Insertion and Removal of Covered Expandable Metal Stents for Closure of Complex Biliary Leaks

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The traditional endoscopic management of bile leaks involves placement of plastic endoprostheses. The success rate for closure of simple leaks (cystic duct, Luschka’s duct) with this approach is high. We describe 3 patients with complex biliary leaks of the gallbladder bed that were successfully closed by using transpapillary placement of covered self-expandable biliary stents. The stents were endoscopically removed after closure of the leak. All 3 patients had previously undergone open subtotal cholecystectomy for severe acute cholecystitis when complete cholecystectomy could not be performed because of dense acute inflammation. In 2 patients the leaks had not responded to traditional plastic biliary stent placement. This novel approach deserves further evaluation.

Bile leak after cholecystectomy is frequently managed with endoscopic techniques consisting of transpapillary placement of plastic biliary stents with or without biliary sphincterotomy. For simple leaks such as small cystic duct leaks and Luschka’s duct leaks, the success rate of endoscopic therapy is high. For more complex leaks, successful closure with endoscopic techniques is more problematic. We present a novel approach to closure of complex leaks by temporary insertion of transpapillary covered expandable metal biliary stents.

Biliary Stent and Data Retrieval

In the first 2 patients the metal stent used was the biliary Wallstent (Boston Scientific Corporation, Natick, MA). It is currently Food and Drug Administration (FDA) approved only for relief of jaundice caused by malignant biliary obstruction. The stent has a predeployment delivery system of 8F and is available in postdeployment diameters of 8 and 10 mm and lengths of 40, 60, and 80 mm. Both patients received 10-mm diameter, 40-mm long stents. The stent is composed of stainless steel and covered circumferentially throughout except for 1.5 mm at the proximal and distal ends with Permalume (proprietary). In the third patient, a Viabil biliary stent (W.L. Gore & Associates, Flagstaff, AZ) was placed. This nitinol stent is FDA approved for malignant disease and is fully lined. Procedural times were obtained from our endoscopy database in which intubation and extubation times and total fluoroscopy times are recorded by a nurse. Patients were contacted by phone for follow-up at the time of this writing. Institutional review board approval was obtained to publish these data.

Case Reports

Case 1

A 56-year-old man was referred for management of a bile leak. He had a remote history Billroth II gastrectomy. Two months before initial evaluation at our institution he underwent open cholecystectomy for severe acute cholecystitis. Postoperatively he developed a bile leak treated with percutaneous drain placement and endoscopic placement of a transpapillary plastic biliary stent. Because of persistent high output from the percutaneous drain, he was referred to our institution. Contrast injection through the percutaneous tube showed a gallbladder remnant with communication into the biliary tree and colon (Figure 1). He underwent 2 additional endoscopic retrograde cholangiopancreatographies (ERCPs) at our institution with replacement of single transpapillary plastic stents. The first stent placed was 10F, 5-cm long. The mid bile duct diameter was 7 mm, and the proximal end of the stent was above the cystic duct takeoff. Another ERCP was performed 3.5 weeks later because there was no change in bile output. The 10F stent was occluded. A new 10F, 5-cm stent was placed, and a biliary sphincterotomy was performed, with little change in drainage output of about 50–100 mL/day. Therefore, it was elected to place a covered expandable metal biliary stent both to divert flow away from the leak and to cover the cystic duct. The stent was deployed across the papilla. Within 1 week the drainage output markedly decreased to 5–10 mL/day.

Abbreviations used in this paper: ERCP, endoscopic retrograde cholangiopancreatography; FDA, Food and Drug Administration.
Subsequent injection of the percutaneous drain 8 weeks later revealed no communication with the bile duct and only a small residual connection with the colon (Figure 2). The percutaneous drain was removed. Later the same day a follow-up ERCP was performed, and the expandable metal stent was removed endoscopically. Initially the distal end of the stent that was lying just outside the papilla into the duodenum was grasped and pulled distally enough to then ensnare the stent with a standard polypectomy snare. The stent was easily withdrawn through the endoscope (Figure 3). Cholangiography showed a gallbladder remnant but without leakage (Figure 4). The duration of procedure from first introduction of the duodenoscope to final withdrawal of the endoscope was 19 minutes and 34 seconds, and the fluoroscopy time

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**Figure 1.** Fluoroscopic image of percutaneous injection into the indwelling percutaneous tube. Note contrast enters the biliary tree and colon. A plastic transpapillary biliary stent is in place.

**Figure 2.** Follow-up percutaneous tube study showing small communication with the colon but no communication with the biliary tree. The covered expandable stent is in place.

**Figure 3.** Covered expandable stent immediately after removal from the patient.

**Figure 4.** Follow-up ERCP immediately after removal of covered expandable metal biliary stent shows filling of the cystic duct and gallbladder remnant but no leak. Contrast is still present in the colon from percutaneous tube study. Note the indentation at the point of contact with the proximal end of the stent (arrowhead).
was 3 minutes and 48 seconds. The bile duct assumed the shape and diameter of the stent (10 mm). The percutaneous tract closed quickly, and the patient remained well 5 weeks later.

Case 2

A 63-year-old man was admitted with acute cholecystitis and was taken to the operating room for attempted laparoscopic cholecystectomy. After the gallbladder could not be mobilized at laparoscopy, the procedure was converted to an open cholecystectomy. The posterior side of the gallbladder was densely adherent to the liver, could not be unresected, and thus was left in situ. Postoperatively, a large biloma developed. A percutaneous drain was placed, and ERCP with biliary sphincterotomy and placement of a 10F, 5-cm long plastic stent was performed. The stent was just at the level of the cystic duct. The distal bile duct was 4 mm, and the proximal bile duct measured just below the cystic duct was 6 mm. Because of high output drainage from the percutaneous drain, a repeat tube injection was repeated, showing persistent large communication with the biliary tree and poor drainage through the biliary stent (Figure 5). A second ERCP was performed; the biliary stent had migrated about 2 cm distally and was removed; the biliary sphincterotomy was extended. No change in drain output occurred (several hundred mL/day); thus a third ERCP was performed. A metal stent was placed as in patient 1, although the proximal end was below the cystic duct takeoff. The bile output decreased rapidly and dramatically, with a percutaneous tube study showing rapid flow through the stent (Figure 6). The percutaneous drain was removed 3 weeks later. Five weeks after initial placement of the metal stent, a follow-up ERCP was performed, and the expandable metal stent was removed endoscopically by ensnaring the distal end of the stent with a standard polypectomy snare. The stent was easily withdrawn along with the endoscope. Cholangiography showed a gallbladder remnant but without leakage (Figure 7). The bile duct diameter had increased to the size of the stent. The duration of procedure from first introduction of the duodenoscope to final withdrawal of the endoscope was 10 minutes and 20 seconds, and fluoroscopy time was 1 minute and 48 seconds. The patient remained well 7 weeks later.

Case 3

A 70-year-old man presented with acute cholecystitis. Because of severe acute illness and perforated gallbladder on abdominal computed tomography scan, a percutaneous cholecystostomy tube was placed. Two months later, laparoscopic cholecystectomy was attempted but was converted to open cholecystectomy because of extensive adhesions and a necrotic gallbladder.
The necrotic gallbladder was removed. Neither the cystic duct nor bile duct could be identified. A pigtail catheter was placed in the liver bed, and a Jackson-Pratt drain was placed into subhepatic space. A large amount of bile drained through both external drains. Twenty-four hours later, ERCP was performed. A pre-cut biliary sphincterotomy was performed, and cholangiography showed a patent cystic duct and large leak into the gallbladder bed. The distal bile duct was 6.7 mm, and the proximal bile duct measured just below the cystic duct was 7.4 mm. A 10-mm internal diameter, 8-cm long stent (Via-bil) was placed across the papilla. The proximal end of the stent did not cover the cystic duct. The patient’s external bile drainage rapidly decreased, and 1 week later, contrast injection into the pigtail catheter filled a gallbladder remnant and bile duct. Contrast drained rapidly through the biliary stent into the duodenum (Figure 8). The Jackson-Pratt drain was removed. Two weeks later, the pigtail catheter was reinjected, did not communicate with the cystic duct, and was removed. An ERCP was performed that day, and the stent was grasped and removed by using a rat-toothed forceps. Follow-up cholangiogram did not show any ductal changes in the area of the stent (Figure 9). The duration of procedure from first introduction of the duodenoscope to final withdrawal of the endoscope was 41 minutes and 13 seconds, and fluoroscopy time was 11 minutes and 48 seconds. The patient remained asymptomatic 10 days later.

**Discussion**

Cholecystectomy in the presence of severe cholecystitis and/or dense fibrosis might be technically difficult. When complete resection cannot be performed, subtotal cholecystectomy, either open or laparoscopic, might be performed, which might result in postoperative bile leaks. Endoscopic closure of bile leaks has become accepted practice, with a high rate of success for simple leaks. Endoscopic biliary sphincterotomy, transpapillary stent placement, or both are the most common endoscopic approaches. Bile leak closure occurs because the transpapillary high-pressure gradient is decreased or eliminated, leading to flow away from the leak and toward the duodenum.

Endoscopic removal of uncovered expandable metal biliary stents is difficult and sometimes impossible because the stent embeds into the bile duct wall. More than 10 years ago, Silvis et al described the histologic differences between uncovered and covered metal biliary stents in a canine model. No embedding into the bile duct wall occurred at the covered portion of the metal stent. Covered expandable metal biliary stents have been used almost exclusively in the palliation of malignant...
biliary obstruction to prolong stent patency by preventing occlusion caused by tumor ingrowth and/or tissue hyperplasia. In the comparative study by Isayama et al., autopsy data confirmed the findings from the animal study by Silvis et al; none of the 9 covered metal stents studied post mortem had embedded into the bile duct wall, and all could be removed easily. This lack of embedding of covered expandable metal biliary stents has led to the observation of their spontaneous migration, endoscopic removal, and potential application for temporary placement for benign strictures. To our knowledge, there are no previous reports of their use for the treatment of complex bile leaks. The 3 cases presented here suggest that covered expandable metal stents might be a viable option for the nonoperative management of benign biliary disorders, including complex bile leaks that are refractory to sphincterotomy with or without placement of a single large-bore plastic stent. As the second and third cases demonstrated, the stent does not have to be above the site of the leak to be effective, and successful closure of the leak is due to the diversion of bile away from the leak through the large-diameter stent.

A variety of endoscopic options other than placement of self-expandable covered stents could have been chosen in the patients presented here. One option is the placement of multiple large-bore (10F or 11.5F) stents to further increase the flow of bile away from the leak and seal the bile duct lumen. However, one of our patients already experienced stent occlusion before leak closure. Each of the multiple stents would also be expected to occlude at the same rate, possibly before leak closure. Another option would have been the placement of either a nasobiliary drain or nasoduodenal drain in addition to internal stents. With the addition of suction, bile is siphoned away from the leak. The disadvantages to the latter approach are the potential need for hospitalization and the resultant discomfort and/or embarrassment to the patient. Although the cost of a self-expandable metal stent is significantly greater than for plastic stents, their use could potentially be more cost-effective for selected patients if the metal stent is more effective in closing the leak. The avoidance of even one additional ERCP would offset the cost of the stent. For example, the first 2 of our patients had already undergone several ERCPs by the time the decision was made to place a metal stent. Only one additional procedure was required (for stent removal) after the leak resolved. On the basis of our experience with the first 2 patients, we elected to proceed directly with a covered stent in the third patient. Rapid closure of an open cystic duct leak was achieved by using 1 stent.

The stent placed in the first 2 patients was the Wallstent, which is covered except for 1.5 mm at each of the sharp ends. These 2 properties might lead to complications after insertion. First, the uncovered portion might imbed into the bile duct wall, making later removal difficult. Second, the sharp ends might cause damage to the bile duct on the proximal end and ulceration or perforation on the distal end within the duodenum. The proximal bile duct damage, indicated by the focal narrowing on follow-up cholangiography in our 2 patients (Figures 4 and 7), could theoretically result in stricture formation. This suggested that alternative stent designs with smooth edges or a complete covering might be preferable for the treatment of benign bile duct disease; thus in the third case we chose a stent that was fully lined and did not produce radiographic alterations in the bile duct (Figure 9).

It might not be appropriate to use larger diameter (10 mm) stents in patients with small-diameter bile ducts, and there is a potential that this mismatch in size could
increase the chance of and severity for bile duct damage. As can be seen in our patients, the bile duct diameter increased in size after stent expansion, as seen on follow-up cholangiography. Smaller-diameter coated stents for patients with smaller bile ducts (6–8 mm) could potentially limit long-term complications to the bile duct.

We do not yet advocate the routine use of covered expandable metal stents for benign biliary disorders. It is advised that these devices not be placed into patients who are noncompliant who might not return for stent removal. If left in place long-term, these devices might not be removable or might cause irreversible ductal injury. Care must be taken to ensure the stent exits the papilla adequately enough (even after additional shortening that occurs with delayed expansion) so that they can be endoscopically removed. It appears that when the Wallstent is grasped with a snare, it constrains the entire stent, if grasped about 0.5 cm above the end. We did not experience difficulty in their removal, but we envision that if placed entirely within the bile duct (or not enough is left in the duodenum after complete expansion and foreshortening), it might not be removable. Because the distal end is in the duodenum, the stent can only imbed at the 1.5-mm proximal end.

The optimal duration that covered metal stents should remain in place for the management of bile leaks is unknown. In our patients, external drains were in place so that we could monitor bile output and remove the stents when the output ceased, indicating the leak had closed. Until more data are available, an arbitrary time of ≤3 months seems reasonable.

In summary, we believe that the use of a covered expandable metal stent might be useful for patients with large bile leaks, especially those that have not been controlled with large-bore plastic stents. At this time questions remain about their efficacy, ease of removal, and cost-effectiveness in a larger patient population. Our experience consists of only 3 cases with covered metal stents, which are not FDA approved for withdrawal. As a result of our experience, we believe that a randomized controlled trial is needed to assess the pros and cons and to determine whether there should be a change in clinical practice in favor of using covered metal stents rather than multiple plastic stents in those patients with complex biliary leaks.

References