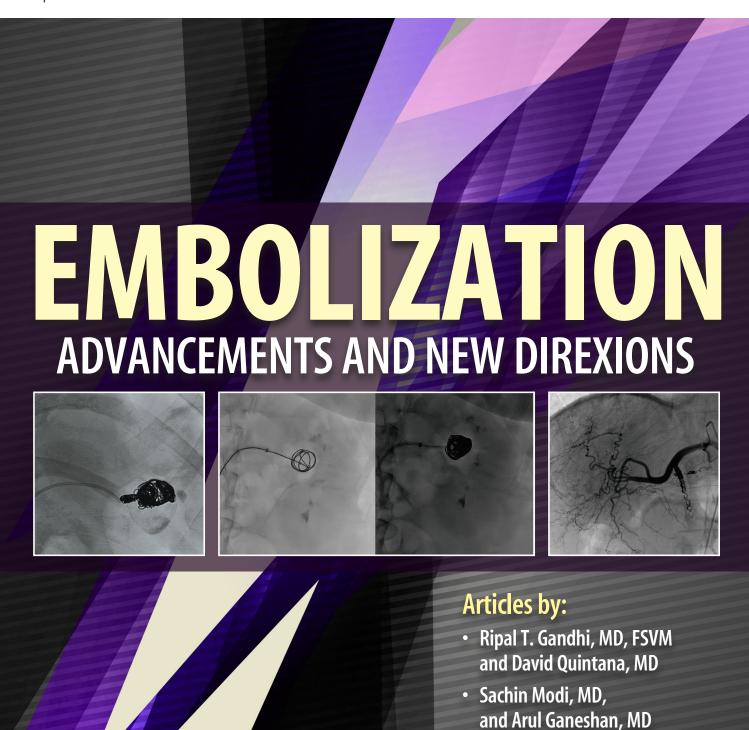
• Florian Wolf, MD, EBIR, EBCR

David L. Smoger, MD

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Utility of Detachable Coils in Renal and Splenic Artery Aneurysms and Gastric Artery Pre-Radioembolization

BY RIPAL T. GANDHI, MD, FSVM, AND DAVID QUINTANA, MD

mbolization is essential to the treatment of various pathologies, including aneurysms, traumatic hemorrhage, arteriovenous malformations, gastro-intestinal hemorrhage, endoleaks, varicoceles, and pelvic congestion syndrome. Embolization of the gastroduodenal artery and right gastric artery is considered the standard of care prior to yttrium-90 radioembolization. An ideal embolic agent is flexible, stable, trackable, repositionable, cost-effective, and allows for precise deployment and rapid vascular occlusion. The Interlock™ Fibered IDC™ Occlusion System meets these characteristics and is approved for use in the peripheral vasculature. The following cases demonstrate the clinical utility of these detachable coils.

CASE 1: RENAL ARTERY ANEURYSM Overview

A 54-year-old woman with a history of fibromuscular dysplasia was found to have bilateral renal artery aneurysms. The patient presented for treatment of a 2.2-cm left renal artery aneurysm arising from the hilum.

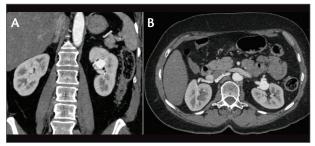


Figure 1. Coronal (A) and axial (B) images showing a complex aneurysm, measuring approximately 2.2 cm and arising from the left renal hilum. There were several outflow vessels arising from the aneurysm. A right renal stent and right renal aneurysm, both incompletely visualized, were also noted.

Computed tomography (CT) angiography showed that the aneurysm was complex, involving a single inflow but multiple outflow vessels (Figure 1).

Procedure Description

A 9-F sheath was placed in the right common femoral artery, and a robotic catheter was used in conjunction with a 0.035-inch hydrophilic guidewire to catheterize the left renal artery (Figure 2). A left renal angiogram showed classic beading of the main left renal artery, consistent with the known history of fibromuscular dysplasia as well as a saccular aneurysm in the distal left renal artery near the hilum with several arterial branches emanating from the aneurysm sac (Figure 3).

After rotational angiography to better define the arterial anatomy, two 18-mm X 40-cm Interlock™ Coils were advanced under fluoroscopic guidance into the aneurysm sac. A final 15-mm X 40-cm Interlock™ Coil was deployed within the aneurysm sac (Figure 4). Intermittent angiography was performed between coils to ensure that the coils did not occlude the outflow vessels. The



Figure 2. A robotic catheter was used to catheterize the left renal artery.

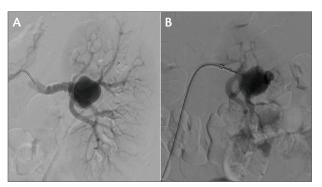


Figure 3. There is a classic beaded appearance of the main left renal artery compatible with fibromuscular dysplasia (A). Several arteries emanating from the aneurysm sac were also noted (B).

postembolization angiogram showed occlusion of the aneurysm without compromise of the adjacent renal branches (Figure 5). No filling defects or wedge-shaped areas of nonperfusion were identified to suggest renal parenchymal infarct.

Discussion

Renal artery aneurysms have a prevalence of 0.1% and are more frequent in women. Etiologies include fibromuscular dysplasia, atherosclerosis, trauma, and iatrogenic injury. Indications for treatment include patients who are symptomatic (eg, rupture, hypertension, hematuria, pain), women who are pregnant or are of child-bearing age, asymptomatic patients with aneurysms > 2 cm, and aneurysms associated with dissection.

Endovascular treatment of renal and visceral aneurysms has been shown to be safe and effective. 1,2 The detachable aspect of the Interlock™ Coil was critical in this case, as occlusion of adjacent renal branches would have resulted in renal infarction. This characteristic allowed for partial deployment followed by coil withdrawal and repositioning until an optimal coil position was attained. Given the precarious location of the aneurysm, the ability to densely pack the aneurysm with repositioning as necessary was key in achieving a successful outcome.

A recent study by Yasumoto et al demonstrated that

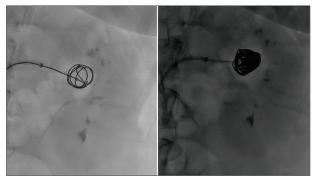


Figure 4. Coil embolization was performed with Interlock™
Coils via the robotic catheter until dense packing was achieved. Repositioning was performed during the procedure to achieve optimal positioning of the coils.

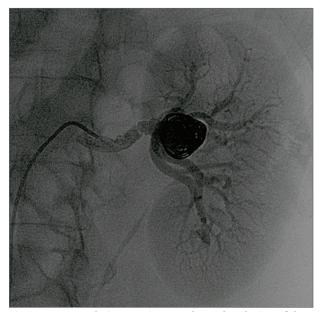


Figure 5. A completion arteriogram showed exclusion of the left renal artery aneurysm and normal opacification of the left renal artery. There were no wedge-shaped areas of nonperfusion identified to suggest renal parenchymal infarct.

inadequate coil packing in visceral aneurysms results in coil compaction and recanalization, underscoring the need to densely pack these aneurysms to achieve long-term success.³

CASE 2: SPLENIC ARTERY ANEURYSM WITH DISTAL EMBOLIZATION

Overview

A 49-year-old woman with no significant medical history presented to the emergency room with severe left-sided abdominal pain. Because the patient was allergic

to iodine, a noncontrast CT scan of the abdomen was performed, which showed a calcified 2.5-cm splenic artery aneurysm without evidence of rupture (Figure 6A). A subsequent abdominal magnetic resonance imaging scan and magnetic resonance angiogram (Figures 6B and 7) again showed the splenic aneurysm with some luminal

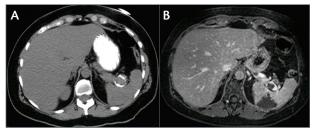


Figure 6. Noncontrast CT scan showing a 2.5-cm calcified distal splenic artery aneurysm with no evidence of hemoperitoneum to suggest rupture (A). A magnetic resonance imaging scan with contrast shows a distal splenic artery aneurysm with intraluminal thrombus and associated wedge-shaped splenic infarction (B).

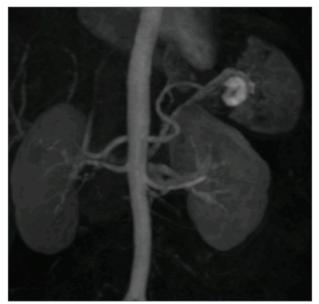


Figure 7. A magnetic resonance angiogram again showing a distal splenic artery aneurysm with some intraluminal thrombus.

thrombus, as well as a wedge-shaped splenic infarction responsible for the patient's abdominal pain.

Procedure Description

After steroid premedication for contrast allergy and administration of pneumococcal vaccine, the right common femoral artery was accessed and a celiac angiogram was obtained with a reverse curved catheter. Figure 8 shows a distal splenic aneurysm arising from the superior branch of the splenic artery. The aneurysm was successfully embolized with three 15-mm X 40-cm Interlock™ Coils, followed by a 6-mm proximal coil (Figure 9). Completion angiography showed complete exclusion of the embolized aneurysm with a small area of nonperfusion to the superior spleen consistent with small infarction (Figure 10).



Figure 8. An angiogram showing a distal splenic aneurysm arising from the superior branch of the splenic artery.

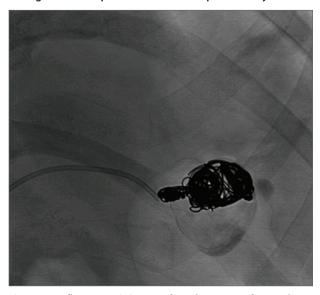


Figure 9. A fluoroscopic image after placement of several Interlock $^{\text{TM}}$ Coils.

The patient tolerated the procedure well and developed no procedural complications. She was treated with antibiotics after the procedure to minimize the risk of infection and abscess.

Discussion

Splenic artery aneurysms are the most common type of visceral aneurysms and are more commonly found in women. Predisposing conditions believed to contribute to the development of these aneurysms include

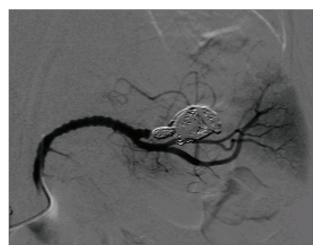


Figure 10. Completion angiogram showing complete exclusion of the embolized aneurysm with a small area of nonperfusion to the superior spleen compatible with small infarction.

medial fibroplasia, pregnancy, and portal hypertension. Splenic pseudoaneuryms are due to pancreatitis, trauma, or infection. Approximately 2% of bland splenic aneurysms rupture; however, when rupture occurs, the

mortality rate is high, especially in patients who are pregnant.

Patients may be symptomatic from rupture or as a result of distal embolization from intraluminal thrombus formation, as in our patient. Indications for therapy include patients who are symptomatic, women who are pregnant or may become pregnant, patients with portal hypertension or status post liver transplantation, and asymptomatic patients with aneurysms > 2 cm. Pseudoaneurysms of any size should be treated.

The long length of the Interlock™ Coils (40 cm) resulted in rapid aneurysm exclusion and necessitated fewer coils than would be required with shorter, pushable coils. The synthetic fibers embedded on these coils also contribute to the system's thrombogenicity, decreasing the time to achieve vascular occlusion. An additional benefit of the Interlock™ Coil delivery system is its ease of use. In contrast to many other detachable coils, which require a special deployment device, the Interlock™ Coil is simply released by pushing the coil beyond the microcatheter. The coil and pusher have interlocking mechanical arms. As long as the operator maintains the mechanical interlocking arms of the coil within the microcatheter, the coil can be retracted for repositioning.

CASE 3: PRE-YTTRIUM 90 EMBOLIZATION OF GASTRODUODENAL ARTERY AND RIGHT GASTRIC ARTERY

Overview

A 66-year-old man with a history of hepatitis C and cirrhosis presented with multifocal hepatocellular carcinoma. A decision was made to perform yttrium-90 radioembolization to help control his disease. The patient had intermediate stage B disease per the Barcelona Clinic Liver Cancer Staging system and had a preserved performance status. Of note, his liver function tests were within normal limits and the portal vein was patent.

Procedure Description

A 5-F vascular sheath was placed via the right common femoral artery, and a celiac angiogram was obtained with a 5-F Cobra-2 catheter (Figure 11). Several hypervascular masses were identified in the right and left hepatic lobes. A typical gastroduodenal artery (GDA) and a small right gastric artery arising just distal to the GDA were also noted. Using a Fathom®-16 Steerable Guidewire, the right gastric artery was selected with a 2.8-F Direxion HI-FLO™ Microcatheter and a selective angiogram was obtained (Figure 12). The right gastric artery was then embolized with a 3-mm X 12-cm Interlock™ Coil, and the GDA was subsequently selected and embolized with 5-mm X 15-cm and 4-mm X 15-cm Interlock™



Figure 11. Celiac angiogram showing multiple bilobar hypervascular masses in the liver. A typical GDA and a small right gastric artery arising just distal to the GDA were also noted.

Coils. Common hepatic angiography after embolization showed successful occlusion of these vessels (Figure 13).

Discussion

After embolization, Tc-MAA administered into the proper hepatic artery demonstrated no significant pulmonary or extra-hepatic shunting, and the patient underwent uncomplicated radioembolization of the right hepatic lobe

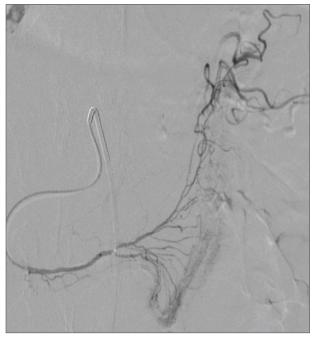


Figure 12. A selective right gastric angiogram via a Direxion HI-FLO™ Torqueable Microcatheter.

followed by the left hepatic lobe. His hepatocellular carcinoma was stabilized with this treatment.

The Interlock™ Coils were placed rapidly and effectively with precision, potentially decreasing procedure time and radiation exposure. The ability to precisely control the deployment of the Interlock™ Coils is specifically advantageous in these procedures should the coil be undersized or oversized for the given vessel, allowing for repositioning and precluding non-target embolization.

The Bern-shape Direxion HI-FLO™ Microcatheter used in this case has a unique shaft that allows for unrivaled torqueability compared to any other microcatheter. During the procedure, there was near 1:1 tip response to hub rotation, which was particularly helpful in catheterizing the challenging right gastric artery in this patient. In addition to its torqueability, the microcatheter demonstrated excellent flexibility and trackability. ■

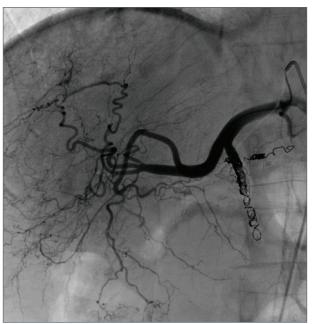


Figure 13. Postembolization common hepatic angiogram showing successful occlusion of the GDA and right gastric artery with Interlock™ Coils.

Ripal T. Gandhi, MD, FSVM, is with Baptist Cardiac and Vascular Institute in Miami, Florida. He has disclosed that he is a consultant to Boston Scientific Corporation and received compensation for the time required to identify, organize, and summarize the case information within the manuscript. Dr. Gandhi may be reached at gandhi@baptisthealth.net.

David Quintana, MD, is with University of Miami Miller School of Medicine in Miami, Florida. Dr. Quintana received no compensation related to this article.

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 $^{2.\} Fankhauser\ GT, Stone\ WM,\ Naidu\ SG,\ et\ al.\ The\ minimally\ invasive\ management\ of\ visceral\ artery\ aneurysms\ and\ pseudoaneurysms.\ J\ Vasc\ Surg.\ 2011;53:966-970.$

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vessel dissection or perforation) • Pain • Hemorrhage • Infection necessitating medical intervention • Foreign body reactions necessitating medical intervention • Emboli • Ischemia • Vassoppasm • Insue necrosis • Undesirable clot formation of the vasculature • Claudication • Recanalization • Death • Temporary neurological deficit. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events and Operators Instructions.

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Embolization of a Large Pulmonary Arteriovenous Malformation

BY SACHIN MODI, MD, AND ARUL GANESHAN, MD

ulmonary arteriovenous malformations (PAVMs) are abnormal communications between pulmonary arteries and pulmonary veins, leading to the formation of an extracardiac right-to-left shunt. These rare lesions are most commonly congenital in nature, but the exact pathogenesis is uncertain. Although it is assumed that the vascular defects are present at birth, they seldom manifest clinically until adulthood, when the vessels have been subject to pressure over several decades. Complications of PAVMs include cyanosis, high-output congestive cardiac failure, hemorrhage, polycythemia, and cerebral embolism/abscess.

Hereditary hemorrhagic telangiectasia (HHT), or Osler-Weber-Rendu disease, is a rare genetic condition in which patients have abnormalities in blood vessel formation in the skin, mucous membranes, and organs such as the lungs. Approximately 50% of patients with the condition will have PAVMs. Current treatment of PAVMs includes endovascular embolization or surgical resection.

CASE PRESENTATION

A 50-year-old man with known HHT and multiple PAVMs was referred to our center from a regional hospital. Aside from regular minor nosebleeds, he was otherwise fit and well. He had presented to his local hospital with debilitating shortness of breath, which had developed over the last few months. He was unable to ascend stairs or walk for long periods without feeling short of breath. He underwent contrast-enhanced CT of the thorax, which revealed multiple bilateral PAVMs (four in the left lung and three in the right lung). One of the AVMs in the right lower lobe was extremely large, with the artery measuring 7 mm and the draining vein 10 mm (Figure 1).

The patient was seen in the interventional radiology clinic, and embolization of the AVMs was discussed in detail; the patient was subsequently scheduled for the procedure.



Figure 1. A CT scan of the thorax showing a large, right lower lobe PAVM with a large draining vein.

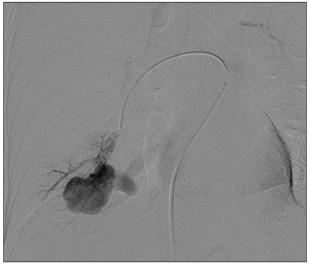


Figure 2. An angiogram of the right lower lobe pulmonary artery confirming the presence of the AVM with a large draining vein.



Figure 3. After embolization with three Interlock™ Coils, there was complete occlusion of the draining vein.

PROCEDURE DESCRIPTION

Using ultrasound guidance, the right common femoral vein was accessed. A wire and catheter were negotiated into the right main pulmonary artery, and a diagnostic angiogram confirmed the presence of a large, right lower lobe PAVM with a large, rapidly draining vein (Figure 2).

A branch of the right lower lobe pulmonary artery was catheterized using an 0.021-inch inner diameter, two-RO marker, 130-cm length Direxion™ Microcatheter and an 0.016-inch Fathom® Steerable Guidewire, followed by selective catheterization of the PAVM distal arterial limb and venous nidus. Embolization was carried out using three 0.018-inch Interlock™ Detachable Coils (two 22-mm X 60-cm coils and one 20-mm X 60-cm coil). The AVM was successfully embolized with no flow seen in the draining vein (Figure 3). There were no procedural complications, and the patient was discharged to home the next day after an uneventful recovery. He is due to be recalled over the next few months for similar embolizations of the remaining PAVMs.

DISCUSSION

Large PAVMs such as in this case are challenging to treat, mainly due to the size of the artery and vein, as well as the high-flow shunt with a significant risk of coil migration through the vein into the heart. Traditionally, plugs have been used for embolizing large high-flow PAVMs; however, use of the Interlock™ Detachable Coils in PAVM embolization is becoming a popular choice due to the availability of large-diameter coils (up to 22 mm).

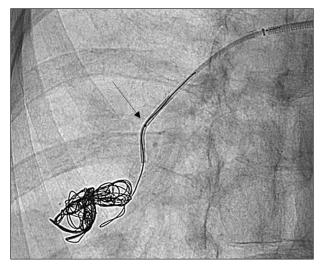


Figure 4. The Direxion™ Microcatheter with proximal marker (arrow) allowing accurate judgment of the microcatheter position.

The 0.018-inch Interlock™ Detachable Coils also enable a complex embolization procedure to be performed through a small catheter/sheath combination (4 F) with the option to retract the partially deployed coil should an unfavorable coil position be noted or evidence of periprocedure coil migration be apparent. This combination of catheters provides the additional option of performing diagnostic angiography in order to appreciate the change the partially deployed coils make to the flow dynamic of the shunt before the coils' full deployment. Because these coils are available in up to 60-cm total length, their use can facilitate cost-effective completion of the procedure with reduced radiation exposure.

The Direxion™ Microcatheter was particularly useful in this case due to the two markers on the catheter. The proximal marker gave an accurate estimate of where the distal end of the catheter was placed before deploying the coils, as it is often difficult to see due to the already deployed coils (Figure 4).

Overall, in this case of a large PAVM, we found the Direxion™ Microcatheter and Interlock™ Coils very useful aids in performing this embolization in a safe, efficient, and controlled manner. ■

Sachin Modi, MD, is a specialist registrar in interventional radiology with Heart of England NHS Trust, Birmingham, United Kingdom. Dr. Modi received no compensation related to this article.

Arul Ganeshan, MD, is a consultant interventional radiologist with Heart of England NHS Trust, Birmingham, United Kingdom. Dr. Ganeshan received no compensation related to this article.

Preoperative Embolization of Thoracic Spine Metastases

BY FLORIAN WOLF, MD, EBIR, EBCR

50-year-old man was sent to our department for preoperative embolization of a thoracic spine metastasis (Figure 1). The patient was undergoing treatment for renal cell carcinoma for 4 years. Three months before presenting to our department, a bone metastasis was diagnosed in the thoracic spine (T8 vertebra). One week before we received the patient for embolic therapy, he was symptomatic due to compression of the spinal cord. An open bone biopsy was performed 2 weeks earlier by the orthopedic surgeons, noteworthy for an intraoperative, life-threatening bleeding.

Bone metastasis is a very common finding in patients with renal cell carcinoma; those metastases are hypervascularized in the majority of cases. In the Austrian Bone and Soft Tissue Tumor Registry,¹ 20% of all patients with bone metastases showed renal cell carcinoma as a primary tumor; this is the second most common reason for bone metastases in the registry—only breast cancer metastases are more common (23%).

Clinical symptoms of bone metastases in this registry were pain (39%), fracture (27%), swelling (28%), and other (6%). In our patient, the symptoms consisted of

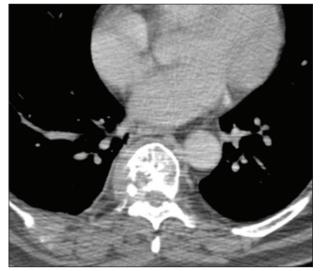


Figure 1. A contrast-enhanced CT scan of the spine metastasis with bone destruction and hypervascularized soft tissue.

neurologic symptoms due to spinal cord compression.

Preoperative embolization of metastases leads to a significant reduction of blood loss during the operation. In 2008, Kickhut et al² published that the intraoperative blood loss during operation of hypervascularized metastases was reduced from 1,788 mL after partial occlusion to 1,119 mL with complete occlusion of the feeding vessels. At our hospital, almost all hypervascularized bone metastases are preoperatively embolized.

PROCEDURE DESCRIPTION

For the embolization procedure, the right common femoral artery was accessed, and a 6-F sheath was inserted. A 5-F sidewinder I catheter was used for diagnostic angiography of the intercostal arteries and guiding catheter purposes.

As a first step, the eighth intercostal artery was probed, diagnostic angiography showed a hypervascularization with a tumor blush (Figure 2), and there were large vessels feeding the diaphragm. For the embolization procedure, a steerable, Bern-shape Direxion™ Microcatheter with a 0.021-inch inner lumen was introduced. Another diagnostic angiogram via the microcatheter was obtained, which is possible using a 2-mL syringe or an

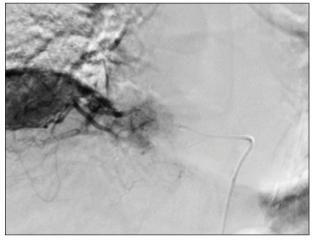


Figure 2. Hypervascularized metastasis of T8 vertebra as well as feeding vessels to the diaphragm, visualized by contrast injection into the feeding intercostal artery.

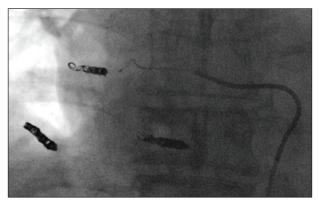


Figure 3. Multiple coils after embolization of two intercostal arteries.

automatic power injector. The right embolization position was reached using a Fathom®-16 Guidewire.

Distal to the hypervascularized tumor, three 2-mm Interlock[™]-18 Fibered Microcoils were placed via the Direxion[™] Microcatheter in order to protect the diaphragm from particle embolization (Figure 3). Using this 0.021-inch microcatheter, delivery of the Interlock[™] Fibered IDC Occlusion System is easy if the microcatheter is flushed with saline before particle or coil delivery.

Next, embolization of the tumor was performed with 100–300-µm particles until there was no more antegrade blood flow. Visibility of particles can be very low, even though they are mixed with contrast media. Especially in dangerous regions, such as the spine or the head/neck, I inject a very small amount of particles followed by a flush of contrast media in order to better visualize the particles and get an impression of the blood flow speed.

Stasis was reached quickly, and the inflow of the feeding artery was occluded using two 2-mm Interlock™-18 Fibered Microcoils. Control angiography showed a satisfying result with no remaining blood flow or tumor blush (Figure 4).

At the end of the procedure, four intercostal arteries had been embolized with particles ($100-300 \, \mu m$) and 15 total microcoils (diameters between 2 and 4 mm). The Direxion Microcatheter had to be repositioned many times in order to reach the optimal embolization position.

After the embolization procedure, there was no hypervascularized part of the tumor left (Figure 5). The patient had the operation the next day with radical resection of the thoracic spine metastases, including the metastatic soft tissue. The orthopedic surgeons reported that the tumor was "dry," with no significant intraoperative blood loss.

Florian Wolf, MD, EBIR, EBCR, is Associate Professor of Radiology, Division of Cardiovascular and Interventional Radiology, Department of Biomedical Imaging and Image-

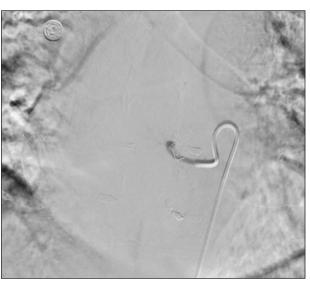


Figure 4. Control angiogram after embolization of the last of the four treated intercostal arteries.

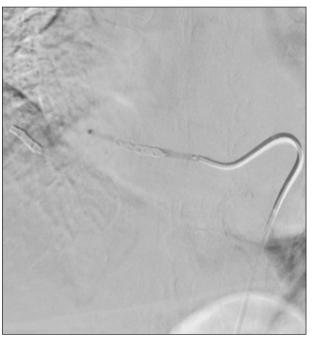


Figure 5. No hypervascularized area visible in the present intercostal artery.

Guided Therapy, Medical University of Vienna, in Vienna, Austria. He received no compensation related to this article. Dr. Wolf may be reached at florian.wolf@meduniwien.ac.at.

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CONTRAINDICATIONS: None known.

WARNING: Compatibility with Magnetic Resonance Imaging (MRI) has not beer established, and the degree of imaging distortion resulting from the coil has not been measured.

ADVERSE EVENTS: • Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, nerve and vessel dissection or perforation) • Pain • Hemorrhage • Infection necessitating medical intervention • Foreign body reactions necessitating medical intervention • Foreign body reactions necessitating medical intervention • Temboli • Ischemia • Vasospasam • Tissue necrosis •

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Embolization of an Internal Iliac Artery Aneurysm

BY DAVID L. SMOGER, MD

n 85-year-old man presented to the emergency department complaining of diffuse abdominal pain. After appropriate workup, a contrastenhanced CT abdomen/pelvis scan showed a distal esophageal tear. Figure 1 shows an incidental finding of a 7.4-cm X 6.9-cm right internal iliac artery aneurysm. The patient was admitted to the hospital for management of his distal esophageal tear and followup with another vascular service for management of the aneurysm. Before presenting to the interventional radiology department, the patient was treated with a covered stent across the origin of the internal iliac artery. Approximately 1 month later, a follow-up CT angiogram of the abdomen/pelvis showed an interval enlargement of the aneurysm, which had grown to 7.9 cm X 7.4 cm, with some increased mural thrombus (Figure 2). The sac was being backfed by the obturator artery.

Figure 1. A 7.4-cm X 6.9-cm aneurysm in the right internal iliac artery.

PROCEDURE DESCRIPTION

Under ultrasound guidance, a 5-F needle/sheath system was used to percutaneously access the aneurysm sac via the right anterior pelvis. Once the sheath was confirmed to be in place, a diagnostic angiogram was obtained (Figure 3). Exchange was made for a 5-F, Berensteinshape Imager™ Angiographic Catheter. Eight 0.035-inch Interlock™ Coils were deployed within the sac until no further contrast flow was demonstrated (Figure 4).

DISCUSSION

This case illustrates the concept of closing the "front door" as well as the "back door." The covered stent closed the "front door" (origin of the internal iliac artery), but in the face of a contributing obturator artery, the "back door" was left open, allowing for continued, pressurized growth of the aneurysm sac. Because access



Figure 2. A follow-up CT angiogram of the abdomen/pelvis approximately 1 month later showing interval enlargement of the aneurysm, now 7.9 cm X 7.4 cm, with some increased mural thrombus.



Figure 3. The initial angiogram after the sheath was confirmed to be in place.

to the sac via the traditional endovascular method was excluded by the presence of a covered stent, percutaneous access was successfully employed. The use of long, detachable Interlock™ Coils allowed for precise and quick deployment and obviated the use of many pushable coils in an aneurysm of this size. This decreased procedure time, procedural cost, and radiation exposure to both the patient and the operator. ■

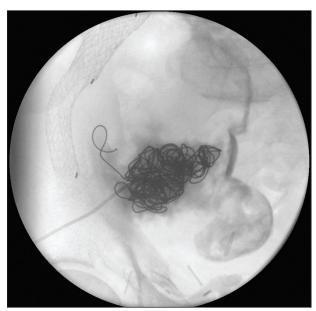


Figure 4. Eight 0.035-inch Interlock™ Coils were deployed within the sac until no further contrast flow was demonstrated.

David L. Smoger, MD, is with Radiology Associates of the Main Line and Riddle Hospital Radiology in Media, Pennsylvania. He received no compensation related to this article. Dr. Smoger may be reached at smogerd@mlhs.org. Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

ABBREVIATED STATEMENTS

Interlock™ - 18 and 35 Fibered IDC™ Occlusion System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

INTENDED USE/INDICATIONS FOR USE: The Interlock - 35 Fibered IDC Occlusion System is a modified interlocking detachable coil indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.

CONTRAINDICATIONS: None known.

WARNING: Compatibility with Magnetic Resonance Imaging (MRI) has not been established, and the degree of imaging distortion resulting from the coil has not been measured.

ADVERSE EVENTS: • Complications related to catheterization (e.g., hematoma at the site of entry, clot formation at the tip of the catheter and subsequent dislodgement, nerve and vessel dissection or perforation) • Pain • Hemorrhage • Infection necessitating medical intervention • Foreign body reactions necessitating medical intervention • Emboli • Ischemia • Vasospasm • Tissue necrosis • Undesirable clot formation of the vasculature • Claudication • Recanalization • Death • Temporary neurological deficit. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, precautions, Adverse events and operators instructions.

Fathom°-14/16 Steerable Guidewire

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE: The Fathom-14 and Fathom-16 Steerable Guidewire families are intended for general intravascular use in the peripheral vasculature. They can be used to selectively introduce and position catheters and other interventional devices in the peripheral vasculature. This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

 ${\tt CONTRAINDICATIONS\ FOR\ USE:\ This\ guidewire\ is\ not\ intended\ for\ use\ in\ the\ coronary\ vasculature.}$

POTENTIAL COMPLICATIONS: Potential complication include, but are not limited to: • Allergic reaction • Death • Embolism (catheter/device, air bubble, plaque, thrombus, air embolism, thromboembolism) • Hematoma at the puncture site • Infection • Pseudoaneurysm • Seizure/stroke • Vascular thrombosis • Vessel occlusion • Vessel spasm • Vessel dissection • Vessel damage • Nerve injury • Perforation of the vessel • Hemorrhage • Bleeding • Failed treatment • Inability to position guidewire • Damage to the catheter. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Renegade HI-FLO $^{\text{\tiny{TM}}}$ Fathom $^{\text{\tiny{8}}}$ System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE: The Renegade HI-FLO Fathom Kit is intended for peripheral vascular use. The Fathom Guidewire can be used to selectively introduce the Renegade HI-FLO Microcatheter in the peripheral vasculature. Once the subselective region has been accessed, the microcatheter can be used for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels.

CONTRAINDICATIONS FOR USE: None known.

WARNING: The Renegade HI-FLO Fathom Kit is not intended for use in the coronary vasculature. This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

POTENTIAL COMPLICATIONS: Potential complication include, but are not limited to: • Allergic reaction • Death • Embolism • Hemorrhage/hematoma • Infection • Pseudoaneurysm • Stroke • Vascular thrombosis • Vessel occlusion • Vessel spasm • Vessel trauma (dissection, perforation, trauma). Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Renegade STC* 18 Microcatheter with HydroPass** Hydrophilic Coating CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE: The Renegade STC 18 Microcatheter is intended for peripheral vascular use. The microcatheter can be coaxially tracked over a steerable guidewire in order to access distal, tortuous vasculature. Once the subselective region has been accessed, the microcatheter can be sued for the controlled and selective infusion of diagnostic, embolic or therapeutic materials into vessels. Diagnostic, embolic or therapeutic agents to be used in accordance with specifications outlined by the manufacturer.

CONTRAINDICATIONS FOR USE: None known.

WARNING: This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

POTENTIAL COMPLICATIONS: Potential complication include, but are not limited to: • Vessel trauma • Embolism • Hemorrhage/hematoma • Vasospasm • Infection • Air embolism • Allergic reaction. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

Direxion™ And Direxion Hi-Flo™ Torqueable Microcatheters CAUTION: Federal Law (USA) restricts this device to sale by or on the order of

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

INDICATIONS: The Direxion and Direxion HI-FLO Torqueable Microcatheters are intended for peripheral vascular use. The pre-loaded Fathom and Transend Guidewires can be used to selectively introduce and position the microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.

CONTRAINDICATIONS: None Known.

ADVERSE EVENTS: The Adverse Events include, but are not limited to: Allergic reaction, Death, Embolism, Hemorrhage/Hematoma, Infection, Pseudoaneurysm, Stroke, Vascular thrombosis, Vessel occlusion, Vessel spasm, Vessel trauma (dissection, perforation, rupture)

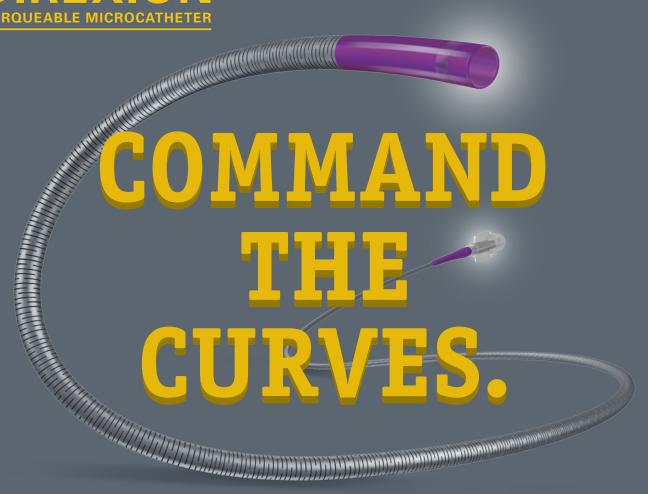
WARNING: Never advance or withdraw an intravascular device against resistance until the cause of resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire against resistance may result in damage or separation of the microcatheter or guidewire tip, or vessel perforation. Direxion Microcatheter family is not intended for use in the coronary vasculature or neurovasculature. The Direxion HI-FLO Microcatheter is not designed for the delivery of embolic coils. Use of excessive force to manipulate the microcatheter against resistance can cause a fracture in the nitinol shaft. Take care not to over-torque the microcatheter, and to relieve any tension before withdrawal by rotating the microcatheter in the opposite direction.

PRECAUTIONS: This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. Do not introduce the microcatheter without guidewire support as this may cause damage to the proximal shaft of the catheter. Because the microcatheter may be advanced into narrow sub-selective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal. If other interventional devices are used with the microcatheter, then refer to that product labeling for intended use, contraindications and potential complications associated with the use of that interventional device. If other interventional devices are used with the microcatheter, then refer to that product labeling for intended use, contraindications and potential complications associated with the use of that interventional device. Always verify tip response under fluoroscopy and the position of the proximal portion of the microcatheter, to avoid shaft coiling and/or fracture. If resistance is felt during rotation of the microcatheter and there is no visible tip response, stop and rotate in the opposite direction to release tension. Should the shaft fracture under too much tension, attempt to advance a guidewire through the fracture point and past the distal lumen, or retract the microcatheter into the guiding catheter. Then withdraw the system in a smooth motion, minimizing any rotation and torquing.



DIREXION

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PRECISION CONTROL IN A MICROCATHETER.

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FEATURES:

- Unique Shaft Design
- **Range of Pre-Loaded Systems**
- Six Tip Configurations
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DIREXION™ AND DIREXION HI-FLO™ TORQUEABLE MICROCATHETERS

Warnings, Precautions, Adverse Events, and Operator's Instructions. **CAUTION**: Federal Law (USA) restricts this device to sale by or on the order of a physician. **INDICATIONS**: The Direxion and Direxion HI-FLO Torqueable Microcatheters are intended for peripheral vascular use. The pre-loaded Fathom and Transend Guidewires can be used to selectively introduce and position the microcatheter in the peripheral vasculature. The microcathete can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into the vessel.

CONTRAINDICATIONS: None Known. ADVERSE EVENTS: The Adverse Events include, but are not limited to:
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and torquing.

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