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Can we preserve sphincter of Oddi function by avoiding sphincterotomy? Do we want to?

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Durable endoscopic treatment of choledocholithiasis requires the extraction of gallstones through the sphincter of Oddi muscle complex. With or without stone fragmentation, this maneuver requires adequate expansion of the ampullary and biliary components of the sphincter of Oddi through sphincterotomy, balloon orifice dilation, or both. In the approach to a patient with choledocholithiasis, the prevailing concern is to remove the stones completely and with as little risk and need for reintervention as possible. A secondary consideration—but perhaps one that should factor in the immediate therapeutic approach—is to minimize the likelihood of delayed adverse events such as common bile duct stone recurrence and symptomatic biliary orifice stenosis. Is it possible to preserve sphincter of Oddi function by dilating only the biliary orifice at the time of stone extraction? Would preservation of sphincter of Oddi function increase or decrease the likelihood of these and other delayed adverse events? The extraordinary effort by Cheon and colleagues¹ to randomize 86 patients with large common bile duct stones to large balloon orifice dilation with or without concurrent sphincterotomy, and then to perform pretreatment, early posttreatment, and delayed (1 year later) sphincter of Oddi manometry is an interesting contribution to the limited literature on sphincter of Oddi physiology. Their findings permit us to speculate on the long-term implications of bile duct stone extraction.

First and foremost, symptomatic common bile duct stones should be removed endoscopically. With few exceptions, endoscopic extraction remains the least morbid approach to accomplish this. Still, performing an adequate sphincterotomy to achieve stone extraction is a complex endoscopic maneuver, especially when performed by low-volume providers.² Is balloon orifice dilation safer? Because the majority of ERCP providers in the United States perform fewer than 2 ERCPs per week, one could argue that balloon orifice dilation may reduce the procedural complexity of ERCP because it mimics the techniques required for luminal strictures. However, on the basis of a randomized controlled trial comparing small balloon orifice dilation with sphincterotomy that resulted in 2 severe episodes of post-ERCP pancreatitis, conventional Western opinion has argued against performing papillary orifice dilation in the absence of antecedent sphincterotomy.³ Conversely, a convincing body of literature, predominantly from expert centers in Asia, reveals higher success rates, comparable adverse event rates, shorter procedure times, and

DISCLOSURE

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reduced need for mechanical lithotripsy with balloon orifice dilation alone or in combination with sphincterotomy when compared with sphincterotomy alone.⁴ Balloon orifice dilation is safe as long as the dilation does not exceed the diameter of the bile duct, and stones are not impacted into the ampulla or biliary epithelium during the process of balloon dilation. Ironically, large (10–12 mm) and longer (5-minute)⁵ balloon dilation of the intact sphincter is probably safer because immediate periampullary edema leading to pancreatic duct obstruction and post-ERCP pancreatitis is more likely when the biliary sphincter is insufficiently separated from the pancreatic component. Patients with larger stones in a dilated and obstructed bile duct can accommodate larger balloon dilation and thus have a lower baseline risk for post-ERCP pancreatitis.

Does balloon dilation of an intact papilla improve efficiency? Most ERCP providers prefer to cannulate the bile duct using a sphincterotome as opposed to a cannula because this facilitates selective cannulation⁶ and the passage of additional devices, including a dilation balloon catheter. If a sphincterotome is used for cannulation, combining a biliary sphincterotomy with balloon orifice dilation should not require the use of additional catheters. Therefore, for the treatment of large common bile duct stones, our preference is to perform at least a moderate biliary sphincterotomy when possible and then to complement this with balloon orifice dilation; the diameter should match that of the largest stone but never exceed the diameter of the bile duct itself. Admittedly, this is based on a general bias among Western experts against balloon orifice dilation of the intact sphincter of Oddi. In any case, the technical success rates and short-term adverse event rates reported by Cheon and colleagues¹ suggest little difference between those approaches, because both treatment groups were associated with very high (>95%) success rates in the removal of all common bile duct stones during the index ERCP. In summary, balloon orifice dilation alone or in combination with a limited sphincterotomy probably does not have an impact on the short-term success rates; most existing literature reports also suggest comparable short-term adverse event rates with these techniques.

A theoretical advantage of balloon orifice dilation is preservation of the sphincter of Oddi muscle complex. Whereas the long-term sequelae of biliary sphincterotomy remain poorly understood, electrocautery to the sphincter of Oddi could lead to symptomatic orifice stenosis and chronic intestinal bacteria translocation into the biliary tree. Bacterial translocation may occur more readily when the orifice is left widely patent after excisional therapy (ie, sphincterotomy); limited data suggest that small balloon orifice dilation may be safer than sphincterotomy in this regard.⁷ These findings need to be confirmed at other centers. Bacterial translocation and consequent chronic inflammation after sphincterotomy have been implicated as a potential risk factor for cholangiocarcinoma, although long-term data do not support this postulate.^{8,9} One could argue that a patient who has demonstrated the metabolic and mechanical predisposition to the development of large common bile ducts should not be left with a functional sphincter of Oddi, although this is admittedly speculative.

The manometric observations provided by Cheon and colleagues¹ have greater relevance to these long-term implications of sphincterotomy. The authors randomized 86 patients undergoing their first ERCP to treat choledocholithiasis, with 1 stone being 12 mm in

diameter, to large balloon orifice dilation with (n = 44) or without (n = 42) sphincterotomy. The authors performed sphincter of Oddi manometry immediately before sphincter therapy, 1 week after the procedure, and then again 1 year (77/86 patients) later. The authors' successful long-term (nearly 1.5 years) follow-up of randomized patients, and their successful repetition of ERCP with sphincter of Oddi manometry even 1 year later, is nothing short of remarkable, given the scarcity of data on sphincter of Oddi function after endoscopic therapy. Basal pressure, peak pressure (amplitude), and contraction frequency were significantly decreased in both treatment groups, including 1 year after the intervention. The observed posttreatment biliary manometric measurements are identical to a recent post hoc analysis of the EPISOD trial, revealing consistently low biliary pressures after biliary sphincterotomy at the time of follow-up ERCP; pancreatic sphincterotomy has a less profound effect, with only 25% of individuals having normal or below-normal basal pressures at the time of repeated ERCP.¹⁰ Irrespective of the approach to initial stone extraction, recurrent symptomatic stones were identified in approximately 16% of patients, many of whom had an intact gallbladder at the time of randomization and some of whom never underwent cholecystectomy during follow-up.

On the basis of studies predominantly from ERCP experts in Asia, bile duct stones can be successfully extracted after balloon orifice dilation of the sphincter of Oddi, with or without adjuvant biliary sphincterotomy. Our practice, and that of most centers in the West, is to perform at least a limited sphincterotomy before balloon orifice dilation when there is no contraindication. Should we revisit this practice? For patients with large common bile duct stones, should we drop the sphincterotomy in an effort to minimize long-term risk? According to the findings from Cheon and colleagues,¹ withholding sphincterotomy to minimize the long-term sequelae on sphincter of Oddi function is unfounded. Remove the stones using the safest techniques in your practice, and be sure to remind patients during the process of informed consent that although ERCP remains the most effective approach to treating choledocholithiasis, stone recurrence and sphincter restenosis may occur in an unlucky few.

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