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Use of Covered Self-Expandable Metal Stents in the Management of Nonstricture Biliary Disorders

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G&H What are the most common nonstricture biliary settings for which covered self-expandable metal stents are used as treatment?

BP The most common nonstricture biliary diagnoses for which covered self-expandable metal stents (CSEMS) are employed include intractable leaks and fistulae, biliary and periampullary perforations, bleeding, and stone disease. Leaks most often occur after surgical procedures, including cholecystectomy, biliary anastomoses, hepatic resections, and other procedures addressing intrahepatic pathology. Plastic stenting with or without sphincterotomy should generally be used as first-line therapy. If a leak persists or does not respond well to the insertion of plastic stents, CSEMS may be helpful; however, due to the increased expense, CSEMS are used only when plastic stenting fails.

Less common causes of leaks include periampullary or perianastomotic perforation and chronic biliary fistulae. Placement of CSEMS at the site of a perforation induced by sphincterotomy or balloon sphincteroplasty, or at a small tear induced by dilation of an anastomotic stricture, often suffices to seal against further enteral or biliary leakage during subsequent days of healing. Stent placement can also facilitate closure of the far less common problem of chronic fistulae to neighboring or distant locations. When leaks or perforations are accompanied by the development of local or regional fluid collections, percutaneous drainage is also usually indicated to prevent abscess formation.

After leaks, the second most common setting for which CSEMS are used is postsphincterotomy bleeding. Brisk bleeding at the time of a sphincterotomy or delayed bleeding 1 to 3 days later is often challenging to manage, particularly when using a side-viewing endoscope in the setting of ongoing active bleeding. Following epinephrine injection, placement of CSEMS across the sphincter will often tamponade the bleeding site for as long as the stents are left in place. While not formally studied, epinephrine injection plus stent placement is often more efficiently and effectively accomplished vs injection plus clipping or cautery. The downside is the cost of both the stent and the necessary relook procedure for stent removal 2 to 4 weeks later. If large-caliber balloon dilation has been performed to remove duct stones, the loose sphincter may not be amenable to stent tamponade, and there may be a higher risk for stent migration. For patients with very high bleeding risk after necessary sphincterotomy, such as those with intractable thrombocytopenia or coagulopathy, the placement of large-caliber CSEMS can be employed for prophylaxis against postsphincterotomy bleeding.

Lastly, CSEMS can be used in patients with difficult-to-treat, large, or numerous bile duct stones that cannot be palliated or removed in 1 procedure, and in whom drainage cannot be ensured with plastic stenting. In these situations, large-caliber CSEMS can be inserted and then removed during a subsequent procedure. Patients with a narrow sphincter may benefit from the more chronic dilation that occurs with CSEMS than with postsphincterotomy large-caliber balloon dilation, facilitating subsequent stone removal.

G&H What is the general deployment mechanism for placing CSEMS?

BP Stent placement in these nonstricture settings is the same as that used for biliary strictures. The patient should

undergo a cholangiogram with contrast to characterize the biliary anatomy while achieving deep biliary access. A guidewire is placed across the area requiring the stent, usually to the intrahepatic bile ducts. The stent is then positioned across the area of concern and deployed under both fluoroscopic and endoscopic guidance, leaving the lower end accessible in the duodenum for subsequent access and removal.

G&H Is training required to place these stents?

BP Yes, familiarity with the stent and the deployment mechanism is required. The technique is routinely taught during endoscopy fellowships but has also been adopted by many practitioners who learned the technique in the course of practice. Placing a stent is not a lengthy procedure and not difficult to learn if a clinician is already familiar with the procedures of endoscopic retrograde cholangiopancreatography (ERCP) and plastic stent placement. Placement of CSEMS requires careful attention to the avoidance of inadvertent occlusion of the cystic duct or hilar branches. Malplacement of CSEMS is somewhat more forgiving than for bare metal stents, as CSEMS are generally removable when necessary.

G&H What are the advantages of using CSEMS over plastic stents?

BP The 2 advantages of using CSEMS over plastic stents are the larger caliber for biliary drainage and apposition of the plastic coating against the area of pathology, whether it is a leak or a bleeding site. In the majority of stent applications, the large caliber of CSEMS yields better and more prolonged drainage. Plastic stents tend to occlude between 4 to 12 weeks, depending on their caliber and the local pathology and biliary physiology. When used for benign strictures, the larger caliber of a single metal stent provides greater drainage with continuous dilation equivalent to 3 to 4 10-French plastic stents.

G&H Are there any disadvantages associated with CSEMS?

BP The main disadvantage of CSEMS, compared with plastic stents, is their significant cost. CSEMS typically are not used as the primary therapy for leaks, as the alternatives are much more cost-effective. CSEMS appear to be indicated as the primary therapy for bleeding only in a very small group of patients with significant bleeds or a very high risk of bleeding. When used in place of non-stent alternatives, CSEMS also suffer from the expense of the necessary second procedure for removal. The use of CSEMS in such situations requires thoughtful selection and consideration of the cost-benefit analysis.

The other limitation is that CSEMS can occlude any side branch ducts that they cross, so they are contraindicated for use at the hepatic bifurcation, where a stent placed in the left side would block the right side, for instance. They need to be placed with caution in patients who have an intact gallbladder, using appropriate lengths and positioning, as obstruction of the cystic duct after placement yields a low but significant risk of cholecystitis.

G&H How long should these stents be left in place before being removed?

BP The duration depends on the disorder being treated. Stents placed to treat leaks or bleeding or used for prophylaxis against postsphincterotomy bleeding can usually be removed 2 to 4 weeks later. If the stents are being used for stricture treatment, they can remain in place for 3 to 6 months or longer. Many clinicians believe that stents should be removed by 6 months, but there are patients in whom stents have been left in place for a year or longer.

G&H Are CSEMS difficult to remove?

BP CSEMS can be tricky to remove, depending on their design. One design features woven metal struts that cause the entire stent to collapse when the lower end is grasped with a snare in the duodenum, making the stent easier to remove. Another design has "laser-cut" struts, which are not interwoven and do not collapse in the same graded continuous fashion. Each 3- or 5-mm segment of the stent is attached to the next segment, but does not weave upward over the entire length of the stent. There is some risk of pulling on a segment and ripping it away from a nearby segment, although the plastic coating makes that possibility less likely.

In my experience, it is helpful to clear food, sludge, or stones from the lumen of the stent before attempting removal. If the stent is obstructed, it may not collapse adequately, complicating removal from the duct. Clearance is easily accomplished with a stone or occlusion balloon passed over a guidewire. The duct above the stent also often requires subsequent clearance of sludge or debris after stent removal.

G&H Is there a risk of stent migration?

BP The risk of stent migration is very low—in the order of only a few percent—and, again, is dependent on the stent design. Some stents have small metal struts that protrude outward, similar to wings; these appear to reduce the risk of migration. Others feature a flare at each end, which prevents movement up or down. Optimal placement with the

flared ends adequately positioned above and below the areas of contact to the wall or sphincter is important to minimize migration. The choice of a stent might vary slightly based on the anatomy being treated. In patients with very large ducts and a large sphincterotomy or sphincteroplasty, migration may be more common.

G&H How should the patient be followed up?

BP Specific follow-up is contingent upon the indication for the stent, but in general, the patient should continue to be observed for clinical signs related to the problem being treated (eg, laboratory studies for bleeding or infection and cross-sectional imaging for leakage). If the patient is doing well, the next step is simply for the patient to return for stent removal at a later date. However, if there is an ongoing bile leak, bleeding, or other concerns, follow-up should include an abdominal radiograph to ensure that the stent has not migrated, or a computed tomography scan to assess the positioning of the stent and growth or resolution of fluid collections. The patient should then undergo a repeat ERCP to assess whether the stent is positioned appropriately to treat the biliary disorder.

G&H Are there any patients in whom stents should be avoided?

BP The intended short-term use of metal or plastic stents should be carefully considered in patients with altered anatomy following gastric bypass or liver transplantation (as for stent dilation, tamponade, or sealing of inaccessible strictures or anastomoses), and avoided if it is not certain that the first procedure can be repeated and that the area in which the stent is positioned can be revisited for removal.

There are also anatomic considerations that perhaps do not warrant the use of metal stents. For example, there is a risk of significant pain in patients with small ducts in whom the caliber of the available stents is too large.

G&H What were the findings of your retrospective study of the placement of CSEMS in benign nonstricture biliary disease?

BP The collected data from both the Mayo Clinic (Rochester, Minnesota) and Virginia Mason Medical Center (Seattle, Washington) identified 40 patients who underwent placement of CSEMS for the treatment of benign nonstricture biliary disease. Of the 40 patients, 24 had bile leaks and 16 had miscellaneous entities, including biliary-enteric anastomotic perforations (n=3), postsphincterotomy perforations (n=3), postsphincterotomy bleeding (n=2), bile duct variceal bleeding (n=2), biliary stone removal (n=2), attempted removal of previously placed metal stents (n=2), biliary sump syndrome (n=1), and a choledochogastric fistula (n=1).

Cystic duct leaks were treated with CSEMS placed across the cystic duct junction. Overall, 19 leaks resolved, 1 failed, and, at the time of publication, the others were being treated and the stents remained in situ.

As for the nonleak disorders, stent placement resolved all 6 perforations and all 4 cases of bleeding. Stents succeeded in biliary stone removal in 1 of 2 cases and in 1 of 2 patients in whom the stent was used to remove another ingrown bare metal stent. Stents failed in the treatment of 1 case of biliary sump syndrome and in the fistula case. Overall, success was achieved in 12 of 16 patients for nonleak indications.

G&H What are the next steps in research in this area?

BP Further research should be related to both device development and enhancing understanding of the use of CSEMS for challenging fistulae and leaks. The development of different calibers and lengths of stents—for example, shorter lengths that can be placed in locations that are currently inaccessible or very difficult to access—would be beneficial. Most CSEMS that are intended to be removed at a later date are left dangling into the duodenum. The availability of very short, small-caliber stents, perhaps with retrieval tails, could enable use in very focused locations above the papilla. The stent could almost become custom-designed based on the anatomy.

In addition, research is needed to determine whether CSEMS can be embedded with radio- or chemotherapeutic agents to add local pharmacologically active therapy to their dilation mechanism. This use of CSEMS has been discussed and pursued over the years, but data and progress have been minimal.

Dr Petersen is a consultant to Boston Scientific pertaining to various nonstent technologies.

Suggested Reading

Akbar A, Irani S, Baron TH, et al. Use of covered self-expandable metal stents for endoscopic management of benign biliary disease not related to stricture (with video). *Gastrointest Endosc*. 2012;76(1):196-201.

García-Cano J. Use of fully covered self-expanding metal stents in benign biliary diseases. *World J Gastrointest Endosc*. 2012;4(4):142-147.