REVIEW

Endoscopic management of biliary stone disease

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ABSTRACT

The management of bile duct stone disease is the most common indication for endoscopic retrograde cholangio-pancreatography (ERCP). The majority of cases may be resolved using standard approaches including endoscopic sphincterotomy and balloon stone extraction. Recent advances in the management of large or challenging stones has come from the clear evidence for the role of endoscopic papillary large balloon dilatation (EPLBD)/sphincteroplasty and the development of cholangioscopically directed lithotripsy. Perhaps the greatest improvement in endoscopic stone management will be achieved through the implementation of plans for more formalised training, reflection and audit of ERCP performance indicators and network-wide coordination of ERCP services.

BACKGROUND

Gallstones are common, affecting 10%–15% of the adult UK population. While 80% of those affected remain asymptomatic, clinical manifestations related to cholecystitis, gallstone pancreatitis and choledocholithiasis carry a significant burden for individual health and service provision. Common bile duct stones (CBDS) are found in 6%–22% of patients undergoing cholecystectomy for gallstones, and retained stones/new stone development occurs in 5% of patients after gall bladder removal.¹ In 10% of patients with CBDS, there are no apparent stones in the gallbladder. Of >50 000 therapeutic endoscopic retrograde cholangio-pancreatographies (ERCPs) performed in the UK each year, >50% are performed for the treatment of CBDS.

Once detected, CBDS should be removed even if asymptomatic, given the significant morbidity associated with them.² ERCP with endoscopic sphincterotomy (ES) and stone extraction has been the first-line treatment for CBDS for more than 30 years. However, there is

wide variation in published rates of successful stone clearance. Online self-reporting systems of ERCP outcome and data from expert tertiary centres have shown very high rates of stone clearance between 96% and 99%.³ Although methodology may play a part in these excellent results (eg, study inclusion requiring initial identification of the ampulla), they appear much better than recently reported studies of broad-based clinical practice. Data from community ERCP practice have showed the rate of stone clearance to be around 77%.⁴ A UK-based audit of ERCP from 2006 captured a 94% unit response rate and revealed completion of intended treatment in only 70.4% of ERCPs.⁵ A recent prospective audit in the Netherlands captured 50% of all ERCPs performed nationally.⁶ Overall procedural success was 85.2% in patients with stone disease. Registration bias was raised as a concern; non-registered procedures included proportionately more failures than those that were entered in the web-based registry (success rate of 76% vs 86%).

What factors influence CBDS clearance at ERCP? Failure to cannulate the bile duct is a fundamental ‘deal breaker’ and may relate to several patient-related factors, including altered surgical anatomy (eg, Billroth II partial gastrectomy), duodenal stricture or deep duodenal diverticulum. Organisational factors, such as lack of availability of anaesthetic support for ERCP⁷ in patients who are intolerant of conscious sedation, may play a role in failure. Unit and individual ERCP case volume may be important, with some studies showing lower success rates in lower volume centres.⁸ Stone characteristics play a part in making duct clearance difficult. Lower rates of stone clearance have been reported with large stones (>15 mm), multiple stones, intrahepatic

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and cystic ducts stones and stones above strictures.^{9 10} However, stone size per se may be a less relevant predictor of successful clearance than stone diameter compared with the more distal common bile duct (CBD). In a retrospectively analysis of >300 patients with CBDS, patients with a median stone diameter of 15.5 mm and a median lower CBD diameter of 16 mm had higher rates of stone clearance than patients with a median CBD stone diameter of 8 mm and a median lower CBD diameter of 3 mm.¹¹

Given the challenges of stone clearance in some patients, is stenting alone a reasonable approach? Randomised trials comparing stenting versus endoscopic therapy have shown unacceptably high rates of morbidity in the stenting group.¹² Stenting as the definitive management of CBD stones without further attempt at extraction is not recommended except in the case of limited life expectancy.

RECENT ADVANCES

Well-established approaches to CBDS clearance at ERCP have involved sphincter disruption (usually by means of ES) followed by balloon-assisted stone extraction±mechanical lithotripsy. Recent advances have centred around balloon dilatation of the biliary sphincter (sphincteroplasty/endoscopic papillary dilatation) and of cholangioscopy-directed laser or electrohydraulic lithotripsy.

A significant advance in the management of large CBDS has come in the increasing use of endoscopic papillary large balloon dilatation (EPLBD), which was first described in 2003. While bespoke 'short wire' biliary dilatation balloons are available up to 10 mm, larger diameter 12–20 mm dilatation for EPLBD is (at present) accomplished using balloons developed for oesophageal or pyloric dilatation. These have the disadvantage of not being compatible with the 'short wire' system that is commonly used for ERCP and so requires the endoscopy team to be familiar with accessory exchange using the 'long wire' technique. Complications after EPLBD and ES appear to be similar to ES alone.¹³ It is necessary to implement some important rules to reduce the risk of complications using EPLBD. The diameter of the dilating balloon should not be wider than the dilated bile duct upstream of the ampulla (and some experts caution not to dilate to >18 mm). Particular care should be taken to ensure that there is no stone impacted in the distal duct, between the inflating balloon and the duct wall. EPLBD should not be performed in the setting of a distal CBD stricture or non-dilated duct (irrespective of stone size). The usual recommended duration of inflation is 30–60 s.¹⁴

The need for ES prior to EPLPD or even small diameter dilatation (EPBD) remains contentious. Dispensing with ES would clearly avoid ES-related complications and might preserve sphincter function, although the latter has not clearly been shown to be

clinically important. Standard advice and practice for the last 15 years has been (and by many experts still is) to perform ES prior to balloon dilatation, in the absence of contraindications to ES, such as coagulopathy. This view was driven in part by a seminal paper,¹⁵ in which 237 patients were randomised to ES or primary EPBD (up to 10 mm diameter) prior to attempted stone extraction. Significantly higher severe complications (7% vs 0%) were seen in the EPBD group, almost all attributed to pancreatitis, with two pancreatitis-associated deaths. It has been argued that inadequate dilatation in combination with oedema around the papilla may cause a compartment syndrome compressing pancreatic outflow and increasing the risk of pancreatitis. Conceptually, ES prior to EPBD may result in the expansile force of dilatation being centred away from the pancreatic sphincter. In 2011, the American Society for Gastrointestinal Endoscopy (ASGE) recommended that primary EPBD (ie, without ES) should not be performed in routine practice.² The advice has shifted recently, with European Society of Gastrointestinal Endoscopy (ESGE) concluding that primary EPBD up to 10 mm is a safe option in the management of small bile duct stones, especially in the presence of coagulopathy or altered anatomy.¹⁶

Direct intrabiliary visualisation (cholangioscopy) was developed in the 1980s, but the 'mother and baby' scope system fell out of widespread clinical use due to various issues, including the requirement for two endoscopic operators and cholangioscope fragility. A sea change of interest came with the introduction of a single operator cholangioscope in 2006. Further developments led to the introduction of the Spyglass DS (Boston Scientific) system in 2015, a single-use 10F cholangioscope with four-way deflection, digital optics, and 1.3 mm therapeutic channel. Stone fragmentation can be performed under direct vision using either electrohydraulic lithotripsy (EHL) or laser lithotripsy (LL) probes passed down the therapeutic channel. Published series suggest stone clearance using EHL in 74%–95% of patients.¹⁷ Early experience from the UK has shown that in patients in whom conventional ERCP was unsuccessful, Spyglass DS and EHL led to complete stone clearance in 81% of cases.¹⁸ It may also have a particular role in the most challenging cases, including Mirizzi's syndrome and intrahepatic stones. Concerns about the cost of available cholangioscopy systems have been raised. However, with the alternative to endoscopic stone extraction being surgery, a recent Canadian retrospective analysis reported potential savings across the whole patient journey by using Spyglass and EHL, compared with proceeding to surgery, of equivalent £969–£1918.¹⁹

FUTURE DEVELOPMENTS

Improvements in the endoscopic management of biliary stones will be driven by developments in

technology, training and service provision. With the increased use of 'short wire' ERCP accessories the development of 12–20 mm diameter EPLBD sphincteroplasty balloons would be welcome. The 'direction of travel' is likely to be towards greater use and confidence with EPLBD and less use of mechanical lithotripsy. Interventional endoscopic ultrasound (EUS) is being increasingly used for biliary access where transpapillary access at ERCP proves impossible (eg, in association with malignant duodenal obstruction or surgically altered anatomy). In this difficult to treat group of patients, EUS-guided transhepatic antegrade biliary puncture and EPBD have allowed a 60% stone clearance rate to be achieved.²⁰ A randomised controlled trial showed an equivalent success rate of EUS-guided CBD stone removal compared with standard ERCP for the treatment of small (<10 mm) CBD stones.²¹ Nevertheless, the procedure is challenging and cannot be considered as a routine alternative to ERCP, where transpapillary access is feasible. The recent development of EUS-deployed lumen apposing stents has led to new approaches to gallbladder and biliary drainage, where surgical or ERCP may be unfeasible. This may lead to new approaches to the management of complex biliary and gallbladder stone disease.²²

An emphasis on training and service provision, with a focus on means to maintain and improve overall delivery of ERCP, has recently been set out by the British Society of Gastroenterology.²³ Implementation of these recommendations seems likely to drive improvements in the endoscopic management of CBDS more than technological advances. The adoption of more structured training programmes and a period of mentorship of newly qualified consultants should allow all operators to reach high levels of independent practice. This will include as a minimum standard a $\geq 85\%$ cannulation rate of virgin papillae and CBD stone clearance for $\geq 75\%$ of those undergoing first ever ERCP. The development of more robust pathways will necessitate the formation of clear triggers for referral. Within the field of CBDS, onward referral should be considered after two ERCPs, as data suggest that further attempts using standard approaches are unlikely to be successful.²⁴ This may in turn require a network model for referral of more complex stone disease cases, allowing all patients to gain prompt access to tertiary care and advanced technologies such as cholangioscopy and EHL/LL.

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