

LAMS for all pancreatic fluid collections?




Author

Marco J. Bruno

Institution

Department of Gastroenterology & Hepatology, Erasmus University Medical Centre, Rotterdam, The Netherlands

Bibliography

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Corresponding author

Marco J. Bruno, MD, PhD, Department of Gastroenterology & Hepatology, Erasmus University Medical Centre, Gravendijkwal 230 3015 CE, Rotterdam 3015 CE, The Netherlands

Fax: +31-0-10-7030352

m.bruno@erasmusmc.nl

In this issue of Endoscopy International Open, Ortizo and co-workers from the Irvine Medical Center of the University of California report on their experience with self-expandable metal biliary and esophageal stents (FCSEMS) for the drainage of pseudocysts (PC) and pancreatic walled off necrosis (WON) [1]. In this retrospective analysis, they demonstrate in a series of 65 patients that use of FCSEMS is highly effective and safe. In patients with a PC they achieved a 100% resolution rate (25 out of 25 patients) without any adverse events (AEs). In WON cases, the resolution rate was 78% (31 out of 40 patients) with an AE rate of 25% (10 out of 40 patients). One patient had self-limiting bleeding after initial placement, two patients had stent migration detected on follow-up imaging without clinical consequence, and seven patients showed signs of stent dysfunction/occlusion with infection for which the FCSEMS was replaced, in some cases, upsizing from a 10-mm biliary to a large 20-mm-diameter esophageal FCSEMS. Of the 40 WON patients, 22% (9 patients) required a radiological intervention or surgery. No inward FCSEMS migration was reported. In 67.5% of WON cases (27 of 40 patients) at least one debridement was required with an average of 3.9 procedures per patient. The authors rightfully point out some limitations to be considered when interpreting their results, most notably the retrospective study design. Nevertheless, their experience adds to a growing body of data that FCSEMS seem to perform at least as good as LAMS with regard to clinical efficacy, with potentially less complications, at lower costs [2, 3].

One advantage of LAMS is the fact that it can serve as an easy access route to facilitate debridement without a need to exchange the LAMS, while in the case of FCSEMS, this is hampered by the long stent length and migration is likely to occur as a result of scope manipulation. Indeed, the authors report that in cases where debridement was needed, often the initially placed FCSEMS was removed and after the debridement was

performed a new FCSEMS was placed, amounting to a total of 79 stents used in 40 patients. Obviously, this needs to be taken into account when making a cost comparison. Nevertheless, from an economic perspective with a current price difference of about \$ 3,500 (United States price levels), this will not likely shift the balance in favor of LAMS.

It is intriguing to speculate about the mechanism and design aspects that explain why FCSEMS would potentially be safer than LAMS. LAMS were designed with a wide proximal and distal flange and a relatively short body in order to appose two lumens, providing a minimal risk of migration and dehiscence. The intention is justified and the solution seems logical. However, when a collection collapses, the opposite wall inherently apposes the distal stent end. With a FCSEMS having had no specific anchoring features, this is likely to push out the stent, as there is little resistance to prevent it. In fact, if migration occurs too soon, the two connected lumens become disconnected while there is not yet a matured fistulous tract, resulting in the clinical picture of perforation. On the other hand, LAMS are intentionally designed to withstand such forces keeping the stent in place with two opposing lumens “firmly” fixed until such time that the LAMS is intentionally removed. This can be considered a good thing for preventing (early) migration, but might turn bad and even ugly once the collection has collapsed and the opposite cavity wall is exposed to chronic mechanical friction by the distal end of the LAMS, which could result in tissue and vessel injury and hence delayed risk of bleeding, as reported by some groups.

The first report of such complication was by Bang and colleagues, who in an ongoing randomized trial comparing plastic stents versus LAMS for drainage of pancreatic fluid collections encountered a much higher than expected rate of serious adverse events (0% vs 50%, $P=0.019$), including delayed bleeding ($n=3$), buried stent syndrome ($n=2$), and obstructive jaundice

secondary to stent-induced biliary stricture (n = 1) [4]. All three patients that presented with severe gastrointestinal bleeding required intensive care unit admission and blood transfusion at 3 weeks (n = 1) and 5 weeks (n = 2) post-LAMS placement. Computed tomography angiograms confirmed the presence of a pseudoaneurysm within the distal flange of the LAMS in all three patients successfully managed by interventional radiology (IR)-guided coil embolization. That risk of bleeding is not unique to use of Hot AXIOS stent, but might be related to the diabolical shape design of LAMS is suggested by another report of Stecher et al. who treated a total of 46 patients with a LAMS design stent; eight patients with a Hot AXIOS stent (Boston Scientific – 15 × 10 mm) and 38 with a Niti-S NAGI stent (TaeWoong 14 × 20 mm) [5]. Bleeding complications occurred in eight patients (17.4%), five of whom suffered from multiorgan failure with two patients dying after unsuccessful coiling and surgery. Seven patients had received treatment with NAGI-S stents and one patient was treated with a Hot AXIOS stent.

Nevertheless, the association between LAMS and complications, in particular delayed bleeding, might not be as straightforward as these two reports suggest. Others have published much larger series of patients without encountering (delayed) bleeding complications using LAMS. For example, Zeissig et al. performed a retrospective review of 219 patients who received 260 LAMS for drainage of a pancreatic fluid collection at three medical centers in Germany [6]. Complete resolution at 6 months after LAMS placement was achieved in 93% of patients. Stents were removed after a median of 71 days (IQR 32–97 days). Rates of hemorrhage were low (6/219 patients, 3%) with only one bleeding episode that occurred after hospital discharge (1/219, 0.5%). Two patients suffered from a severe bleeding from the gastroduodenal and splenic artery which was successfully managed with embolization. Others have reported similar favorable outcomes of LAMS without an apparent higher risk of complications, in particular delayed bleeding [7–10].

It remains puzzling why such different experiences with LAMS are obtained and reported by different groups around the globe. It should be noted that almost all literature reports are based on retrospective case series or consecutive case series, and hence, potentially suffer from recall, selection, observation, confirmation or publishing bias. Although the study of Bang was one of the smallest, the data were obtained within the framework of a randomized controlled trial, which therefore makes their report particularly valuable and important.

Sometimes when comparing devices or treatment modalities there is a clear winner. Often, however, either approach has some good and some less favorable qualities. Combining the best of both worlds circumventing the shortcomings of either existing treatment seems the obvious way forward to devise a solution likely to improve the outcome of patients and to be universally adopted by physicians. Obviously, the features of certain lumen apposing stent solutions with an all-in-one design providing easy endoscopic ultrasound (EUS)-guided access either over-the-wire after EUS-guided puncture or by free-hand with a direct puncture using electrocautery, and subsequent FCSEMS deployment with one single device, are remarkably ingenious and handy. Without a doubt these devices have revolutionized

drainage procedures that have never been easier to accomplish under EUS guidance, without the need for x-ray, within a matter of minutes. A possible way forward is to keep the one-step delivery system but adapt the stent, if stent design is truly involved in a higher risk of complications. As is so often the case in medicine, the only way forward to prove the superiority of a distinct stent design in the drainage of PCs or WON is to perform a well-designed and adequately powered randomized controlled trial to evaluate the success of treatment, occurrence and severity of complications, and all costs involved.

Competing interests

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