Current Status of Biliary Metal Stents

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Many advances have been achieved in biliary stenting over the past 30 years. Endoscopic stent placement has become the primary management therapy to relieve obstruction in patients with benign or malignant biliary tract diseases. Compared with plastic stents, a self-expandable metallic stent (SEMS) has been used for management in patients with malignant strictures because of a larger lumen and longer stent patency. Recently, SEMS has been used for various benign biliary strictures and leaks. In this article, we briefly review the characteristics of SEMS as well as complications of stent placement. We review the current guidelines for managing malignant and benign biliary obstructions. Recent developments in biliary stenting are also discussed.

Key Words: Self expandable metallic stents; Biliary stenting; Malignant; Benign

INTRODUCTION

Biliary obstruction can result from various benign and malignant diseases, including primary pancreaticobiliary cancer, metastatic disease, malignant lymphadenopathy, cholecodocholithiasis, chronic pancreatitis, and postoperative strictures. Hepatobiliary malignancy causes obstruction in 70% to 90% of patients. For patients with malignant biliary obstruction, curative resection is only possible in less than 20% of candidates because of an inoperable condition secondary to local spread and distant metastases. In addition, benign biliary strictures can cause jaundice, pain, pruritus, hepatocellular dysfunction, biliary cirrhosis, and cholangitis. Endoscopic biliary stenting was first introduced in the early 1980s. In the late 1980s, the self-expandable metallic stent (SEMS) was introduced and has been shown to improve patency better than plastic stents. Since their development, biliary stents have been widely used to manage not only malignant biliary obstruction but also benign biliary diseases. In 2012, the European Society for Gastrointestinal Endoscopy (ESGE) published clinical guidelines for biliary stenting that included the indications, choice of stents, and results (Table 1). In this article, we review the characteristics of metallic biliary stents and complications of stent placement. We also describe the use of stents in a variety of clinical settings and the technical considerations for stenting. Recent advancements and future directions in biliary stenting including some novel stent designs are also discussed.

SELF-EXPANDING METALLIC STENT

Metallic stents are usually made with cobalt-chromium (stainless steel) or an alloy, including nickel-titanium (nitinol), which is a shape memory alloy. SEMS, which expands to full diameter once it is placed in the body, is widely used. Because the diameter at full SEMS expansion is 6 to 10 mm, the duration of patency is much longer, approximately 10 months. The stent length is typically 4 to 12 cm; however, some manufacturers will create stents of different lengths to order. A biliary SEMS is released by retracting the sheath from a preloaded, through-the-scope delivery system with a diameter of 6 to 8.5 Fr. The primary disadvantage of SEMS is the expense.
Stents can be classified as either a closed-cell or open-cell type, depending on the lattice structure. Most stents are the closed-cell type. Depending on the weave of the metallic fibers, these stents can be further classified into cross wire, hook wire, or hook and cross wire structures. Most manufacturers use a hook and cross wire structure to take advantage of the positive features of both structures.

A Zilver stent is an open-cell type stent that does not shorten. The delivery system diameter is 7 Fr, and it is easy to access the stenotic lesion in the bile duct. However, its expandability is weaker than other products; the restoring force is high, and it is difficult to reposition the stent when trying to modify the position.15,16

Ingrowth, in which a tumor grows between the mesh lines of the stent, and overgrowth, in which a tumor blocks either the proximal or distal end of the stent, are primary mechanisms of SEMS occlusion.7,15,16 To overcome these limitations and prolong the patency duration, a covered SEMS (CSEMS) was developed. The covering materials include polyurethane, silicone, and polytetrafluoroethylene, all of which are effective. An uncovered SEMS (USEMS) is completely buried inside the tumor and helps to prevent migration. It can be placed in the intrahepatic duct.12 Disadvantages of USEMS are that it is impossible to change or remove once placed and early occlusion can occur due to tumor ingrowth. Although a CSEMS could decrease occlusion, many studies have reported no differences in patency duration between CSEMS and USEMS.11,17-19 Furthermore, cholecystitis or pancreatitis can occur because the stent covering blocks the opening of cystic or pancreatic ducts, but this is not largely different from a USEMS.18,19 The frequency of stent migration is much higher with CSEMS than with USEMS (Table 2).11,20

### EFFICACY AND OUTCOMES

#### Benign biliary disease

**Benign biliary strictures**

Benign biliary strictures can result from postoperative biliary injuries (mainly cholecystectomy or liver transplantation), chronic pancreatitis, primary sclerosing cholangitis, or other chronic inflammatory disorders.13 The standard strategy for benign biliary strictures is endoscopic management by placing a SEMS. Other options include multiple plastic stents or a covered SEMS.13

**Sphincterotomy**

In cases where sphincterotomy is considered, it may facilitate more complex procedures. Adapted from Moy et al.12

CT, computed tomography; MRI, magnetic resonance imaging; SEMS, self-expanding metal stent; ERCP, esophageal retrograde cholangiopancreatography.
ment of multiple plastic stents, with or without balloon dilatation, until resolution of the stricture. According to the ESGE guidelines, temporary simultaneous placement of multiple plastic stents for benign common bile duct (CBD) strictures is technically feasible in more than 90% of patients, and endoscopy provides superior long-term stricture resolution; 90% of postoperative injuries and 65% of strictures are related to chronic pancreatitis. The main limitation of the multi-stenting strategy is that the stent should be exchanged periodically (on average, between 3 to 5 sessions) for more than 1 year for complete resolution of the stricture, which increases costs and may decrease patient compliance.

Recently, SEMS has become available for various benign biliary strictures. Although USEMS is strongly discouraged in benign biliary strictures, CSEMS, which can be removed using an endoscopic approach, could potentially decrease the number of endoscopic procedures. Technically, it is also easier than insertion of multiple plastic stents. In a recent, large, prospective multinational study, the rates of stricture resolution were 90.5%, 88.0%, and 90.9% for chronic pancreatitis, orthotopic liver transplantation, and cholecystectomy groups, respectively, who underwent scheduled fully CSEMS (FCSEMS). However, CSEMS can increase the risk of stent migration, and pancreatitis is a well-known complication. Cholecystitis and cholangitis due to obstruction of the cystic duct by the inserted stent are not uncommon adverse events. The potential risk of contralateral biliary occlusion could also be a limitation to the use of CSEMS in hilar strictures. Therefore, CSEMS might be a suitable alternative therapeutic option in select conditions only, such as refractory benign biliary stricture or stricture from chronic pancreatitis, especially for calcific pancreatitis, which is difficult to treat, and should not be used routinely. The respective roles of treatment strategies for benign biliary strictures of various causes are shown in Table 3.

**Biliary leaks**

Bile leaks could successfully be treated with plastic stent placement with or without sphincterotomy in 70% to 100% of patients. A single plastic stent with or without sphincterotomy could be used first in postoperative bile leaks because the CBD is usually not dilated and an insertion of multiple stents or SEMS is difficult. In case of refractory bile leaks, multiple stents or SEMS could be considered. Some studies with small sample sizes have demonstrated complete resolution of large complex leaks and refractory bile leaks with failed plastic stent placements using partially CSEMS or FCSEMS. The placement of SEMS may reduce the pressure of the sphincter of Oddi and also seal the fistula.

**Biliary stones**

A previous study reported that biliary stone removal fails 5% to 10% of the time after endoscopic retrograde cholangiopancreatography (ERCP). Biliary stenting can help relieve biliary obstruction by bile drainage and stone dissolution. Short-term plastic stent placement could reduce the size or number of biliary stones and facilitate stone removal in over 90% of cases in subsequent procedures. Cerecice et al. reported a sim-
ilar outcome using temporary CSEMS placement for complex biliary stone clearance during initial ERCP after a previous unsuccessful stone extraction.

**Bleeding and perforation**

Recent studies described the use of CSEMS for hemostasis (mainly post sphincterotomy bleeding). CSEMS works by tamponading the bleeding site and provides simultaneous and effective drainage of the bile duct, especially when occluded with blood clots.\textsuperscript{36,41,42} Perforations from a guidewire or basket insertion are usually small and can be treated with conservative management. The management of a periampullary perforation remains controversial. Recently, FCSEMS has become a therapeutic option to seal perforations and prevent entry into the perforation site.\textsuperscript{39,44}

**Malignant biliary disease**

**Distal malignant biliary obstruction**

Distal malignant biliary obstruction is usually due to pancreatic cancer, distal cholangiocarcinoma, ampullary cancer, and less commonly gallbladder cancer and metastatic diseases.\textsuperscript{16} USEMS, partially CSEMS, and FCSEMS are used for palliation of patients with a distal malignant biliary obstruction. In patients with a prognosis of less than 4 months, plastic stents are a better choice because they are cost-effective and the risk of both migration and occlusion within approximately 3 months is low.\textsuperscript{12,45} If expected survival is more than 4 months; however, a recent meta-analysis reported that, compared with a plastic stent, SEMS in the management of malignant biliary obstruction is associated with significantly longer stent patency, fewer ERCPs, and longer patient survival.\textsuperscript{36,46} A meta-analysis showed no differences between CSEMS and USEMS in the patency rates at 6 or 12 months. There was also no difference in pancreatitis, cholecystitis, perforation, bleeding, cholangitis, length of hospital stay, or number of recurrent biliary obstructions.\textsuperscript{47} However, CSEMS is associated with a higher rate of stent migration than USEMS.\textsuperscript{47} In a multicenter, randomized controlled trial with 400 patients, there was no significant difference in stent patency between USEMS and CSEMS for distal malignant biliary disease.\textsuperscript{18}

All of these studies support the guidelines issued by the ESGE in 2012 for nonresectable malignant biliary obstruction and show that plastic stents are a good option when patient prognosis is less than 4 months, while SEMS is a better option if the prognosis is more than 4 months (Table 1).\textsuperscript{11,12} The guidelines do not identify a benefit for CSEMS over USEMS in the treatment of nonhilar biliary obstructions,\textsuperscript{11,12} and the best choice remains controversial.

**Hilar malignant biliary obstruction**

Hilar obstruction can be caused by primary tumors such as cholangiocarcinoma (Klatskin tumor), local extension from gallbladder carcinoma, hepatocellular carcinoma, pancreatic cancer, and metastatic diseases or compression from lymph nodes. Tumor resectability should be evaluated using imaging techniques before biliary stenting in malignant hilar obstruction.\textsuperscript{11} The benefit of preoperative drainage in malignant hilar obstruction is less clear.

A meta-analysis of 11 studies reported no difference in mortality or length of postoperative stay with and without preoperative biliary drainage in jaundiced patients with hilar cholangiocarcinoma, as well as increased overall rates of postoperative and infectious complications.\textsuperscript{48,49} Therefore, preoperative biliary drainage should not be routinely performed. However, in Korea and Japan, biliary drainage via a percutaneous approach is preferred for patients with hilar cholangiocarcinoma.\textsuperscript{50,51} Preoperative biliary drainage can be a reasonable choice under certain conditions such as right lobectomy for Bismuth type IIIA or IV hilar cholangiocarcinoma or preoperative portal vein embolization with chemo-radiation therapy.\textsuperscript{52}

Endoscopic palliation, combined percutaneous and endoscopic procedures (especially after a failed endoscopic procedure), or percutaneous drainage alone have been used for unresectable malignant hilar tumors.\textsuperscript{53} In general, endoscopic management is the preferred treatment for palliation. Previous studies suggest that SEMS is superior to plastic stents for the treatment of hilar malignancy.\textsuperscript{53-56} The placement of SEMS is especially recommended for patients with expected survival more than 3 months or with infected bile duct. CSEMS is not appropriate for palliative drainage of hilar malignant obstruction because it occludes the contralateral biliary duct and has migration issues.\textsuperscript{11} Although the use of unilateral or bilateral stents is debated, the important step is draining more than 50% of the liver volume, which reportedly results in a greater decrease in bilirubin level, lower incidence of early cholangitis, and longer patient survival.\textsuperscript{19}

Bismuth classification is useful for endoscopic stent placement planning. In patients with Bismuth type I cholangiocarcinoma, only one stent in the common duct is appropriate for drainage. Palliation of the other lesion types, especially types III and IV, risks incomplete drainage and requires multiple stents.\textsuperscript{54,55,56} Additionally, contrast injection into an undrained biliary system can lead to a higher rate of post-procedure cholangitis and decrease the survival rate.\textsuperscript{56} Prophylactic antibiotics are needed routinely. Bilateral stent insertion preserves the functional liver volume, decreases the potential risk of cholangitis, and lowers complications when there are bilateral infected ducts, extending patient survival.\textsuperscript{50} The Asia-Pacif-
Biliary stents have been used in various malignant and benign biliary obstructions. SEMS has been traditionally used for inoperable malignant biliary obstructions. Regardless of the number of stents deployed, drainage of more than 50% of the liver volume is important for longer patient survival, and endoscopic bilateral metallic stenting could be the preferred treatment for hilar malignant biliary strictures with high-grade obstruction. Although guidelines are lacking, FCSEMS...
has been proposed as a reasonable alternative therapeutic option for benign biliary disease. Currently, various types of SEMS such as antimigratory, antireflux, drug-eluting, radioactive, and bioabsorbable stents are being studied. Many studies are at a stage of early investigation or in early clinical studies. However, a customized functional stent appropriate to the disease characteristics of the patient and various other situations should be considered in the future.

Conflicts of Interest

The authors have no financial conflicts of interest.

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