Dilation-Assisted Stone Extraction: Does One Balloon Fit All?

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Received: 5 December 2013 / Accepted: 5 December 2013 / Published online: 11 January 2014
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The story of dilation-assisted stone extraction is characterized by tragedy and triumph. Although initially proposed as a means to preserve the native state of the bile duct, controlled studies indicated that dilation without endoscopic sphincterotomy (EST) was associated with a high risk of pancreatitis [1, 2]. However, dilation after EST is a safe and effective means of treating large bile duct stones. In this month's *Digestive Diseases and Sciences*, Li et al. [3] extend the use of this method to manage bile duct stones of all sizes. Although generalizability may be limited by the specific study population and techniques, the approach suggests exciting possibilities of more widespread potential application.

Balloon dilation that facilitates bile duct stone removal was first espoused as a means of avoiding long-term exposure of the biliary tree to enteric contents. Nevertheless, a multicenter randomized controlled trial of balloon dilation versus EST revealed a concerning incidence of pancreatitis among those who underwent balloon dilation compared with those who underwent EST [2]. In addition, nearly half of these cases were severe and two study patients died. Further confirmatory work led investigators to conclude that balloon dilation was not appropriate for clinical practice [1].

Endoscopic biliary sphincterotomy combined with balloon and basket maneuvers enables removal of 85 % of bile duct stones [4]. Nevertheless, perivaterian diverticuli

and other anatomic abnormalities of the papilla complicate removal [5]. Large or impacted concretions may also be difficult to retrieve. Although, for these refractory stones, intraductal and extracorporeal shock wave and intraductal laser lithotripsy have been used, these approaches require extensive technical expertise, are not widely available, and are time consuming [6–8].

A critical variation of papillary balloon dilation has been proposed for removal of difficult bile duct stones [9]. By dilating the papilla after endoscopic sphincterotomy, complete clearance of difficult bile duct stones was achieved for 93 % of patients without elevated incidence of pancreatitis [9]. Subsequent work has confirmed that balloon dilation after EST is of comparable efficacy and as safe as conventional approaches for removal of large bile duct stones, and may be less likely to result in complications [10–13]. It is postulated that the biliary sphincter separates the biliary orifice from the pancreatic orifice, directing the force of dilation predominantly toward the bile duct and away from the pancreas [13]. Large retrospective studies also suggest that EST combined with large balloon dilation requires less mechanical lithotripsy, and that the duration of the procedure is shorter [11, 12].

In their study, Li et al. randomized 462 patients with bile duct stones to small EST combined with balloon dilation (sEST + EPBD) compared with EST. The study differed from previous controlled trials in that the number of subjects was much larger and that subjects bearing stones of all sizes were included. Consistent with previous work, complete stone removal and incidence of complications were equivalent in the sEST + EPBD and EST groups. This prospective study also convincingly demonstrated that procedure and fluoroscopy duration are briefer for sEST + EPBD, with reduced requirement for mechanical lithotripsy than EST.

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The authors' suggestion that the results of their study are indicative of its suitability for treatment of "all comers" with stones is limited by several features of their population. Approximately 40 % of the patients in both groups had perivaterian diverticuli and large stones (>12 mm) which increase the difficulty of stone removal. Moreover, although the authors advocate use of sEST + EPBD for all sizes of bile duct stone they reported success was not significantly different for concretions <10 mm in diameter. Their positive findings may have been driven by the improved success of biliary dilation for large stones—97.8 % for sEST + EPBD versus 87.3 % for EST. Furthermore, they routinely placed nasobiliary drainage tubes which were removed after confirmatory cholangiography. Although this practice may favor reliable stone clearance, it is uncomfortable for patients and is rarely used in the western world. This approach somewhat limits the generalizability of their results.

Several important points are raised by this study. The authors make a case for the efficiency of sEST + EPBD which is well supported by their data. Mean procedure time was 38.6 min for sEST + EPBD compared with 47.1 min for the EST group. In addition, complete stone clearance in the first session was 87.7 % by use of sEST + EPBD versus 71.4 % for EST alone. Also, ERCP is performed in most community centers whereas mechanical lithotripsy requires more specialized expertise and many practitioners refer cases requiring lithotripsy to tertiary centers. In contrast, balloon dilation is universally used for esophageal strictures. As the safety and efficacy of papillary balloon dilation after sphincterotomy are established, it is likely that community practitioners will be comfortable using this approach.

Although not entirely applicable to the western population, this large randomized trial by Li et al. demonstrates the safety and efficacy of sEST + EPBD for stones of all sizes. The approach substantially reduces procedure and fluoroscopy duration and virtually eliminates the requirement for multiple procedures to complete duct clearance. These findings have particular importance in the United States where the ongoing implementation of the Affordable Care Act has increased emphasis on improving efficiency while maintaining quality. The development of balloon-equipped sphincterotomes may further reduce costs [14]. Although balloon dilation after EST is now used routinely for large bile duct stones, additional trials and clinician

preference will determine whether balloon dilation will become part of the routine approach for all bile duct stones.

Conflict of interest None.

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