EDITORIAL

Incisionless stone extraction 2.0: clever, but costly

We all love a simple solution. Especially when it's easier, safer, and cleaner than the old one and makes use of shiny new technology. And with good timing, too—sphincterotomy just celebrated its 40th birthday last year.

In 1974 Kawai et al[1] and Classen and Demling[2] catapulted ERCP into the realm of therapeutic intervention when those groups each published novel descriptions of endoscopic sphincterotomy. This small monopolar incision has since become the foundation on which much of the therapeutic robustness of the ERCP platform is based, allowing us to do bigger things. However, we also have long known that the benefits of biliary sphincterotomy come at a cost to both the patient and the endoscopist. In the short term, the patient sustains an increased risk of acute procedure-related pancreatitis, bleeding, and retroperitoneal perforation.[3-5] In the long term, the patient loses his or her duodenobiliary antireflux barrier, incurring a lifetime risk of primary common bile duct (CBD) stones and associated acute cholangitis, gallstone pancreatitis, secondary sclerosing cholangitis, and biliary cirrhosis.[6-8] We have assumed these short-term and long-term risks to be the prices the patient and the endoscopist together must pay for being able to clear bile duct stones "definitively." How definitive is it, though, if stones recur a few years later?

In this issue of *Gastrointestinal Endoscopy*, Jun et al[9] show us that we may now have another choice in selected patients: one that is potentially easier and safer than sphincterotomy. In this case, the better mousetrap is a fully covered self-expanding metallic biliary stent (FCSEMS), placed temporarily across the ampullary outlet into the bile duct in lieu of sphincterotomy or balloon sphincteroplasty, thereby allowing extraction of bile duct stones through the stent lumen, and, if needed, mechanical lithotripsy. Although using an FCSEMS to facilitate bile duct stone extraction sans sphincterotomy is novel, the idea of obviating the need for sphincterotomy in biliary stone extraction is not. In the 1990s, balloon sphincteroplasty was introduced.[10-12] The idea was to preserve the sphincter of Oddi by performing a relatively large balloon dilation of the sphincter of Oddi in lieu of sphincterotomy. This technique quickly gained traction because of its technical ease and the prospect of long-term benefits of sphincter preservation, along with potential for reducing procedure-related bleeding and perforation. However, enthusiasm was short lived after reports that cited increased incidences of severe acute pancreatitis.[13,14] By the turn of the millennium, the technique had been all but abandoned except in specific, one-off situations.

The clever, off-label use of an FCSEMS described in this study demonstrated no such severe downside risk; in fact, none of the 10 patients in the small series experienced pancreatitis, perforation, or bleeding. The absence of procedure-related pancreatitis is less surprising, given the indication for ERCP (for clearance of bile duct stones), the short dwell time of the FCSEMS (<20 minutes), and the lack of evidence of sphincter of Oddi dysfunction both clinically and manometrically. Although the procedures were short, the investigators were still careful to choose a single stent length that would not obstruct the cystic duct-CBD insertion, and 8-mm and 10-mm diameter stents were matched to CBD diameter. The stents were removed easily in all patients.[15-19] FCSEMS, as a category of devices, possesses some degree of heterogeneity in design and operational characteristics, so it is difficult to determine, without comparative data, how generalizable the results of this study are to other brands of FCSEMSs. It should be noted that in this series the stone burden was extremely mild, with a mean count of only 1.5 stones and a mean stone diameter of a paltry 5.6 mm. This does much to explain the need for mechanical lithotripsy in only 1 patient and the lack of any stent dislodgement encountered during stone extraction. It also undoubtedly contributed to the mean procedure duration being a rapid 19 minutes. To be fair, the authors set out, in this study, to describe this technique specifically for patients with narrow-diameter bile ducts (<11 mm), given what they describe as the greater risks

> We need better ways to remove all stones in 1 sitting. Doing so potentially reduces adverse effects, cost, and resource utilization in general, not only for the patient and the patient's family, but also for institutions and for society at large.

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and lower effectiveness of biliary sphincterotomy in patients with this profile.

It is always hard to know what to make of data from a descriptive, nonrandomized, observational, feasibility study with 10 study participants. The study, though, had solid practical aims behind it, and the authors executed their uncontrolled pilot study in a prospective fashion, cleanly and dutifully, with attention to detail both before and after the procedure with the intent of demonstrating feasibility and short-term efficacy. Furthermore, the investigators diligently demonstrated that, unlike sphincterotomy, FCSEMS technique did not cause dysfunction of the sphincter of Oddi, as measured by postintervention sphincter of Oddi manometry (SOM) on all 10 patients 7 days after ERCP, and they even withheld anticholinergic agents, nitrates, calcium channel blockers, and glucagon, along with opiates and cholinergic agents, for at least 24 hours before SOM. Yes, the investigators did compare the manometric findings with historical normal control data rather than performing preintervention SOM on the patients themselves; but, as the authors fairly point out, the ethics of performing SOM both before and after the surgical procedures might be considered dubious by some and be difficult to justify. But undertaking SOM at all during an ERCP performed solely for clearance of bile duct stones would be a complex enough proposal to clear through a study review committee; a second SOM on the same patient solely for study purposes would undoubtedly pose even greater challenges. Furthermore, the added risk and cost of the ERCP with SOM undertaken a week after stone extraction in each patient, strictly for the purpose of the study, already accounts not only for increased risk but also for added procedural costs that would need to be accounted for. These points alone render the data from this small series even more valuable—both now and for comparison in the foreseeable future, when, we can hope, additional higher-grade evidence related to this topic becomes available.

The generalizability of the data derived from this small series is admittedly limited: a mean of 1.5 stones with a mean stone diameter of 5.6 mm represents relatively low-hanging fruit from a stone burden perspective. This study does nothing to address the challenge of the patient at the other end of the spectrum: the patient with a massively dilated bile duct packed full of large piston stones with mortarlike sludge filling the crevasses in between. But, to be fair, the authors indicated clearly, up front, that this study specifically targeted patients with a small CBD (which they defined, for the purposes of this study, as <11 mm in diameter) because sphincterotomy with stone extraction can more often result in basket impaction and various procedure-related adverse events in this subset of patients. Curiously, they do not offer a specific reference to support this contention; instead, and in seeming contradiction, they cite the seminal study of Freeman et al,[5] which conversely found that, in endoscopic biliary sphincterotomy, the overall adverse event risk was not related to CBD diameter. The likelihood is that there is an additional, rather obvious reason for limiting the study to patients with a CBD smaller than 11 mm in diameter: presently available biliary-specific FCSEMSs are not offered in a diameter larger than 10 mm. Of course, the method described in this study works only if the bile duct diameter is no greater than the stent; otherwise, the stent would likely migrate upon sweeping the duct to extract the stones. As saliently, stones would have to be smaller in dimension than the diameter of the stent to be removed reliably through the FCSEMS without lithotripsy. Here, it appears that the end justifies the means.

We should also not be too quick to dismiss the post-procedure short-term benefit that sphincterotomy may afford the patient undergoing ERCP for choledocholithiasis, especially if ERCP is undertaken before cholecystectomy, but cholecystectomy is not likely to occur within a few days immediately after ERCP with CBD stone clearance. In the elective setting, it is not unusual for a patient to wait several weeks before undergoing scheduled laparoscopic cholecystectomy, particularly when cholecystitis, cholangitis, or acute pancreatitis may have complicated the original clinical presentation. During the interval between ERCP and cholecystectomy in these situations, having undergone biliary sphincterotomy may offer the patient with the gallbladder in situ some protection.[20-25] In the present study, given that the FCSEMS is removed at the conclusion of ERCP, no protection above baseline would be afforded the patient against stone migration into the CBD with an intact sphincter. This potential downside of not undertaking a sphincterotomy is not addressed by the investigators.

In the end, however, the greatest barrier to widespread adoption of this choledocholithiasis management paradigm is likely to be cost, which could be prohibitive for many patients and providers alike, especially if the procedure is used on a routine basis. Choledocholithiasis is the most common indication for ERCP.[26-30] The cost of an FCSEMS in the United States is typically in excess of $2000. This magnitude of added cost, on a scale that would be encountered if applied to a condition as ubiquitous as choledocholithiasis, would be a difficult additional cost to absorb, particularly in an era of bundled reimbursements. Nothing short of long-term cost-effectiveness data would have to appear in the foreseeable future to justify an added per-procedure cost this high. Such long-term cost effectiveness would be demonstrated most robustly by showing that, after ERCP with CBD stone clearance using the FCSEMS treatment paradigm outlined in this study, patients do not return for additional future ERCPs for management of primary bile duct stones, as they do after undergoing ERCP with biliary sphincterotomy for this indication.

Although a randomized controlled trial with long-term follow-up comparing these 2 approaches to the management of choledocholithiasis—one that incorporates the