Supplement to

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Endovascular TODAY

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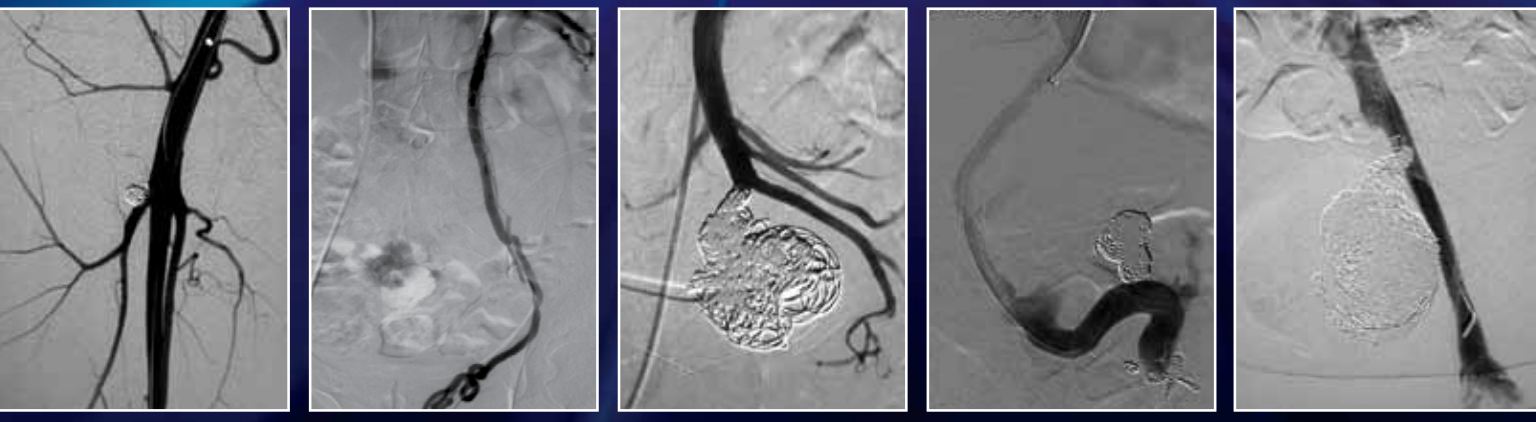
PERIPHERAL EMBOLIZATION ADVANCES



A case-based review of favorable outcomes in challenging scenarios.

Embolization With Detachable Coils in Traumatic Cases

BY DANA TOMALTY, MD, Huntsville Hospital

INTRODUCTION

Embolization is an important weapon in the armamentarium of the interventional radiologist, particularly those who practice in a Trauma center. In a perfect world, an embolization agent would offer ease of deliverability in terms of system trackability and preparation, precise placement, stability, avoidance of non-target embolization, and cost-effectiveness. While the "pushable" coil has historically offered many of these assets, its lack of retrievability, poor packing density, and potential for nontarget embolization have limited its use. Until recently, "detachable" coil systems have been limited to the Neurointerventional world. However, focused developments of 0.018-inch and 0.035-inch fibered detachable coil systems such as the Interlock™ Fibered IDC™ Occlusion System have been approved for use in the peripheral vasculature. As a result, many cases that could not have been performed without detachable coils are now approachable.

The following cases demonstrate the application of detachable coils in trauma patients with uncontrollable bleeding.

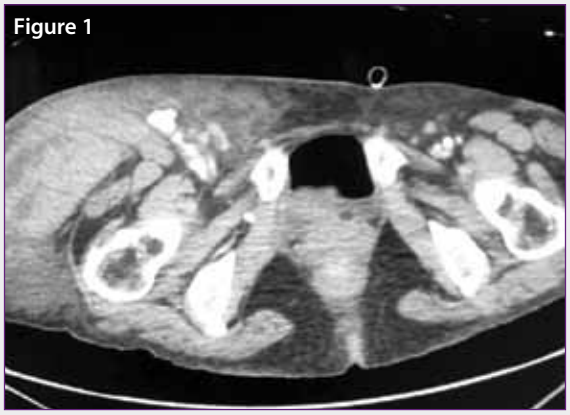
CASE 1: POST-CARDIAC CATHETER HEMORRHAGE

Overview

A 67-year-old woman was catheterized 2 days prior to admittance into the OR. Upon arrival, the patient was hypotensive, had a hemoglobin of 7 gm/dL, and was sent for a CT of her pelvis.

CASE 1

Figure 1



CASE 1

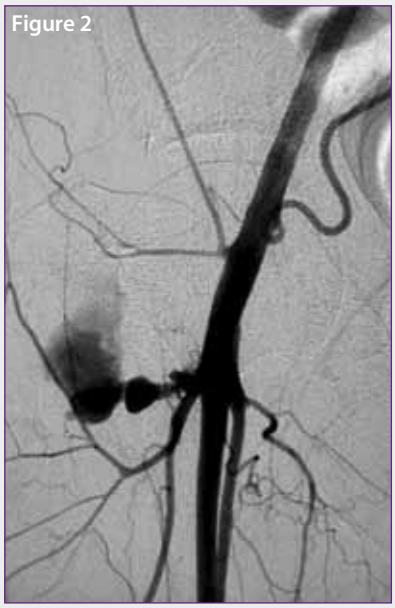


Figure 2

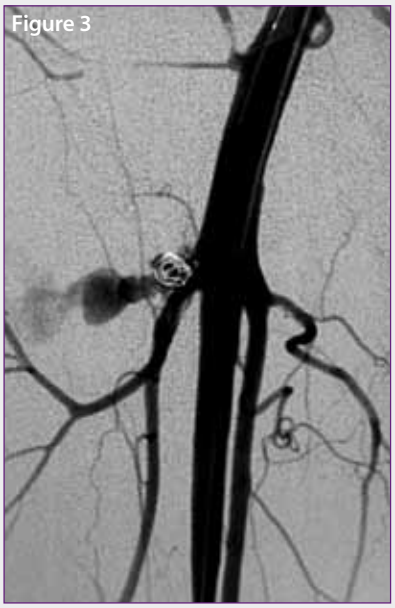


Figure 3

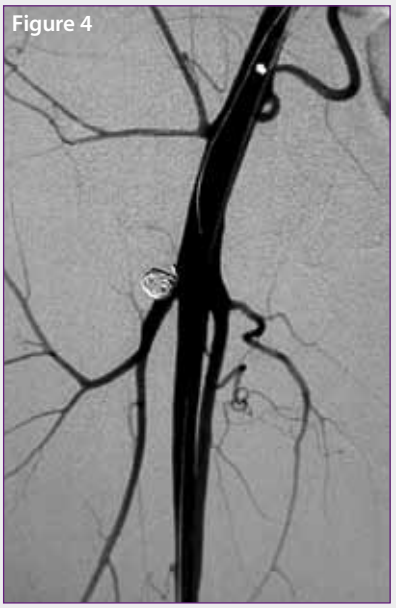


Figure 4

Figure 1 shows a CT of a large right thigh hematoma with active extravasation from the common femoral artery region. The patient was immediately sent to Angio and catheterized through the left common femoral artery.

An angiogram of the right external iliac showed acute extravasation from the right proximal profunda, just proximal to the common femoral artery trifurcation (Figure 2).

Procedure Description

With a 5-F, 0.038-inch diagnostic catheter in place within the common femoral artery, an angled Renegade® STC Catheter was coaxially directed into the extravasation.

Once the catheter was put in place, three Interlock™ Coils were placed in the location of the extravasation, and special care was taken to pack the coils in a manner that did not disrupt the blood flow within the trifurcation (Figure 3). Figure 4 demonstrates this occlusion and the uncompromised adjacent branches.

Discussion

In a case such as this, a variety of different options may be deemed valid. However, all are accompanied by some degree of risk. Although the use of an indicated stent would have been simple, the placement of such a stent would have occurred across a joint and would have compromised a major branch. A second option for this patient was surgery. The final option, which was ultimately selected, was embolization. The obvious downside of this approach was the potential for nontarget embolization, as the landing zone for the coil nest was very small, and there was minimal margin for placement error. As discussed previously, the use of detachable Interlock coils allowed for rapid and precise coil placement, which minimized the risk of nontarget embolization.

CASE 2: SPLENIC ARTERY ANEURYSM

Overview

An elderly patient on Coumadin was admitted to the ER after a fall at home. Upon admission, the patient was in shock and had a systolic blood pressure of approximately 70 mm Hg and a hemoglobin of 8 gm/dL. The patient was consulted by trauma surgeons for preoperative splenic artery embolization to allow for resuscitation prior to attempted laparoscopic splenectomy.

A CT showed a massive perisplenic hematoma with acute intraparenchemal bleed (Figure 5). The superior mesenteric artery (SMA) angiogram showed an occluded celiac origin and a splenic blood supply from the SMA, via the pancreatic duodenal collaterals (Figure 6).

Procedure Description

A 5-F, 0.038-inch Cobra-shaped diagnostic catheter was used to gain access into the proximal superior mesenteric artery. A Renegade® STC Catheter was introduced through the diagnostic catheter and into the proximal splenic artery (Figure 7).

Multiple Interlock™ Coils were used for the embolization of the proximal splenic artery (Figure 8).

Discussion

The patient was stabilized and resuscitated with fluids and blood. The patient's coagulopathy was corrected, and an uneventful laparoscopic splenectomy was performed the next morning. In this case, detachable coils allowed for precise placement through very tortuous anatomy.

As a result of the interlocking connection between the coil and the pusher wire, we experienced no coil loss, which, in this case, would have been very difficult to retrieve. In addition, the long lengths of the coil allowed for fewer coils than would have been required with short, pushable coils.

CASE 2

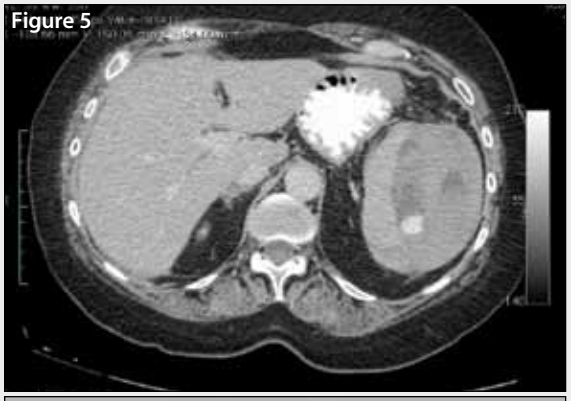


Figure 5

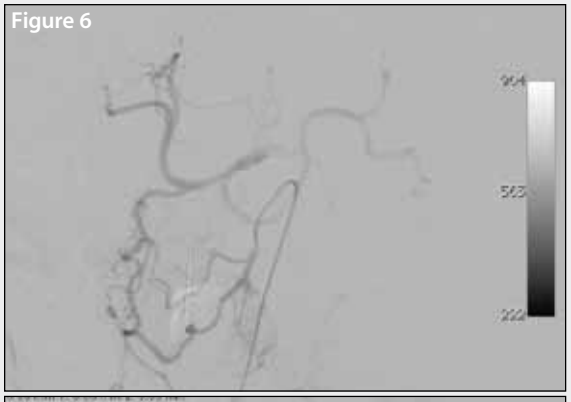


Figure 6


Figure 7

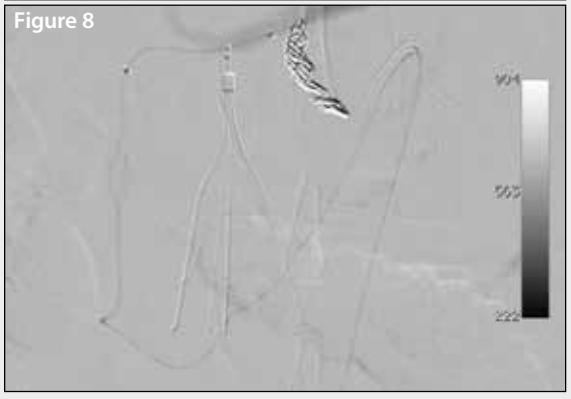


Figure 8

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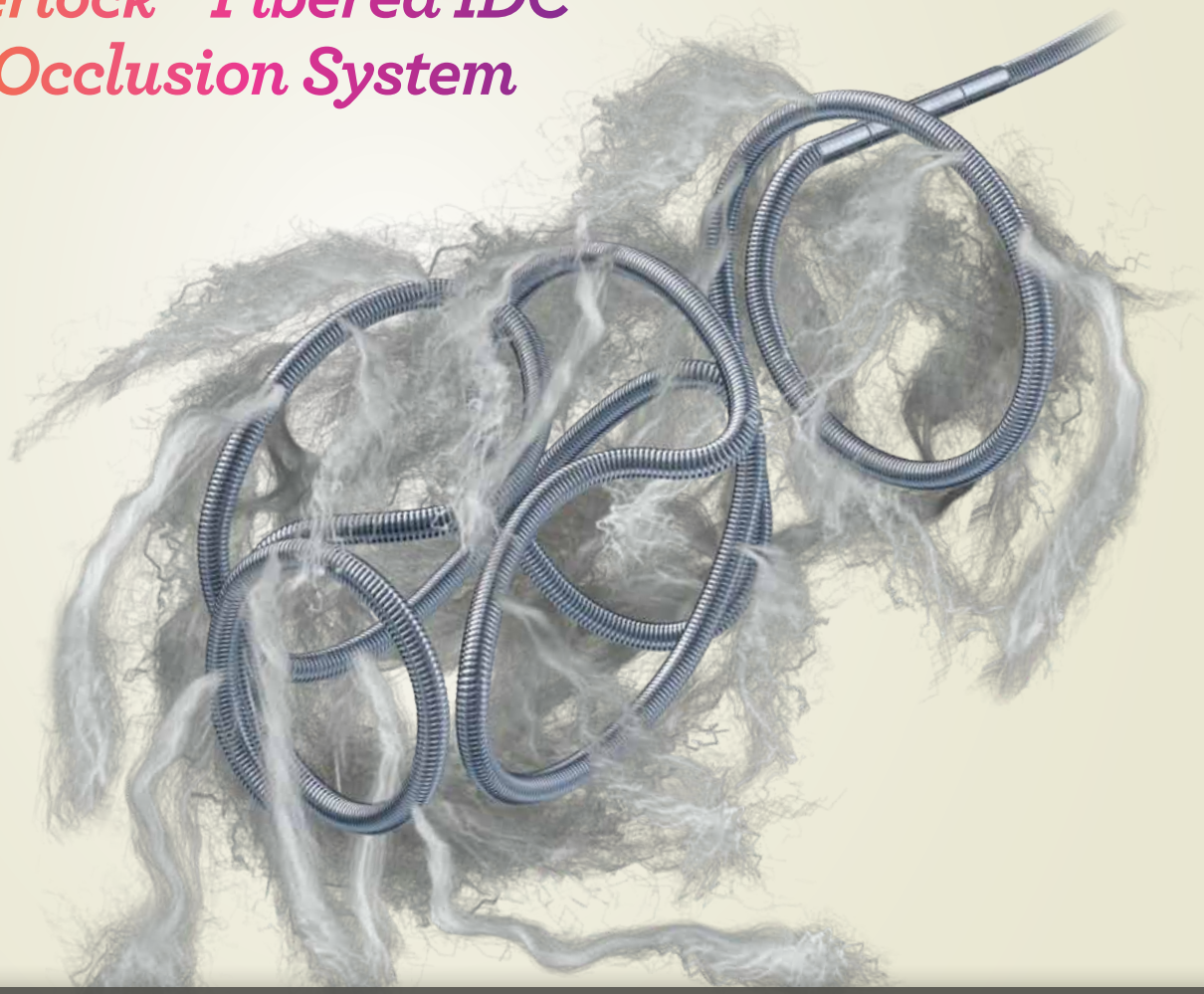
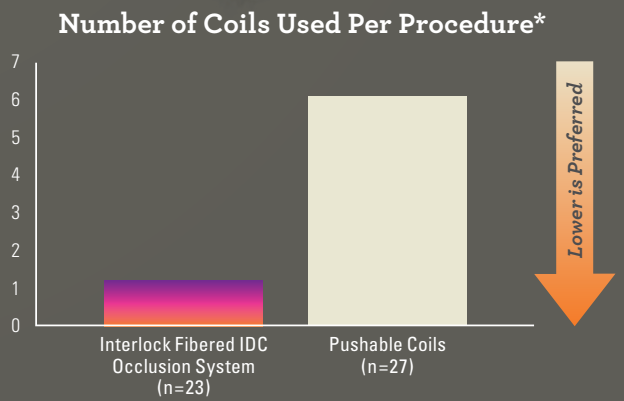
Interlock™ Fibered IDC™ Occlusion System



Place, Don't Push.

83.6% of embolic procedures (19 of 23) achieved complete occlusion with one Interlock Fibered IDC Occlusion Coil



CRV

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*Dudek, et al, Embolization of the Gastroduodenal Artery Before Selective Internal Radiotherapy: A Prospectively Randomized Trial Comparing Standard Pushable Coils with Fibered Interlock Detachable Coils. CVIR, April 14, 2010.

INTERLOCK™ AND INTERLOCK™-35 FIBERED IDC™ OCCLUSION SYSTEMS Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **CAUTION:** Federal law (USA) restricts these devices to sale by or on the order of a physician. **INTENDED USE/INDICATIONS FOR USE:** Interlock and Interlock - 35 Fibered IDC Occlusion Systems are modified interlocking detachable coils indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. These devices are 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 coils 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.

CASE 3: MASSIVE SUPERIOR MESENTERIC ARTERY ANEURYSM

Case 3 is a 40-year-old man with a prior history of HIV. The patient developed a new large mesenteric mass, which was detected on CT. After imaging, the patient was sent for a core biopsy procedure with the working diagnosis of lymphoma. Pulsatile blood came from a 17-gauge needle guide, and the patient was sent immediately to angiography for possible embolization (Figure 9).

Procedure Description

A 5-F, 0.038-inch Cobra 2–shaped catheter and a hydrophilic guidewire were used to gain access into the SMA. A 6-F guide sheath was then placed. A 5-F, 0.038-inch Bern-shaped catheter was used to access the aneurysm. The aneurysm was then framed with multiple 20-mm X 40-cm Interlock™ – 35 Coils. After numerous 20-mm X 40-cm coils, smaller-diameter coils were used to begin filling the framed portion of the aneurysm (Figure 10).

Upon filling the aneurysm, a 14-mm Amplatzer™ Vascular Plug was utilized in an attempt to embolize the proximal portion of the IMA. However, the rapid blood flow quickly moved the device toward the base of the nest of coils (Figures 11 and 12).

The case was finished by packing multiple additional Interlock™ – 35 Coils in the neck of the inferior mesenteric artery. In total, thirty-six 40-cm-long coils were utilized to attain complete stasis (Figure 13).

Discussion

This patient had a difficult situation, and removal of the guide would have resulted in massive hemorrhage. The precise, safe, and quick embolization of the IMA saved his life. As was demonstrated by the migration of the Amplatzer™ Vascular Plug, the blood flow was quite rapid, and the detachable nature of the Interlock™ – 35 Coils allowed confidence when addressing this embolization procedure. In addition, the extremely long coil lengths offered by the Interlock™ – 35 Coil allowed for a total of more than 1,500 cm of coil to be delivered very efficiently in this case. ■

Dana Tomalty, MD, is an Interventional Radiologist at Huntsville Hospital in Huntsville, Alabama.

CASE 3

Figure 9

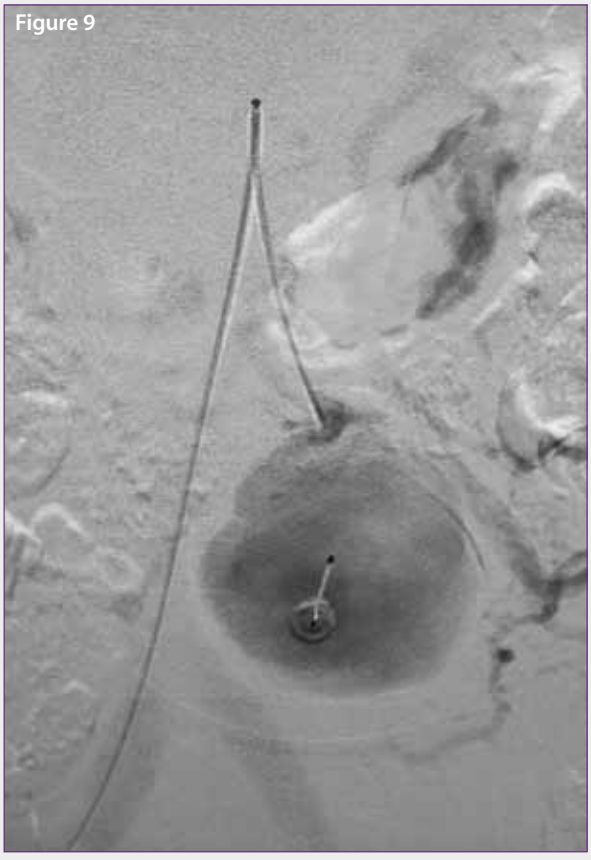


Figure 10

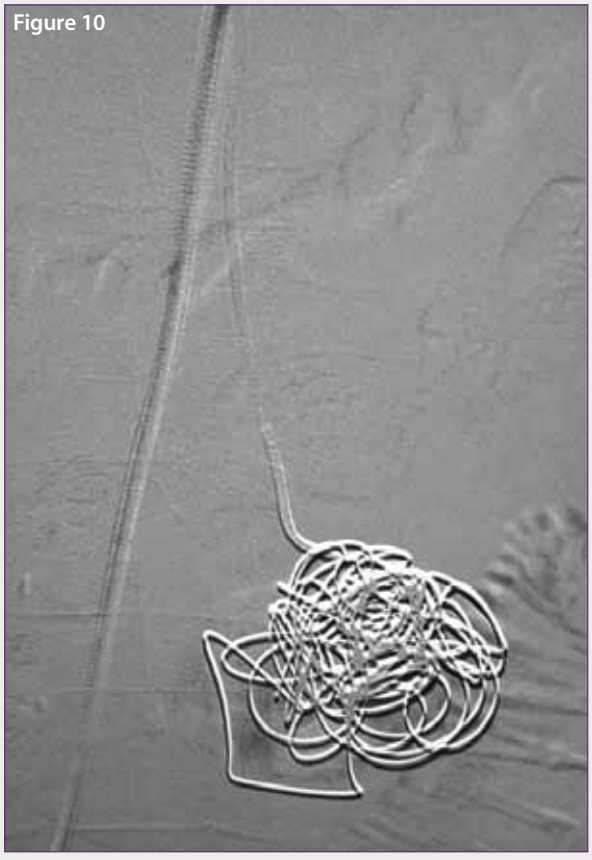


Figure 11

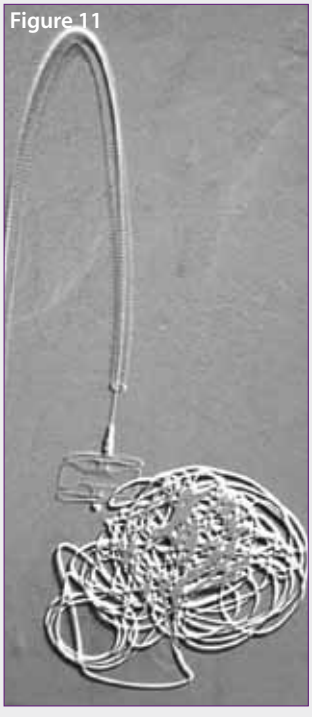


Figure 12

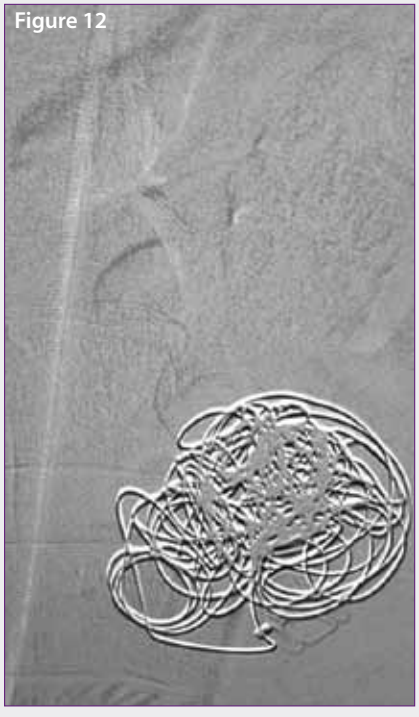
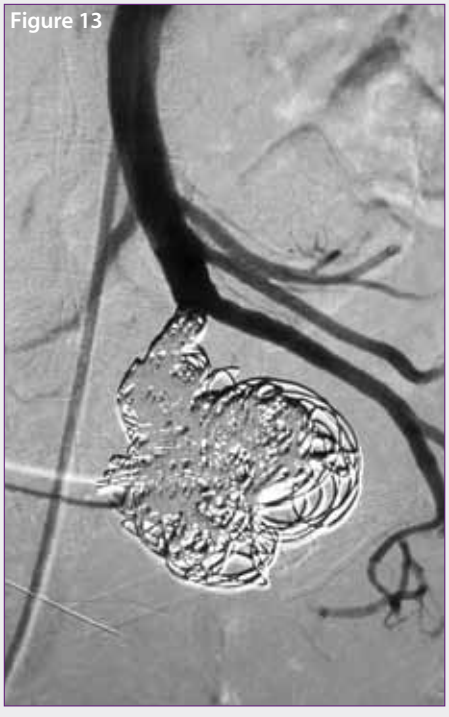


Figure 13



Embolization of Variceal Hemorrhage

BY ANDREW MARSALA, MD, Willis Knighton Medical Center

INTRODUCTION

For more than 20 years, the placement of transjugular intrahepatic portosystemic shunts (TIPS) has been a widely accepted procedure for the treatment of portal hypertension. Resulting from a variety of conditions, the most common of which is liver cirrhosis, portal hypertension can lead to the formation of esophageal or gastric varices, which are often accompanied by a strong tendency to develop bleeding. In conditions of uncontrollable bleeding, procedures such as gastric banding or coil embolization can be used to suppress or alleviate symptoms.

The following cases describe coil embolization of gastric varices after TIPS, using the Interlock™ – 35 Fibered IDC Occlusion System.

CASE 1

Overview

A 77-year-old man presented with a history of end-stage liver disease, intractable ascites, and multiple episodes of esophageal variceal hemorrhage. He was referred to Interventional Radiology from the Gastroenterology department for a TIPS procedure. The patient had no history of encephalopathy and a bilirubin of 1.8.

Procedure Description

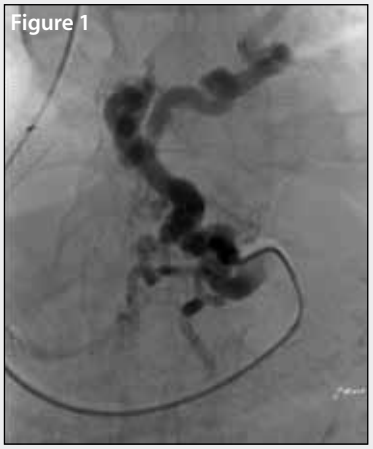
The TIPS procedure was performed using a Gore® Viatorr® TIPS Endoprosthesis with a 2-cm exposed segment and a 7-cm covered segment. After implantation, a wide, short gastric varix was noted exiting the splenic vein, coursing toward the fundus of the stomach and distal esophagus (Figure 1).

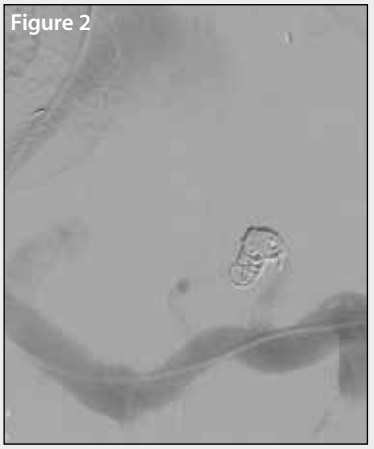
The varix was engaged with a 5-F, 0.038-inch, H1H-shaped catheter, and venography was performed. Venography demonstrated that the caliber of the varix varied between 9 mm and 12 mm.

After venography, which was performed at 4:09 PM, two Interlock™ – 35 Fibered IDC Coils were placed within the varix. Each of these coils was 10 mm in diameter and 40 cm in length, and the completion of coil deployment occurred at 4:22 PM, only 13 minutes after embolization began.

Placement of the coils resulted in total occlusion of flow toward the varices (Figure 2). Thirty days after the procedure, the patient had improvement in his ascites. No hepatic encephalopathy was noted, and stable hepatic and renal functions have been observed.

CASE 1





CASE 2

Overview

A 44-year-old man presented with a history of end-stage liver disease and recurrent, life-threatening variceal hemorrhage. He was referred from two outside hospitals where a TIPS procedure was attempted unsuccessfully due to the presence of a small right portal vein.

Procedure Description

Under general anesthesia, an Accustick® Needle was used to engage the small right portal system, with percutaneous portography documenting a right portal vein of 6 mm in diameter. A percutaneous portal venogram allowed for the visualization of a target, facilitating conventional TIPS placement. Incidental note was made that multiple coils were present adjacent to the splenic vein, located in the hepatic artery secondary to previous splenic artery embolization for hypersplenism (Figure 3).

After placing a 9-mm Gore® Viatorr® TIPS Endoprosthesis, the venogram confirmed persistent hepatofugal flow through a large varix with a diameter of at least 20 mm. The varix was engaged with a 5-F, 0.038-inch, H1H-shaped catheter to a depth where the variceal diameter approached 15 mm (Figure 4).

Once proper catheter positioning was obtained, embolization of the varix with the Interlock™ – 35 Fibered IDC Occlusion System began. Over the course of the next 21 minutes, eleven (11) 15-mm X 40-cm sized coils were packed into the varix. Figure 5 depicts the midpoint of the embolization, as six coils can be seen tightly packed into the varix.

The eleventh coil was placed at 2:03 AM, and complete stasis was observed at 2:24 AM (Figure 6).

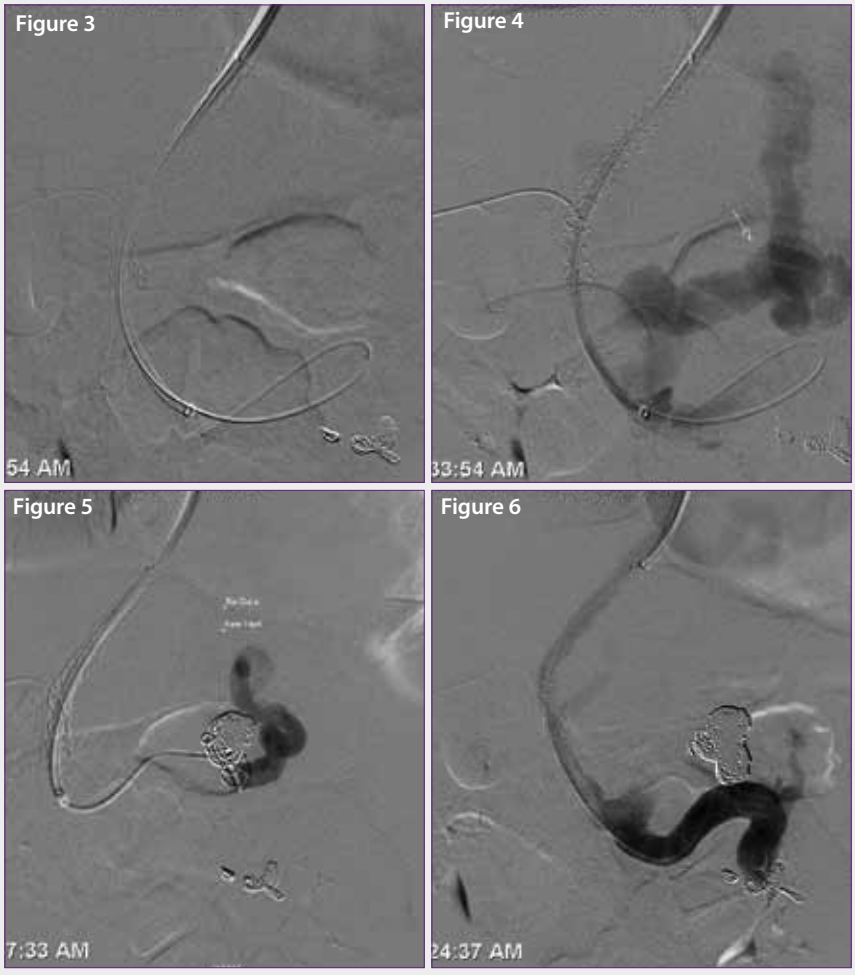
Thirty days after performing this TIPS procedure and variceal embolization, the patient had stable hepatic and renal function and no further esophageal bleeding.

Discussion

These cases presented demonstrate two different extremes of variceal embolization. Case 1 illustrated a moderate-sized varix that required only two coils, each 40 cm long. The coils used in the case were placed rapidly and effectively, resulting in a tight coil nest and complete embolization. Case 2 illustrated the embolization of a much larger varix that required 11 coils to attain complete stasis. Although case 2 required a greater number of coils, the total time needed for embolization was only 21 minutes. The placement of Interlock™ – 35 Coils was efficient and effective, which reduced procedure times and radiation exposure in these cases. ■

Andrew Marsala, MD, is Chief of Radiology at Willis Knighton Medical Center in Shreveport, Louisiana.

CASE 2



Varicocele Embolization Utilizing the Interlock™ Detachable Coil System

BY KELVIN HONG, MD, Johns Hopkins University Medical School

INTRODUCTION

Varicoceles are abnormal dilatations of the pampiniform venous plexus resting just above each testicle that can result in either symptoms (eg, pain, swelling) or suboptimal fertility. The primary cause of varicoceles is the absence of functioning venous valves of the left spermatic vein. Treatment of varicoceles includes surgery or percutaneous embolization with the intention of occluding the incompetent spermatic vein. To date, results for both approaches have similar outcomes, with embolization having the distinct advantage of being minimally invasive and having fewer periprocedural complications. The selection of a durable, effective embolic agent is critical despite working in the relative safety of a closed venous system, as local anatomical constraints (hidden collaterals) and propensity of the spermatic vein to spasm can contribute to recurrences and treatment failure.

The following case study highlights the use of an embolization agent that allowed for quick and effective spermatic vein embolization.

Procedure Description

A 30-year-old man presented with painful left scrotal swelling diagnosed on ultrasound as a left varicocele. Catheterization of the origin of the left spermatic vein was achieved with a 7-F Hopkins Guide Catheter, and the venogram demonstrated an incompetent left gonadal vein. Multiple collaterals joined at the level of the acetabulum, in the main incompetent gonadal vein, with an additional small, separate medial collateral vein. We proceeded with catheterization, advancing a 5-F JB1 Catheter and 0.035-inch Bentson Guidewire to the main distal gonadal vein, approximately 2 cm above the internal inguinal ring. We placed a Renegade® STC Microcatheter through the JB1 Catheter and advanced it into the main spermatic vein (Figure 1).

The main spermatic vein was coiled with a combination of 2D Helical Interlock™ Fibered IDC Occlusion Coils (4 mm X 8 cm, 5 mm X 15 cm, 6 mm X 20 cm, 8 mm X 20 cm, and 10 mm X 30 cm) for scaffolding wall apposition and stability and filled with VortX® Diamond-shaped coils (5 mm X 5.8 cm, 6 mm X 8 cm). The medial collateral vein was then catheterized, which bypassed the main spermatic vein to fill the varicocele and embolized with two small VortX® Diamond-shaped coils (3 mm X 2.3 cm).

The end-of-procedure venogram with Valsava demonstrated complete embolization of the spermatic vein feeders with a tight nest of nine total Interlock™ Detachable Coils (Figure 2). Total procedure time was 45 minutes.

CASE 1

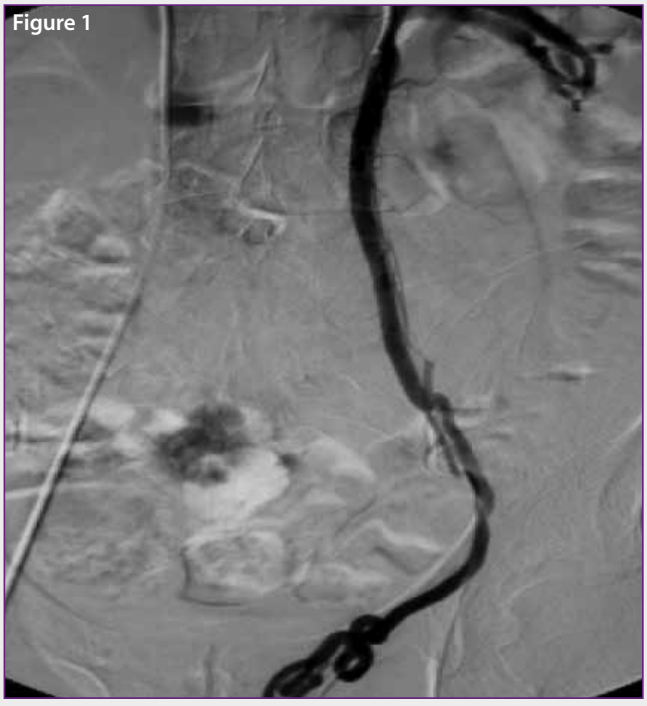


Figure 1

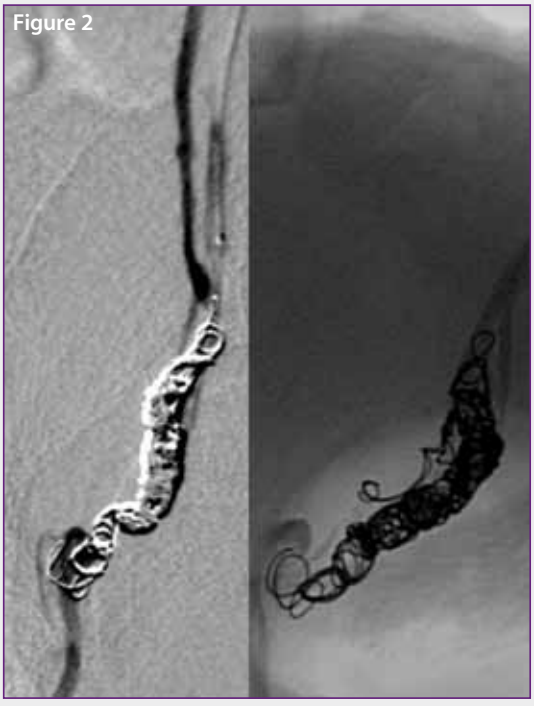


Figure 2

Discussion

In selecting the embolic coil for varicocele embolization, several features of the spermatic vein have to be considered. Despite the relatively low risk of nontarget embolization within a varicocele, the spermatic vein is very susceptible to spasm and can have hidden collateral veins that contribute to both technical failure and recurrence. The Interlock coil offers the clinician the ability to retract and manipulate the coil prior to detachment, which allowed for optimal packing of a tight nest of coils in this case. In addition, the wide variety of available lengths shortened procedures, reducing gonadal radiation exposure, which is especially important in the adolescent male. Moreover, inadequate coil nesting, as is sometimes seen with pushable coils, may leave slow residual spermatic vein flow and allow collateral veins to remain obscured and treated. ■

Kelvin Hong, MD, is an Interventional Radiologist at Johns Hopkins University Medical School in Baltimore, Maryland.

Tortuous Hepatic Artery Embolization Using the Fathom® Guidewire

BY RIAD SALEM, MD, MBA, Northwestern Memorial Hospital

INTRODUCTION

Hepatocellular carcinoma (HCC) is the most common primary liver cancer worldwide, and its incidence is rising. Unfortunately, conventional therapies such as systemic chemotherapy or external radiation have proven ineffective as treatment options. Moreover, few patients presenting with malignant hepatic tumors are candidates for surgical resection.

The development of catheter and guidewire technology has facilitated embolization, allowing for the superselective placement of catheters for the safe and effective delivery of therapeutic and radioactive agents to hepatic tumors. With experience and a trained hand, microcatheters and guidewires can be safely placed, even in the presence of aberrant vessels or a collateral blood supply.

This case study highlights the transarterial hepatic embolization technique in a complex case of unresectable HCC.

Procedure Description

A 65-year-old man presented with unresectable HCC. The celiac artery was accessed using a reverse-curve catheter. Upon evaluation, extremely tortuous vasculature was observed, much more challenging than what is typically seen in liver embolization cases. A 180-cm Fathom® 16 Steerable Guidewire was placed within a Renegade® HI-FLO™ Microcatheter, shaped, and inserted into the celiac artery and right hepatic artery. The guidewire's combined shapeability and torquablity facilitated navigation through very tortuous anatomy, including one hepatic trifurcation and six tight vascular 360º loops. The Renegade® HI-FLO™ Microcatheter provided excellent trackability and radiopacity, allowing accurate delivery of the embolic agent to the tumor site, as expected.

The total procedure time was 30 minutes. The fact that the Fathom® Guidewire maintained its body and facilitated placement and catheter tracking without vessel spasm may have contributed to the abbreviated procedure time.

Discussion

In selecting a guidewire for complex cases, a balance of attributes may be considered. The Fathom® Guidewire offers the nice balance of a soft, shapeable tip to cater to various patient anatomies, combined with excellent torquability. In this case, the trackability, pushability, and kink resistance of the guidewire allowed for the navigation of the microcatheter through extremely tortuous anatomy. ■

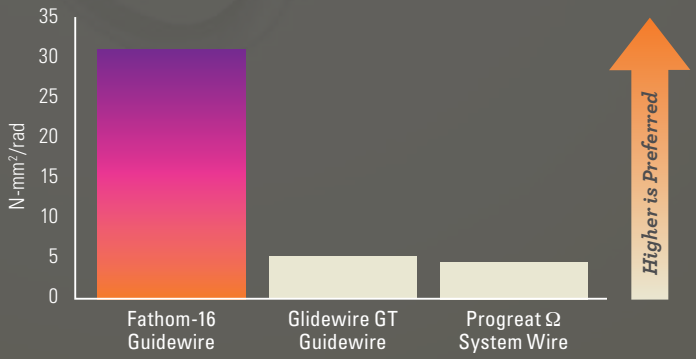
Riad Salem, MD, MBA, is the Director of Interventional Oncology at Northwestern Memorial Hospital in Chicago, Illinois.

Boston Scientific

Renegade® HI-FLO™ Fathom®

Pre-loaded System

In bench testing, the Fathom-16 Guidewire was over 5 times more torque responsive than the Glidewire® GT Guidewire or the Progreat® Ω System Wire



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N=15. Std Dev: 2.87, 0.57, 0.29. Test Description: Distal tip is constrained (attached to a load cell). Guidewire is rotated at the proximal end. Torsional stiffness is torque required to rotate the guidewire of a defined length by a defined angle.

Data on file at Boston Scientific. Testing data represents an average measurement taken across the range of available guidewires. Test results shown are for models deemed most typically selected for placement in peripheral vasculature. Bench test results may not necessarily be indicative of clinical performance.

RENEGADE® HI-FLO™ FATHOM® SYSTEM Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, 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. **INTENDED USE/ INDICATIONS FOR USE:** The Renegade HI-FLO Fathom System is intended for peripheral vascular use. The Fathom guidewire can be used to selectively introduce and position the Renegade HI-FLO microcatheter in the peripheral vasculature. The microcatheter can be used for controlled and selective infusion of diagnostic, embolic, or therapeutic materials into vessels. **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). **WARNINGS:** The Renegade HI-FLO Fathom System is not intended for use in the coronary vasculature. **PRECAUTIONS:** This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures.

Embolization of a Large Iliac Aneurysm

BY TIMOTHY RILEY, MD, St. Joseph's Hospital

INTRODUCTION

The embolization of iliac and abdominal aneurysms can often be very challenging. Because of the large aneurysmal volumes that often accompany these aneurysms, wide-diameter, highly thrombogenic devices are often required to obtain stasis. Additionally, navigation of catheters and wires to these aneurysms, particularly when embolizing type II endoleaks, often requires the clinician to traverse through challenging anatomy with smaller, more precise embolization devices. With these conflicting priorities, very few embolization platforms satisfy the need for precise delivery and high thrombogenicity.

One of the most important advances that has assisted physicians in the embolization of these challenging anomalies is the development of long, fibered detachable coils. These devices have allowed for the delivery of large volumes of embolic materials quickly and accurately. As a result, many of the procedures that have traditionally been very time consuming and challenging have become common practice for experienced interventionalists.

The following case demonstrated the utility of the Interlock™ Fibered IDC™ Occlusion System in a patient suffering from a massive iliac aneurysm.

Iliac Vein Aneurysm

A 47-year-old man was imaged using CT, which revealed a large, 7-cm X 14-cm iliac vein aneurysm on the left side.

Due to the size of the aneurysm, collateral vessel embolization with fibered platinum coils was attempted. The aneurysm was accessed, and coil embolization of the three collateral vessels filling the aneurysm sac was attempted. Because of the need to precisely select the collateral vessels inside the aneurysm sac, an angled Renegade® STC Microcatheter and Fathom® Guidewire were selected, so that control of the wire and the tip of the catheter could be maintained. Following catheter placement, eight 14-mm X 30-cm .018-inch Interlock™ Fibered Coils were placed into the three collateral vessels (Figure 1).

After 3 to 4 minutes, the embolized vessels were completely shut down. However, numerous additional collateral vessels were observed filling the sac. Due to the number of collaterals observed and the magnitude of the aneurysm, we determined that complete embolization of the aneurysm would provide the patient with the greatest chance for long-term success. We opted to remove our microcatheter-based system and embolize the aneurysm using a 5-F catheter and the Interlock™ – 35 Fibered Coils. We did this by using a 6-F sheath and a 5-F, 100-cm Bern-shaped catheter to re-access the aneurysm sac.

Due to the number of coils anticipated for completion, special care was taken to hook up a bag of continuous flush to the Bern-shaped catheter before placing coils. We placed the catheter at the distal portion of the aneurysm and began working our way proximally, with 20-mm X 40-cm and 18-mm X 40-cm Interlock™ – 35 Coils.

A total of thirty 20-mm X 40-cm coils and eight 18-mm X 40-cm coils were placed (Figure 2). We utilized both 20-mm X 40-cm Cube-shaped coils and 18-mm X 40-cm 2D Helical-shaped coils in an attempt to make the coil nest as tight as possible by alternating shapes. We achieved a very tight pack, and there was absolutely no flow going into the aneurysm sac (Figure 3).

CASE 1

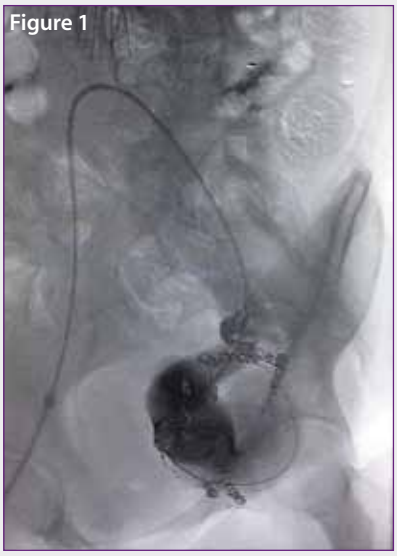
Figure 1

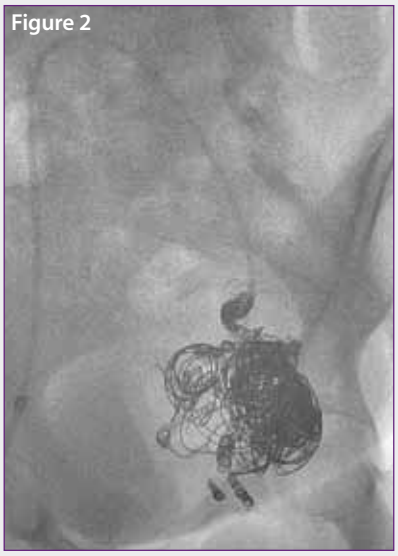
Figure 2

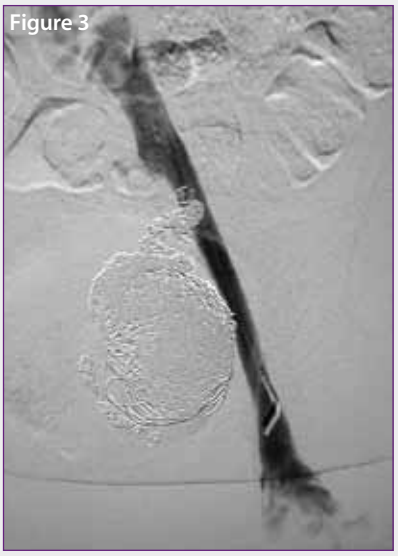
Figure 3

Discussion

Although the initial objective of the procedure was simply to embolize the collateral vessels of the aneurysm, the presence of multiple new collateral vessels appearing post-embolization caused us to alter our approach. Due to the enormous size of this iliac vein aneurysm, a total of more than 1,700 centimeters of coil was introduced into the patient in a very rapid and efficient manner. The presence of 40-cm-long coils assisted greatly in the speed of the procedure. ■

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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 used 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.