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Endoscopic management of difficult common bile duct stones

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Abstract

Endoscopy is widely accepted as the first treatment option in the management of bile duct stones. In this review we focus on the alternative endoscopic modalities for the management of difficult common bile duct stones. Most biliary stones can be removed with an extraction balloon, extraction basket or mechanical lithotripsy after endoscopic sphincterotomy. Endoscopic papillary balloon dilation with or without endoscopic sphincterotomy or mechanical lithotripsy has been shown to be effective for management of difficult to remove bile duct stones in selected patients. Ductal clearance can be safely achieved with peroral cholangioscopy guided laser or electrohydraulic lithotripsy in most cases where other endoscopic treatment modalities have failed. Biliary stenting may be an alternative treatment option for frail and elderly patients or those with serious co morbidities.

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INTRODUCTION

Common bile duct (CBD) stones are seen in approximately 7%-12% of patients who undergo cholecystectomy for symptomatic cholelithiasis and are a common indication for referral to a biliary endoscopist^[1]. They vary in size ranging from rather small (approximately 1-2 mm) to very large (> 3 cm). Endoscopic retrograde cholangiopancreatography (ERCP) with endoscopic sphincterotomy (ES) and basket or balloon extraction are well established therapeutic procedures for the management of CBD stones. It is estimated that nearly 85%-95% of all CBD stones can be managed effectively by these conventional endoscopic methods^[2,3]. Failure to clear the bile duct renders the patient vulnerable to biliary obstruction, cholangitis and pancreatitis, thereby increasing the morbidity^[4,5]. The occurrence of acute cholangitis is associated with significant mortality, especially in the elderly, underscoring the need for early intervention to clear the bile duct of stones and to relieve the obstruction to achieve adequate biliary drainage. Extraction of CBD stones is one of the most commonly performed procedures by therapeutic endoscopists. With novel advances in extraction techniques and instruments emerging routinely, it is vital to keep abreast of the new developments in order to improve the outcome. This review focuses on the alter-

native endoscopic management options for the treatment of difficult to remove CBD stones.

REVIEW CRITERIA

In July 2011, we searched MEDLINE from 1982 to the present using the Medical Subject Headings terms common bile duct stone, endoscopic retrograde cholangiopancreatography, difficult stone, endoscopy, and the key word “common bile duct stone”. Full papers and abstracts in English language were considered. Important developments in research, reports from centers of excellence, and our own clinical experience in managing them, form the basis of this review article.

FACTORS ASSOCIATED WITH DIFFICULT TO TREAT BILE DUCT STONES

Multiple factors have been postulated to govern the success or failure of endoscopic extraction of CBD stones. In approximately 10%-15% of patients, managing biliary stones becomes formidable primarily due to difficulties in accessing the bile duct (periampullary diverticulum, sigmoid shaped CBD, post-gastrectomy Billroth type II anatomy, Roux-en-Y-gastrojejunostomy), large number of stones (greater than 10), large size of stones (stones with a diameter > 15 mm which cannot be grasped with a basket), unusually shaped stones (barrel-shaped) or location of the stones (intra hepatic, cystic duct, proximal to strictures)^[6]. In addition, endoscopic management becomes challenging in Mirizzi syndrome, in which stones in the cystic duct cause obstruction of the main bile duct^[7]. Kim *et al*^[8] prospectively evaluated the factors contributing to technical difficulty during endoscopic clearance of CBD stones. They reported that older age (> 65 years), previous gastrojejunostomy, larger stone size (≥ 15 mm), impaction of stones, shorter length of the distal CBD arm (≤ 36 mm), and more acute distal CBD angulation (≤ 135 degrees) are all contributors to technical difficulty for endoscopic removal of bile duct stones^[8].

MANAGEMENT OF DIFFICULT STONES

In high risk patients, the risks and benefits of alternative techniques for removal of bile duct stones not amenable to conventional endoscopic techniques must be carefully balanced against each other and with surgery. The individual decision concerning the appropriate therapy is also influenced by the local expertise and the availability of the technical equipment.

CBD stones up to 1.5 cm in diameter can be extracted intact after endoscopic sphincterotomy. The rate of successful retrieval progressively declines with increasing size of the stone^[9]. Larger stones especially those with a diameter ≥ 2 cm may need fragmentation before removal to reduce the risk of stone impaction.



Figure 1 Example of a three-layered mechanical lithotripsy device with the basket, inner plastic sheath and an outer metal sheath. The stone is captured by the basket and crushed against the outer metal sheath.

Mechanical lithotripsy

In 1982, Riemann *et al*^[10], first introduced mechanical lithotripsy (ML). ML is currently the most widely used technique for fragmentation of stones. Contemporary lithotripter baskets have a high breaking strengths and have improved the success rate of ML for extraction of large CBD stones (> 2 cm) to well over 90% without serious complications^[11]. Broadly speaking, there are two types of baskets for ML. The type of basket used depends on whether lithotripsy is done on an elective (“through the scope”) basis or on an emergent basis (salvage device) for basket impaction^[12]. The ‘through the scope’ model is typically a three-layer system with the basket, inner plastic sheath, and an outer metal sheath (Figure 1). The stone is captured with the basket and the outer metal sheath is advanced to the stone which will be crushed against it. Sometimes, unexpectedly, stone and basket impaction can occur even during routine extraction of smaller stones. Under such circumstances, stone fragmentation can be done after removing the handle from the basket and the duodenoscope from the patient. An endotripter (a spiral metal sheath) is introduced under fluoroscopic guidance, over the basket wires, and the stone is crushed after connecting the bare basket wires to the crank handle (Figure 2). The broken basket and the stone are then removed. The shaft of the endotripter is generally shorter and thicker than that employed in standard ML^[13]. Although basket impaction can occur with through the scope lithotripsy baskets; it is more commonly encountered with extraction baskets, which have thinner wires and weaker handles not suitable for fragmentation of stones.

In patients with multiple large stones, lithotripters with a sleeve system can be employed multiple times without withdrawal of the endoscope, facilitating stone fragmentation^[14,15].

ML has been widely used as it is a readily available, cost effective, and simple procedure. Unfortunately the failure rate is high especially in patients with stones greater than 2.8 cm in diameter^[15]. In a retrospective study the size of the stone was the only factor that significantly af-



Figure 2 Image of a mechanical lithotripter which can be used as a “salvage device” for removal of impacted baskets.

affected the success or failure of bile duct clearance. In this study of 162 patients, the cumulative probability of bile duct clearance ranged from > 90% for stones with a diameter less than 10 mm to 68% for those greater than 28 mm in diameter ($P < 0.02$)^[15]. A subsequent prospective study by Garg *et al*^[16] however reported that stone size alone may not be important unless considered together with the diameter of the bile duct. They concluded that the only important predictive factor that compromised the success of mechanical lithotripsy was stone impaction in the bile duct, with either an inability to pass the basket proximal to the stone or a failure of the basket to open fully around the stone to allow it to be grasped properly^[16]. Although stone composition was not included in the study by Leung *et al*^[12], some endoscopists believe that stones that are hard and densely calcified (visualized on a plain radiograph) resist mechanical fragmentation, resulting in an extraction failure with standard baskets. Although the stones which are molded to the shape of the bile duct may be softer, they are more difficult to crush because they may not be easily engaged by the lithotripter basket^[12].

A multi-center study reported the rate of complications associated with ML to be around 3.6%^[13]. Among the spectrum of complications, basket impaction or fracture of the basket wire are uniquely associated with ML. Non-surgical interventions that have been utilized in this setting include extension of sphincterotomy, awaiting spontaneous passage of the impacted basket and stone after successful stent placement, use of a second lithotripter, extracorporeal shock wave lithotripsy (ESWL), laser lithotripsy, electrohydraulic lithotripsy, and transhepatic lithotripsy and stone dislodgement^[13-18]. Other complications include broken handle and perforation or injury to the bile duct^[13-18].

In about 10% of the patients ML proves to be cumbersome, protracted and ineffective^[6] wherein one has to resort to other methods such as electrohydraulic, or laser lithotripsy for stone fragmentation and subsequent removal.

Electrohydraulic lithotripsy

Initially used as an industrial tool for fragmenting rocks in mines, its application was extrapolated to medical use

when Koch attempted fragmentation of biliary stones using this technology^[19]. Electrohydraulic Lithotripsy (EHL) consists of a bipolar lithotripsy probe which discharges sparks with the aid of a charge generator in an aqueous medium. The sparks generated under water generate high-frequency hydraulic pressure waves, the energy of which is absorbed by nearby stones and results in their fragmentation^[20]. The shock waves can cause inadvertent injury or perforation of the bile duct wall if the probe is not deployed close to the stone and away from the ductal wall. EHL can be performed under fluoroscopic guidance by using centering balloons or direct cholangioscopic vision^[20]. The disadvantage of using only fluoroscopic guidance is related to the two dimensional imaging and the inability to confirm correct positioning of the probe. Therefore direct visualization is frequently preferred to avoid damage to the ductal wall^[21]. A cholangioscope is inserted through the instrument channel of the mother scope. One or two dedicated biliary endoscopists are needed for this procedure. Continuous irrigation with water during the procedure generates a fluid medium for propagation of the shock waves and in addition offers a clear view of the stones by flushing away the debris^[20].

The overall complication rate ranges from 7% to 9%^[22,23], with most common complications being hemobilia, cholangitis, and less commonly, ductal perforation. Binmoeller *et al*^[6], in one of the earlier large studies reported that EHL was successful in 63 of the 64 patients who had failed previous attempts of ML. Smaller published studies report stone fragmentation rates between 77%-100% for peroral EHL with minimal complications^[22,24-28]. Arya *et al*^[23], reported a stone fragmentation rate of 96% and final stone clearance of 90%. In a retrospective study of 94 patients who had failed stone extraction by conventional techniques, Hui *et al*^[29], compared the outcomes of EHL with further endoscopy to stenting alone in a subset of elderly and infirm patients. They demonstrated that EHL and further ERCPs had a higher success rate (80%) with a low complication rate (7.7%) and recommended that elderly and frail patients should be referred to tertiary centers for EHL in order to prolong survival and decrease biliary complications^[29].

The EHL equipment is compact, requires no special electricity, and is relatively inexpensive^[30]. Other advantages are that the EHL procedure does not require special training or protective gear. In the United States, use of EHL for fragmentation and removal of biliary stones is quite common in centers with special interest in biliary disorders.

Laser lithotripsy

In laser lithotripsy (LL), laser light at a particular wavelength is focused on the surface of the stone to induce a wave-mediated fragmentation. The pulsed laser energy utilized in stone fragmentation is in contrast to the continuous laser energy used in tumor ablation^[7]. The first successful use of pulsed laser for shock-wave lithotripsy of bile duct stones was reported in 1986^[31]. Since then

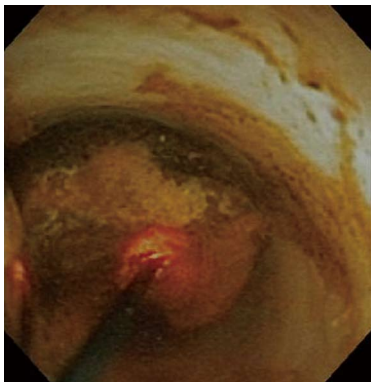


Figure 3 Laser lithotripsy of a bile duct stone under cholangioscopic guidance.

the technology has evolved and other laser types such as neodymium: yttrium-aluminum-garnet (Nd: YAG), flash lamp-pulsed dye (coumarin), the flash lamp-pulsed dye (rhodamine) with an automatic stone recognition system and the new Frequency Doubled Double Pulse Nd:YAG (FREDDY) system have been introduced^[32-35]. LL is typically performed perorally under cholangioscopic or fluoroscopic guidance or by the transhepatic approach. As with EHL, LL under direct visualization using a cholangioscope is often preferred to avoid damage to the ductal wall (Figure 3).

Based on some reports, ductal clearance can be accomplished in 64% to 97% of patients by using^[7,36] LL. In the majority of patients ductal clearance could be achieved in one session, although more sessions were required occasionally. LL has been demonstrated to be more effective than ESWL in terms of stone clearance rate and more rapid stone fragmentation with a shorter duration of treatment leading to a significant reduction in cost^[37,38]. In some centers where the laser equipment is available, laser lithotripsy has gained popularity and has managed to replace EHL as the primary modality for fragmentation of difficult to remove stones.

A recent innovation worth mentioning is the introduction of a double-lumen basket which allows passage of a laser probe for effective laser lithotripsy after the stone is captured by the basket^[39]. For a selected group of patients, this technique was shown to be feasible and effective, and the authors hope that continuous improvements in designs and construction materials would further enhance the success rate of this device.

Extracorporeal shockwave lithotripsy

In ESWL, high-pressure shock waves are generated outside the body (extracorporeal) by underwater spark gap (electrohydraulic) generated by piezoelectric crystals or electromagnetic membrane technology^[30]. The shock waves are focused by elliptical transducers to the designated target through a liquid or tissue medium which prevents the energy attenuation. ESWL is performed under ultrasound or fluoroscopic guidance. Since most

biliary stones are radiolucent and are not adequately visualized by fluoroscopy alone, placement of a nasobiliary tube for contrast instillation is required if ESWL is performed under fluoroscopy. In case of first generation lithotripters, the patients needed to be immersed in a water bath. Subsequent ESWL lithotripters employ water-filled compressible bags and a gel is applied to the skin surface for interface with the patient. Comparison between the lithotripters at a single center showed no significant difference in fragmentation of CBD stones^[40]. General anesthesia is usually needed as the discomfort produced may not be adequately controlled by conscious sedation. The critical determining factor for success of single ESWL session is stone size and microcrystalline structure and architecture of the stone^[41,42]. The presence or absence of bile duct stenosis can also influence the success of ESWL^[43]. Sauerbruch *et al*^[44], reported the efficacy of ESWL in achieving CBD stone fragmentation in over 90% of patients with minimal side effects.

In most institutions that already have access to ESWL for treatment of renal calculi, no other purchases of equipment needs to be made. For ESWL direct contact with the calculi is not needed, and multiple stones can be managed simultaneously^[41]. ESWL can be of particular help in patients with abnormal anatomy such as those who have undergone Billroth- II or Roux-en-Y surgeries in whom endoscopic access to the major papilla is difficult.

Although in general ESWL is tolerated well, it can be associated with adverse events such as transient biliary colic, subcutaneous ecchymosis, cardiac arrhythmia, self limited hemobilia, cholangitis, ileus and pancreatitis^[7,45]. Perinephric hematoma, biliary obstruction, bowel perforation, lung injury and splenic rupture are among the rarely reported complications^[42]. Multiple ESWL sessions may be required in a subset of patients to achieve ductal clearance, and endoscopic procedures between the ESWL sessions may become necessary to clear the bile duct of debris to assure drainage. The recurrence rate of CBD stones after ESWL clearance during a 1 to 2 year follow up was considerable and was around 14%^[45,46]. In a randomized trial comparing fluoroscopic guided ESWL and LL, LL was preferable not only for successful stone free rate (73% *vs* 97%), but also in terms of the number of sessions needed to clear the duct (3 in ESWL *vs* 1.2 in LL) and the duration of treatment^[30]. Another randomized trial comparing ultrasound guided ESWL and laser lithotripsy in the treatment of CBD stones refractory to conventional treatment clearly showed superior stone clearance rate and cost effectiveness in laser lithotripsy (52.4% *vs* 82%)^[40]. However, a prospective trial comparing EHL *vs* ESWL showed no difference in success rates for clearing the CBD, duration and cost of hospitalization between the two modalities^[24].

In the United States, ESWL is rarely performed for management of biliary stones and most centers prefer cholangioscopy-guided LL or EHL for this purpose.

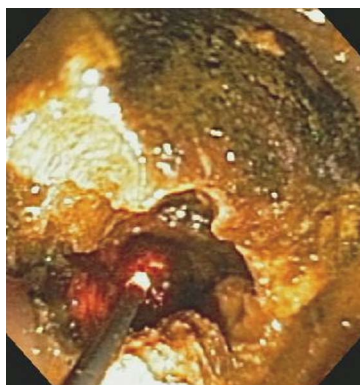


Figure 4 Direct peroral cholangioscopy guided laser lithotripsy of a bile duct stone. The red laser light makes targeting of the stone easier).

Cholangioscopy-guided lithotripsy

EHL or LL is ideally performed under direct visual control using a cholangioscope. The traditional cholangioscopy systems consist of a duodenoscope (also called “mother scope”) and a dedicated cholangioscope (also called “baby scope” or “daughter scope”) which is introduced into the bile duct through the accessory channel of the mother scope. The baby scope itself has an instrument channel through which the EHL or laser probe is introduced. Peroral cholangioscopy guided EHL or LL is cumbersome and can be labor intensive requiring an additional endoscopic unit and often participation of two skilled endoscopists, one to handle the duodenoscope and the other to maneuver the cholangioscope. The traditional cholangioscopes are capable of only 2-way steering, which may limit the field of view. These cholangioscopes are also extremely vulnerable to damage, requiring frequent expensive repairs. Furthermore, sharp angulations in the biliary tree may limit access into intrahepatic ducts or the cystic duct^[47].

To negate these limitations, the Spyglass Direct Visualization System (Boston Scientific Corp, Natick, Mass) was designed for single operator examination of the bile ducts, 4-way steering, and dedicated irrigation channels^[48,49]. In a large international multicenter study conducted at 10 centers in the United States and 5 centers in Europe, ductal clearance was successfully achieved in 71% of the patients using the Spyglass cholangioscopy system^[50]. Despite its effectiveness, the spyglass system has been underutilized mainly due to its fiber optic image quality which is inferior to the video image quality offered by the new videocholangioscopes^[51].

Direct peroral cholangioscopy

In direct peroral cholangioscopy (DPOC), an ultraslim upper endoscope is maneuvered across the biliary sphincter and into the bile duct for direct observation. With the introduction of high-definition ultraslim endoscopes with narrow band imaging capability, direct peroral cholangioscopy has gained popularity. This is mainly due to the many advantages of this technique. Compared to ductoscopy using a dedicated cholangioscope, direct cholangios-

copy has several advantages. It offers a single operator platform, digital image quality and simultaneous irrigation and therapeutic capabilities. The most profound disadvantage of DPOC, however, is the difficulty associated with traversing the biliary sphincter to gain access to the bile duct. This is mainly due to looping of the ultraslim upper endoscope in the stomach or in the duodenum. To enhance the success rate of DPOC, specialized accessories or techniques are needed to advance the ultra slim endoscope into the proximal biliary system.

Larghi and Waxman^[52] reported their experience in which the ultraslim upper endoscope was inserted with the aid of a guidewire placed during ERCP to maintain access. Additional use of manual pressure applied on the patient’s abdomen has been shown to ease the passage of the ultraslim endoscope into the hilar area in some patients^[53]. The main drawback encountered with passage of an ultraslim upper endoscope over a guidewire for gaining access to the bile duct is the dislodgement of the guidewire from the bile duct and also large loop formation hindering the entrance of the endoscope into the biliary system. Moon *et al*^[54] demonstrated the ropeway technique using an intraductal balloon that can be anchored within an intrahepatic bile duct to advance an ultraslim upper endoscope into the biliary tree for performance of DPOC. However, withdrawal of the balloon may cause technical difficulties in maintaining access which underscores the need for other accessories to maintain the scope’s position within the bile duct. The same group also reported use of an overtube balloon originally designed for double balloon enteroscopy to facilitate the introduction of an ultraslim upper endoscope into the biliary tree^[55]. However the large inner diameter of the overtube (10.8 mm) compared to the outer diameter of the ultraslim upper endoscopes (5.2-6 mm), makes it difficult to manipulate both instruments and results in discomfort to the patient, looping of the endoscope in the duodenum, and difficulty in reaching the proximal bile duct^[55,56].

In a recent study, we assessed utility of a novel anchoring balloon for performance of DPOC. Use of the anchoring balloon allowed consistent access to the biliary tree for performance of diagnostic and therapeutic DPOC distal to the confluence of the right and left hepatic ducts. More proximal access, however, was challenging owing to looping of the ultraslim endoscope after balloon removal.

Efforts are underway to develop the combined use of an intraductal anchoring balloon and an overtube especially designed for DPOC. Very recently, air embolism was reported following DPOC, resulting in a left sided hemiparesis^[57]. Endoscopists must be conscious of the fact that air embolism could remain asymptomatic, as in regional embolism (portal venous gas) or manifest as hypoxia, shock, cardiac arrest or cerebral ischemia as noted in this case^[57].

Once the hurdle of introducing an ultraslim upper endoscope into the bile duct has been overcome, a laser



Figure 5 Large diameter papillary balloon dilatation to remove bile duct stone.

or an EHL probe can easily be passed through the working channel of the ultraslim endoscope. Stones can be directly visualized before and during lithotripsy by DPOC (Figure 4). Lithotripsy is performed using this technique until the stones are satisfactorily fragmented to allow removal through the biliary sphincter. In a small study with 18 patients who had failed conventional endoscopic therapy including ML, DPOC guided EHL or LL was successful in approximately 90% of the patients with an average of 1.6 treatment sessions per patient^[58].

Specialized ultraslim upper endoscopes are being designed to facilitate access to the biliary tree for DPOC^[59]. Ultraslim upper endoscopes can be passed through the nasal cavity for performance of DPOC. Direct transnasal cholangioscopy has been reported for successful extraction of CBD stones^[60].

Endoscopic papillary balloon dilatation

Endoscopic papillary balloon dilation (EPBD) was introduced as an alternative to endoscopic sphincterotomy for removal of bile duct stones in 1980's^[61]. In an initial report involving 10 patients with CBD stones, biliary sphincteroplasty to 15 mm allowed removal of CBD stones in 6 patients^[61]. In the other 4 patients, ductal clearance required a combination of biliary sphincterotomy and mechanical lithotripsy. The use of large diameter papillary balloon dilatation (up to 20 mm in diameter) for management of difficult to remove biliary stones was reported by Ersoz *et al*^[62] in 2003. They reported a high success rate for stone removal. However, their complication rate was also high. Several reports have suggested that EPBD is associated with risk of severe pancreatitis which raises safety concern of this procedure^[61,63]. In our institution, we use EPBD selectively and try to avoid its use in those with high risk of post ERCP pancreatitis (Figure 5).

Since those initial reports, multiple studies have shown that EPBD alone or in combination with other techniques can be of use for management of difficult to remove biliary stones^[62-68]. EPBD is especially attractive in patients who are at risk for bleeding after endoscopic sphincterotomy or in those with altered anatomy

in whom a full sphincterotomy cannot be successfully achieved.

Some authors have suggested that the stone recurrence rate may also be higher with EPBD than with endoscopic sphincterotomy and mechanical lithotripsy^[69]. However the results of a Japanese multicentric trial with a mean follow up of 6.7 years demonstrated that there is lesser risk of stone recurrence following EPBD when compared with sphincterotomy^[70]. Further, a recent meta-analysis which included 15 randomized trials comparing EPBD and endoscopic sphincterotomy showed reduced risk of bleeding and infections and is especially indicated in older patients, those who are at risk for infection and coagulopathy^[71]. Despite its effectiveness, EPBD has been associated with serious complications^[63]. A higher risk of post ERCP pancreatitis has been observed which has been attributed to the inadequately loosened sphincter of Oddi and the intra mucosal hemorrhage and inflammation/edema around the papilla. This may cause compression of the pancreatic duct and may accentuate the risk of pancreatitis^[72]. In this regard, a randomized controlled trial demonstrated that a 5-min dilation time as opposed to the conventional 1-min time resulted in an adequately loosened sphincter of Oddi and consequently reduced the risk of post ERCP pancreatitis and improved its efficacy^[73]. The rate of these complications can be reduced by strict patient selection, avoidance of forced procedures, optimal dilation duration and immediate conversion to an alternative procedure if any difficulty is encountered during EPBD.

Endoscopic biliary stenting

In very old patients and those with serious co-morbidities where other endoscopic or surgical procedures may confer unacceptably high risks, endoscopic biliary stenting is a useful alternative^[69]. Biliary drainage by stenting is mandatory if ductal clearance cannot be achieved during ERCP or in between procedures in patients who require more than one session for ductal clearance. CBD stones have been reported to reduce in size in 60% of patients within one to two years after biliary stenting^[69].

Mechanical irritation of the stent on the stone is postulated to be one of the mechanisms.

In a study involving 28 geriatric patients with CBD stones refractory to conventional endoscopic removal, endoscopic biliary stent placement combined with oral ursodeoxycholic acid and terpene therapy for a mean of six months led to significant reduction in the size of CBD stone^[74]. Subsequently, endoscopic stone removal was successfully performed in 26 of 28 patients with a mean of 1.7 ERCP procedures. This combination therapy may be of use for treatment of difficult to remove CBD stones in a subset of patients with significant co-morbidities and intolerance to prolonged endoscopic treatment modalities.

In conclusion, the past several years have witnessed the emergence of new technologies and techniques for management of difficult to remove biliary stones. Treat-

ment of such stones is generally accomplished using a multimodal approach combining conventional techniques such as endoscopic sphincterotomy, use of extraction balloons and baskets and mechanical lithotripsy, with newer techniques such as cholangioscopy guided laser or electrohydraulic lithotripsy. Recent advances in the development of videocholangioscopes, single operator catheter-based cholangioscopes and specially-designed ultrathin upper endoscopes for DPOC have made lithotripsy under direct visual guidance safer, more reliable, and more routine. Future studies will certainly shed more light on the safety of different modalities for stone extraction and will help determine the best management approach for different subgroup of patients with difficult to remove bile duct stones.

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