Use of the Viabil Covered Stent in the Treatment of a Benign Biliary Stricture with the Subsequent Development of Acute Pancreatitis

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ABSTRACT

The use of bare metal stents for benign biliary strictures is typically avoided due to historically poor long-term patency. Thus, in patients who are not surgical candidates, the management of benign biliary strictures can be a frustrating process. This article describes a patient who developed a common bile duct stricture following a complex endovascular thoracoabdominal aneurysm repair. The stricture was treated with the placement of a covered metallic biliary stent; a procedure complicated by the development of acute pancreatitis.

KEYWORDS: Common bile duct stricture, Viabil covered stent, pancreatitis

Objectives: Upon completion of this article, the reader should recognize a potential pitfall of using covered stents in the biliary system.

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Obstruction from benign biliary strictures can be difficult to manage and frustrating for both the patient and physician. Patients who fail conservative therapy often require surgery for definitive treatment. In those patients for whom surgery is not an option, metallic stenting does provide hope for a more durable solution. Unfortunately, although metallic stents provide improved short-term drainage, the long-term patency is poor, and there is often a continued need for additional interventional procedures. With the development of new covered stents designed specifically for malignant biliary strictures, there is hope for improved long-term patency.

This case illustrates the use of covered stents for a benign biliary stricture and the subsequent development of acute pancreatitis following stent placement.

CASE REPORT

An 81-year-old woman with a multiple medical problems, including right and left heart failure secondary to diastolic dysfunction, was referred to our institution for evaluation of a type 4 thoracoabdominal aneurysm. The aneurysm measured 7.1 cm in diameter and had enlarged 1 cm over the past 6 months. Given the large size and

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rapid growth, repair of the aneurysm was indicated. However, the patient's comorbidities precluded a large open surgical procedure, and a plan was developed to fix the aneurysm with endovascular techniques. This required a two-stage procedure, initial visceral bypass followed by endograft placement. Right iliac artery to right renal artery bypass and right iliac artery to superior mesenteric artery bypass procedures were performed. Six weeks after the visceral bypass surgery, a tubular stent graft was implanted from the distal thoracic aorta to the abdominal aorta, and a bifurcated stent graft was implanted in the abdominal aorta.

On the day following the endovascular aneurysm repair, the patient developed severe abdominal pain. An abdominal computed tomography (CT) without oral or intravenous contrast was performed to exclude retroperitoneal hemorrhage. This study demonstrated a hydropic gallbladder, and a diagnosis of acalculous cholecystitis was made based on the clinical picture and CT findings. An 8F drainage catheter (Flexima; Boston Scientific, Natick, MA) was placed into the gallbladder using ultrasound guidance without complication.

The patient's abdominal pain resolved after catheter placement, and follow-up cholecystogram performed 2 weeks later demonstrated cystic duct occlusion and no gallstones. On discharge from the hospital, the patient was doing well and tolerating a regular diet. A follow-up cholecystogram 3 months later demonstrated complete obstruction of the distal common bile duct. The patient was referred for endoscopic retrograde cholangiopancreatography (ERCP) to further evaluate the cause of obstruction and possibly provide endoscopic management. The pancreatic duct was noted to be widely patent; however, due to a high-grade stricture, the distal common bile duct could not be cannulated.

The patient was evaluated for possible surgery but was still considered a high surgical risk. Therefore, it was decided to try to manage the stricture with endobiliary techniques. The cystic duct was catheterized with a 5F Kumpe catheter (Cook, Bloomington, IN) and a 0.035-inch hydrophilic wire (Glidewire; Terumo, Tokyo, Japan). Cholangiogram confirmed the distal common bile duct stricture (Fig. 1), and the stricture was dilated with a 6-mm angioplasty balloon; a 10F internal/external biliary drain (Flexima; Boston Scientific, Natick, MA) was placed with side holes extending from the gallbladder to the duodenum. Brush biopsy of the stricture was also performed and was negative for malignancy.

The patient returned multiple times for repeat balloon dilations of the common bile duct stricture. Despite multiple interventions, the obstruction persisted. Approximately 6 months after the initial cholecystostomy catheter was placed, a 10 mm × 4 cm self-expanding nitinol stent (LUMINEXX; Bard, Billerica, MA) was placed across the stricture to facilitate long-term internal

Figure 1 Transcholecystic cholangiogram demonstrates mild dilation of the common bile duct and common hepatic duct. There is a focal stricture of the distal common bile duct (curved arrow).

drainage. Nonetheless, the patient returned in 3 weeks with recurrent abdominal pain, nausea, and vomiting. Repeat cholangiogram demonstrated severe intrastent stenosis (Fig. 2) for which balloon dilation was performed.

Figure 2 Repeat cholangiogram 3 weeks after initial stent placement demonstrates diffuse intrastent narrowing (arrowheads).

Figure 3 Cholangiogram following covered stent placement. There is significantly improved bile drainage. The ends of the fabric are marked with gold rings (arrows).

The patient continued to require multiple further interventions to maintain stent patency and relying on an internal/external catheter for drainage. Therefore, it was decided to place a covered stent. A 10 mm × 4 cm Viabil (W.L. Gore, Flagstaff, AZ) stent was deployed within the previously placed LUMINEXX stent (Fig. 3). Following stent placement, intrastent debris was identified and swept into the bowel using a 10-mm angioplasty balloon.

On the following morning, the patient again complained of abdominal pain. Laboratory tests showed both amylase and lipase values to be elevated: The amylase was 3123 U/L (normal range, 30 to 110 U/L), and the lipase was 18,154 U/L (normal range, 44 to 232 U/L). These findings were indicative of acute pancreatitis. The patient's abdominal pain was controlled with intravenous morphine. The lipase declined during the patient's hospital stay and was 459 U/L at time of discharge 7 days later. The patient was able to return to the nursing home with minimal pain and tolerating a regular diet.

DISCUSSION

This case report brings up two important points for discussion: the use of covered stents for benign biliary strictures and the potential for pancreatitis following the placement of a covered stent across the pancreatic duct orifice. The use of metallic stents in patients with benign biliary strictures remains controversial because long-term patency is poor and overall results have consistently trailed surgical reconstruction. Unfortunately, surgery is occasionally precluded by patient comorbidities or

difficult ductal anatomy. Therefore, metallic stenting may be considered to optimize biliary drainage when other conservative therapies fail.

Although the use of metallic stents for malignant biliary obstruction is well established, no large studies have investigated their use for benign strictures. There are several small series available that predictably demonstrate a wide range in patency rates. Overall, the patency rates are reported between 10 and 60 months.¹⁻⁴ The etiology of the stricture and the type and length of stent placed both appear to contribute to overall patency.² In a review by Lopez et al, patients who had strictures secondary to iatrogenic injuries fared worse with stenting than patients whose strictures were the result of gallstones.¹ This was postulated to be secondary to ischemic injury of the duct. In our case, because the distal common bile duct stricture was most likely due to ischemia from the bypass surgery and complex endovascular aneurysm repair, it should not be surprising that the initial stent went on to early occlusion.

The reason bare metal stents occlude is thought to be due to a combination of mucosal hyperplasia and bile sludge and stone formation.^{1,5} Covered stents may be beneficial by reducing the impact of mucosal hyperplasia. To date, though, very little data support the use of covered stents in benign biliary disease, and the use in malignant disease has met with mixed results. Two separate studies comparing covered and uncovered Wallstents (Boston Scientific, Natick, MA) for malignant biliary obstruction showed no advantage in using the covered stent.^{6,7} However, a prospective, randomized trial comparing polyurethane diamond stents with uncovered diamond stents showed a clear advantage for the covered stents.⁸ Two studies, thus far, have evaluated the expanded polytetrafluoroethylene/fluorinated ethylene-propylene (polymer) (ePTFE/FEP) covered stent (Viabil) used in this case. Both studies were done in the setting of malignant disease, and both studies were limited by poor patient survival. However, the reported 12-month patency rates were a respectable 76 to 77%.^{9,10} The improved patency was postulated to be from prevention of tumor ingrowth from the stent covering as well as reduced biofilm formation by the ePTFE/FEP.¹⁰

Despite its advantages, covering of the stent has the potential disadvantage of also covering biliary and pancreatic ductal side branches. In the biliary system, this may lead to occluding the cystic duct or the pancreatic duct. Covering the cystic duct may lead to cholecystitis, one of the more common complications encountered thus far. The reported incidence of cholecystitis is 5 to 10%.^{8,9} Schoder et al reported 3 of 42 patients treated with ePTFE/FEP-covered stents developing cholecystitis.¹⁰ Two patients were successfully treated with catheter drainage, and one required cholecystectomy. To avoid this complication, the Viabil stent graft comes available with multiple transmural holes at

the proximal end to allow for continued cystic duct drainage while maintaining adequate fixation within the common hepatic duct.

Interestingly, thus far, the incidence of pancreatitis from covering the pancreatic duct with ePTFE/FEP-covered stents appears quite rare. In a study by Han et al, there was no significant elevation of either amylase and lipase levels following placement of polyurethane-covered stents across the pancreatic duct.¹¹ This corresponds with the infrequency of the development of clinical symptoms of pancreatitis with the use of covered stents in malignant biliary obstruction. The reported incidence of pancreatitis with the covered Wallstent is 0 to 6%.^{6,7,12} However, when compared with uncovered Wallstents, this is not statistically different.⁶ In a review of 42 patients who had Viabil stents placed for malignant biliary obstruction, there was only one instance of pancreatitis.⁹ This was described as "mild" and resolved completely with conservative therapy. In our case, however, the patient developed severe symptoms from pancreatitis, although the symptoms also abated with conservative therapy. The difference may be due to the fact that the pancreatic duct was widely patent prior to stent placement, as documented on ERCP, as opposed to malignant biliary obstructions in which the pancreatic duct is frequently chronically compromised. In this case, there are two possible reasons why our patient developed pancreatitis: Either debris was forced into the pancreatic duct during balloon dilation resulting in a temporary obstruction or it was a result of the covering of the pancreatic duct with the fabric of the stent.

In summary, surgical management remains the optimal therapy for patients with benign biliary strictures. However, in patients with limited life expectancy due to other comorbidities, improving technology with commercially available ePTFE/FEP-covered stents provides an interesting, minimally invasive option. The long-term patency in this setting remains uncertain, and the potential for complications such as described in this report does exist.

REFERENCES

1. Lopez RR Jr, Cosenza CA, Lois J, et al. Long-term results of metallic stents for benign biliary strictures. *Arch Surg* 2001; 136:664-669
2. Tesdal IK, Roeren T, Weiss C, et al. Metallic stents for treatment of benign biliary obstruction: a long-term study comparing different stents. *J Vasc Interv Radiol* 2005;16: 1479-1487
3. Gabelmann A, Hamid H, Brambs H-J, et al. Metallic stents in benign biliary strictures: long-term effectiveness and interventional management of stent occlusion. *AJR Am J Roentgenol* 2001;177:813-817
4. van Berkel AM, Cahen DL, van Westerlo DJ, et al. Self-expanding stents in benign biliary strictures due to chronic pancreatitis. *Endoscopy* 2004;36:381-384
5. Hausegger KA, Kugler C, Uggowitz M, et al. Benign biliary obstruction: is treatment with the Wallstent advisable? *Radiology* 1996;200:437-441
6. Park do H, Kim MH, Choi JS, et al. Covered versus uncovered Wallstent for malignant extrahepatic biliary obstruction: a cohort comparative analysis. *Clin Gastroenterol Hepatol* 2006;4:790-796
7. Yoon WJ, Lee JK, Lee KH, et al. A comparison of covered and uncovered Wallstents for the management of distal malignant biliary obstruction. *Gastrointest Endosc* 2006;63: 996-1000
8. Isayama H, Komatsu Y, Tsujino T, et al. A prospective randomized study of "covered" versus "uncovered" diamond stents for the management of distal malignant biliary obstruction. *Gut* 2004;53:729-734
9. Bezzi M, Zolovkins A, Cantisani V, et al. New ePTFE/FEP-covered stent in the palliative treatment of malignant biliary obstruction. *J Vasc Interv Radiol* 2002;13:581-589
10. Schoder M, Rossi P, Uflacker R, et al. Malignant biliary obstruction: treatment with ePTFE-FEP-covered endoprostheses—initial technical and clinical experiences in a multicenter trial. *Radiology* 2002;225:35-42
11. Han Y-M, Jin G-Y, Lee S-O, et al. Flared polyurethane-covered self-expandable nitinol stent for malignant biliary obstruction. *J Vasc Interv Radiol* 2003;14:1291-1301
12. Nakai Y, Isayama H, Komatsu Y, et al. Efficacy and safety of the covered Wallstent in patients with distal malignant biliary obstruction. *Gastrointest Endosc* 2005;62:742-748