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EDITORIAL

Safely Stretching Our Options for Removing Large CBD Stones

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In 10–15 % of endoscopic retrograde cholangiopancreatography (ERCP) procedures performed for the indication of suspected choledocholithiasis, identified stones can be difficult to remove [1]. Common factors associated with failure include stones >1 cm, numerous stones, and altered biliary anatomy. There are several techniques for removing these "difficult CBD stones". Leaving a plastic biliary stent in place with or without ursodeoxycholic acid therapy with subsequent ERCP is often successful [2]. Mechanical lithotripsy (ML) fragmentation combined with biliary sphincterotomy (EST) successfully removes many large stones [3, 4]. Complications following biliary sphincterotomy and ML include bleeding, pancreatitis, and perforation and are usually mild and self-limited but on rare occasions can cause short-term morbidity or even death [5]. Electrohydraulic lithotripsy can be useful for disintegrating stones prior to removal, but requires direct visualization of the stone with cholangioscopy with attendant risks such as hemobilia, cholangitis, and ductal perforation [6].

Endoscopic papillary balloon dilation (EPBD), or balloon sphincteroplasty, has evolved as another technique for removing large bile duct stones. Controlled radial expansion (CRE) balloons 6–10 mm in diameter stretch the intact sphincter of Oddi to facilitate stone removal. Though early experience with balloon sphincteroplasty was promising, subsequent multicenter, randomized controlled trials reported overall higher rates of pancreatitis including severe pancreatitis leading to death in some patients treated with balloon sphincteroplasty [7, 8]. While balloon sphincteroplasty remains an accepted practice in some parts of the world, the American Society for Gastrointestinal Endoscopy only recommends EPBD for patients in whom sphincterotomy is considered too risky or difficult such as patients medically anticoagulated or those with post-surgical anatomy or a periampullary diverticulum [1].

Endoscopic papillary large-balloon dilation (EPLBD) is a technique introduced in 2003 that dilates with a 12 to 20-mm CRE balloon following biliary sphincterotomy [9]. Balloon size is chosen to be at least the same diameter as the stone but no larger than the diameter of the bile duct. The initial published retrospective series reported that biliary stones too large to be removed despite a complete sphincterotomy and use of an extraction balloon or basket could be successfully removed in most cases without the use of ML [9]. Furthermore, the overall complication rate was an acceptable 15.5 %, consisting of mild-to-moderate cholangitis, pancreatitis, and bleeding, with no deaths [9].

Several retrospective studies, prospective series, and randomized controlled studies have reported that EPLBD is an effective and mostly safe method for the removal of large CBD stones [10–16]. A recent systematic review of

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Table 1 Guidelines for performing safe EPLBD removal of challenging CBD stones

Do not perform EPLBD if there is distal CBD stricture
Limit length of endoscopic sphincterotomy to <2/3 of the length of ampulla immediately prior to large-balloon dilation to prevent perforation or bleeding
Inflate the balloon gradually until the "waist" disappears
Discontinue balloon inflation when resistance is encountered in the presence of a persistent balloon "waist" or if a "waist" persists in the balloon after inflation to 75 % of the balloon manufacturer's maximum recommended balloon pressure
Do not inflate balloon beyond the maximal size of the upstream dilated CBD
Consider alternative stone removal methods such as mechanical lithotripsy, electrohydraulic lithotripsy, or placing a plastic stent when meeting any difficulty in removing stones via EPLBD

Modified from reference [18]

21 studies involving 1,292 patients who underwent treatment with EPLBD for choledocholithiasis revealed an overall successful clearance of the CBD in 98 % of subjects with only 9.3 % requiring ML [17]. The vast majority (91 %) could be completed during the initial ERCP. Adverse events (5 %) were mostly mild-to-moderate pancreatitis and bleeding, but also included cholecystitis, cholangitis, and duodenal and biliary perforation, similar to those reported for ML [3–5].

In the current issue of Digestive Diseases and Sciences, Park et al. [18] report a retrospective analysis of the largest dataset every compiled on the topic of EBPLD in order to evaluate performance characteristics of the procedure. They retrospectively collected data from 12 Japanese and Korean academic medical centers on 946 consecutive adult patients who had been treated with EPLBD or large-balloon sphincteroplasty in the treatment of ≥10 mm common bile duct (CBD) stones, in order to risk-stratify the population for the development of procedure-related adverse events. Most patients were treated with either a limited (44 % of patients, "Mid-EST". <2/3 ampulla length) or complete (23 %, "Full-EST", >2/3 ampulla length) sphincterotomy. The remaining 33 % of patients were treated with sphincteroplasty alone ("No-EST"). Dilation was completed under endoscopic and fluoroscopic guidance using a 5.5-cm-long CRE balloon 12–20 mm in diameter to match the size of stone and/or bile duct diameter. Successful stone removal was achieved in 97 % of the procedures with 21 % requiring use of ML. The average stone size was 15.3 mm. Adverse events occurred in 95 patients (10 %) comprising of bleeding (6 %), pancreatitis (2.5 %), biliary or duodenal perforation (1 %), and cholangitis (0.6 %). Most events were mild (82 %) or moderate (13 %) in severity; however, there were five cases with a severe adverse event (one hemorrhage and four perforations), four of which were fatal.

Multivariate analysis revealed four significant independent predictors of adverse events. Three variables, cirrhosis, full-EST, and stone size ≥16 mm, were each associated with significantly higher risks of any adverse event or bleeding. The presence of a distal CBD stricture was associated with a 17-fold increased risk of perforation.

One patient died after severe bleeding occurred in the setting of thrombocytopenia ($84 \times 10^3/\mu l$) and a full sphincterotomy. The other three deaths occurred in patients who had a distal CBD stricture and had undergone a complete sphincterotomy. A distal CBD stricture was not always cholangiographically visualized prior to dilation. In some instances, the stricture became evident only during dilation, manifesting as either sustained resistance to balloon inflation or as a persistent fluoroscopically visualized "waist" in the balloon despite inflation of a 20-mm balloon to 75 % of the recommended maximal pressure.

The authors conclude by listing several guidelines for performing EPLBD as listed in Table 1. These recommendations provide excellent guidelines for practitioners to safely perform EPLBD. Additionally, the use of leaving a plastic stent in place (with or without ursodeoxycholic acid) and repeating ERCP at another time (and perhaps by a different endoscopist) is also worth considering. Practitioners should be aware that 10 % of patients still required mechanical lithotripsy to remove the stones, and ideally ML should be available if attempting EPLBD. They should also inform their patients that on average it takes more than one ERCP session (average 1.4 ERCPs) to remove the stones.

There are still unanswered questions regarding optimal sphincterotomy length (or even the need for sphincterotomy), balloon size, the impact of prior endoscopic sphincterotomy, and subsequent recurrence rate of CBD stones. It is also unclear if the performance characteristics of EPLBD will be different in the community of general gastroenterologists with much lower ERCP volume. Future prospective studies might compare EPLBD directly with ML, EHL, plastic stents, and surgery to define the optimal approach.

In summary, EPLBD is now an accepted strategy in the treatment of challenging biliary stones, incorporated into several management algorithms [19, 20]. Given the relative simplicity of this method that utilizes commonly available and familiar equipment, EPLBD is a very attractive alternative to mechanical lithotripsy, having the potential for widespread worldwide use. This study by Park et al. helps guide our patient selection and technique performance of EPLBD to optimize the safe and effective removal of challenging CBD stones.

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