Supplement to

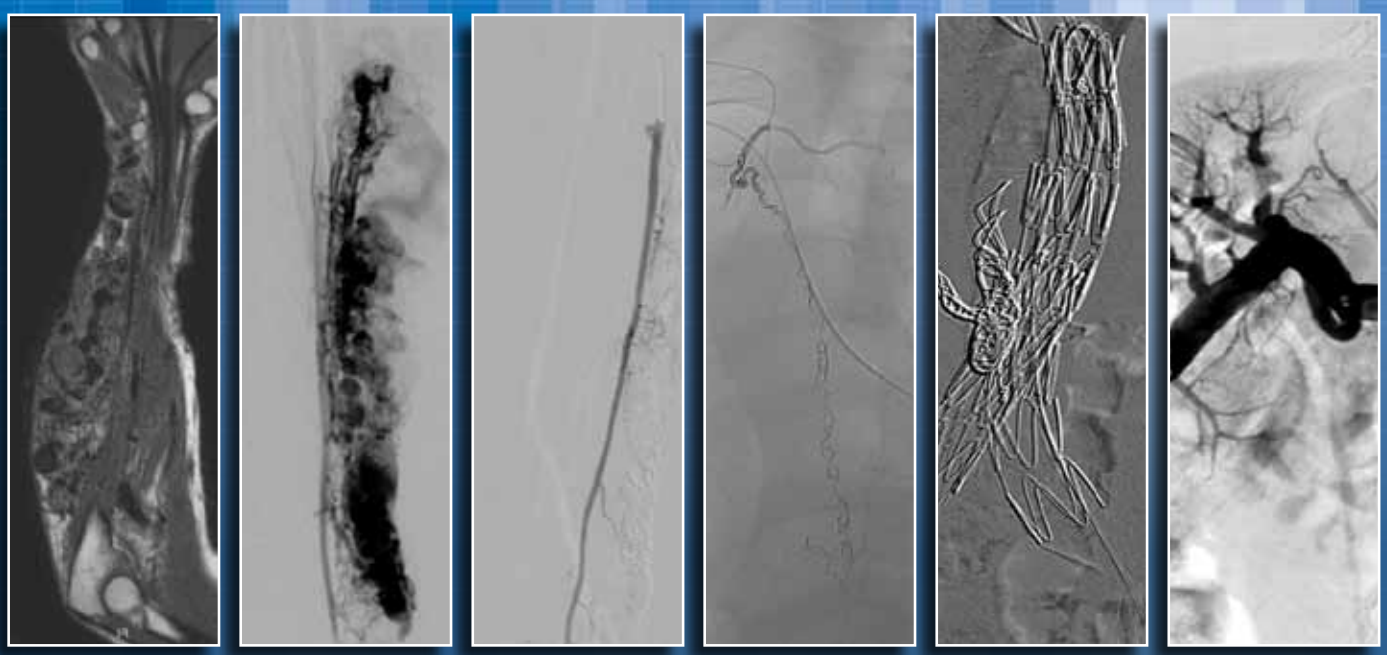
Sponsored by Boston Scientific Corporation

Endovascular TODAY

April 2013

Versatility in the Embolic Spectrum

Making successful outcomes possible even in challenging cases.



Embolization of Challenging Type II Endoleaks

BY J. TIMOTHY RILEY, MD, ST. JOSEPH'S HOSPITAL

INTRODUCTION

Despite significant advances in the devices used in the endovascular repair of abdominal aortic aneurysms, the occurrence of clinically relevant type II endoleaks remains relatively common. Although there are a variety of ways to successfully treat type II endoleaks, one of the most frequently used techniques involves accessing the feeding vessels via an endovascular approach. As a result of the significant tortuosity, the navigation of catheters and wires to these aneurysms can be difficult, and it typically requires the clinician to use smaller, more precise microembolization devices (0.018-inch), which are often less occlusive than larger 0.035-inch embolization devices. Historically, this requirement has made it challenging to achieve the desired level of hemostasis because large aneurysmal volumes typically need a large quantity of highly thrombogenic devices to achieve stasis. As a result of these conflicting priorities, very few embolization platforms are available that satisfy the need for precise delivery and high thrombogenicity.

One of the most important advances in the field of embolization has been the development of long detachable coils that contain significant amounts of thrombogenic fibers. These devices allow delivery of large volumes of embolic materials quickly and accurately. As a result, many of the procedures that are traditionally very time consuming and challenging have become common practice for experienced interventionists.

The following cases demonstrate the utility of the Interlock™ Fibered IDC™ Occlusion System in patients with challenging type II endoleaks.

CASE 1

An 84-year-old man underwent endovascular aortic repair and was monitored for an enlarging aneurysm sac and a type II endoleak.

As a result of the location of the stent graft and the endoleak, an endovascular approach via the lumbar vessels was selected. Using a 5-F, 0.038-inch inner diameter selective diagnostic catheter, the origin of the feeding vessel was identified with a contrast injection. Because of the small diameter and the significant tortuosity of the lumbar vessel, the 5-F catheter was advanced only slightly beyond the origin of the vessel.

A 0.021-inch inner lumen diameter microcatheter (Renegade® STC Microcatheter) and a torquable 0.016-inch

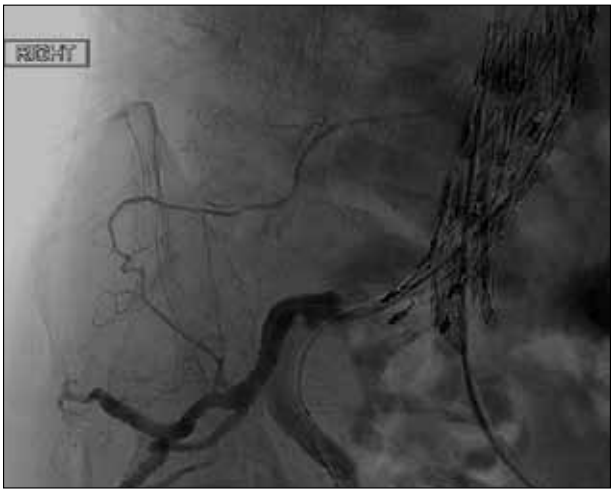


Figure 1. The origin of the feeding vessel was identified with a contrast injection.

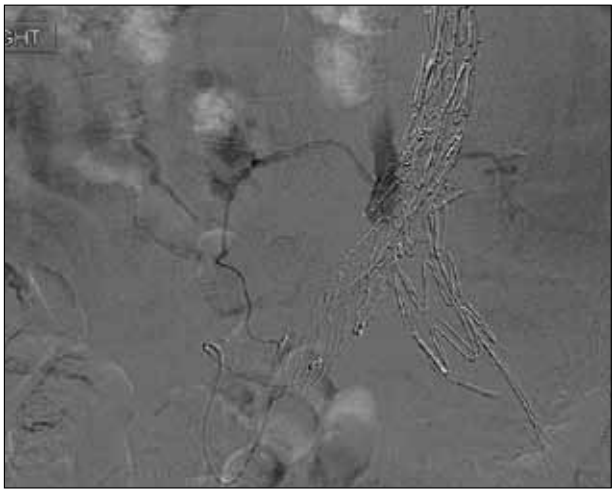


Figure 2. Selective contrast injection revealed a large aneurysm.

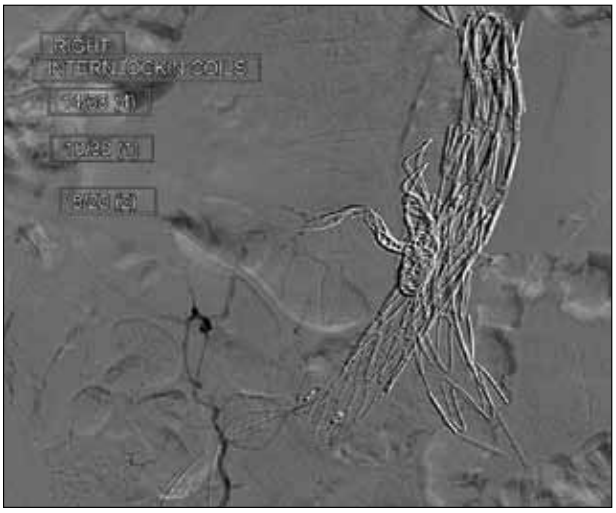


Figure 3. Coil embolization of the aneurysm sac.

microwire (Fathom® – 16 Steerable Guidewire) were passed through the diagnostic catheter into the distal vasculature. After significant catheter and wire manipulation, access to the sac was achieved, and a contrast injection revealed a large aneurysmal void that was causing the endoleak.

After positioning the microcatheter within the aneurysm and removing the guidewire, the process of embolizing both the sac and the feeding vasculature began. The embolization procedure was completed using a number of Interlock™ – 18 Fibered Platinum Coils, each with a wide diameter and a long length to ensure adequate wall apposition. Using a total of seven coils, 210 cm of coil was rapidly deployed, and hemostasis was achieved.

CASE 2

Approximately 6 months after endograft implantation, a CT scan revealed the continued expansion of a large aneurysm sac.

Using a radial access site, a 120-cm, 5-F hydrophilic catheter was used to select the left internal iliac artery. After cannulation of the internal iliac artery with the 5-F catheter, a lumbar vessel was selected using a 150-cm Renegade® STC Microcatheter and a Fathom® – 16 Guidewire. Selective angiography revealed that the large aneurysm sac was being fed by two lumbar vessels.

Figure 4. Selective angiography revealed that a large aneurysm sac was being fed by two lumbar vessels.

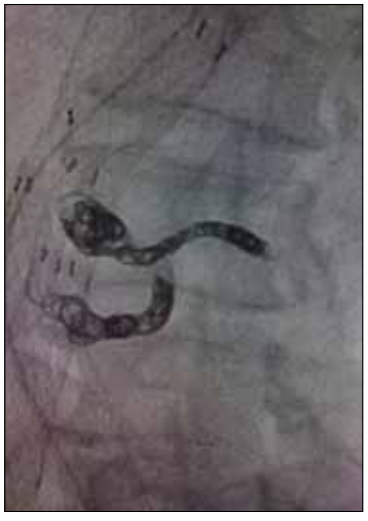


Figure 5. Twenty-two coils were used, and complete stasis was achieved.

Once positioned appropriately, the microcatheter was used to deliver embolic coils in an attempt to halt flow into the enlarging aneurysm sac. To begin the coil embolization, a number of 14-mm Interlock™–18 Fibered Platinum Coils were packed into the wide-diameter aneurysm sac. In an effort to fill the aneurysm with a dense network of coils, varying diameters were selected. After the embolization of the sac itself, the same microcatheter was used to deliver additional long coils into the feeding vessel. In total, 22 coils were used, and complete stasis was achieved.

CASE 3

A 76-year-old man with an enlarging aneurysm and type II endoleak was treated via the inferior mesenteric artery (IMA).

Interrogation of the superior mesenteric artery was done using a standard technique from the right femoral artery. Using the 5-F, 0.038-inch catheter, the superior mesenteric artery was imaged, and the middle colic artery was identified. The 5-F catheter was used to cannulate the origin of the middle colic artery, and a small-lumen microcatheter was then used to further access the distal vasculature.

Using a small-lumen 0.021-inch inner lumen microcatheter (Renegade® STC Microcatheter) and a torqueable microguidewire (Fathom® – 16 Steerable Guidewire), navigation through the mesenteric arch and into the ascending branch of the left colic artery was gradually achieved. Due to the tortuous path of the vasculature and the relative lack of proximal support, a guidewire with significant rail support was required to ensure adequate push through the vasculature.

After significant manipulation of the microcatheter and microwire, access to the ostium of the IMA was achieved.

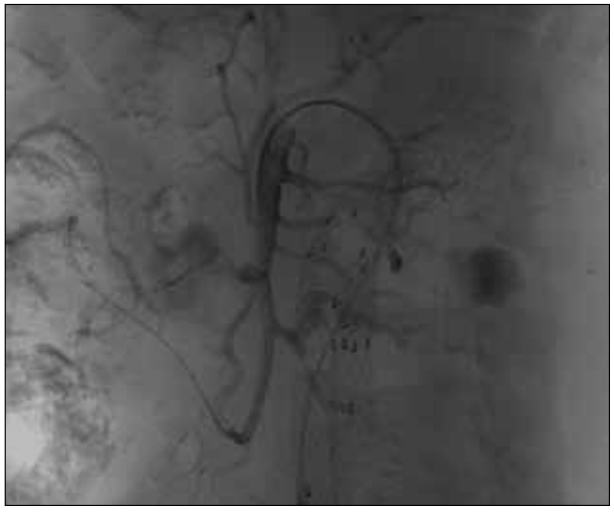


Figure 6. Interrogation of the superior mesenteric artery was done using a standard technique from the right femoral artery.

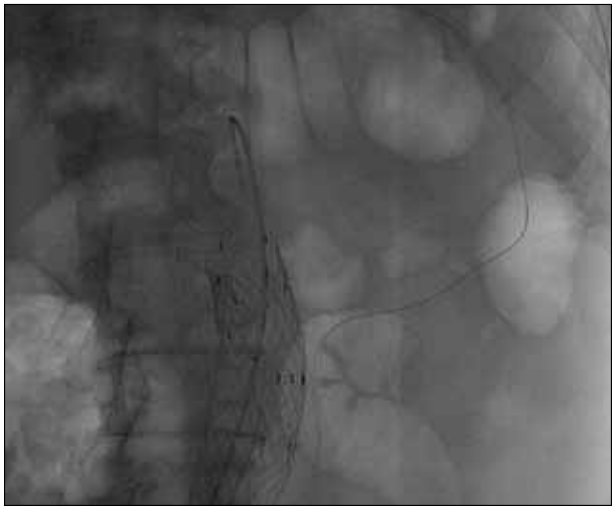


Figure 7. Navigation through the mesenteric arch was achieved with a microcatheter and microguidewire.

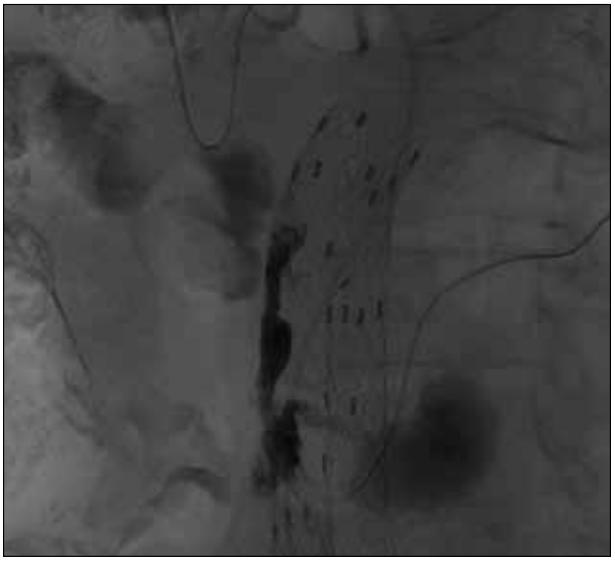


Figure 8. Contrast injection revealed a large, patent IMA feeding the aneurysm sac.

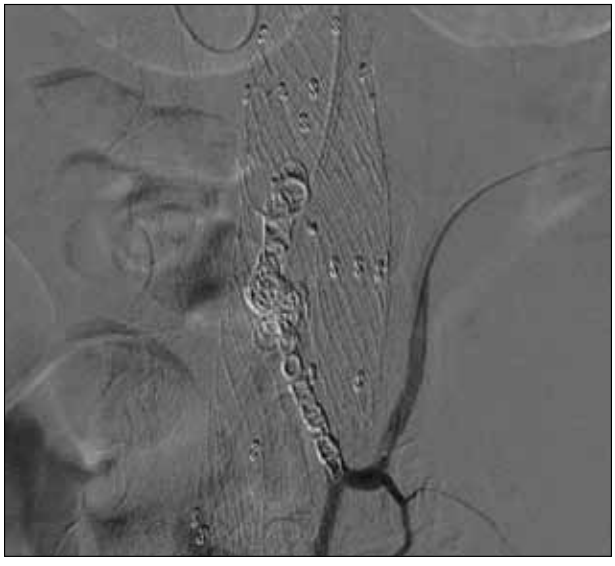


Figure 9. Nine long, fibered detachable coils were used, and complete stasis was achieved.

After removal of the microwire, a contrast injection revealed a large, patent IMA feeding the aneurysm sac.

After further advancement of the microcatheter, numerous detachable coils (Interlock™ – 18 Fibered IDC™ Occlusion System) were deployed in an attempt to fully embolize the vessels feeding the endoleak. In total, nine long, fibered detachable coils were used, and complete stasis was achieved.

DISCUSSION

Although improvements have been made to commercially available endovascular aortic repair devices over the past decade, the endovascular repair of type II endoleaks remains a relatively common procedure. As the cases presented illustrate, significant technical skills with small-lumen delivery systems and embolic platforms are often required due to the challenging nature of the vasculature that is involved. In addition, although the vasculature that must be traversed is often challenging due to the small diameter of the vessels and the tortuosity of the path, the area that must ultimately be embolized is often quite large and requires a significant amount of embolic material to achieve adequate stasis. Embolic systems that offer long coil lengths and a dense network of thrombogenic fibers can be valuable tools in these procedures. ■

J. Timothy Riley, MD, is a Vascular Surgeon at St. Joseph's Hospital Health Center in Syracuse, New York. All cases performed in collaboration with Interventional Radiology. He has disclosed that he has no financial interests related to this article.

Percutaneous Management of a Large Renal AVM

BY PETER WAYBILL, MD, AND JERRON L. FISCHER, MD, HARRISBURG MEDICAL CENTER

INTRODUCTION

A 30-year-old man with no significant medical history experienced blunt trauma to the right flank while playing flag football. Subsequently, he developed gross hematuria and visited the emergency room. The imaging workup revealed a large right renal vascular lesion (Figure 1). At the patient's initial evaluation by the urology department, it was suggested that the lesion might be a congenital arteriovenous malformation (AVM), which can be managed surgically, but would likely require a nephrectomy. The other option was to pursue a percutaneous nephron-sparing intervention.

PROCEDURE DESCRIPTION

Abdominal aortography was performed to identify the location and number of renal arteries (Figure 2). This revealed single renal arteries bilaterally. A diagnostic catheter was exchanged for a 5-F, RC-1 catheter, which was advanced into the right renal artery. Right renal arteriography was performed, and the images showed a massive right renal AVM arising from a dilated branch of a lower pole right renal artery.

The 5-F catheter was then exchanged for a 6-F Ansel sheath. Through the sheath, a 5-F Cobra 2 catheter was used to select the lower pole right renal artery branch, which supplied the AVM. There was a very small vessel supplying a small segment of normal renal parenchyma arising at the origin of the AVM (Figure 3). We decided to start coil embolization in this small branch vessel and then allow the coil to prolapse into the large vessel supplying the AVM. This allowed the coil to be anchored and was a good starting point for our coil nest by ensuring that the coil would not migrate through the AVM to the venous outflow. As an additional safety measure to prevent the coil from migrating, an Interlock™ Coil was chosen for the first coil. The coil was deployed in the appropriate position, without prolapse into the outflow vein.

A total of three Interlock™ 0.035-inch Coils were placed: first, a 15-mm X 40-cm coil, followed by two 12-mm X 20-cm coils. Two pushable vortex-shaped coils were then used as fillers. Follow-up arteriography showed no flow within the AVM. Flow was maintained to 80% of the right renal parenchyma (Figure 4).

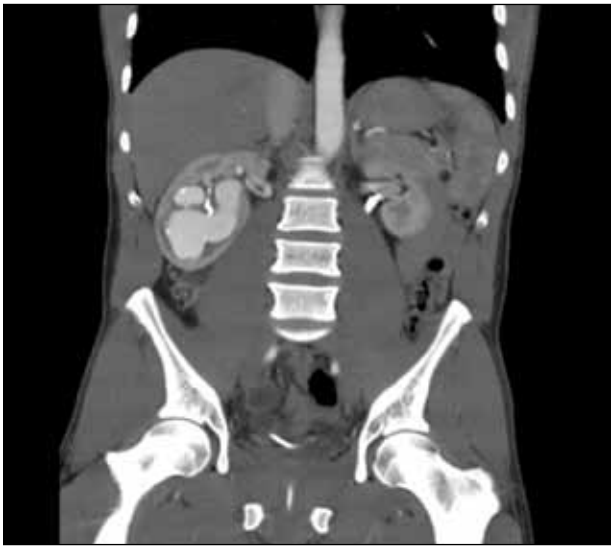


Figure 1. The imaging workup revealed a large right renal vascular lesion.

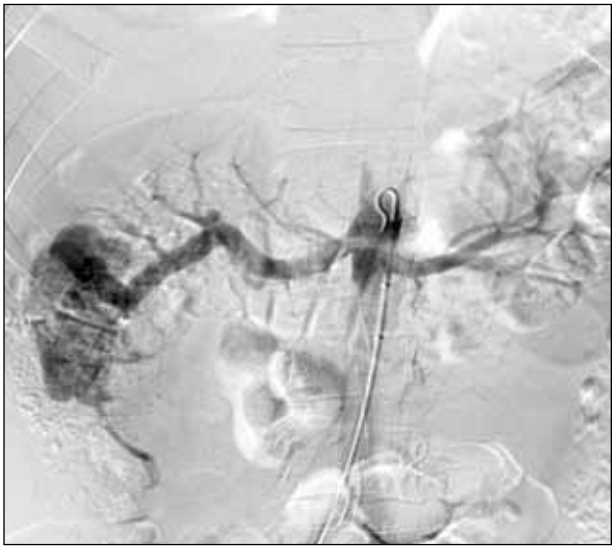


Figure 2. Abdominal aortography was performed to identify the location and number of renal arteries.

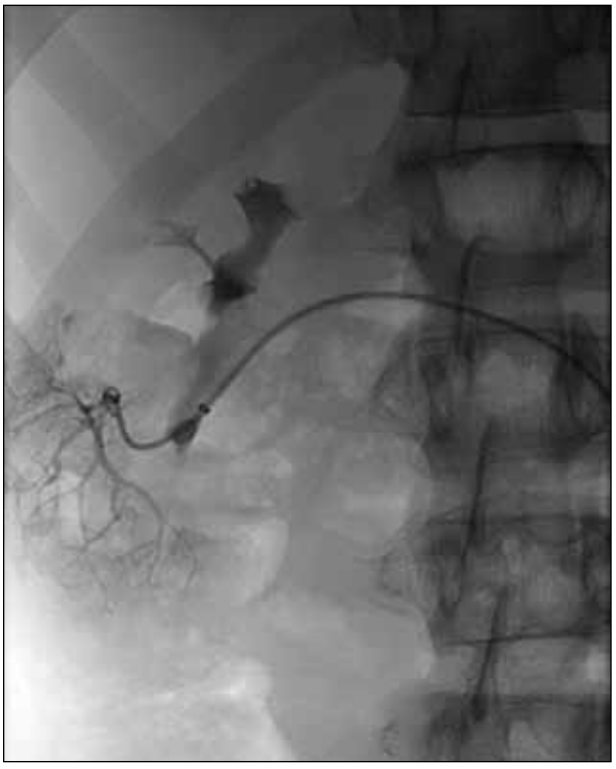


Figure 3. Through the sheath, a 5-F Cobra 2 catheter was used to select a lower pole right renal artery branch, which supplied the AVM.

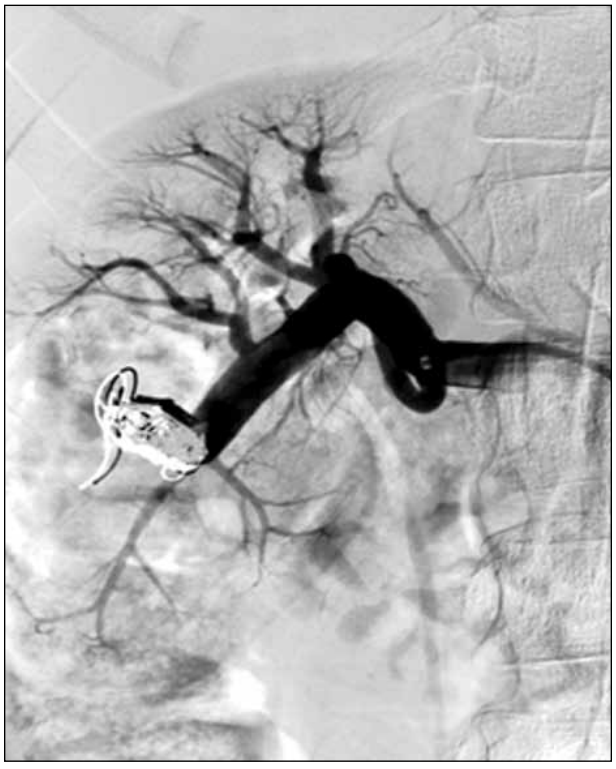


Figure 4. Three Interlock™ 0.035-inch Coils were placed.

DISCUSSION

AVMs refer to a congenital type of malformation and are found more often in women. Renal AVMs are very rare. There are two types of congenital renal AVMs described in literature: the cirsoid type, which is more common, and the cavernous type. The cirsoid type consists of multiple small, dilated arteriovenous communications with corkscrew appearances and tends to be adjacent to the collecting system. Patients present with gross hematuria. Cavernous AVMs have a single dilated vessel. We suspect that our patient had a cavernous AVM.

In comparison, arteriovenous fistulas (AVFs) are acquired and typically have a single feeding artery and a single draining vein. Acquired AVFs are the most common type of renal arteriovenous communication, and represent 75% to 80% of renal vascular anomalies. These are usually a result of trauma, surgery, biopsy, tumors, or erosion of aneurysms into a vein. Renal AVMs and AVFs are potentially lethal conditions, but most remain small and resolve spontaneously. If symptomatic, the most common clinical manifestation is hematuria. Cardiomegaly or congestive heart failure can occur. Ischemia in the renal parenchyma distal to the AVM or AVF may induce renin-mediated hypertension and/or impaired renal function. On imaging, the cirsoid AVM has tortuous varix-like vessels.

Embolization is considered the primary treatment option in cases of renal AVM or AVF because it preserves maximal normal renal parenchyma while eliminating the risk of recurrent hemorrhage. The goal of AVM or AVF embolization is eradication of the nidus. Recent reports describe the ablation of feeding vessels with various embolic agents, including particles, metallic coils, and liquid embolics. AVM radiofrequency ablation has also been attempted. ■

Peter Waybill, MD, is an Interventional Radiologist at the Harrisburg Medical Center in Harrisburg, Pennsylvania. He has disclosed that he has no financial interests related to this article.

Jerron L. Fischer, MD, is an Interventional Radiologist at the Harrisburg Medical Center in Harrisburg, Pennsylvania. He has disclosed that he has no financial interests related to this article.

Embolization of a Large Arteriovenous Malformation in the Forearm

BY PÄR GERWINS, MD, PHD, UPPSALA UNIVERSITY HOSPITAL

INTRODUCTION

Arteriovenous malformations (AVMs) arise due to developmental errors in the capillary bed during embryogenesis. The lack of a capillary bed results in rapid shunting of blood from the arterial to venous circulation. Although lesions are present at birth, they might not become evident until childhood or later in life. AVMs are sensitive to hormonal changes and often progress in adolescence, during pregnancy, and during intake of estrogen-containing contraceptives. Lesions are pulsatile with a palpable bruit or thrill, warm, and not easily compressible. The rapid shunting of blood leads to insufficient capillary perfusion with reduced oxygen delivery causing ischemia, pain, and development of wounds and bleedings. AVMs grow in size due to increased filling and enlargement of both supplying arteries and draining veins, which might cause disfigurement, destruction of tissues, and impaired organ function. When large enough, AVMs can cause congestive heart failure. Treatment of AVMs is based on endovascular embolization, surgical resection, or a combination of both. Complete cure is rare, and treatments therefore aim at controlling the malformation. Endovascular embolizations are performed using transarterial, transvenous, or direct-puncture techniques, and techniques are often combined. The embolic material can be liquid or solid, such as coils, plugs, and particles. It is important that the embolic material penetrates to the nidus and ideally to the point of the initial venous drainage.

PROCEDURE DESCRIPTION

A 17-year-old adolescent boy was referred from an outside hospital due to acute bleeding from an extensive ruptured AVM in his right forearm. The patient was taken to the OR and, in a bloodless field, the rupture was localized to a large draining subcutaneous vein, which was sutured. Subsequent digital subtraction angiography and magnetic resonance imaging revealed the true nature of the AVM with countless feeding arteries from the ulnar, interosseus, and radial arteries (Figure 1). Venous drainage was achieved through multiple large subcutaneous veins, and the lesion was embolized using a transvenous strategy. Under general anesthesia, a diagnostic catheter was advanced from the right femoral artery to the right brachial artery to visualize the AVM during the procedure. Using ultrasound guidance, an enlarged subcutaneous vein was accessed on the upper right arm. A draining vein at the nidus close to the wrist was reached using venous access with a Renegade® STC Microcatheter and a Fathom® Guidewire (Figure 2). Embolization was performed with 0.018-inch Interlock™ Coils. Control angiography revealed that this strategy was successful with markedly decreased shunting (Figure 2). The

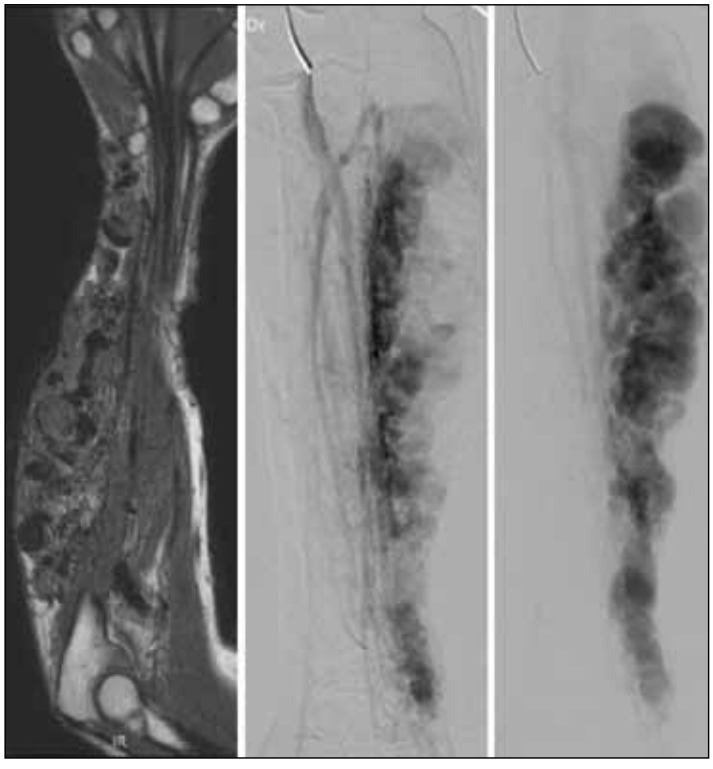


Figure 1. The AVM had countless feeding arteries from the ulnar, interosseus, and radial arteries.

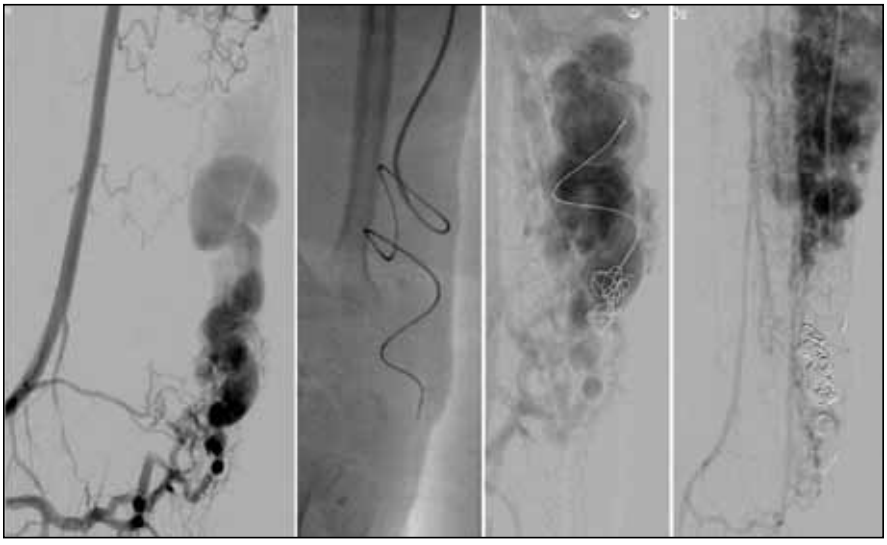


Figure 2. A draining vein at the nidus was reached via venous access with a Renegade® STC Microcatheter and a Fathom® Guidewire, and embolization was performed with 0.018-inch Interlock™ Coils. Control angiography revealed that this strategy was successful with markedly decreased shunting.

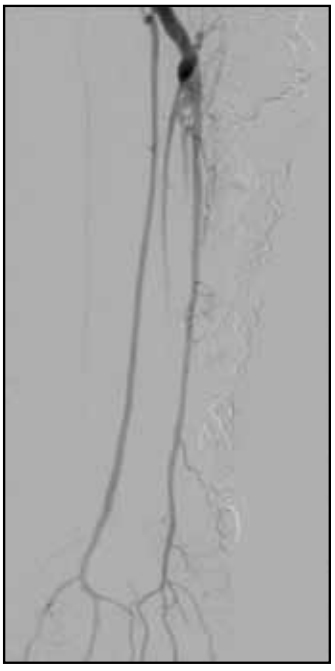


Figure 3. Final angiogram of the brachial artery.

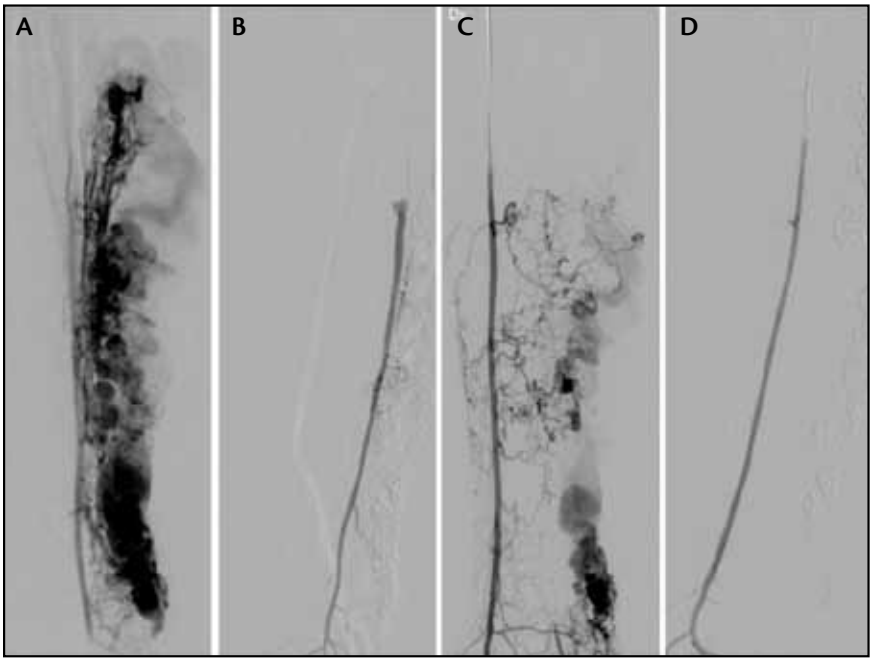


Figure 4. The final angiogram showed that almost all shunts were occluded: the ulnar artery before (A) and after (B) and the radial artery before (C) and after (D).

coiling procedure was repeated in nine separate procedures during a 6-month period with 0.018-inch Interlock™ Coils in veins that were hard to reach with a 0.035-inch system and 0.035 Interlock™ Coils in larger veins. The final angiography (Figure 3 and 4) showed that almost all shunts were occluded. The patient's symptoms of pain and discomfort, as well as the volume of the arm, were markedly reduced. At the time of the last embolization, it was observed that one coil was protruding through the skin due to shrinkage of the AVM. Because this could be a potential site of infection, the thrombosed AVM was surgically resected. The surgical resection was performed in a safe and controlled manner, without significant blood loss, due to the preoperative embolization. Postoperative healing was uneventful, and 6 months later, the patient was free of symptoms and able to return to a normal life.

DISCUSSION

AVMs are challenging lesions to treat. Embolization from the arterial side was not an option due to the countless number of arterial feeders, and the risk of spillover of embolic material would be devastating for the hand. This case demonstrates efficient closure of the draining vein at the nidus. Because lesions like this one have a very high flow rate, there is a concern that embolic material might dislodge and cause nontarget embolization. The availability of detachable, long, and fibered coils made it possible to perform the procedure in a safe and efficient manner. ■

Pär Gerwins, MD, PhD, is a Professor of Vascular Biology and an Interventional Radiologist at Uppsala University Hospital in Uppsala, Sweden. He has disclosed that he has no financial interests related to this article.

Preoperative Embolization of a Large Mediastinal Tumor Using Detachable Coils

BY HAMI MEHRZAD, MD, AND A. GANESHAN, MD, HEART OF ENGLAND NHS TRUST

CASE PRESENTATION

A 17-year-old adolescent boy presented with sudden-onset dyspnea after an appendectomy. Chest x-ray (Figure 1) revealed a large opacity occupying the right hemithorax. The patient was referred for thoracic surgery.

Further questioning revealed a 5-year history of dysphagia and dyspnea upon lying prone. High-resolution computed tomography of the thorax (Figure 2) showed a heterogeneous calcified mass that was 20 cm X 11 cm X 8 cm and compressing the main bronchi and great vessels, which is suggestive of teratoma.

Resection via a right thoracotomy was attempted, but the tumor was closely adherent to the mediastinum, and profuse bleeding was encountered from the tumor bed, resulting in significant hypotension. Hemostasis was obtained with difficulty, the thoracotomy was closed, and samples were sent for histology. Postoperatively, the patient showed symptoms of spinal cord ischemia. Magnetic resonance imaging localized the lesion to T5.

Initial histology indicated that the mass was potentially a solitary fibrous tumor of the pleura, but immunohistochemical staining was not entirely congruent. A second opinion diagnosed benign schwannoma but was atypical for the presence of multiple arteriovenous malformations. There was considerable mass effect exerted on vital structures, and the tumor was confirmed to be benign, intensifying the desire to definitively resect. This was tempered by the previously inflicted ischemic lesion to the spinal cord, from which the patient was fortunately recovering well.

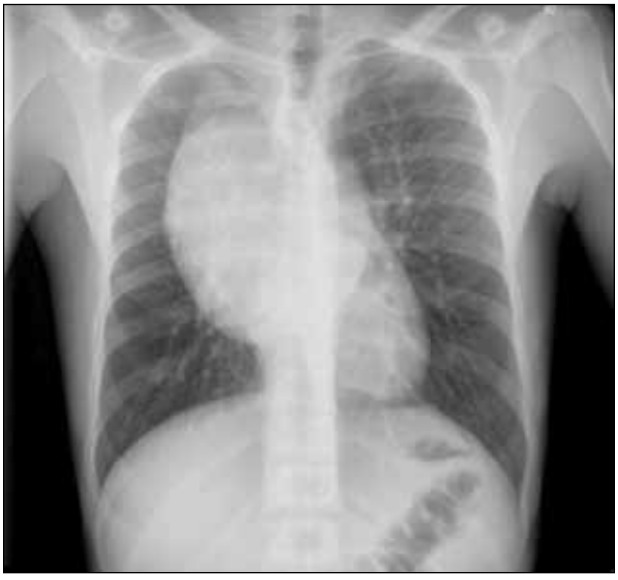


Figure 1. Chest x-ray showing a large opacity in the right hemithorax.

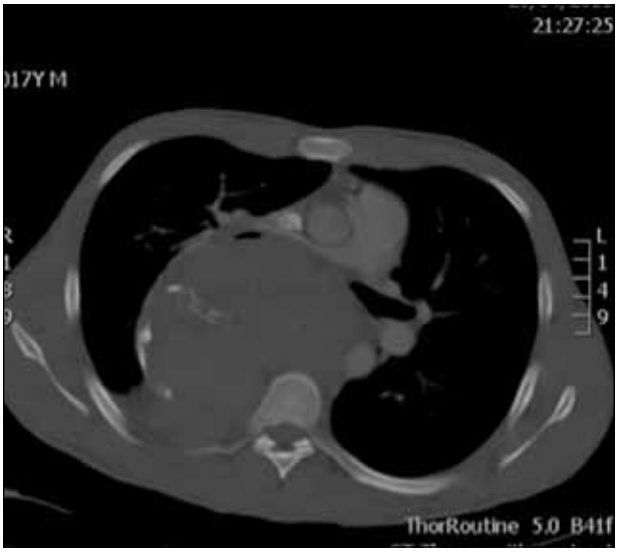


Figure 2. A heterogeneous calcified mass in the thorax compressing the main bronchi and great vessels.

PROCEDURE DESCRIPTION

Multiple selective coil embolizations of feeding vessels were undertaken before further surgery. Initial angiography determined several tortuous feeding vessels arising from the right intercostal, subclavian, internal mammary, and thyrocervical arteries.

The origins of these vessels were selectively cannulated with a catheter. A Renegade STC® Microcatheter

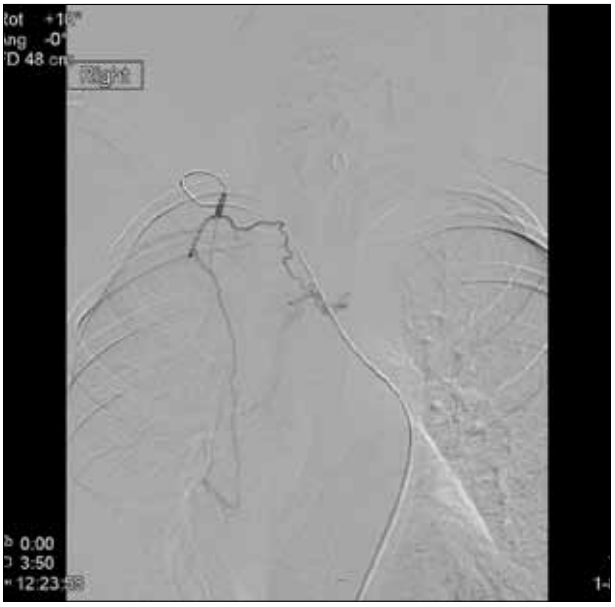


Figure 3. Angiogram of the thyrocervical trunk branch showing significant supply to the tumor during the first session.

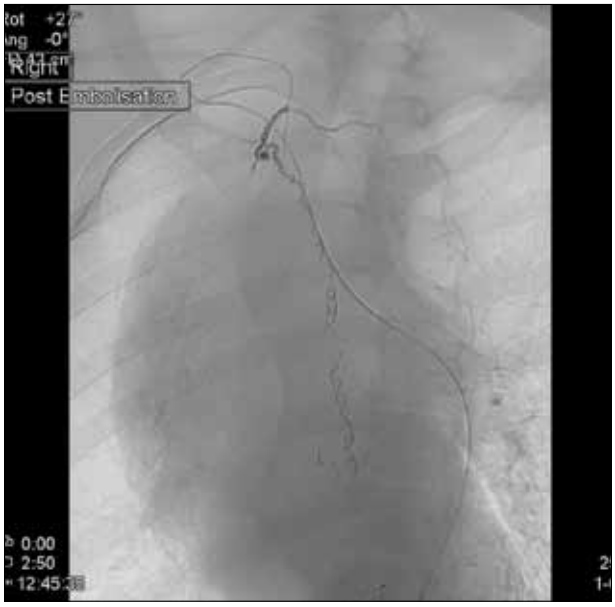


Figure 4. Several Interlock™ 0.018-inch Detachable Coils were successfully used to embolize the feeding vessels.

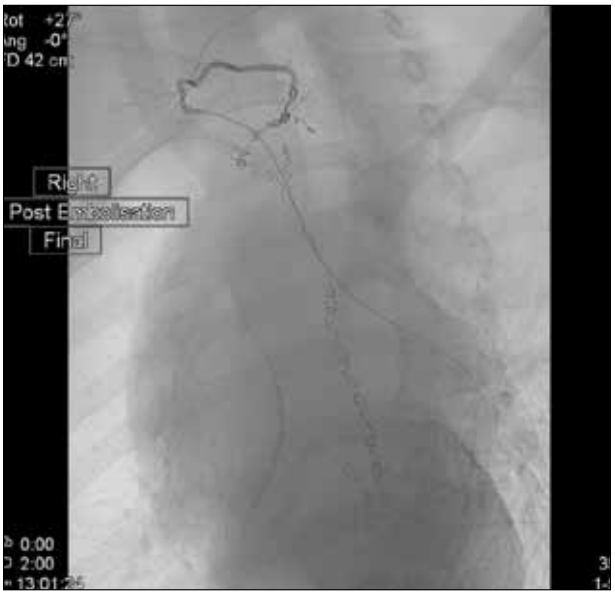


Figure 5. Final angiogram showing almost complete reduction in the tumor blood supply from this vessel.

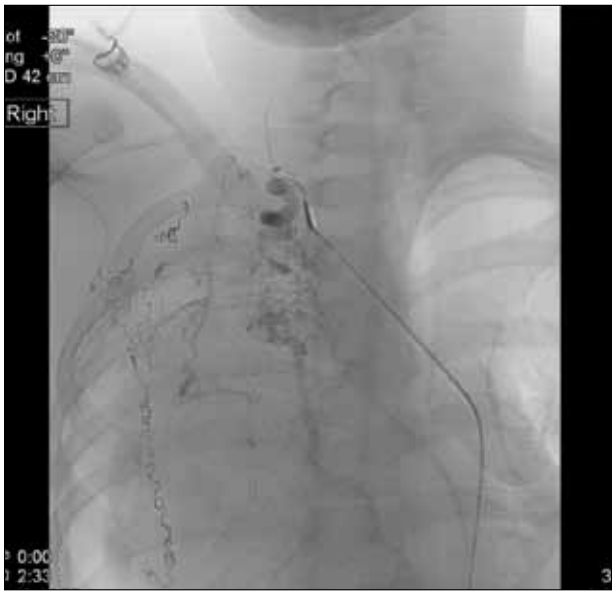


Figure 6. In the second session, further supply from the right internal mammary and subclavian branches was found on the angiogram. There was some early venous filling suggestive of arteriovenous malformation within the tumor.

was used to further super selectively cannulate the vessels. Due to the fact that the main catheter was just engaged into the orifice of the vessels, Interlock™ 0.018-inch Detachable Coils were used to allow greater control at the time of deployment and because fewer total coils were needed to embolize the tumor. Because of the coils' length, there was also less chance of distal migration into the arteriovenous shunts of the tumor. A range of coils (from 4 to 10 mm) was used with an angiographically successful outcome after two sessions. There was almost complete reduction in tumor blood supply without any serious complication (Figures 3-7).

Follow-up computed tomography angiography monitored for tumor shrinkage and watched for future resection.

DISCUSSION

In this selective case, we found that the Renegade STC® Microcatheter and Interlock™ Detachable Coil system were very useful tools in the interventional armamen-

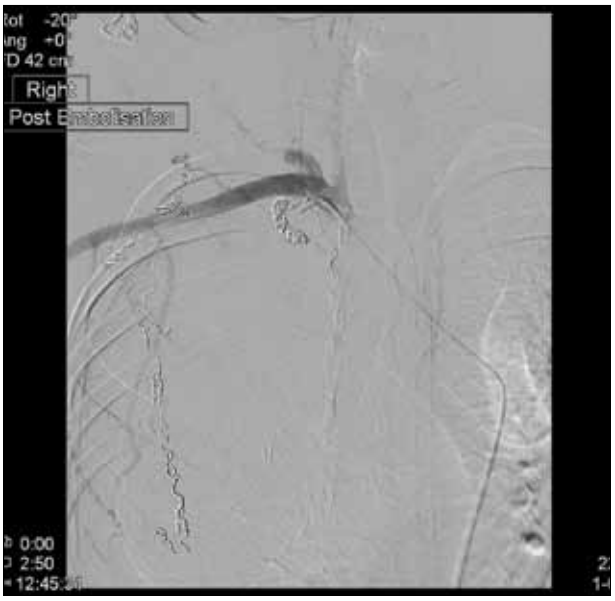


Figure 7. Further Interlock™ 0.018-inch Detachable Coils were used to reduce the risk of distal migration of any coils into the arteriovenous shunts. There was almost complete embolization of the tumor blood supply at the end of the procedure, as shown.

tarium for treating such a large, complicated, mediastinal tumor. It allowed for accurate, controllable, convenient, and successful embolization before surgery without any untoward complication. We hope that this example will be useful for others who may encounter a similar interesting—but—complex case. ■

Hami Mehrzad, MD, is with the Interventional Radiology department, Heart of England NHS Trust in Birmingham, United Kingdom. He has disclosed that he has no financial interests related to this article.

A. Ganeshan, MD, is with the Interventional Radiology department, Heart of England NHS Trust in Birmingham, United Kingdom. He has disclosed that he has no financial interests related to this article.

Embolization of a GI Bleed

BY TREVOR CLEVELAND, MD, SHEFFIELD VASCULAR INSTITUTE

OVERVIEW

A 94-year-old woman presented to the accident and emergency department in the early hours of the morning (approximately 2:00 AM) with rectal bleeding.

When she arrived to the hospital, she was hemodynamically stable but had further rectal bleeding. After initial assessment, she was referred to the acute medicine team who organized for her to have an emergency upper gastrointestinal (GI) endoscopy. Clinically, it was most likely that the bleeding source was in the lower GI tract, but an upper GI source needed to be excluded at an early stage. Proctoscopy was obscured by the blood in the rectum.

The upper GI endoscopy was normal, with no evidence of blood as far as the second part of her duodenum.

Despite the administered clear fluids and blood, her hemoglobin, which was 11 g/dL on admission, had fallen to 8 g/dL.

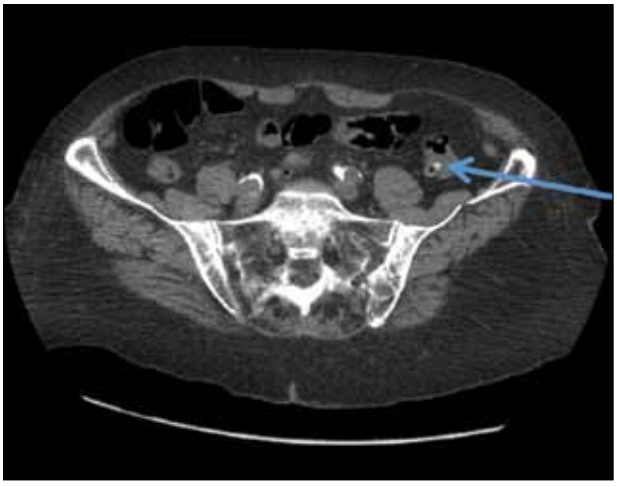


Figure 1. Calcification in the diverticular disease, which simulates contrast extravasation.

PROCEDURE DESCRIPTION

At 7:30 AM, the interventional radiology team (radiologist, radiographer, and nurse) was contacted to consider trying to find the bleeding source and treat it with embolization. A triple-phase (plain, arterial, and venous) computed tomography (CT) scan was immediately organized.

The unenhanced CT showed diverticular disease of the colon, with calcification associated with multiple diverticula (Figure 1); this can look like contrast extravasation. After injection of contrast, the arterial phase scan showed active bleeding in the sigmoid colon, with contrast in the lumen (Figure 2). The delayed scan showed further contrast spreading from the bleeding point (Figure 3).

After speaking with the patient in the CT scanning room, we transferred her directly to the interventional radiology suite, where she underwent selective angiography of the inferior mesenteric artery (IMA). She had significant atheroma in her aorta and at the origin of the IMA (which was seen on the CT). As a result, despite great care, there was a mild, non–flow-limiting dissection

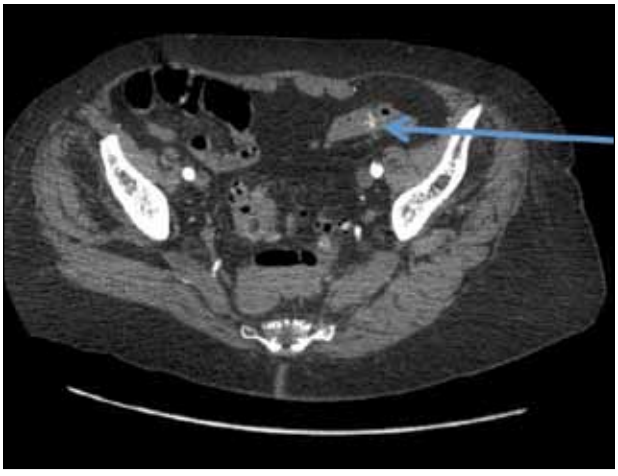


Figure 2. Contrast extravasation in the sigmoid colon.

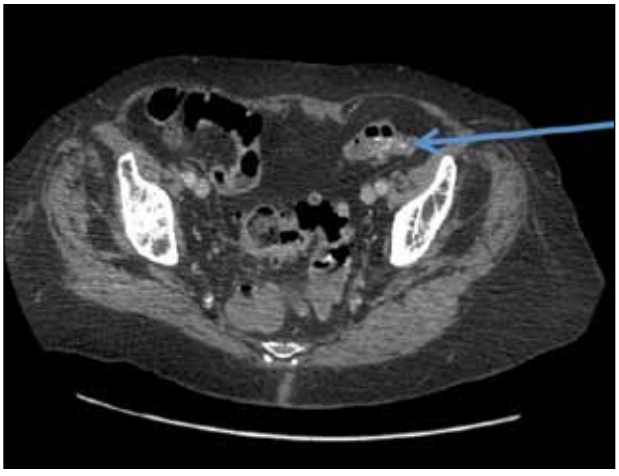


Figure 3. Contrast spreading from the bleeding point on the delayed scan.

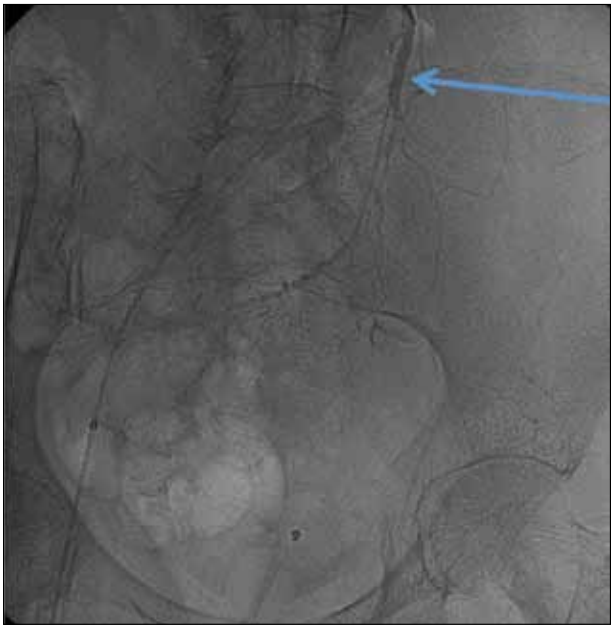


Figure 4. Dissection of the origin of the IMA.

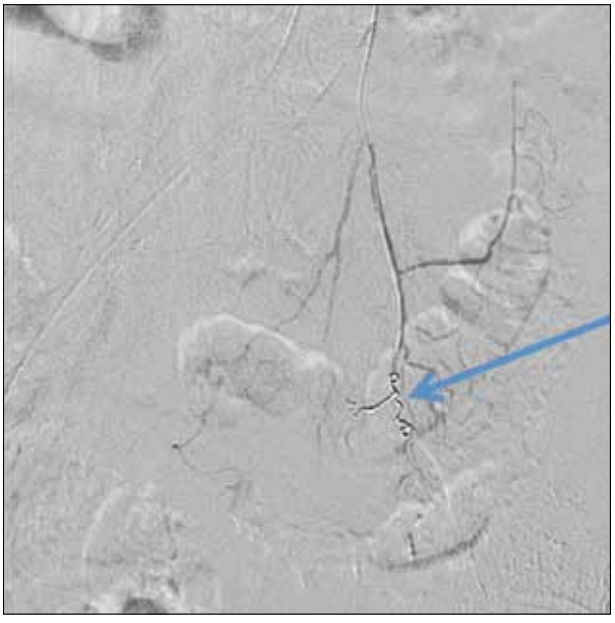


Figure 6. Bleeding stopped after placement of two Interlock™ Coils.

of the IMA (Figure 4). However, it did prove possible to selectively catheterize the IMA with a microcatheter, and the bleeding point was identified (Figure 5). Using the microcatheter, Interlock™ Coils were used to selectively embolize the bleeding point (Figure 6), and the bleeding was stopped.

DISCUSSION

The use of emergency three-phase CT can identify bleeding if it is active. A precontrast CT avoids some false-positive scans. The CT scan will direct angiographic

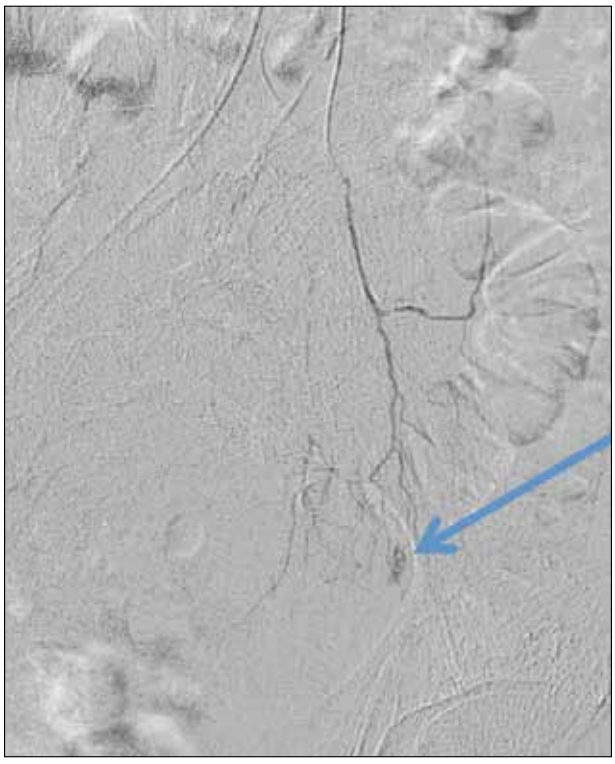


Figure 5. Active bleeding on the angiogram.

imaging, and there should be minimal delay between the positive CT and angiography. Elderly patients have arteries prone to catheter and wire damage. Embolization is a quick and effective treatment for lower GI bleeding. ■

Trevor Cleveland, MD, is Consultant Vascular Radiologist at the Sheffield Vascular Institute in Sheffield, England. He has disclosed that he has no financial interests related to this article.

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.

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™ Fathom® 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.