Editorial

Plastic stents or covered self-expandable metal stents for benign biliary strictures: same song, different verse?

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Biliary self-expandable metal stents (SEMS) were originally developed to overcome the patency issues of fixed diameter, rigid plastic stents. The larger diameters of these early uncovered (bare metal) stents were shown to significantly prolong patency when used for palliation of distal malignant biliary obstruction. Early clinical experience using uncovered stents for benign disease were met with disappointment as tissue hyperplasia resulted in occlusion, and the embedding of the wire stent mesh into the bile duct wall rendered them non-removable. Interestingly, the subsequent addition of stent covering was intended to further improve patency, similar to what had been shown for expandable metal esophageal stents. However, an elegant study by Silvis *et al.* published more than 20 years ago shed light on the bile duct reaction to covered SEMS (1). Stents used in this study had a covering on half of the stent lumen. The uncovered portion became deeply embedded in bile duct epithelium, but the covered portion did not. The authors concluded that covered stents may be removable, making them an appropriate treatment for benign biliary strictures.

Since that time, a large amount of retrospective clinical experience accrued using covered metal stents for a variety of benign biliary diseases in humans (2,3). These studies confirmed the animal studies showing that as long as the covering remained intact, the stents were removable.

Prior to the use of covered stents for benign disease, the treatment of choice for benign biliary strictures was placement of multiple large-bore plastic stents (4). Disadvantages of multiple plastic stents are the need for aggressive dilation to allow insertion, and the inability to place the intended maximal number during the first procedure. This is often due as much to the downstream duct, which may be rather small, as it is to the severity of the stricture. Additional procedures are needed for stent exchange and upsizing. Conversely, self-expandable stents are technically easier to place than multiple plastic stents, can achieve the desired diameter in one session, often without need for dilation, and because of prolonged patency may remain in place for many months (5). A 10 mm covered metal stent is slightly larger in diameter than three radially arranged 10 Fr plastic stents.

Several prospective clinical studies have demonstrated efficacy of covered metal stents for benign biliary strictures. In one large prospective multinational study, 187 patients with benign biliary strictures underwent placement of fully covered metal stents. Removal was performed at 10–12 months for patients with strictures due to chronic pancreatitis or post-cholecystectomy, and 4–6 months for liver transplant patients. Stent removal was successful in all attempts. Stricture resolution occurred in 76% of patients. After a median follow-up of 20 months stricture recurrence was 15% (6).

The recent publication of a noninferiority study by Coté *et al.* is the first direct comparison of covered metal stents to plastic stents for the treatment of benign biliary strictures (7). In this multicenter, open-label, parallel, randomized clinical trial, 112 previously untreated patients with benign biliary strictures located at least 2 cm below the hepatic confluence. Stricture etiologies included

orthotopic liver transplant (n=73), chronic pancreatitis (n=35), or postoperative injury (n=4). Patients with a bile duct diameter less than 6 mm were excluded, as were patients with an intact gallbladder and a cystic duct orifice location that would have been occluded by a covered stent. Patients who received multiple plastic stents were assessed for stricture resolution at scheduled stent exchanges every 3 months, with placement of additional plastic stents in those with persistent strictures, whereas those with a single metal stent (8) were assessed every 6 months, with SEMS replacement for stricture persistence.

There were 55 patients in the plastic stent group and 57 patients in the covered stent group. Stricture resolution with plastic stents was 85% and with covered SEMS 93%. The mean number of ERCPs to achieve resolution was lower for covered metal stents (2.14) *vs.* plastic stents (3.24), P<0.001. It is worth noting however, that the median cumulative stent diameter achieved in the plastic stent group was 20 Fr (range, 7–30 Fr). This represents many fewer stents per patient than placed in the seminal study by Costamagna *et al.* where excellent results were achieved with a mean cumulative stent diameter of 45 Fr (4.5 stents of 10 Fr caliber per patient) in patients with post-operative biliary strictures (4). Other differences from the Costamagna studies include a relatively high number of early post-orthotopic liver transplant anastomotic strictures (2/3 of patients), which are certainly less refractory than strictures due to chronic pancreatitis and those due to bile duct injury, and a relatively short-term follow-up of 1 year, compared to 10 years.

What can we conclude from this most recent study by Coté *et al.*? It confirms that a single 8 or 10 mm fully covered metal stent is as efficacious as two 10 Fr plastic stents for resolution of benign biliary strictures with a more rapid rate of resolution and with fewer procedures in this subset of patients. Covered stent removal was achieved in all patients. Overall adverse events were similar in each group and no stent-induced strictures occurred in the metal stent group. While not statistically significant, recurrent strictures in those who achieved resolution occurred in 14% in the covered SEMS group compared to only 5% in the plastic stent group. Stent migration occurred in a relatively high rate in both arms; 16/57 in the covered metal stent group, of which 9 were at time of stricture resolution.

Questions remain regarding covered stents as the primary therapy for benign bile duct strictures. In a patient with intact gallbladder and stricture location that would overlap the cystic duct an absolute contraindication to metal stent use? If so, should a transpapillary plastic stent placed into the cystic duct to prevent cholecystitis as has been previously described (8)? What about post-liver transplant patients with duct-to-duct anastomosis who have excessively long combined native and donor duct lengths where covered stents would not be long enough to extend transpapillary? Should they remain intraductally or should overlapping metal stents be placed? How should patients with benign proximal common hepatic duct and hilar strictures be optimally treated? Are all expandable metal stents equally efficacious? The stent used in this study did not have anti-migration features, which are available on some stents.

Cost has long been a consideration when choosing plastic or metal stents for relief of malignant non-hilar biliary obstructions (9). Similar questions pertain to benign stricture management. The overall treatment cost would seem to favor the use of metal stents by the significant reduction in endoscopic procedures. However, is this cost translated to the physician and medical center? Will such stents be fully reimbursed by third party payers?

The bottom line is that expandable metal biliary stents are superior devices to plastic biliary stents (10). Studies such as the one performed by Coté *et al.* are now proving this clinically, the limitations mentioned above notwithstanding. The authors should be congratulated on moving this field forward. However, improvements in stent design to prevent migration are needed.

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Footnote

Conflicts of Interest: Dr. TH Baron is consultant and speaker for Boston Scientific Corporation, Cook Endoscopy, W.L. Gore, and Olympus. IS Grimm has no conflicts of interest to declare.

References

1. Silvis SE, Sievert CE Jr, Vennes JA, et al. Comparison of covered versus uncovered wire mesh stents in the canine biliary tract. Gastrointest Endosc 1994;40:17-21.
2. Zheng X, Wu J, Sun B, et al. Clinical outcome of endoscopic covered metal stenting for resolution of benign

biliary stricture: Systematic review and meta-analysis. Dig Endosc 2016. [Epub ahead of print].
3. Irani S, Baron TH, Akbar A, et al. Endoscopic treatment of benign biliary strictures using covered self-expandable metal stents (CSEMS). Dig Dis Sci 2014;59:152-60.
4. Costamagna G, Tringali A, Mutignani M, et al. Endotherapy of postoperative biliary strictures with multiple stents: results after more than 10 years of follow-up. Gastrointest Endosc 2010;72:551-7.
5. Baron TH. Covered self-expandable metal stents for benign biliary tract diseases. Curr Opin Gastroenterol 2011;27:262-7.
6. Devière J, Nageshwar Reddy D, Püspök A, et al. Successful management of benign biliary strictures with fully covered self-expanding metal stents. Gastroenterology 2014;147:385-95; quiz e15.
7. Coté GA, Slivka A, Tarnasky P, et al. Effect of Covered Metallic Stents Compared With Plastic Stents on Benign Biliary Stricture Resolution: A Randomized Clinical Trial. JAMA 2016;315:1250-7.
8. Gosain S, Bonatti H, Smith L, et al. Gallbladder stent placement for prevention of cholecystitis in patients receiving covered metal stent for malignant obstructive jaundice: a feasibility study. Dig Dis Sci 2010;55:2406-11.
9. Grimm IS, Baron TH. Biliary Stents for Palliation of Obstructive Jaundice: Choosing the Superior Endoscopic Management Strategy. Gastroenterology 2015;149:20-2.
10. Baron TH, Grimm IS. Relief of obstructive jaundice from pancreatic cancer: the end of the plastic stent era? Gut 2016;65:191-2.

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