manifest as hypoxia, cardiac arrest or severe cerebral ischemia [54, 56–58]. To reduce this risk, copious water or saline irrigation and using CO2 instead of air for insufflation is recommended [40].

Endoscopic Biliary Stenting

Endoscopic biliary stenting has been utilized as a definitive therapy in certain patient population in whom stones are difficult to retrieve and they are at high risk for adverse events. These patients usually have serious comorbid medical conditions, are on anti-thrombotic, or are frail and cannot undergo surgery as definitive therapy [59]. The exact mechanism of how biliary stents can aid in stone removal is unclear, but it is postulated that when stents are left for a period of time, they cause mechanical friction against the stone which can lead to stone fragmentation facilitating its clearance on subsequent ERCP [60].

In a recent study by Slattery et al., 201 patients who were deemed unfit for repeated ERCP for stone extraction underwent plastic biliary stenting as primary therapy for CBD stones. All patients had a single 7-Fr double pigtail plastic stent placed. There were no scheduled re-interventions unless patients presented with worsening symptoms. Their study showed excellent median biliary flow (with bile flowing most likely from the side of the stent) of 5 years with low risks of adverse events (cholangitis in 6 patients) [60]. This approach was implemented in various studies showing the utility of biliary stenting as a stand-alone approach or a bridge to subsequent ERCP with a success rate ranging between 86 and 93% [60, 61].

Recently, some centers have reported using fully covered self-expandable metal stent (FCSEMs) for managing difficult bile duct stones either due to the size of the stones or their number [62••, 63]. Hartery et al. showed in the largest retrospective study to date the success rate in achieving bile duct drainage in 44 patients with difficult stones using FCSEMs. All patients had FCSEMs placed after incomplete stone clearance at the index ERCP. In 36 patients (82%), stones were cleared at the second ERCP session. This study highlights the utility of using FCSEMs in managing difficult bile duct stones but does not provide superiority to placing plastic stents which are cheaper [62••].

Patients with Altered Anatomy

ERCP remains a challenging procedure in patients altered anatomy such as Roux-en-Y gastric bypass or Billroth-II with long afferent limbs. There are many challenges particularly the difficulty of reaching the papilla and the inability to use conventional side-viewing duodenoscope, hence losing the elevator capability to advanced accessories into the bile duct. In such circumstances, balloon-assisted ERCP using single-balloon enteroscopy (SBE) or double-balloon enteroscopy (DBE) have emerged as a therapeutic tool that enables the enteroscope to negotiate long afferent limbs and get access to the papilla [64–66]. However, this approach has its limitations such as lack of dedicated long accessories which may preclude performing therapeutic interventions.

The reported success rate in achieving successful biliary cannulation using balloon-assisted ERCP in patients with Roux-en-Y gastric bypass ranges between 33 and 80% [67, 68]. Hence, laparoscopy-assisted transgastric ERCP (LAERCP) has gained popularity. Access to the excluded stomach is created surgically in the operating room to allow passage of the side view duodenoscope to the papilla. The reported success rate of this approach in achieving biliary cannulation ranges between 94 and 100% [69, 70]. In a study by Snauwaert et al., 23 patients underwent LAERCP for biliary indications mainly CBD stones. All patients had successful biliary cannulation and stone extraction with a mean endoscopic time of 40 min. None of the patients had surgical or ERCP-related complications. Others have reported complication such as perforation of the posterior gastric wall by the trocar when accessing the stomach, intraabdominal abscess, and hematoma [71]. This approach has been implemented by many institutions. In a recent large international multicenter center that included 34 centers, 579 patients with Roux-en-Y gastric bypass underwent LAERCP where almost half of the procedures were done for biliary indication, mainly common bile duct stone disease. The reported success rate was 99% for biliary intervention with a median total procedure time of 152 min, of which 40 min was ERCP time: reported complications of post-ERCP pancreatitis of 7% which is comparable to standard ERCP [72••].

In patients with Billroth-II anatomy, the ability to reach the papilla using a side view duodenoscope or standard forward viewing scope is achievable, obviating the need for SBE or DBE in the majority of cases [73]. However, technical challenges in biliary cannulation arise from the inverted approach to the papilla necessitating the use of Billroth-II sphincterotomy with cutting wire directed at 6 O'clock position when performing biliary sphincterotomy or using needle knife over a plastic stent that is placed in the bile duct [74, 75]. The success rate in retrieving CBD stones in patients with Billroth-II anatomy has been extensively evaluated in many studies [75–77]. Bove et al. reported their 30-year experience in the largest series of 713 patients with Billroth-II reconstruction; 51% of patients had CBD stone where ERCP was done using side view duodenoscope in 97% of patients. They reported a success rate of almost 90% in retrieving stones with overall complication rate of 4.3% [75]. In a recent multicenter study from Korea using cap-fitted forward viewing endoscope, balloon dilatation of the papilla was performed to retrieve bile duct stones in 133 patients with Billroth-II anatomy. Successful stone removal was achieved in 86% of the patients with a complication rate of pancreatitis and perforation of 8 and 2%, respectively. On multivariate analysis, CBD stone ≥ 12 mm and ≥ 2 ERCP sessions were significant risk factors for ERCP-related complications [76].

Endoscopic Ultrasound-Guided Stone Extraction

Recently, endoscopic ultrasound (EUS)-guided access techniques to the bile duct has been gaining popularity as an alternative to percutaneous transhepatic biliary approach for patients with failed biliary cannulation, or in whom access to the papilla is difficult due to malignant duodenal obstruction, large duodenal diverticulum, or with altered surgical anatomy as in Roux-en-Y gastric bypass [78, 79]. This technique involves puncturing the biliary system under EUS guidance. Puncture site can be either from the stomach from where a dilated left intrahepatic duct is easily accessible or from the duodenal bulb where the needle puncture is directed to the extra-hepatic bile duct. After the initial puncture, a wire is advanced through the FNA needle and advanced under fluoroscopy into the duodenum. This rendezvous technique is only performed in patients where the papilla is accessible. In patients where the papilla is not accessible, the papilla can be dilated with a balloon-pushed antegrade through the EUS access site, and the stone is then pushed out with a retrieval balloon [80, 81]. Weilert et al. used this approach in six patients with Roux-en-Y gastric bypass with a success rate of 67%. One patient developed a subcapsular hematoma. Two patients in whom they could not advance the dilating balloon underwent ERCP using DBE where the rendezvous wire placed by EUS has assisted in identifying the afferent limb and facilitated bile duct cannulation and stone removal [80]. Iwashita et al. in a retrospective study on 29 patients with altered surgical anatomy also used EUS-guided antegrade approach for bile duct stones with a success rate of 72%. Seventeen percent of patients had adverse events that included mild pancreatitis that was managed conservatively [76].

Summary

Over 90% of bile duct stones can be removed using the standard approach of biliary sphincterotomy with balloon/basket extraction. Large (>1.5 cm), hard, multiple, or faceted stones or stones above a bile duct stricture may be difficult to remove. In the majority of cases, medium size EST followed by EPLBD is sufficient to extract these difficult stones. This approach could be supplemented with ML to fragment the stone. In patients with impacted bile duct stones where there is difficulty advancing ML basket across the stone, cholangioscopic lithotripsy (EHL or laser) can be used.

In patients with altered anatomy where the papilla is not easily accessible as in Roux-en-Y gastric bypass, balloon enteroscopy-assisted or transgastric laparoscopic-assisted ERC can be performed. EUS-guided rendezvous as an alternative to percutaneous transhepatic rendezvous approach is gaining popularity in center with expertise for those with failed biliary cannulation. Using this approach, biliary stones can also be pushed out in an antegrade manner. In select patients with significant co-morbidities and large bile duct stones, a more conservative approach of placing plastic or metal stents over an extended period of time to fragment stones can be tried.

Compliance with Ethical Standards

Conflict of Interest Kulwinder Dua reports fees paid to the Medical College of Wisconsin for a multicenter research study using biliary stents in pancreatic cancer from Boston Scientific, support from Cook Medicals for a Clarity Study using esophageal stents in esophageal stricture, and support for Evolve Study from Merit Medical, outside the submitted work.

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Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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•• Of major importance

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