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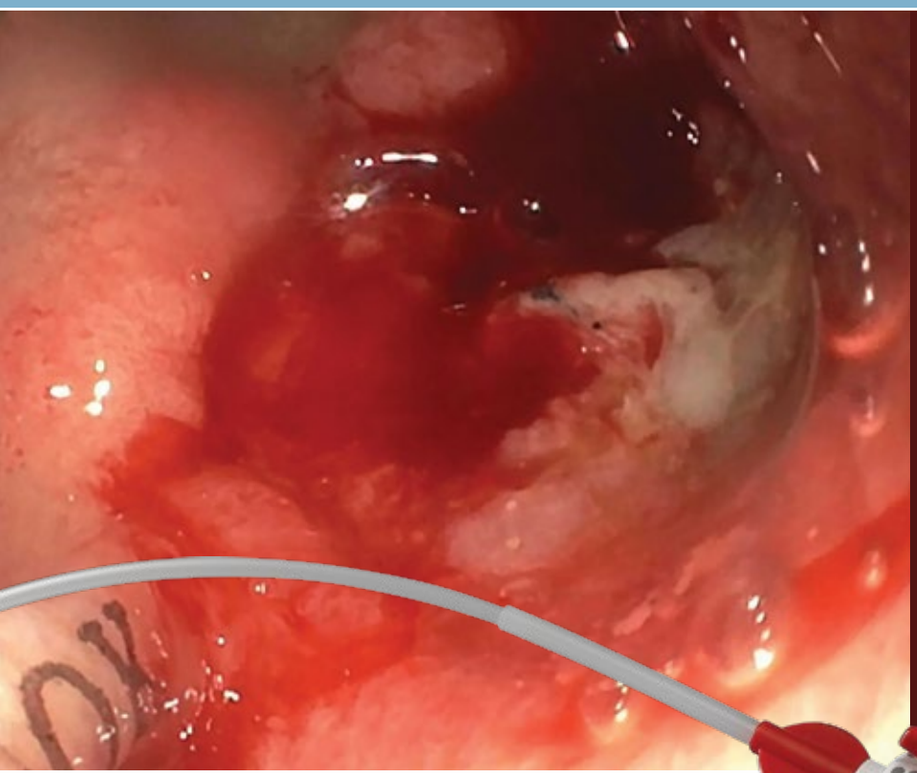

A pioneering solution for hemostasis management

Hemospray® Endoscopic Hemostat continues to expand its impact as a treatment modality for nonvariceal bleeding in the gastrointestinal tract. With growing initial case experience by US endoscopists, more firsthand clinical perspective is adding to the multiple international clinical study outcomes established for this unique device. Join us in this issue for some key examples of treatment decisions with Hemospray and expert clinical opinion on its use.

“ Hemospray is a must-have tool for all gastroenterologists.”

Mel A. Ona, MD, MS, MPH, MA

Department of Gastroenterology
Pali Momi Medical Center
Aiea, HI

Dr. Mel Ona of Hawaii opens The Channel’s new case report series which will be an opportunity to share many of the initial and significant Hemospray patient outcomes achieved by US endoscopists thus far. Dr. Ona also discusses his perspective on Hemospray’s role in GI bleeding management challenges as well as his thoughts on the device’s future impact.

In the case discussion that follows, we are provided a focus on a life-threatening and actively bleeding metastatic malignant tumor and a recalcitrant duodenal bulb ulcer bleeding scenario.

Read on to learn more about Hemospray’s use in these situations and to consider why Dr. Ona states, “Hemospray is a must-have tool for all gastroenterologists.”

Dr. Mel Ona is not a paid consultant of Cook Medical.

Q&A

with

Dr. Mel Ona

During early case experience, how has the availability of Hemospray changed your decision making in the management of nonvariceal GI bleeding?

In my opinion, Hemospray has been a life-saver for many of our patients, particularly for patients with refractory bleeding and for lesions that are difficult to access.

Why was adding Hemospray to your armamentarium of interest for you?

We added Hemospray not only for secondary hemostasis in lesions that fail to respond to primary treatment with coaptive coagulation or mechanical means (clips, banding, etc.) but also as potential first-line treatment in patients with massive GI bleeding or for lesions that do not respond well to conventional hemostatic maneuvers (such as the pancreatic tumor case report on page 4).

What bleed scenarios have been involved in your first cases using Hemospray, and in general what key learnings and results have you experienced thus far?

We have applied Hemospray in a variety of clinical situations including diffuse bleeding from malignant tumors and large ulcers in the stomach, duodenum, and rectum. Results have been remarkable for immediate, definitive and sustained hemostasis. Though not a proven nor claimed therapeutic benefit, we have noticed that the mucosa appears to heal faster after Hemospray application and this is one avenue of research that interests us.

How has your endoscopy team reacted to the inclusion of Hemospray as a bleed management option during these initial cases?

Our endoscopy team is thrilled about Hemospray and its ease of use, safety, and efficacy. We have been impressed by the clinical results and the lives that have been saved.

How do you foresee Hemospray impacting the treatment paradigm for non-variceal bleeding as more case experience is achieved with the device?

Hemospray is a must-have tool for all gastroenterologists. When GI bleeding fails to respond to conventional hemostatic therapies, Hemospray is the best option. I foresee Hemospray as potential first-line treatment for high-risk bleeding lesions in areas that are difficult to access or visualize.

Dr. Mel Ona

Invasive pancreatic tumor and erosive, ulcerated gastric mass

Stabilizing active malignant bleeding

A 60-year-old presented to the hospital with worsening epigastric abdominal pain, 30-pounds (lb) weight loss, and bright-red hematemesis. Hemoglobin decreased from 12.4 (two weeks prior to admission) to 6.9. Contrast-enhanced computed tomography (CT) scan of the abdomen and pelvis demonstrated a large (7 cm x 6.5 cm), heterogeneous, hypodense mass arising from the body of the pancreas invading into the proximal stomach and surrounding the splenic artery and vein. Esophagogastroduodenoscopy (EGD) demonstrated a large, infiltrative, ulcerated, cratered mass with friable edges in the proximal posterior gastric body with oozing blood. Hemostasis was achieved using five grams (g) of Hemospray (Cook Medical Inc., Winston-Salem, North Carolina, USA) through a 10 French application catheter. No further episodes of hematemesis were reported.

Biopsies of the gastric mass revealed poorly-differentiated pancreatic adenocarcinoma with immunohistochemical testing positive for CA 19-9 and cK19. Imaging of the patient's brain, chest, abdomen, and pelvis demonstrated widespread metastasis. Due to these findings and poor prognosis, hospice referral was arranged. The patient was discharged with stable hemoglobin and died one month later in hospice.

In this case, Hemospray stopped bleeding from a large pancreatic tumor that had invaded the posterior gastric wall. After treatment, there were no further bleeding episodes and the patient experienced no adverse side effects. The ease and effectiveness of treating a diffusely bleeding malignant lesion with a single application of Hemospray was beneficial in helping transition the patient to hospice without the need for multiple blood transfusions or repeat procedures.

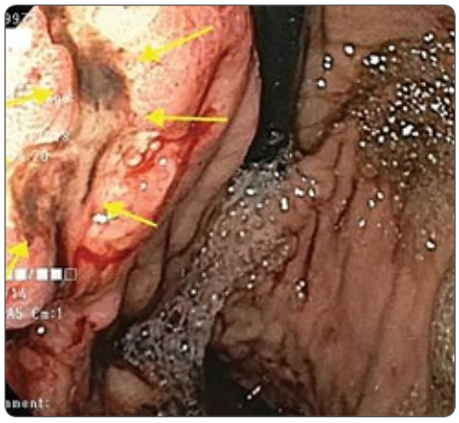

Figure 1. Large gastric ulcer from a pancreatic mass eroding into the proximal stomach.

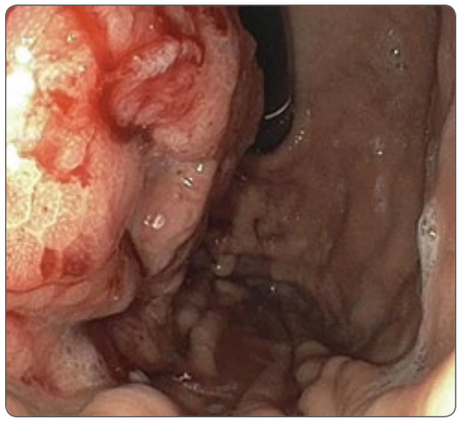

Figure 2. Diffuse oozing from a pancreatic mass invading into the stomach.

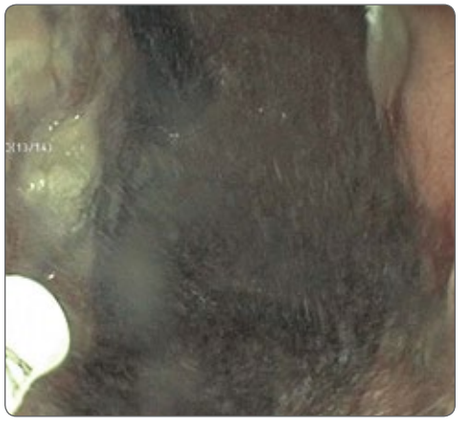

Figure 3. Application of Hemospray to the large ulcerated area in the proximal stomach.

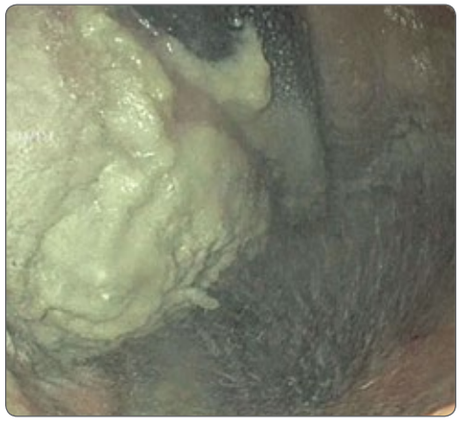

Figure 4. Hemostasis achieved with application of Hemospray.

Dr. Mel Ona

Duodenal bulb ulcer bleeding management

Concerns of repeated blood loss and therapeutic options available

A 69-year-old Jehovah's Witness with history of hypertension, dyslipidemia, osteoarthritis, gout, and long-standing NSAID use presented with epigastric abdominal pain and multiple episodes of maroon-colored loose stool with blood clots. Labs were significant for anemia (Hgb 9.6, Hct 30.3). Hemoglobin and hematocrit five months prior were normal (Hgb 14.6, Hct 44.8). EGD revealed several small clean-based gastric ulcers and a large, excavated, duodenal bulb ulcer with an adherent clot.

The clot was carefully removed and the ulcer had no visible vessels and no overt bleeding was seen. Hemoglobin remained stable until four days later when the patient passed melenic stool, and hemoglobin decreased to 7.2. Interventional radiology was consulted and mesenteric angiogram showed hyperemia in the region of the known duodenal ulcer with no frank extravasation. Successful coil embolization of the gastroduodenal artery was performed. Hemoglobin dropped to 6.3 and a repeat EGD showed active oozing from the duodenal ulcer. Hemospray was applied with hemostasis achieved. Discharge followed without further episodes of bleeding. EGD performed two months later demonstrated complete healing of the duodenal bulb ulcer. Hemoglobin was 12.8 (two months post-discharge).

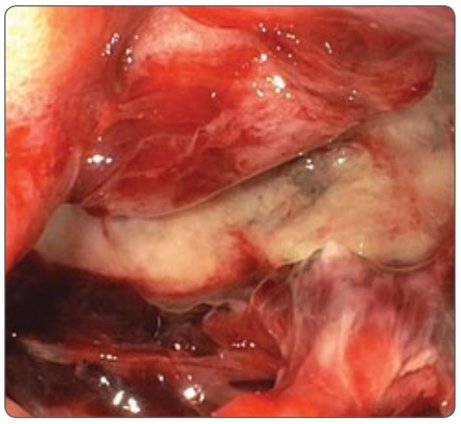

Figure 1. Excavated duodenal bulb ulcer with an adherent clot.

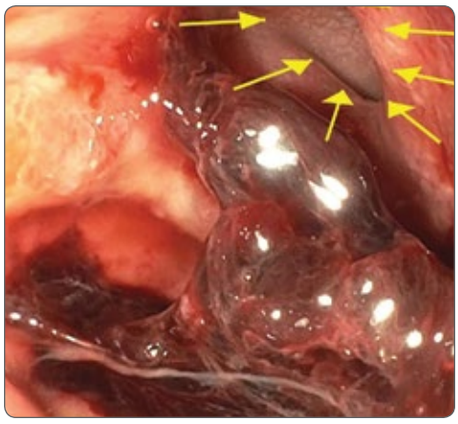

Figure 2. Duodenal ulcer with no overt bleeding.

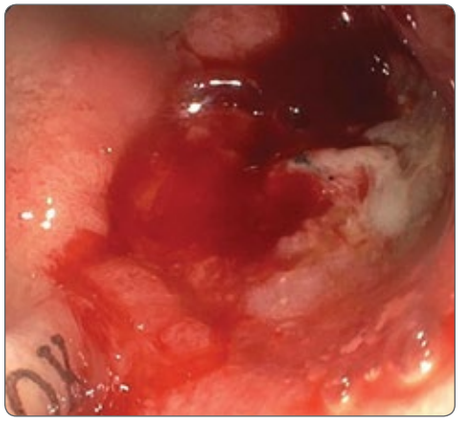

Figure 3. Duodenal bulb ulcer oozing blood.

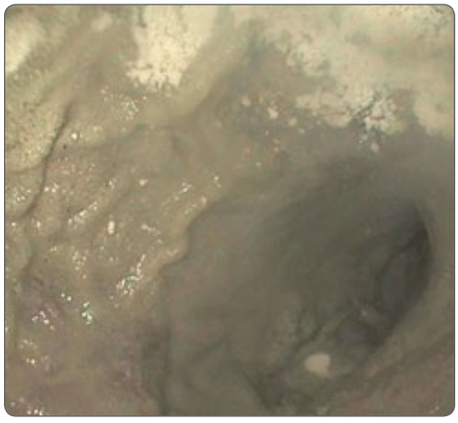

Figure 4. Hemospray applied with cessation of bleeding.

In this case, Hemospray was successfully applied to an actively oozing deep duodenal bulb ulcer. Hemostasis was achieved without giving blood transfusions (due to religious reasons), and the duodenal ulcer appeared completely healed upon follow-up endoscopy.

Hemospray provided a protective barrier to prevent further bleeding and potentially promote mucosal healing.

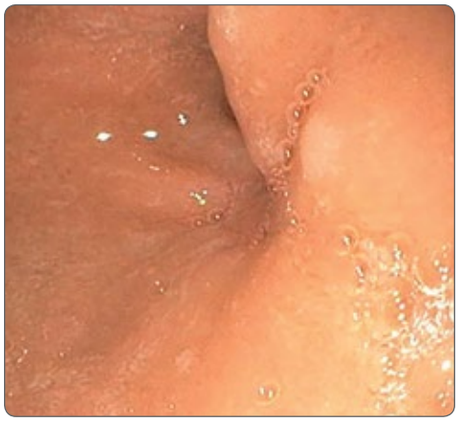

Figure 5. Complete healing of duodenal mucosa (follow-up endoscopy at 2 months).

Dieulafoy's lesion and its treatment challenges

Active bleed management and lesion location call for a new device decision

Ajay Jain, MD, FRCPC, FACG

Gastroenterologist
Therapeutic Endoscopy
Meridian Medical Group, PC
Indiana University Health – Methodist Hospital

Our 85-year-old patient had a history of atrial flutter treated with apixaban, coronary artery disease, pacemaker placement, situs inversus totalis, hypertension and transient ischemia attack. After undergoing exploratory laparotomy and small bowel resection secondary to small bowel obstruction, discharge occurred to a rehab facility.

At our institution, the patient presented for evaluation of a near syncopal event, melena and maroon-colored stools. With a hemoglobin of 5.8 gm/dL on admission, we administered two units of packed red blood cells, arranged ICU admission and intubated for airway control and performed emergent EGD that revealed fresh blood in the duodenum. However, no site of bleeding was identified with irrigation. There was diffuse erythema, inflammation of the gastric fundus and views of the gastric mucosa were largely obscured due to the presence of several large dark red clots in the gastric lumen. An abdominal CT scan with bleeding protocol was negative for site of bleeding.

After two days of monitoring, during which the patient remained stable, we performed a second-look endoscopy with no further clinical evidence of re-bleeding. This revealed a clot within the gastric fundus that then subsequently started to ooze followed by active bleeding via a spurting vessel and consistent with a Dieulafoy's lesion. Two metal clips were deployed but given the relatively poor angle, they did not adhere well to the mucosa. A third metal clip was placed that slowed the rate of bleeding. As a result, we applied Hemospray to the actively bleeding site and hemostasis was achieved. The site was observed for several additional minutes and no further bleeding was noted. The patient remained stable without clinical evidence of bleeding and was discharged from hospital three days later.

Treating a lesion such as a Dieulafoy in the gastric fundus can be technically challenging as the scope is usually in the retroflexed position. Placement of a metal clip proved to be difficult. The use of Hemospray provided a distinct advantage in this particular situation given the aggressiveness of this arterial bleeding site in a technically challenging location.

Dr. Ajay Jain is not a paid consultant of Cook Medical.

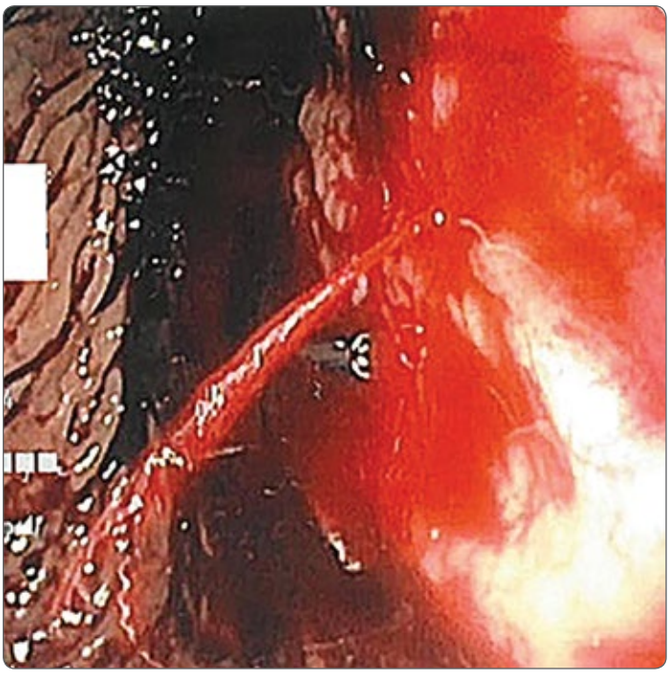

Figure 1. Torrential arterial bleed from the proximal aspect of the gastric body.

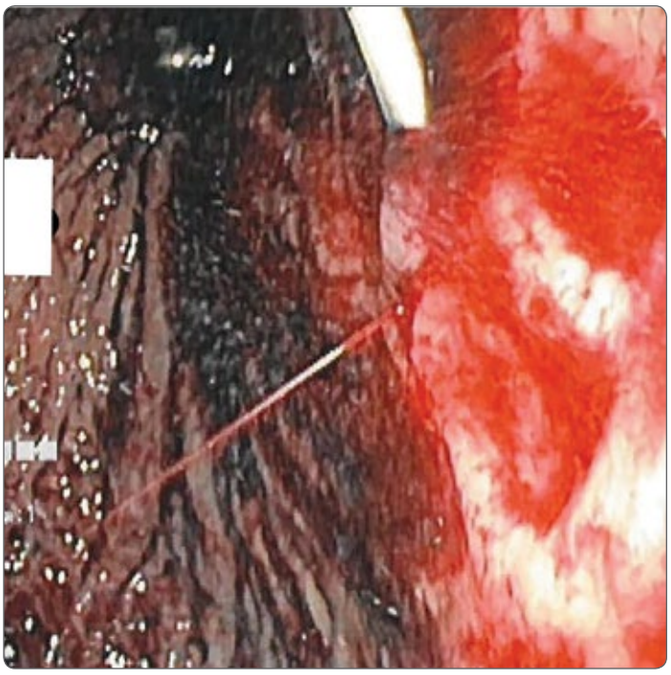

Figure 2. Persistent active bleeding after deployment of metal clips where views were obscured by active bleeding in a technically challenging position (scope in retroflexion).

Figure 3. Endoscopic view of site after application of Hemospray. Hemostasis was maintained after observation of the site for two minutes.

SPECIAL FEATURE

Endoscopic Stricture Remodeling

Stent management of post-liver transplant biliary stricture

Endoscopic therapeutic management of post-liver transplant biliary strictures has become an important treatment option for these patients. The Channel recently had an opportunity to speak with Dr. Bradley Confer (*pictured right*) and Dr. Harshit Khara (*pictured left*) of Geisinger Health about the challenges these strictures can present and how stent placement decisions are changing outcomes for these patients. In addition to offering their thoughts on latest treatment trends, both physicians share case reports discussing specific examples of their respective approach to stricture management intervention.

Q&A

with

Dr. Bradley Confer

What are some of the main risk factors for post-transplant strictures?

Biliary anastomotic strictures (BAS) occur in 8 to 20% of patients undergoing LT. BAS are classified either as early (≤60 days after LT) or late (≥1 year after LT). Early BAS is usually related to technical factors during surgery such as increased suture tension on the duct to duct anastomosis. Late BAS strictures are mainly related to ischemia and vascular insufficiency. The etiology of the underlying ischemic event is broad including hepatic artery thrombosis or stenosis, ischemia/reperfusion injury, prolonged cold ischemia time, infections such as cytomegalovirus, small caliber bile duct and donor-recipient duct mismatch.

Can you share some key points regarding the treatment algorithm for these patients?

*The current treatment algorithm for managing BAS in most cases involves ERCP with hydrostatic balloon dilation and placement of progressively more plastic stents until resolution of the stricture. ERCP is routinely repeated every 3 months with a total stent time of usually 12-24 months. The primary success rate after this period and usually 4-6 ERCP procedures is around 90 to 95%.

What stent characteristics factor into selection decisions for treating these patients, and how does this correlate with the multiple stent placements often seen in these cases?

In many liver transplant centers in the United States, the current trend is to deploy an increasing number of multiple plastic stents (MPS). The usual preference is to attempt placement of a larger diameter stent such as a 10 Fr stent, which may afford a longer time to occlusion compared to a 7 Fr stent. My personal preference is to use the Cook Fusion OASIS One Action Stent Introduction System as it allows rapid placement of multiple plastic stents without the need to cannulate the bile duct after each stent placement.

There is now a paucity of data including some well-done randomized control trials demonstrating that covered self-expandable metal stents (cSEMs) yielded a similar rate of stricture resolution compared to MPS. The main utility of cSEMs in the most recent randomized control trial is that significantly fewer number of ERCPs are needed until stricture resolution (2 ERCP in cSEMs group vs 4 ERCP in MPS group ($P < 0.001$)). A concern with cSEMs is the risk of inward migration and if there is truly a cost benefit compared to MPS. First line therapy with cSEMs in many centers in the U.S. has not been adopted for a variety of reasons. My feeling is that with the emergence of more high quality randomized studies and evolving characteristics of cSEMs within the next several years cSEMs placement will likely supplant MPS as initial therapy for BAS.

What are the major long-term management challenges in the event of stricture development?

The main long-term challenge for patients with BAS is failure to resolve the stricture or stricture recurrence. Fortunately, the former is a rare situation with either MPS or cSEMs and occurs in < 5% of BAS. When the stricture fails to resolve, options include continued stent exchanges (usually cSEMs) via ERCP or surgical revision (repair of anastomosis or Roux-en-Y choledochojejunostomy). Stricture recurrence is common and can be seen in 20 to 30% of patients usually within 1-2 years and most commonly manifests with recurrent elevation in liver enzymes. Treatment with repeat ERCPs and hydrostatic balloon dilation and stenting has a high success rate. It is important to manage recurrent BAS aggressively as progression can lead to secondary biliary cirrhosis and failure of the allograft.

*See references on page 10

Post-transplant multiple stent placement

Resolution of severe anastomotic biliary stricture

Bradley Confer, DO

Geisinger Medical Center
Danville, PA

A 73-year-old patient who is one-year post-liver transplant (LT) for alcohol-induced cirrhosis was referred for ERCP for evaluation of abnormal liver tests. The labs at the time of referral revealed an AST 139 U/L (normal 10-50 U/L), ALT 174 U/L (10-50 U/L), alkaline phosphatase 669 U/L (0-153 U/L), and bilirubin 0.6 mg/dL (0-1.2 mg/dL). In addition, a right upper quadrant ultrasound revealed new mild intra-hepatic biliary dilation.

The patient underwent successful ERCP, which revealed a severe anastomotic biliary stricture (Figure 1). After biliary sphincterotomy the anastomotic stricture was dilated with a 4.8-6 Fr tapered dilating catheter followed by a 6-mm hydrostatic balloon and then placement of a 10 Fr x 10 cm plastic Cotton-Leung Biliary Stent across the stricture.

Liver tests subsequently normalized. A repeat ERCP in 3 months revealed a moderate persistent anastomotic stricture which was dilated to 8 mm with a hydrostatic balloon and three plastic stents were placed (two 10 Fr x 10 cm and one 7 Fr x 10 cm).

The patient continued to do well with normal liver tests. Repeat ERCP in 4 months showed mild persistent anastomotic stricture (Figure 2) which was dilated with a 10 mm hydrostatic balloon and five plastic stents were placed (four 10 Fr x 10 cm and one 7 Fr x 10 cm) (Figures 3a and 3b). Subsequent ERCP in 4 months demonstrated the previously placed, partially occluded stents (Figure 4) and complete resolution of the anastomotic stricture (Figure 5).

Dr. Bradley Confer is not a paid consultant of Cook Medical.

*References for Q & A on page 9

1. Stratta RJ, Wood RP, Langnas AN, et al. Diagnosis and Treatment of Biliary Tract Complications After Orthoptic Liver Transplantation. Surgery 1989; 106: 675-683.
2. Tabibian JH, Asham EH, Han S, et al. Endoscopic Treatment of Postorthotopic Liver Transplantation Anastomotic Biliary Strictures with Maximal Stent Therapy (with video). Gastrointest Endosc 2010; 71: 505-512.
3. Oliver Tal A, Finkelmeier F, Filmann N, et al. Multiple Plastic Stents Versus Covered Metal Stent for Treatment of Anastomotic Biliary Strictures After Liver Transplantation: A Prospective, Randomized Multicenter Trial. Gastrointest Endosc 2017; 86: 1038-1045.
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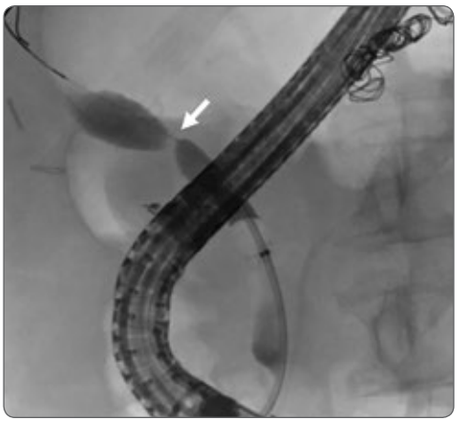

Figure 1. Arrow demonstrates severe biliary anastomotic stricture.

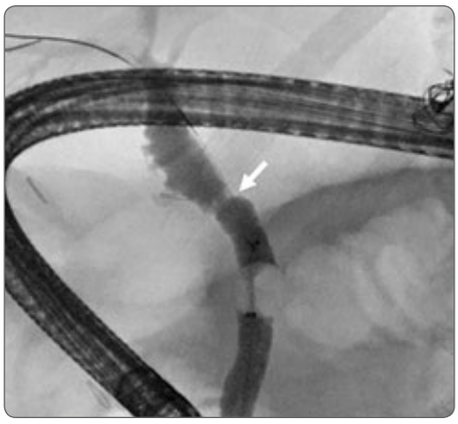

Figure 2. Arrow demonstrates mild persistent biliary anastomotic stricture.

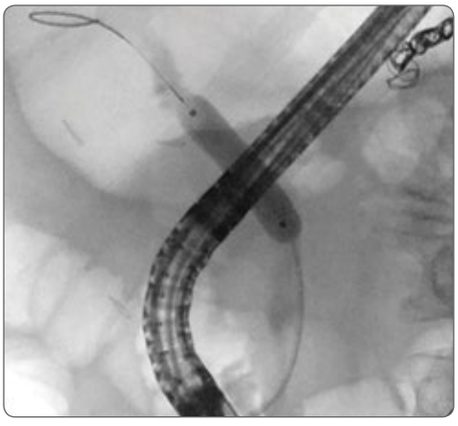

Figure 3a. Shows 10 mm hydrostatic balloon dilation of anastomotic stricture.

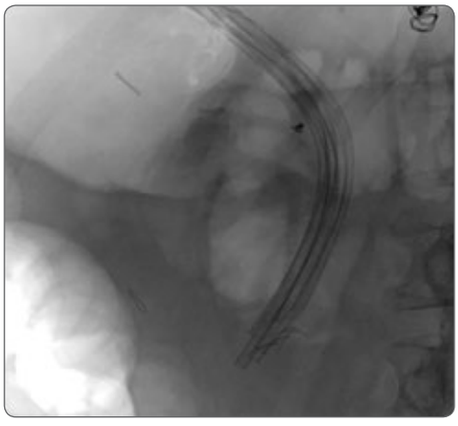

Figure 3b. Fluoroscopy image demonstrating the five plastic Cotton-Leung Biliary Stents bridging the stricture.

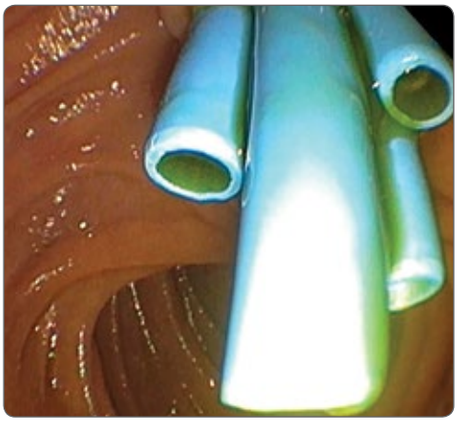

Figure 4. Demonstrates transpapillary and ex vivo view of the plastic Cotton-Leung Biliary Stents.

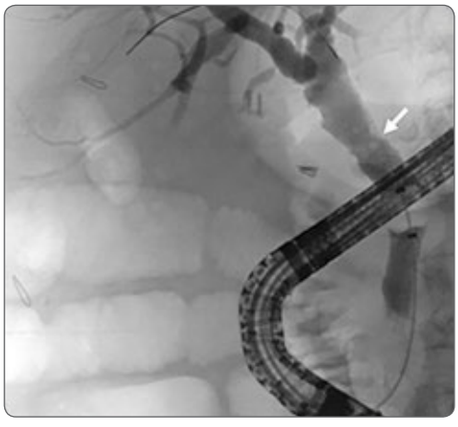

Figure 5. Cholangiogram revealing resolved anastomotic stricture.

Placing multiple stents to decrease procedure frequency

Stent placement considerations post-liver transplant

Harshit S. Khara, MD, FACG

Clinical Assistant Professor of Medicine
Director of Endoscopic and Translational Research
Advanced Therapeutic Endoscopy
Geisinger Medical Center
Danville, PA

A 58-year-old previously underwent an orthotopic liver transplant with a duct-to-duct biliary anastomosis. Two years post-transplant, the patient had elevated liver enzymes with imaging showing intrahepatic biliary ductal dilation, which was not attributed to infection or rejection. An ERCP showed a benign biliary anastomotic stricture, for which treatment involved 10 Fr plastic Cotton-Leung Stent placement.

Our patient has undergone multiple ERCPs since then with sequential increase in the stent number as well as balloon dilations with hopes to remodel the stricture. With each increase in the stent number, the stent deployment technically gets more and more difficult. The patient also had a trial of a 10 mm x 8 cm fully covered self-expanding metal biliary stent placement, which was unsuccessful due to acute right-angle turn that the biliary anastomosis makes, resulting in downward stent displacement below the stricture. We have also pursued a treatment plan having sequential increase in balloon dilation of stenosis with sizes up to 15 mm.

At the time of the most recent ERCP, a plan was made to maximize the number of 10 Fr plastic Cotton-Leung Biliary Stents that could be placed so as to decrease the frequency of the procedures and maximize the stretch needed for stricture remodeling. This makes it more technically challenging to keep biliary access with each stent placement and maximize the number of stents that can be placed side-by-side.

We employed the use of the Cook Medical OASIS One Action Stent Introduction System and were able to successfully place seven 10 Fr plastic biliary stents with internal and external flaps of varying lengths (one 10 Fr x 12 cm, three 10 Fr x 11 cm, three 10 Fr x 10 cm) so as to stagger the tops of the stents. The benefit of this system is that we were able to push multiple stents over the same wire without ever once losing biliary access and thus making the procedure more technically safe and easier.

Dr. Khara is not a paid consultant of Cook Medical.

Biliary strictures are observed in about 32% of post-orthotopic liver transplant patients after living donor transplantations.[1] Until recently, surgery had been the standard of care for treatment of these strictures, but innovation and availability of devices, such as the Cook Fusion OASIS, has made endoscopic stricture remodeling the new standard of care, with surgery limited to failed endoscopic response patients only[2]. However, ERCP needs to be repeated every 3 months to assess the response to stenting and minimize the risk of stent occlusion, development of cholangitis or stone formation above the stricture[3].

In the event of a refractory stricture, increasing number of stents could be placed at each follow-up procedure to continue stricture remodeling and prior reports describe the use of two to four plastic stents, with an average number of 2.8 stents, with an average success rate of 87.2%, compared to 61.8% with metal stents[4].

Our case is even more interesting as we have been able to gradually increase the patient's stents from initially two plastic stents, up to now seven 10 Fr plastic Cotton-Leung Biliary Stents in a single setting using the Fusion OASIS system.

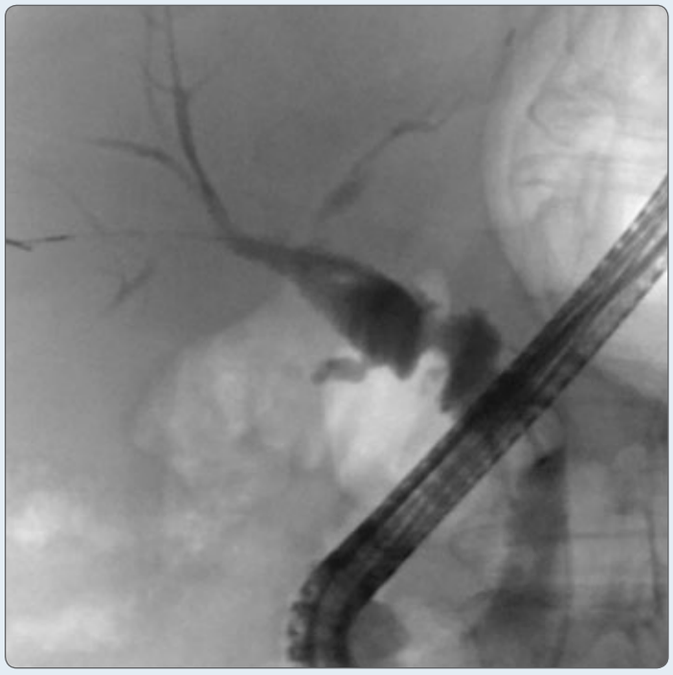

Figure 1. ERCP cholangiogram showing persistent refractory biliary stricture at the duct-to-duct post-transplant anastomosis.

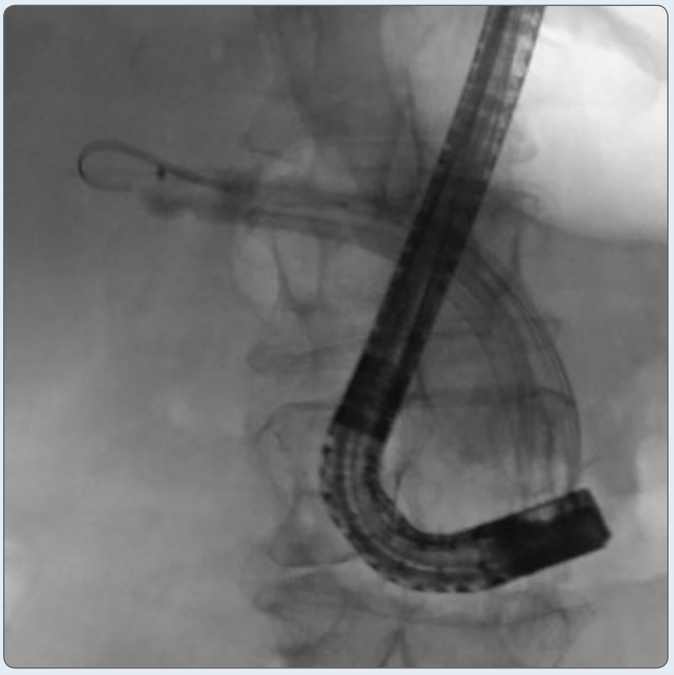

Figure 2. Multiple 10 Fr plastic stents placed under fluoroscopic guidance using the OASIS One Action Stent Introduction System platform to maintain wire guide access across the stricture.

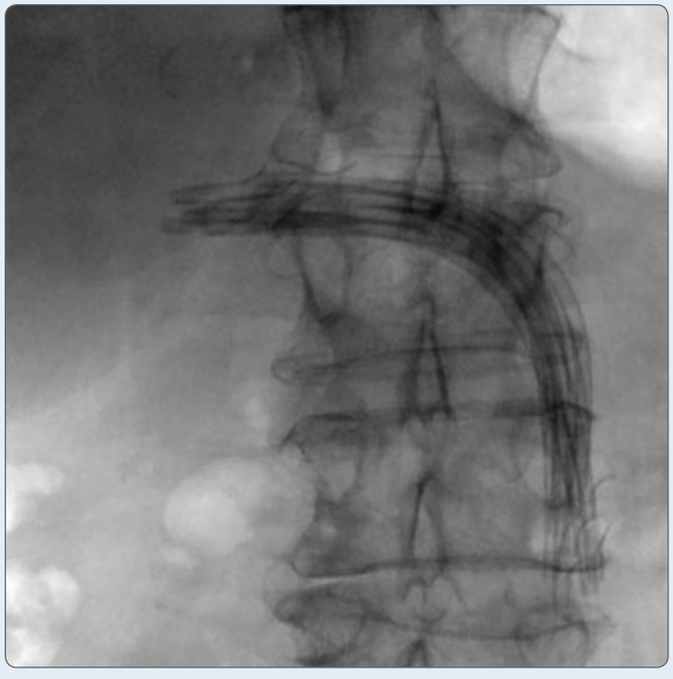

Figure 3. Fluoroscopic view of successful side-by-side placement of seven 10 Fr plastic Cotton-Leung Biliary Stents for stricture remodeling.

Figure 4. Endoscopic view of the OASIS One Action Stent Introduction System platform for side-by-side placement of multiple plastic stents.

Figure 5. Final endoscopic view of seven 10 Fr transpapillary plastic Cotton-Leung Biliary Stents for anatomic biliary stricture remodeling.

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A multicenter randomized trial comparing a 25-gauge EUS fine-needle aspiration device with a 20-gauge EUS fine-needle biopsy device.[1]

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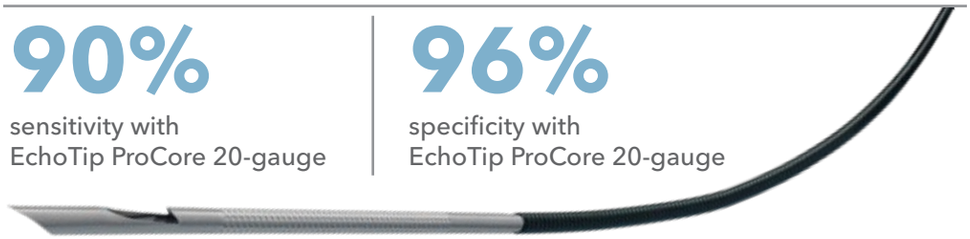
96%

specificity with EchoTip ProCore 20-gauge



13

participating centers

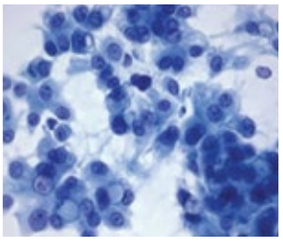
Reference:

[1]van Riet PA, Larghi A, Attili F, Rindi G, Nguyen NQ, Ruszkiewicz A, Kitano M, Chikugo T, Aslanian H, Farrell J, Robert M, Adeniran A, van der Merwe S, Roskams T, Chang K, Lin F, Lee JG, Arcidiacono PG, Petrone M, Doglioni C, Iglesias-Garcia J, Abdulkader I, Giovannini M, Bories E, Poizat F, Santo E, Scapa E, Marmor S, Bucobo JC, Buscaglia JM, Heimann A, Wu M, Baldaque- Silva F, Moro CF, Erler NS, Biermann K, Poley JW, Cahen DL, Bruno MJ. Gastrointestinal Endoscopy, 2019 Feb; 89(2):329–339.

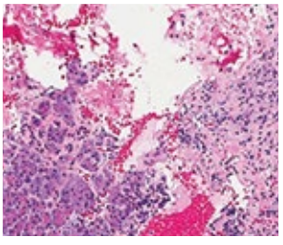
This study was supported by a restricted grant from Cook Medical. Cook Medical had no influence over study design or final results reported.

Cytology, cell block or core: Results you can see.

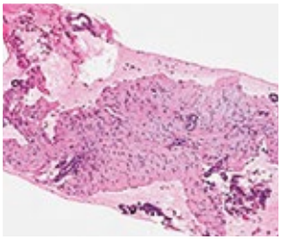
Balancing sample capacity and needle flexibility, Cook's EUS needles allow you to target small lesions in even the most difficult locations, while increasing valuable yields with potentially fewer needle passes.



Cytology



Cell Block



Core

EchoTip ProCore®

HD ULTRASOUND BIOPSY NEEDLE

EchoTip® Ultra

ENDOSCOPIC ULTRASOUND NEEDLE

Pathology images courtesy of James Farrell, MD
Interventional Endoscopy and Pancreatic Diseases Section of Digestive Diseases,
Yale University School of Medicine.

2019 SPRING/SUMMER EVENTS

MAY		
18 - 21	DDW	**San Diego, California**
31 - 2	JGES	**Tokyo, Japan**
JUNE		
13 - 15	IMAGE Live Endoscopy 2019	**Milano, Italy**
16 - 18	GEEW	**Brussels, Belgium**
AUGUST		
29 - 31	Central America and Caribbean Gastroenterology and Endoscopy Congress	**Tegucigalpa, Honduras**

2019 FALL EVENTS

SEPTEMBER		
8 - 10	Australian Gastroenterology Week (AGW)	**Adelaide, Australia**
11 - 13	National Congress in Gastroenterology and Endoscopy	**Mendoza, Argentina**
19 - 20	EUS-ENDO International Live Course	**Marseille, France**
OCTOBER		
2 - 5	DGVS 2019	**Wiesbaden, Germany**
19 - 23	UEGW	**Barcelona, Spain**
27 - 29	ACG	**San Antonio, Texas**

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We welcome your comments and suggestions.