## **EDITORIAL**

## **Endoscopic Removal of Large Common Bile Duct Stones: Time to Arm the Laser?**

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Since its inception nearly 40 years ago, endoscopic retrograde cholangiopancreatography (ERCP) has become the therapeutic cornerstone for removal of common bile duct (CBD) stones. Removal of the vast majority of stones with endoscopic sphincterotomy (EST), followed by sweeping the duct with either balloon or basket is successful in most cases, with an acceptable safety profile. Nevertheless, despite considerable refinements in ERCP over the last four decades, management of large, "difficult" CBD stones remains a therapeutic challenge. The definition of "large" CBD stones varies, ranging from >1 to >2 cm in diameter. Although the size of a stone is a prime determinant of its resistance to extraction, factors other than size are important. In a multivariate analysis, acute angulation of the distalmost aspect of the CBD and a shorter length of this distal CBD "arm" were associated with difficulty of ductal clearance [1]. Other factors inversely associated with stone clearance include very large stones such as those >3 cm, surgically altered anatomy, and firmness of the stones. The endoscopist must also consider not only the absolute stone size, but its diameter relative to the width of the distal duct through which it must be removed.

Several different fragmentation modalities have been studied for the removal of difficult stones: extracorporeal shock wave lithotripsy (ESWL), mechanical lithotripsy (ML), electrohydraulic lithotripsy (EHL), and laser lithotripsy (LL) (Table 1). Each technique works reasonably well, albeit with significant drawbacks. ESWL achieved ductal clearance in 84 % of 283 patients with an acceptable minor complication profile [2]. However, this technique is

notoriously cumbersome, requiring multiple treatment sessions: initial ERCP with placement of nasobiliary drain, ESWL with stone fragmentation, followed by at least one additional ERCP with removal of smaller stone fragments. A randomized study comparing LL with ESWL showed that LL cleared the duct with fewer fragmentation sessions and endoscopic procedures [3].

Mechanical lithotripsy (ML) has a long track record in the therapy of large stones. It utilizes a metal basket and overlying sheath, into which stone fragments become trapped and crushed. Its advantage is that it is a widely available accessory which can be deployed in the course of a "routine" ERCP without bringing in additional, expensive equipment. However, it can be challenging to set up and deploy; furthermore, its use does not entirely prevent the feared scenario of impacted basket and stone in the biliary tree, which transforms an endoscopic dilemma into a surgical emergency. Results are generally favorable, but not universally successful. In a review from a Canadian referral center, nearly one-quarter of patients treated with ML required more than one endoscopic treatment [4].

Electrohydraulic lithotripsy (EHL) relies upon the generation of shock waves, which under continuous saline irrigation of the bile duct are transmitted to stones, which then shatter. It has been traditionally performed using a dedicated smaller caliber cholangioscope which fits inside the working channel of a therapeutic duodenoscope, a so-called "mother-baby" scope arrangement. Unfortunately, this arrangement is extremely time-consuming, requires two endoscopists, and the cholangioscopes are extremely fragile. These formidable barriers have detracted from the appeal of EHL, even in tertiary referral centers.

Laser lithotripsy (LL) works on a similar general principle to EHL. LL uses a high power light wavelength to deliver shockwaves to stones, thereby fragmenting them.

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Table 1 Modalities for removal of large common bile duct stones

Fragmentation modalities

Extracorporeal shock wave lithotripsy (ESWL)

Mechanical lithotripsy (ML)

Electrohydraulic lithotripsy (EHL)

Laser lithotripsy (LL)

Large balloon dilation of the ampullary orifice (LBD)

The two lasers used most commonly for this indication are the Nd:YAG (FREDDY) and holmium-based systems. The Nd:YAG system is sometimes referred to as a "smart" laser, because it ostensibly possesses the ability to distinguish between tissue and stones. In order to avoid ductal trauma, LL is performed under either direct endoscopic guidance using "mother-baby" scopes or, more recently, the Spyglass system (Boston Scientific, Natick, MA, USA) or under direct fluoroscopic control. There is a relative paucity of data evaluating the efficacy of LL in stone fragmentation and extraction. In a non-randomized, retrospective study of 52 Korean patients with CBD stones >15 mm using the Nd:YAG laser, 48/52 patients (92 %) had complete stone clearance in one to two sessions (mean 1.4 sessions). The investigators performed this technique with fluoroscopic guidance only (not direct endoscopic visualization) in 45/52 cases. They reported a relatively high complication rate of 23 %, including eight cases of hemobilia, but none were serious and all responded to conservative management [5].

The holmium laser was used in an Indian study, in which 50 of 60 patients (83 %) with CBD stones not amenable to removal by standard techniques, balloon dilation or ML had complete clearance of the biliary tree in one session. Mean procedure time was 46 min; relatively mild complications occurred in 13 % of patients. The laser fiber was deployed through the Spyglass SpyScope accessory channel [6].

An overlooked but important adjunct to advanced therapies aimed at direct stone removal is plastic CBD stent placement. Endoscopists often place CBD stents as a temporizing measure after an arduous, ultimately incomplete attempt at ductal clearance. Yet this maneuver may be therapeutic as well as temporizing; in a series of patients treated with double-pigtail stent placement after large or multiple CBD stones were incompletely removed at index ERCP, the number and size of retained stones were decreased at subsequent ERCP 2 months later [7].

A landmark innovation in the management of large CBD stones is large balloon dilation (LBD) of the ampulla following EST as an aid to stone removal. EST is performed, followed by through-the-scope balloon dilation of the major papilla to the size of the duct and/or stone, with a

maximal dilation of 20 mm. Endoscopists were understandably reluctant to employ this technique after Disario et al. published their results comparing balloon dilation without EST versus EST alone. The investigators enrolled patients with known or suspected bile duct stones, i.e. this was not a study of large stones specifically. Accordingly, dilatation was performed to a maximum of 8 mm in this study. A marked increase in post-ERCP pancreatitis was noted in the dilation group (15 vs. 1 %), including a 5 % risk of severe pancreatitis (none in the EST group) and two deaths from acute pancreatitis in 117 patients in the balloon dilation arm [8].

However, several papers published subsequently have established the safety of this technique when LBD is combined with EST. In a randomized study of 90 patients with stones between 12 and 20 mm in diameter randomized to EST followed by either LBD or ML, similar rates of stone clearance were achieved in the two groups (98 vs. 91 %), but a significantly higher complication rate was observed in the EST + ML group (20 vs. 4 %), with 13 % of the EST + ML patients developing post-procedure cholangitis vs. none in the EST + LBD group [9]. A Japanese group reported in a retrospective analysis that adding LBD to EST decreased the procedure and fluoroscopy time as well as the need for ML compared with patients who underwent EST alone for extraction of stones >12 mm [10]. A US multi-center retrospective series of 103 patients with stones >12 mm demonstrated a 95 % success rate of ductal clearance with EST followed by LBD, although ML was required in 27 %. Balloon dilation was performed to 12-18 mm. Notably, there were no cases of pancreatitis. Nonetheless, two severe complications were reported: cystic duct perforation requiring prolonged hospitalization and bleeding necessitating angiographic therapy [11].

It is important to evaluate the data from Sauer and colleagues on LL in the context of the emerging data regarding the utility of LBD. In this month's journal, Sauer and colleagues add to the evidence on LL for CBD stones [12]. In this single-center review from a highly regarded endoscopic unit, LL using the holmium laser was deployed in 20 cases from 2001 to 2009 in which previous ERCP with standard techniques failed in stone extraction. Mean stone size was quite large at 2.2 cm, with a range of 1.1–3.5 cm. Initially, the "mother-baby" system was used, but since 2006 the Spyglass system was used for direct endoscopic visualization. A mean of 1.4 laser sessions and 1.9 ERCPs were needed to achieve a ductal clearance rate of 90 %. Five complications occurred in 20 patients, including three bile leaks which resolved with stenting. No serious complications were reported.

This was a single center, retrospective review with no comparison arm, with the usual limitations inherent in this type of work. The study included only 20 patients collected



over almost 9 years. This low number suggests that many similar patients were excluded from the study for reasons not supplied by the authors. Patients and their families should be advised that more than one session is often required to clear the duct. The development of three bile leaks in 20 patients suggests that this technique may carry a significant risk of injury to the biliary tree. It is fortunate that none of these leaks evolved into serious complications. The cases still took an average of 85 min to complete, a substantial time commitment. All patients in the study were sedated with general anesthesia, which is probably the most prudent option for these long, complex procedures.

Nonetheless, the work by Sauer and colleagues represents a valuable contribution to the relatively sparse literature on the use of LL for large CBD stones. Their results suggest that this technique is safe and effective. As a paper originating from the United States, it may hold particular relevance for American and Western clinicians. The results support the feasibility of Spyglass as an effective tool in facilitating laser fragmentation of CBD stones, which is more user-friendly than "mother–baby" scopes.

How should the endoscopist approach the removal of large, difficult CBD stones in 2012? Once standard techniques fail, the best first option in most patients with CBD stones <2 cm is large balloon dilation of the papilla followed by attempts at extraction with standard balloons or baskets. If this fails, mechanical lithotripsy is a reasonable option for the experienced operator. If stones remain, a plastic stent should be placed. Patients are generally stable enough to allow for a second, elective procedure, at which time standard basket or balloon retrieval or mechanical lithotripsy may prove successful. Advanced techniques such as laser lithotripsy should be reserved for cases in which the aforementioned therapeutic strategy fails, in cases where large balloon dilation is not feasible, e.g., coagulopathy, periampullary diverticulum, portal hypertension, postoperative anatomy, and in cases of stones >2 cm. For now, the choice of which lithotripsy technique to utilize depends on local availability and expertise.

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