

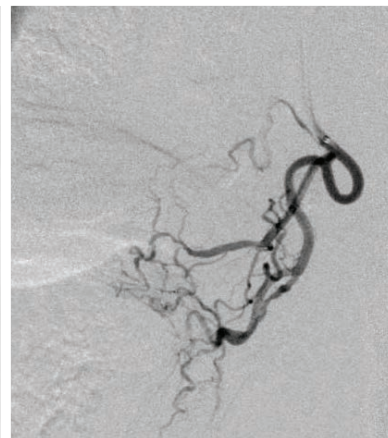
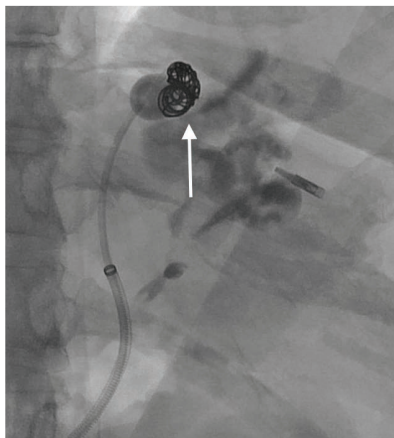
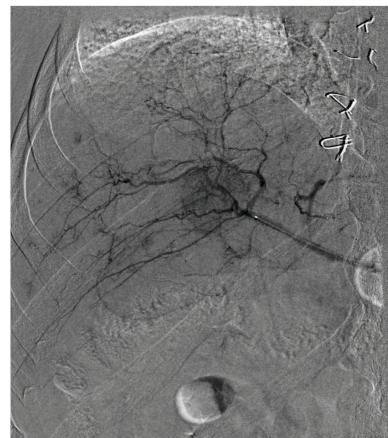
Endovascular

TODAY

April 2015

CONTROL THE FLOW

Overcoming Global Procedural Challenges:
Liver Cancer, Gastric Varices, and Enlarged Prostate



Preablative Embolization for Solitary HCC

BY BRIAN S. GELLER, MD, AND HUGH DAVIS, MD

A 79-year-old man with a history of a solitary hepatocellular carcinoma (HCC) in segment 6 presented to the interventional radiology department for hepatic angiography and preablative embolization (Figure 1A).

After using standard techniques to access the right common femoral artery, a 5-F (1.67-mm) sheath was placed. Subsequently, a selective 4-F (1.33-mm) reverse-curve catheter and a hydrophilic guidewire were used to cannulate the celiac artery. There was difficulty advancing the 4-F (1.33-mm) catheter over the wire and into the common hepatic artery, so it was decided to park the selective catheter at the celiac artery origin and use a microcatheter from there. A 0.027-inch (0.69-mm) Renegade HI-FLO™ Microcatheter and a Fathom®-16 Steerable Guidewire were used to cannulate the right hepatic artery (Figure 1B). The angiogram (contrast injector set for flow rate of 4 mL/s for total volume of 8 mL at pressure of 800 psi [5,516 kPa]) showed the tumor, but there were other areas in question. The microcatheter was exchanged for a 0.027-inch (0.69-mm) Direxion™ Torqueable Microcatheter, and a repeat angiogram (contrast injector set for flow rate of 5.2 mL/s for a total volume of 10 mL at pressure of 1,200 psi [8,274 kPa]) showed innumerable smaller tumors as well (Figure 1C). An intraoperative decision was made to forego embolization and administer macroaggregated albumin to prepare for yttrium-90 treatment.

DISCUSSION

The higher flow rates and pounds per square inch that the Direxion™ Microcatheter provides completely changed

this patient's management. Had he gone on to ablation, only one of his tumors would have been addressed. By changing his treatment to yttrium-90, all of his tumors were treated, and most had a near-complete treatment response (Figure 1D). ■

Brian S. Geller, MD, is the Chief of Interventional Radiology and Vice Chairman of Radiology at the University of Florida in Gainesville, Florida. He has disclosed that he received no compensation related to this article and is not a consultant to Boston Scientific Corporation.

Hugh Davis, MD, is a fellow at the University of Florida in Gainesville, Florida. He has disclosed that he received no compensation related to this article and is not a consultant to Boston Scientific Corporation.

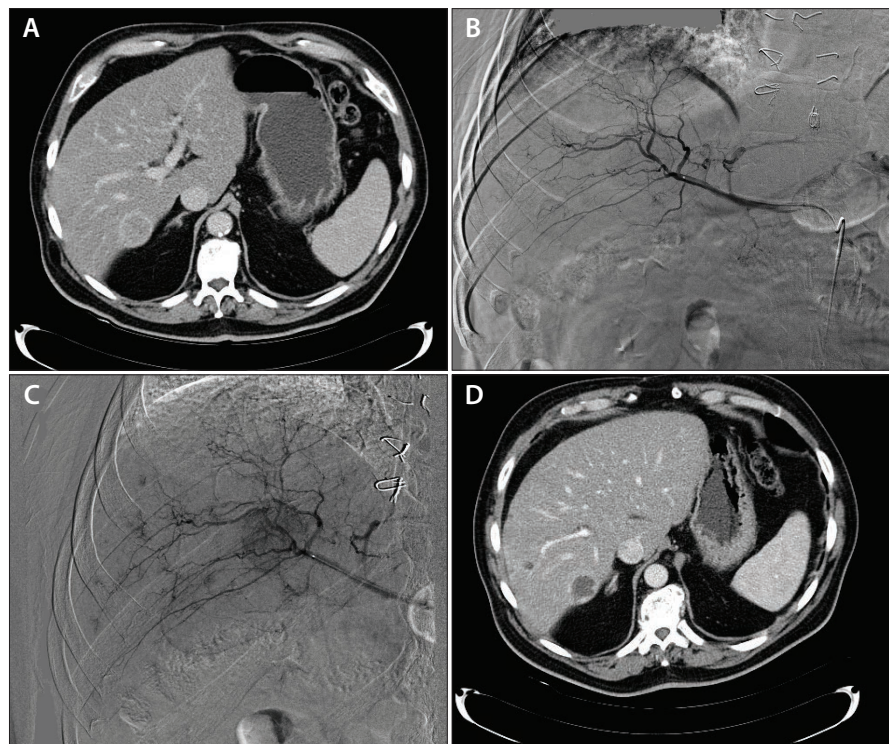


Figure 1. The HCC in segment 6 (A). Imaging obtained with the Renegade HI-FLO™ system (B). Imaging obtained with the 0.027-inch (0.69-mm) Direxion™ HI-FLO™ Microcatheter (C). Follow-up CT scan (D).

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

Embolization for a Spontaneous Chest Wall Hemorrhage

BY BRIAN S. GELLER, MD, AND CHRIS STEPHENS, MD

A 58-year-old woman was admitted to the hospital for sacral wound debridement. The patient had a history of hypercoagulability and was on anticoagulation medication before and after surgery. She presented to the interventional radiology department for treatment of a spontaneous chest wall hemorrhage several weeks after her surgery.

After using standard techniques to access the right common femoral artery, a 5-F (1.67-mm) sheath was placed. Subsequently, a VERT catheter and a hydrophilic guidewire were used to cannulate the right axillary artery. An angiogram failed to show the source of bleeding (Figure 1). The VERT catheter was retracted and, using a 0.021-inch (0.53-mm) Direxion™ Torqueable Microcatheter and Fathom®-16 Guidewire, the thyrocervical trunk was cannulated. The following angiogram result was also negative.

The VERT catheter was repositioned proximal to the internal mammary artery. The Direxion™ Microcatheter

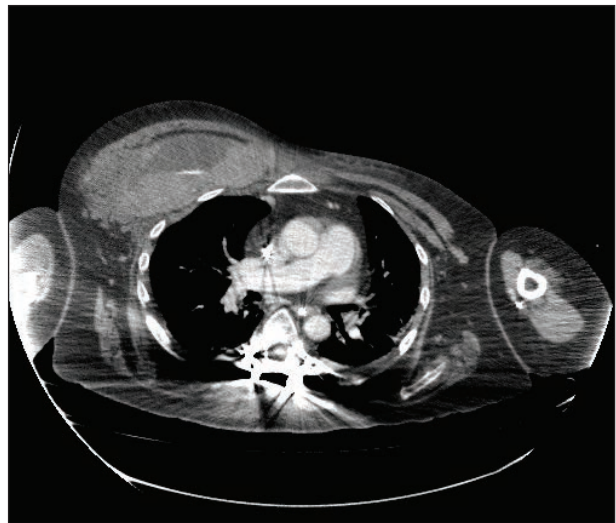


Figure 1. A CT scan showing active hemorrhage.

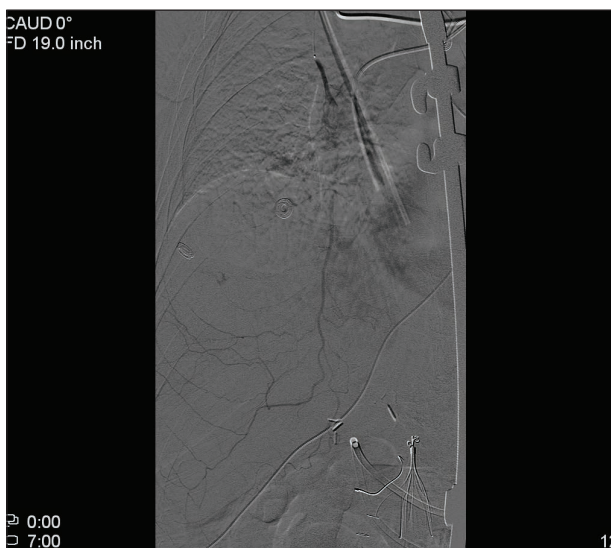


Figure 2. An angiogram showing questionable blush.



Figure 3. There was active hemorrhage from a perforator vessel.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

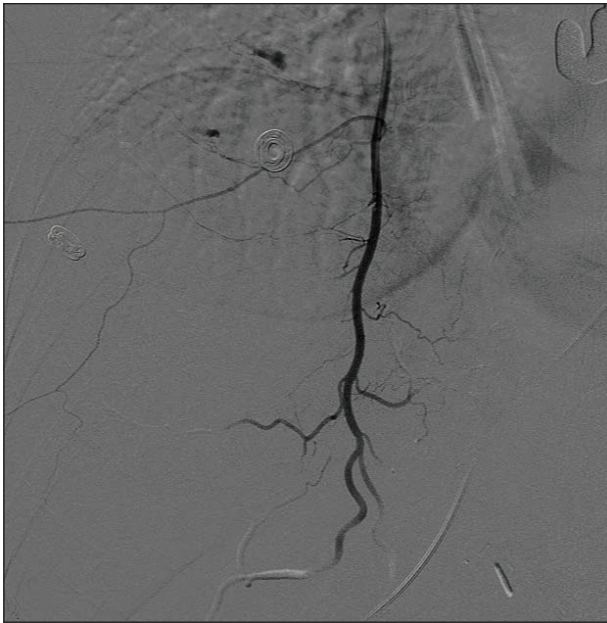


Figure 4. Gelfoam slurry resolved the initial hemorrhage, but two additional areas of bleeding were found.

and Fathom®-16 Guidewire were used to cannulate the right internal mammary artery. The angiogram showed a questionable blush (Figure 2). The Direxion™ Microcatheter was advanced below the level of the diaphragm. The angiogram showed active hemorrhage from a perforator vessel (Figure 3). Gelfoam slurry was instilled through the Direxion™ Microcatheter. A follow-up angiogram showed no further hemorrhage from that artery; however, two additional vessels were bleeding (Figure 4), which also responded well to gelfoam (Figure 5).

DISCUSSION

Based on the CT scan, it was originally thought that the treatment of this hemorrhage would require coil embolization; therefore, a 0.021-inch (0.53-mm) microcatheter would be required. I also thought that we would need higher flow rates to visualize the area of



Figure 5. The final angiogram showing no area of active hemorrhage.

hemorrhage. Normally, this would require starting with a 0.027-inch (0.69-mm) microcatheter and then exchanging for a 0.021-inch (0.53-mm) microcatheter for coil placement. By starting with the 0.021-inch (0.53-mm) Direxion™ Microcatheter, this reduced overall procedure time and equipment cost. ■

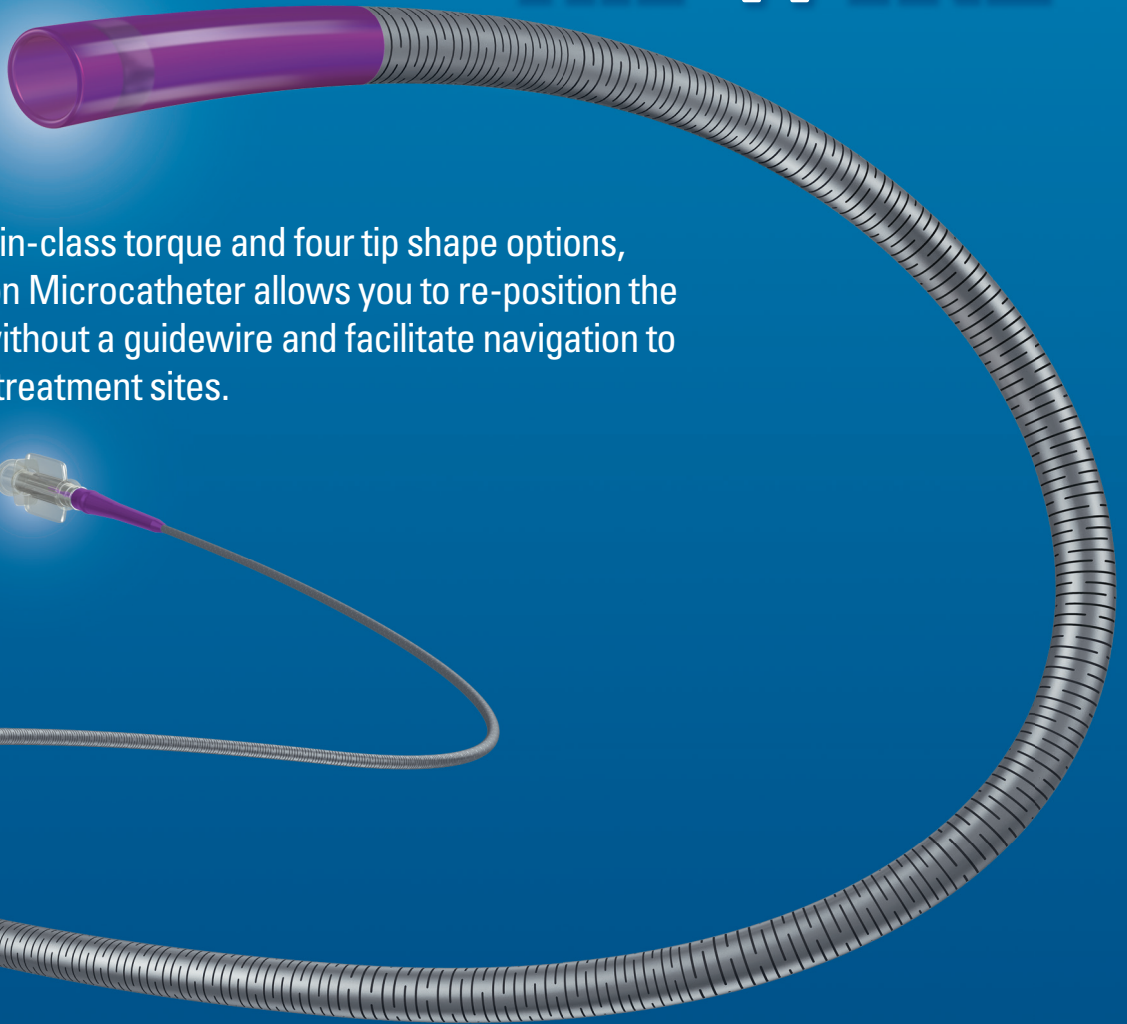
Brian S. Geller, MD, is the Chief of Interventional Radiology and Vice Chairman of Radiology at the University of Florida in Gainesville, Florida. He has disclosed that he received no compensation related to this article and is not a consultant to Boston Scientific Corporation.

Chris Stephens, MD, is a fellow with the Department of Radiology, College of Medicine, University of Florida in Gainesville Florida. He has disclosed that he received no compensation related to this article and is not a consultant to Boston Scientific Corporation.

DIREXION™ Torqueable Microcatheter

REPOSITION WITHOUT THE WIRE

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Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Information not intended for use or distribution in France.

DIREXION™ DIREXION HI-FLO™

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: 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. **WARNINGS:** • 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. • This 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. **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) **REV AB**

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Embolization of Benign Prostatic Hyperplasia

BY SANDEEP BAGLA, MD

Benign prostatic hyperplasia (BPH) affects more than 15 million men in the United States. Pathologically, this most common benign tumor of the prostate undergoes smooth muscle and adenomatous glandular hyperplasia, usually beginning in the third or fourth decade of life. Patients typically present with symptoms such as frequency, nocturia, urgency, weak stream, and feeling of incomplete emptying. Although medical therapy or lifestyle modification may be suitable for most patients, those with moderate or severe symptoms will likely require surgical intervention. Currently available transurethral procedures, such as transurethral resection or photoselective vaporization, work by increasing the luminal diameter of the prostatic urethra. These come at a significant cost of complications, including incontinence, impotence, bleeding, or retrograde ejaculation.

Because BPH is also hypervascular,^{1,2} particularly in the central gland, interventional radiologists have used prostatic artery embolization (PAE) to reduce the size of these hypervascular nodules and improve symptoms from BPH. Results from clinical trials³ have dem-

onstrated a significant reduction in symptoms from BPH with a very low risk of complication. Significant technical challenges exist with PAE, including tortuous anatomy with small distal target vasculature and the need for high-quality imaging and embolic material injection.

CASE PRESENTATION

A 62-year-old man with severe lower urinary tract symptoms from BPH was referred to the clinic for evaluation of PAE. His peak urine flow rate was severely decreased at 2 mL/sec, and his prostate was enlarged to 90 cc (Figure 1). He was in good health, sexually active, and wanted to avoid transurethral therapy because of the risk of sexual side effects. After discussion with the patient and consulting urologist, the patient was scheduled for the procedure.

PROCEDURE DESCRIPTION

A 6-F (2-mm) vascular sheath was placed in the right common femoral artery, and a 6-F (2-mm) guid-

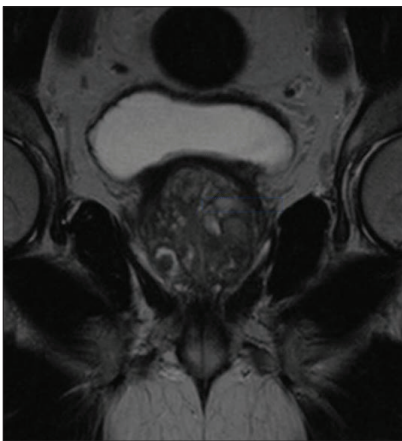


Figure 1. Coronal T2-weighted MRI shows nodular enlargement of BPH impinging on the bladder above.



Figure 2. Digital subtraction angiography of the left hypogastric artery depicts the tortuous left prostatic artery (white arrow).



Figure 3. Microcatheter selection of the left prostatic artery with hypervascular gland. The catheter is small enough to allow for adequate antegrade flow during embolization. Note that the pre-shaped tip is directed laterally.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

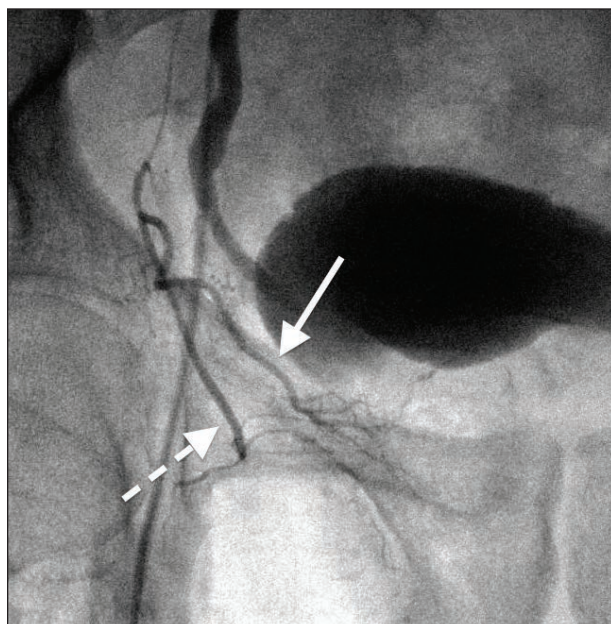


Figure 4. Injection performed through the microcatheter allowed for good visualization of an obturator branch (dashed white arrow) and the prostatic artery (solid white arrow).

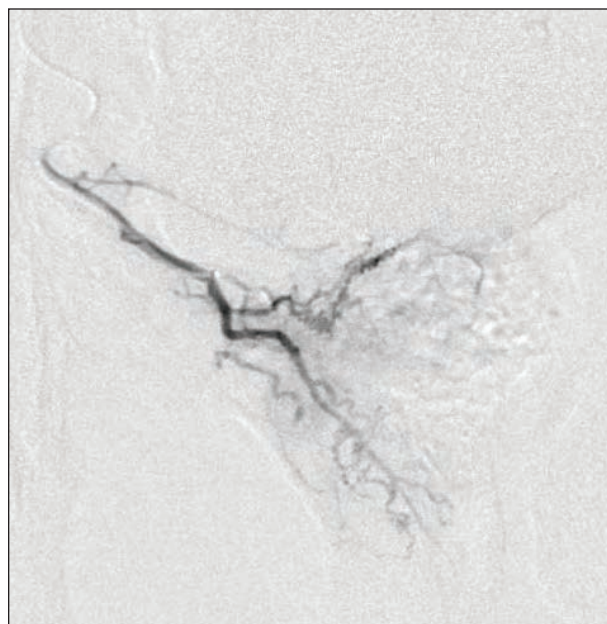


Figure 5. Careful catheter manipulation to select the prostatic artery without a wire in this case.

ing catheter was placed in the left hypogastric artery. Digital subtraction angiography depicts a tortuous left prostatic artery (Figure 2), which is typical in appearance. A preshaped 2.4-F (0.79-mm) Direxion™ Torqueable Microcatheter was used to select the left prostatic artery, and subselective angiography was performed (Figure 3).

Embolization was performed proximally through the Direxion™ Microcatheter and then advanced distally without a wire to allow for further embolization. Smaller-size spherical particulate (100 μ m) and gelfoam were used in the main trunk. On the right side, the prostatic artery originated from the obturator artery (Figure 4), and the preshaped tip was directed into the prostatic artery to perform selective angiography and embolization (Figure 5). Embolization was performed to stasis, and the patient was discharged without complications. He noted more than 50% reduction in his symptoms by 1 month and has continued to do well at his routine follow-up.

DISCUSSION

Tortuosity and size of the prostatic artery remain the greatest challenges to PAE. Ideal microcatheters are \leq 2.4 F (0.79 mm) and allow for torque and manipulation without kinking, high-pressure injection rates, and the ability to deliver embolic agents. In this

case, the Direxion™ Microcatheter allowed for reliable torqueability of the distal preshaped tip. This can be used to select the prostatic artery when originating from a distal nontarget vessel, as on the right side in this patient. It is also useful when the operator would like to advance within the target vessel with careful rotation. Although not used in this case, high-pressure angiography can allow for better imaging if guide catheters cannot be taken distally. Embolic agents of varying size were also delivered through the catheter with ease. Overall, the Direxion™ Microcatheter performed safely and reliably in our experience with PAE and can be useful in overcoming challenges associated with the procedure. ■

Sandeep Bagla, MD, is with the Association of Alexandria Radiologists, PC at Inova Alexandria Hospital, Alexandria, Virginia. He has disclosed that he received no compensation related to this article and is not a consultant to Boston Scientific Corporation. Dr. Bagla may be reached at sandeep.bagla@gmail.com.

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3. Schreuder SM, Scholtens AE, Reekers JA, Bipat S. The role of prostatic arterial embolization in patients with benign prostatic hyperplasia: a systematic review. *Cardiovasc Intervent Radiol*. 2014;37:1198-1219.

Utility of the Direxion™ Torqueable Microcatheter in Challenging Cases

BY ILAN RZADKOWOLSKY-RAOLI, MD

A microcatheter is an essential tool in an interventionist's armamentarium. We are fortunate to have a bounty of low-profile catheters to choose from today, most of which display an assortment of the qualities ascribed to a successful device: good torque response, distal flexibility, kink resistance, fluoroscopic visibility, low stretch, high pressure, and the ability to easily pass materials, including guidewires and embolic materials. Each of us has a favorite; however, this preference is mostly derived from default experience during training and availability in the face of tight financial constraints during practice rather than from real-world testing of each device.

One of the most widely used microcatheters has been the Renegade HI-FLO™ System from Boston Scientific. It is truly a workhorse, able to navigate tortuous vessels and retain a measure of torqueability and trackability. I confess it was my go-to microcatheter throughout most of my career. Because of my fondness for it, I eagerly jumped at the chance to put the



Figure 1. A celiac angiogram showing active extravasation of contrast from a posterior branch of the right hepatic artery supplying the HCC. Note the poor perfusion to the remaining liver due to systemic low blood pressures.

Direxion™, the newest microcatheter from Boston Scientific, to the test.

Billed as the “world’s first truly torqueable microcatheter,” it is constructed from a slotted, nitinol hypotube. The proximal cuts are farther apart to retain pushability, while the distal slots are closer together to sustain flexibility. This unique shaft contributes to its smooth trackability, as it easily navigates twisting vessels and acute branches without the buckling (and loss of access), which lengthens procedure times and increases radiation exposure. Four different preformed tip configurations are available, further facilitating superselective manipulation.

I submit here two sample cases where this singular tool allowed me to successfully complete therapy where other microcatheters failed.

CASE 1

A 65-year-old man with large hepatocellular carcinoma (HCC) occupying segments 7 and 8 of the liver presented



Figure 2. Angiogram taken during coil embolization, showing traversal of the difficult turn and the superselective position of the catheter tip.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

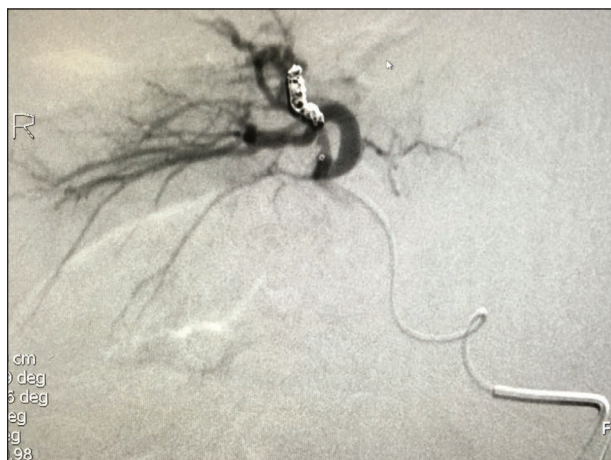


Figure 3. Final angiogram showing successful exclusion of the ruptured artery.

with rapid decompensation with hypotension, tachypnea, and a 6-g/dL drop in hemoglobin in 12 hours. A quick noncontrast CT scan showed evidence of tumor rupture with a large amount of hemoperitoneum. A celiac angiogram showed active extravasation of contrast from a posterior branch of the right hepatic artery supplying the HCC (Figure 1). There was poor perfusion to the remaining liver due to systemic low blood pressures.

The first twist after the tip of the guiding catheter just before the gastroduodenal artery branch is a very acute turn, reversing almost 135° on itself. Another microcatheter would not make this turn without kicking out the guiding catheter. This was the first case in which I was able to use the Direxion™ Microcatheter.

After the tight loop was surpassed (Figure 2) while maintaining guiding catheter placement, three more turns were navigated, including another relatively sharp angulation at the branching of the offending artery. Most other small-bore catheters would have surrendered their torqueability after the first turn. Gaining this position was the key to successfully prosecuting the case (Figure 3).

CASE 2

A 57-year-old woman with a history of primary neuroendocrine tumor of the colon was treated with hemicolectomy. A metastatic lesion straddling segments 7 and 8 of the liver had been previously treated with percutaneous thermal ablation (both radiofrequency and microwave) with partial success. The patient presented for bland embolization.

A celiac angiogram showed faint tumor blush near the dome of the liver, with hepatic arterial supply derived

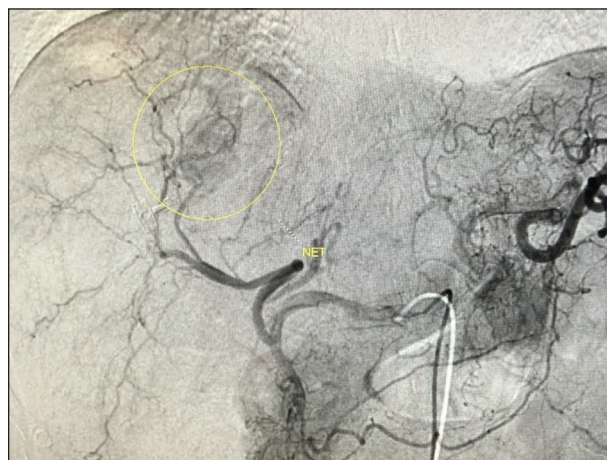


Figure 4. A celiac angiogram showed faint tumor blush near the dome of the liver with hepatic arterial supply derived from both segment 7 and 8 branches. Note the bend of the proper hepatic artery after the GDA and the severe, near-180° angulation of the right hepatic artery distal to the left hepatic artery take-off.



Figure 5. A superselective angiogram from the segment 8 hepatic artery after embolization of the medial branch.

from both the segment 7 and 8 branches (Figure 4). There was severe bend of the proper hepatic artery after the gastroduodenal artery and near-180° angulation of the right hepatic artery distal to the left hepatic artery takeoff. This second flexure could not be crossed with a conventional microcatheter without buckling the support catheter.

Embolization of the medial branch was performed (Figure 5). This position was gained using the Direxion™ Microcatheter, which did not yield trackability despite the unfavorable anatomical bend of the proximal right hepatic artery.

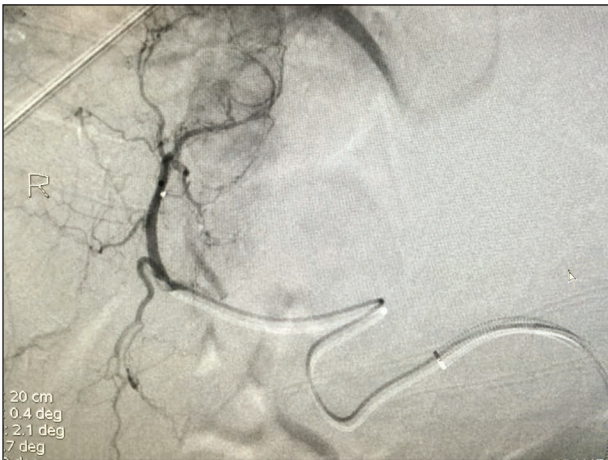


Figure 6. A superselective angiogram from the segment 7 hepatic artery at a different position than Figure 5. There is tumor blush medially. The mouse pointer shows the general location of the catheter tip, seen as a dark spot slightly distally.



Figure 7. Completion celiac angiogram showing successful embolization of the tumor-feeding arterial branches with stasis of contrast and cast of vessels.

A superselective angiogram from the segment 7 hepatic artery showed tumor blush medially, and preparation was made for embolization (Figure 6). Again, this location was attained despite power-bleeding anatomy. Embolization of the tumor-feeding arterial branches was successful, with stasis of contrast and cast of vessels (Figure 7).

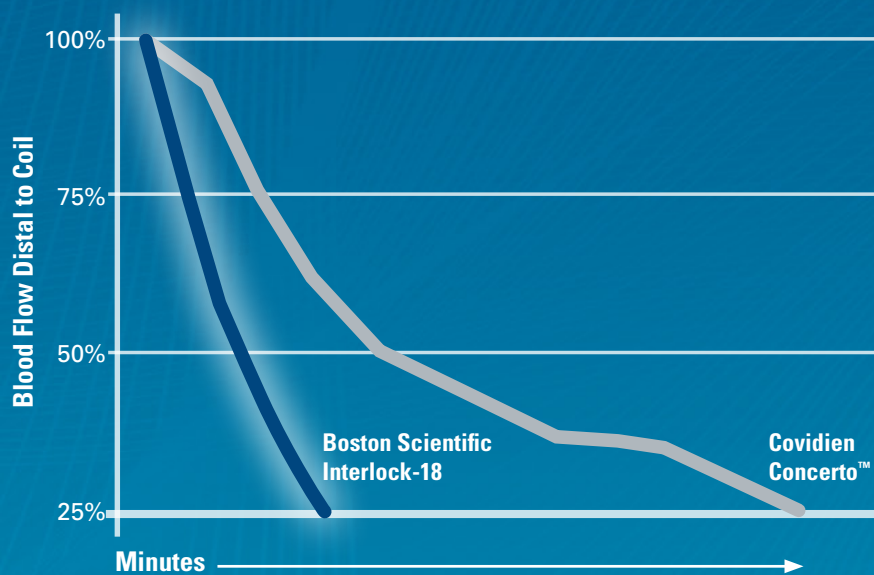
DISCUSSION

The cases in this article illustrate the capabilities of the Direxion™ Microcatheter to outperform most other examples of its class. With its unmatched torqueability and trackability as a consequence of its unique shaft design, as well as its slick feel due to its lubricious outer coating, the Direxion™ is rapidly becoming my first choice for slightly challenging anatomy. Add to this mix the array of tip configurations and both high-flow and low-profile diameters, and there is no location that cancer is safe! ■

Ilan Rzadkowsky-Raoli, MD, is with Palmetto General Hospital in Hialeah, Florida. He has disclosed that he received no compensation related to this article and is not a consultant to Boston Scientific Corporation.

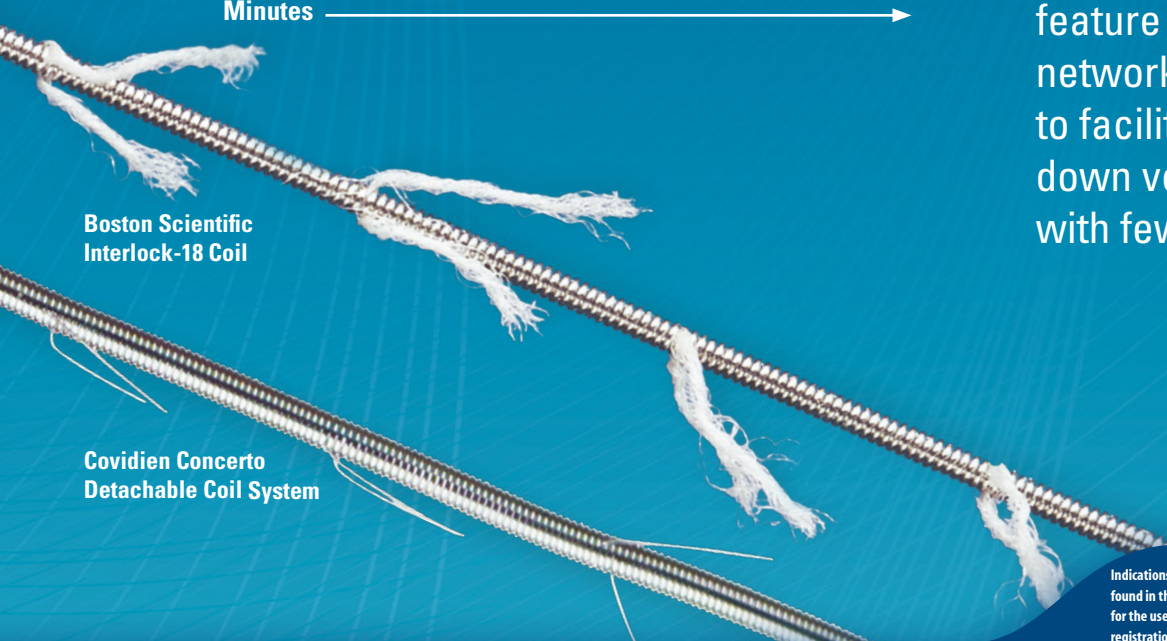
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and replace the microcatheter and coil if necessary. **ADVERSE EVENTS:** The complications that may result from a peripheral embolization procedure include, but are not limited to: • Complications related to catheterization (e.g., hematoma at the site of entry, vessel injury, etc.) • Death • Emboli • Foreign body reactions necessitating medical intervention • Hemorrhage • Infection necessitating medical intervention • Ischemia • Pain • Recanalization • Temporary neurological deficit • Tissue necrosis • Undesirable clot formation of the vasculature • Vasospasm (REV AA)

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Modified Balloon-Occluded Retrograde Transvenous Obliteration of Gastric Varices

BY MONI STEIN, MD, FSIR

Transjugular intrahepatic portosystemic shunt (TIPS) has been the main alternative to treating bleeding related to esophageal or gastric varices in the context of portal hypertension. Recently, as a less-invasive alternative, balloon-occluded retrograde transvenous obliteration (BRTO) of gastric varices has been introduced to treat bleeding gastric varices, which are less amenable to endoscopic sclerotherapy and banding. We describe a successful case of modified BRTO in the acute setting of gastric variceal bleeding.

CASE PRESENTATION

A 61-year-old woman presented to the emergency department at Adena Regional Medical Center in Chillicothe, Ohio, with upper gastrointestinal bleeding. She had established liver cirrhosis with portal hypertension. A

CT scan obtained earlier showed gastric varices and a well-developed splenorenal shunt (Figures 1 and 2). Endoscopy was performed identifying mostly gastric varices with active bleeding. An attempt was made to place a clip across a bleeding varix, which achieved only temporary relieve.

The patient was determined to be a good candidate for BRTO, which was performed in the angiographic suite via a femoral vein approach. After establishing access into the femoral vein with a 5-F (1.67-mm) Cobra C2 catheter, the left renal vein was selectively catheterized, and renal venography was performed. A 7-F (2.33-mm) vascular sheath was introduced and, using a 5-F (1.67-mm) Berenstein catheter and a stiff hydrophilic guidewire, the splenorenal shunt was catheterized, and venography was performed (Figure 3).

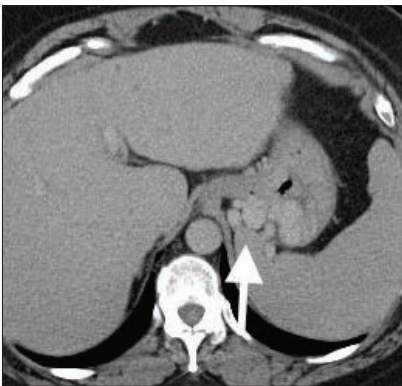


Figure 1. A CT scan of the abdomen with contrast showed gastric varices but no esophageal varices (white arrow).



Figure 2. A CT scan of the abdomen with contrast showed the spontaneous splenorenal shunt (yellow arrow).

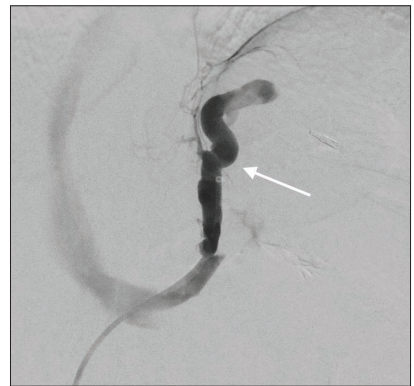


Figure 3. Catheter venography showed the splenorenal shunt (white arrow) with a flow from the gastric varices to the renal vein.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

The catheter was advanced further into the portion of the shunt closest to the varices, and a Berenstein 8.5/11.5-mm occlusion balloon was introduced over an Amplatz wire and was inflated with a 0.55-mL mixture of saline and contrast at 50% strength. A 10-mL mixture

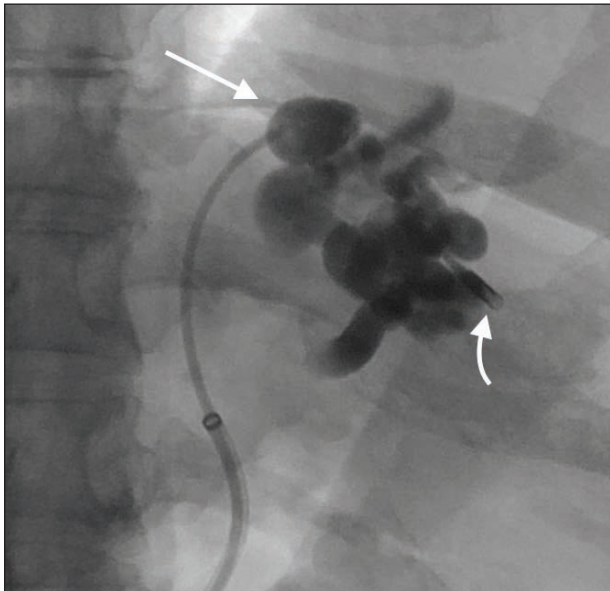


Figure 4. Catheter venography showed the inflated occlusion balloon (straight white arrow) and the stasis in the gastric varices distal to the balloon. Note the metallic clip placed during endoscopy (curved arrow).

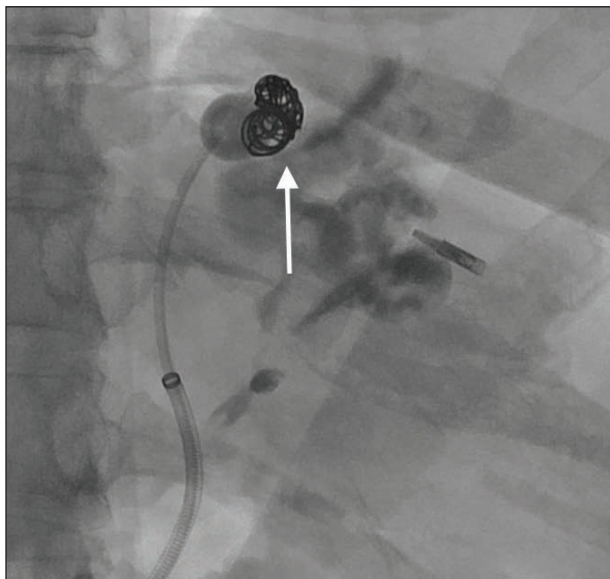


Figure 5. Following injection of the sclerosing agent, coils were deployed just distal to the balloon (white arrow).

of contrast material, gelfoam, and 1% sodium tetradecyl sulfate was processed as a slurry in a 10-mL syringe and injected through the lumen of the occlusion balloon and was left in place for 15 minutes (Figure 4).

Subsequently, coil embolization was performed through the same lumen while the balloon was still inflated. Two 8-mm X 40-cm (400-mm) and three 8-mm X 20-cm (200-mm) Interlock™-35 Coils were deployed (Figures 5 and 6) into the varices and spleno-renal shunt to trap the sclerosing agent and prevent the possibility of migration into the systemic circulation and potentially the pulmonary arteries. The patient remained stable, and the access was removed safely. The patient was discharged from the hospital a day later.

DISCUSSION

This case exemplifies the value of a minimally invasive procedure such as BRTO, which takes advantage of the patient's anatomy in order to access and sclerose bleeding gastric varices without having to perform a TIPS with all its potential risks and complications. ■

Moni Stein, MD, FSIR, is Chief of Interventional Radiology at Columbus Radiology in Columbus, Ohio. He has disclosed that he received no compensation for this article and is not a consultant to Boston Scientific Corporation.

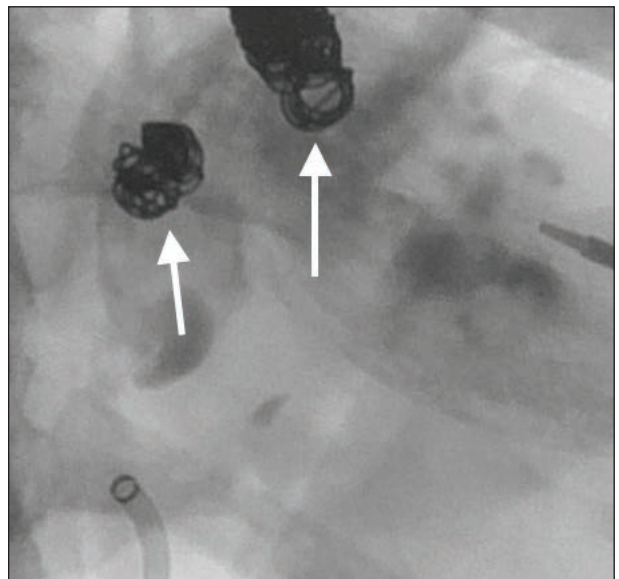


Figure 6. Final image showed the Interlock™ Coils (white arrows) blocking the outflow from the gastric varices after sclerotherapy. Contrast was still noted in the varices, indicating flow stasis.

Chemoembolization for Extrahepatic Arteries Feeding HCC

BY JOAN FALCO, MD, AND EVA CRIADO, MD

Today, the standard endovascular treatment of hepatocellular carcinoma (HCC) is transcatheter arterial chemoembolization (TACE) with calibrated particles preloaded with doxorubicin. This is a more selective and challenging technique compared to classical chemoembolization with ethiodized oil, especially concerning the use of microcatheters. New-generation microcatheters are developed to go further distally in more tortuous and smaller arteries and thus achieve more favorable results.

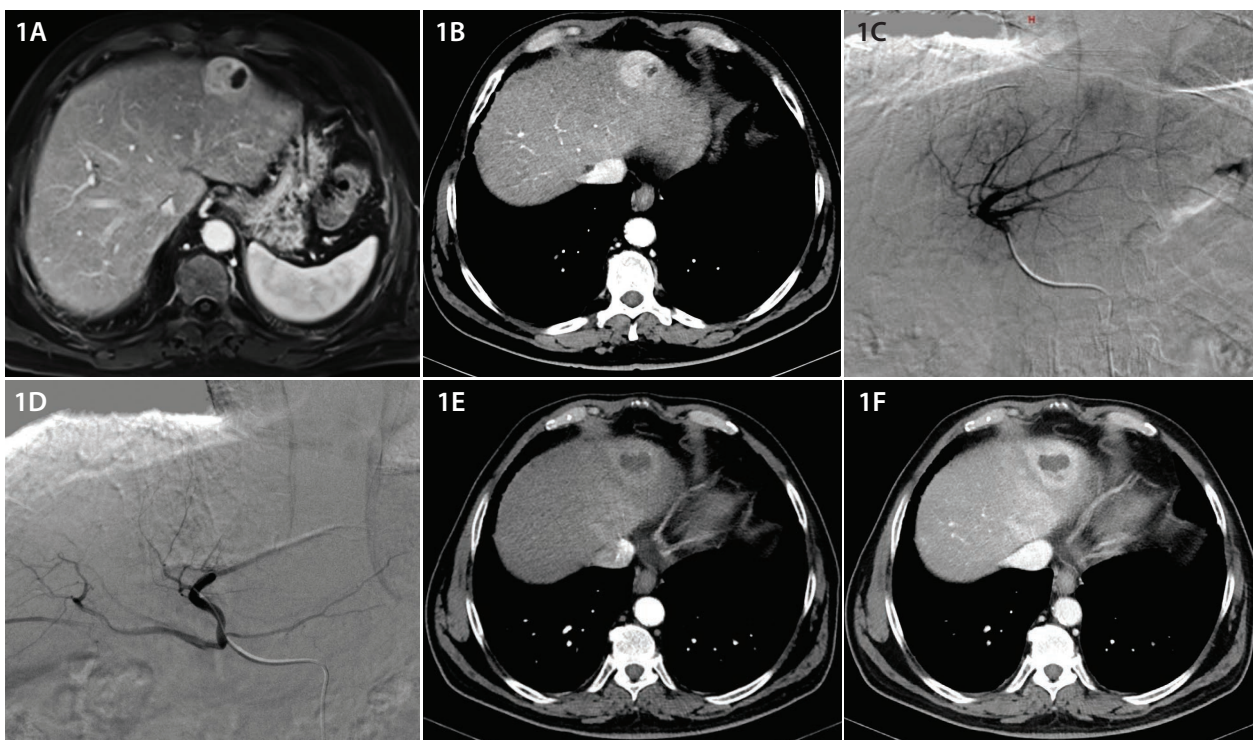
In this sense, HCC with extrahepatic feeding arteries represents a more challenging condition for its treatment, and it is present in a nonnegligible proportion of cases. Although a conventional 2.7-F (0.9-mm) micro-

catheter usually reaches its goal in most procedures, the use of new-generation microcatheters in these particular cases is mandatory to achieve successful treatment of these lesions.

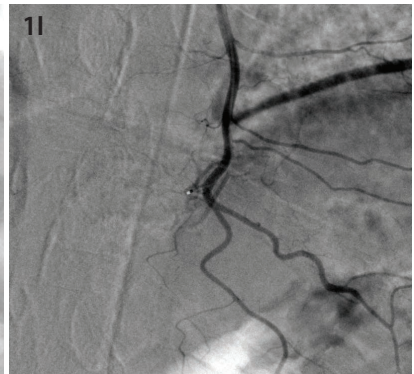
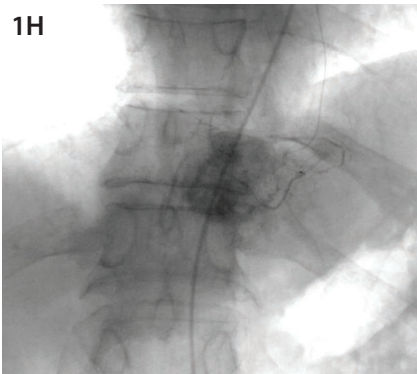
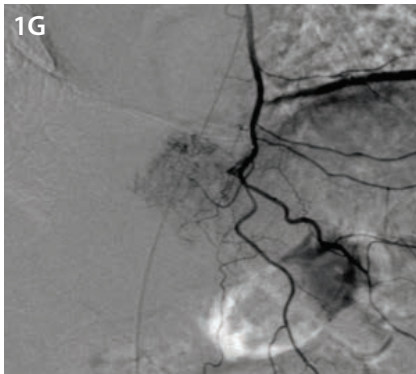
This article presents our recent experience with the new 2.4-F, 150-cm- (0.8-mm, 1,500-mm-) long Direxion™ Torqueable Microcatheter with a distal radiopaque marker.

CASE PRESENTATION

A 59-year-old man presented with a medical history of stable ischemic heart disease. He had no known liver disease. An abdominal MRI was performed (Figure 1A) and showed an incidental liver lesion of 3.8 cm (38 mm)



Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.



in segment 2 with typical characteristics of HCC.

The final diagnosis was nonalcoholic steatohepatitis cirrhosis in a patient with Barcelona Clinic Liver Cancer early-stage A, Child-Pugh A, candidate to orthotopic liver transplant. Treatment with drug-eluting bead chemoembolization was decided as a bridge to liver transplant.

After MRI diagnosis and before treatment, a dynamic angio-CT scan (Figure 1B) was also obtained, which showed the described lesion with arterial enhancement.

Through a right femoral access, a celiac trunk arteriogram showed a mild enhancement in the area of segment 2 (Figure 1C). Treatment with doxorubicin-loaded, 100–300- μ m beads was administered. No additional tumoral branch or suspicious foci of enhancement was detected (Figure 1D).

Dynamic angio-CT scans performed 1 month later with arterial and venous phase (Figures 1E and 1F), showed partial response of the nodule, but no additional information about the pathway of new feeding arteries.

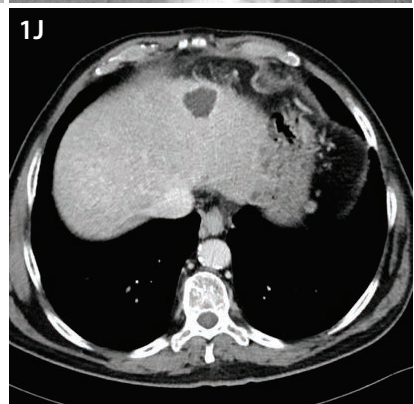
A second TACE was planned. Angiography focused on extrahepatic vessels showed a left mam-

mary artery feeding the remaining viable tumor (Figure 1G). Using a 2.4-F, 150-cm (0.8-mm, 1,500-mm) Direxion™ Torqueable Microcatheter, superselective catheterization of the final tumoral branch was accomplished (Figure 1H). Superficiality of the parietal branches of the mammary artery discouraged us from performing a nonsuperselective embolization with doxorubicin. The final run showed a lack of enhancement of the lesion (Figure 1I). No complications, such as pain or ulcerations, were seen.

Control with angio-CT scan showed a complete response of the lesion in segment 2 (Figure 1J).

DISCUSSION

Although the majority of selective chemoembolization can be accomplished with standard 2.7-F (0.9-mm) microcatheters, suspicion of extrahepatic feeding arteries with HCC or inability to accomplish a superselective catheterization makes it crucial to use more efficient microcatheters. The use of these more technically developed microcatheters, designed with a lower-caliber profile and more torqueability and pushability, permits not only the injection of



particles up to 300 μ m, but also good trackability through tortuous routes. In our initial experience using the Direxion™ Microcatheter, we succeeded in completing the treatment of all of our cases. ■

Joan Falco, MD, is an interventional radiologist at the UDIAT-CD, University Hospital Parc Taulí in Sabadell, Spain. He has disclosed that he received no compensation related to this article and is not a consultant to Boston Scientific Corporation.

Eva Criado, MD, is an interventional radiologist at the UDIAT-CD, University Hospital Parc Taulí in Sabadell, Spain. She has disclosed that she received no compensation related to this article and is not a consultant to Boston Scientific Corporation.

The Direxion™ HI-FLO™ Torqueable Microcatheter in the Preprocedural Planning of Y-90 Radioembolization for HCC

BY ORSOLA PERRONE, MD; ROSSELLA SCANDIFFIO, MD; ALESSANDRO GRIGOLINI, MD; AND ROBERTO CIONI, MD

Yttrium-90 transarterial radioembolization (Y-90 RE) is emerging as a promising treatment modality for managing patients with unresectable primary and secondary hepatic lesions. In patients with hepatocellular carcinoma (HCC), Y-90 RE represents a valid treatment option in selected cases of advanced-stage disease with portal vein neoplastic thrombosis or when other locoregional approaches are contraindicated or fail to achieve tumor response.¹

Meticulous preprocedural planning with digital subtraction angiography (DSA) and technetium^{99m}-labeled macroaggregated albumin (^{99m}Tc-MAA) scintigraphy is essential to avoid nontarget embolization and to ensure adequate delivery of microspheres to all the tumors.

Therefore, DSA diagnostic work-up requires precise definition of all the feeding arteries, identification and potential embolization of parasitized collaterals, and visualization of extrahepatic vessels arising from the hepatic circulation.² In this scenario, the performance of the high-flow coaxial microcatheters used during DSA becomes extremely important.

CASE PRESENTATION

A 55-year-old man with a history of hepatitis C and cirrhosis (ECOG Performance Status 0, Child-Pugh class A) presented with multifocal, infiltrative-type, slightly hypervascular hepatocellular carcinoma (HCC) (Figure 1),

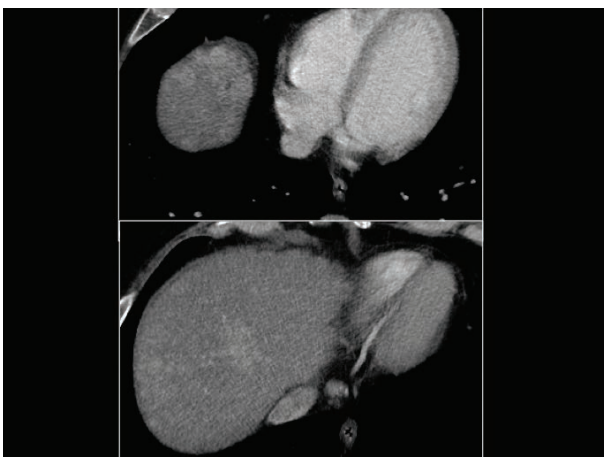


Figure 1. The multifocal, infiltrative-type HCC.



Figure 2. A celiac angiogram obtained with a 5-F (1.67-mm) Cobra catheter.

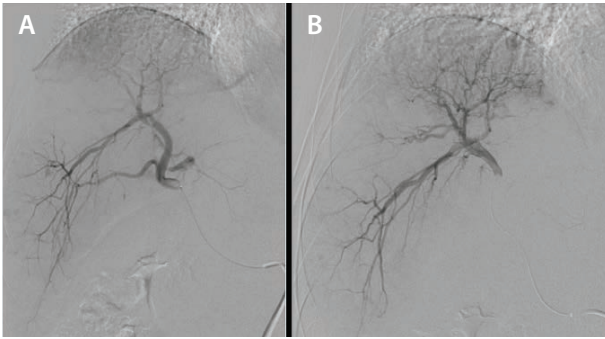


Figure 3. The initial angiogram did not have clear depiction of the lesions (A). When the microcatheter was advanced into the main branch of the hepatic artery, the hypervascular nodules were clearly shown (B).

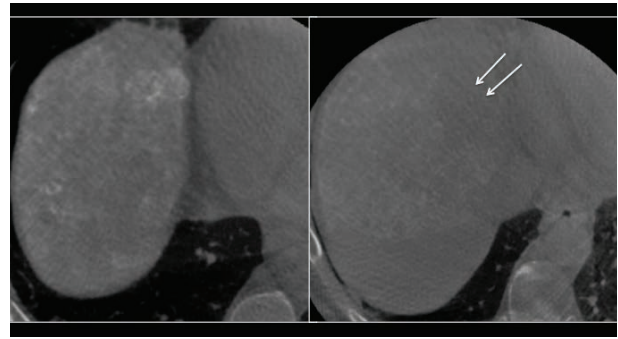


Figure 4. A C-arm CT scan showing a lack of opacification of the caudal-medial portion of the lesions (arrows).

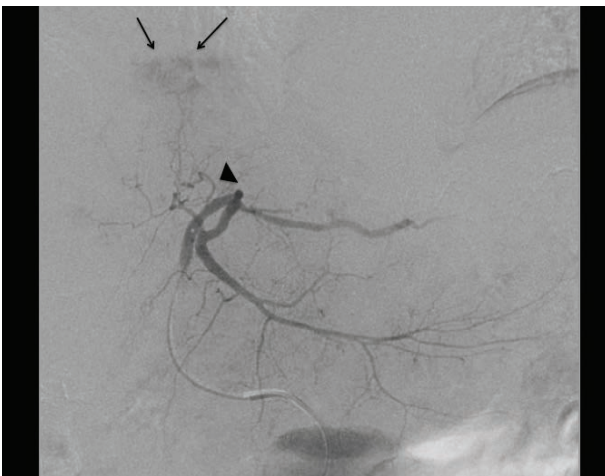


Figure 5. A small arterial feeder (arrowhead) shown on an angiogram of the left hepatic artery (arrows).

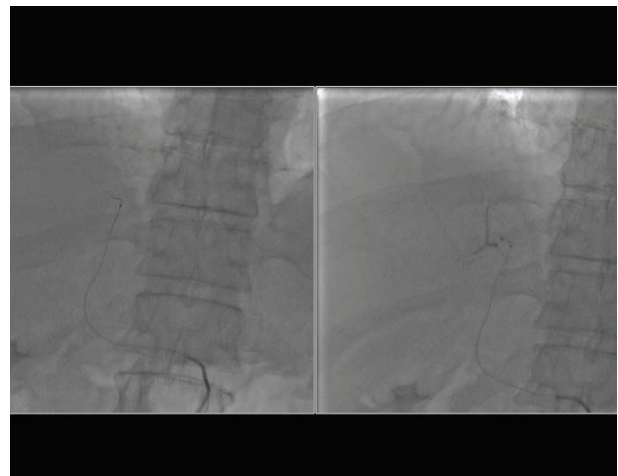


Figure 6. The small arterial feeder was catheterized with a J-tip Direxion™ HI-FLO™ Microcatheter.

without macrovascular invasion or extrahepatic tumor spread. After multidisciplinary tumor board discussion, the patient was selected for Y-90 RE, and preprocedural diagnostic work-up was scheduled.

A 5-F (1.67-mm) vascular sheath was placed through the right common femoral artery, and a celiac angiogram was obtained with a 5-F (1.67-mm) Cobra catheter (Figure 2). A 2.8-F (0.93-mm) J-shape Direxion™ HI-FLO™ Microcatheter was placed in the right hepatic artery, and initial angiography was performed with 10 mL of iodized contrast media injected at a flow rate of 2 mL/sec with 750 psi (5,171 kPa), without clear depiction of the lesions (Figure 3A). The microcatheter was then slightly advanced into the main branch of the right hepatic artery, and angiography was repeated with 10 mL iodized contrast media, injected at a flow rate of 3 mL/sec with 900 psi (6,205 kPa), and clearly demonstrated the hypervascular nodules (Figure 3B).

With similar injection parameters, a C-arm CT scan was obtained (Figure 4), which showed the lack of opacification of the caudal-medial portion of the lesions (Figure 4, arrows).

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A small arterial feeder (Figure 5, arrowhead) of this portion was depicted on angiography of the left hepatic artery (Figure 5, arrows). To enable flow redistribution,³ this small feeder was easily catheterized, taking advantage of the J-shape tip of the microcatheter (Figure 6). Embolization was successfully performed with a 3-mm X 6-cm (60-mm) Interlock™ Detachable Coil (Figure 7).

Finally, the microcatheter was positioned in the feeding branch of the right hepatic artery (Figure 8) and, after ^{99m}Tc MAA injection, SPECT-CT scans were obtained, showing homogeneous intratumoral MAA accumulation with no evidence of extrahepatic shunting (Figure 9).

Two weeks later, Y-90 RE was performed.

DISCUSSION

Accurate angiographic planning is essential for Y-90 RE safety and efficacy.² In this case, diagnostic work-up was initially complicated by the relatively low arterial vascularization of the lesions. The Direxion™ HI-FLO™ Microcatheter allowed contrast media injection at high

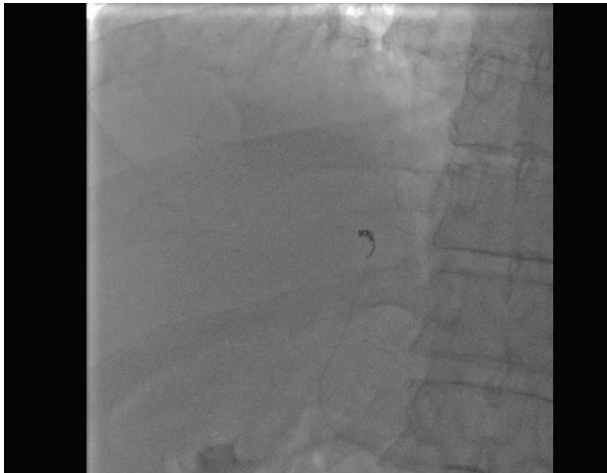


Figure 7. Successful embolization with an Interlock™ Detachable Coil.

pressures and flow rates, thus favoring depiction of these infiltrative and moderately hypervascular lesions.

Moreover, the unique nitinol shaft configuration ensures great torqueability, while maintaining trackability and flexibility. In fact, the selective catheterization of the tiny vessel arising from the left hepatic artery wound up being simpler than expected, despite the use of a 2.8-F (0.93-mm) catheter inside a very small vessel lumen. The morphology of the nitinol hypotube is different in the proximal and distal tracts; proximal nitinol cuts are spaced to provide pushability, while distal nitinol cuts are closer together to ensure flexibility.

The different tips' configurations can be used for selective catheterization of the vessels, particularly in difficult anatomies. In our example, the tiny parasitized artery showed proximal tortuosity; the J-shape microcatheter facilitated its selective catheterization.

In conclusion, the Direxion™ HI-FLO™ microcatheter offers unique features that can be taken advantage of in the diagnostic angiographic work-up of Y-90 RE, enabling high-flow contrast injections and facilitating selective and superselective catheterization of the hepatic arterial branches, even in case of difficult vascular anatomies and small arteries. ■

Orsola Perrone, MD, is with the Department of Diagnostic and Interventional Radiology, Pisa University Hospital in Pisa, Italy. He has disclosed that he received no compensation for this article and is not a consultant for Boston Scientific Corporation. Dr. Perrone may be reached at +39 050 996961; orsolaper@gmail.com.

Rossella Scandiffio, MD, is with the Department of Diagnostic and Interventional Radiology, Pisa University Hospital in Pisa, Italy. She has disclosed that she received no compensation for this article and is not a consultant for Boston Scientific Corporation.

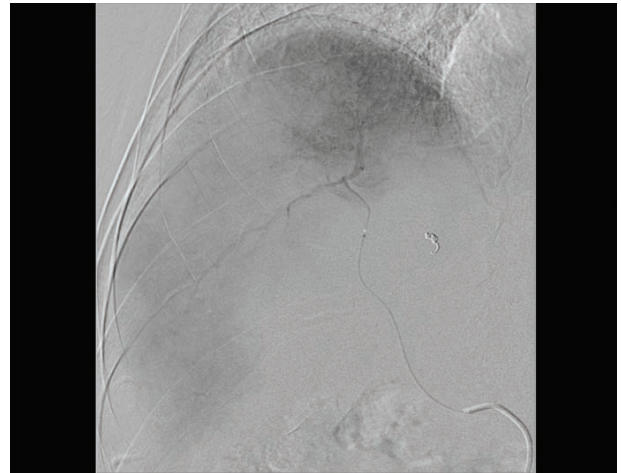


Figure 8. The microcatheter positioned in the feeding branch of the right hepatic artery.

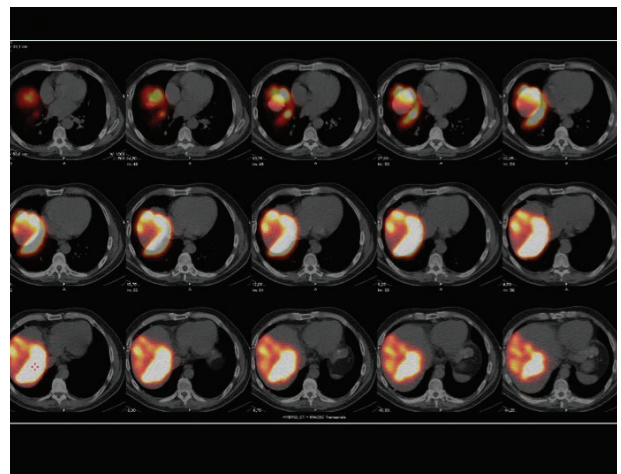


Figure 9. A SPECT-CT scan showing homogenous intratumoral MAA accumulation with no evidence of extrahepatic shunting.

Alessandro Grigolini, MD, is with the Department of Diagnostic and Interventional Radiology, Pisa University Hospital in Pisa, Italy. He has disclosed that he received no compensation for this article and is not a consultant for Boston Scientific Corporation.

Roberto Cioni, MD, is with the Department of Diagnostic and Interventional Radiology, Pisa University Hospital in Pisa, Italy. He has disclosed that he received no compensation for this article and is not a consultant for Boston Scientific Corporation.

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3. Spreafico C, Morosi C, Maccauro M, et al. Intrahepatic flow redistribution in patients treated with radioembolization. *Cardiovasc Intervent Radiol*. 2014 Jun 14. [Epub ahead of print.]

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

ABBREVIATED STATEMENTS

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Information not intended for use or distribution in France.

Interlock™-18 Fibered IDC™ Occlusion System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The Interlock 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.

GENERAL PRECAUTIONS: Do not advance the Interlock Fibered IDC Occlusion System if it becomes lodged within the microcatheter. Determine the cause of the resistance and replace the microcatheter and coil if necessary.

ADVERSE EVENTS: The complications that may result from a peripheral embolization procedure include, but are not limited to: • Complications related to catheterization (e.g., hematoma at the site of entry, vessel injury, etc.) • Death • Emboli • Foreign body reactions necessitating medical intervention • Infection necessitating medical intervention • Ischemia • Pain • Recanalization • Temporary neurological deficit • Tissue necrosis • Undesirable clot formation of the vasculature • Vasospasm

Interlock™-35 Fibered IDC™ Occlusion System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The Interlock - 35 Fibered IDC Occlusion System is indicated for obstructing or reducing blood flow in the peripheral vasculature during embolization procedures. This device is not intended for neurovascular use.

CONTRAINDICATIONS: None known.

PRECAUTIONS: Do not attempt to use the Interlock - 35 Fibered IDC Occlusion System with a soft-walled delivery catheter. Do not advance the Interlock - 35 Fibered IDC Occlusion System if it becomes lodged within the catheter. Determine the cause of the resistance and replace the catheter and coil if necessary.

ADVERSE EVENTS: The complications that may result from a peripheral embolization procedure include, but are not limited to: • 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, etc.) • Pain • Hemorrhage • Infection necessitating medical intervention • Foreign body reactions necessitating medical intervention • Emboli • Ischemia • Vasospasm • Tissue necrosis • Undesirable clot formation of the vasculature • Recanalization • Death • Temporary neurological deficit

Fathom®-16 Steerable Guidewires

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The FATHOM-16 Steerable Guidewire is intended for general intravascular use in the peripheral vasculature. It can be used to selectively introduce and position catheters and other interventional devices within the peripheral vasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

CONTRAINDICATIONS FOR USE: None known.

WARNINGS: The FATHOM Steerable Guidewire is not intended for use in the coronary vasculature or the neuro vasculature.

ADVERSE EVENTS: Complications attributed to endovascular procedures are the following: • Vessel trauma • Vessel damage • Embolism (catheter/device, air bubble, plaque, thrombus, air embolism, thromboembolism) • Pseudoaneurysm • Seizure/stroke • Vessel dissection • Hematoma at the puncture site • Nerve injury • Infection • Perforation of the vessel • Vessel spasm • Hemorrhage • Vascular thrombosis • Vessel occlusion • Death • Bleeding • Failed treatment • Inability to position guidewire • Damage to the catheter

Renegade HI-FLO™ Fathom® System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: The Renegade HI-FLO FATHOM Kit 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 FOR USE: None known.

WARNINGS: Never advance or withdraw an intravascular device against resistance until the cause of resistance is determined by fluoroscopy. Movement of the microcatheter or guidewire may result in damage or separation of the microcatheter or guidewire tip, or vessel perforation. Renegade™ HI-FLO™ FATHOM™ Kit is not intended for use in the coronary vasculature or the neurovasculature. The Renegade HI-FLO microcatheter is not designed for delivery of embolic coils.

PRECAUTIONS: This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. Because the microcatheter may be advanced into narrow subselective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal.

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)

Occlusion Balloon Catheter

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions.

INTENDED USE/INDICATIONS FOR USE: Boston Scientific Occlusion Balloon Catheters are indicated for temporary vessel occlusion in applications including arteriography, preoperative occlusion, emergency control of hemorrhage, chemotherapeutic drug infusion and renal opacification procedures. The Occlusion Balloon Catheter product line consists of two specific designs—Standard and Berenstein Occlusion Balloon Catheters. Only the Berenstein Occlusion Balloon Catheter has been designed for coaxial delivery of small catheters or embolic agents.

CONTRAINDICATIONS: Boston Scientific Occlusion Balloon Catheters are not designed for use in embolectomy procedures. Boston Scientific Occlusion Balloon Catheters are not designed for use as vascular flow-directed catheters (Swan-Ganz type). Any use for procedures other than those indicated in the instructions is not recommended.

PRECAUTIONS: Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions.

ADVERSE EVENTS: The complications that may result from an occlusion balloon procedure include: • vessel perforation • vessel spasm • hemorrhage • hematoma • arrhythmias/bradycardia • sepsis or infection • systemic embolization • short-term hemodynamic deterioration or instability • death • vascular thrombosis • allergic reactions to contrast medium • pyrogenic reaction • arteriovenous fistula • thromboembolic episodes • vessel dissection • air embolism

Direxion™ And Direxion HI-FLO™ Torqueable Microcatheters

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions

INTENDED USE/INDICATIONS FOR USE: 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.

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. This 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.

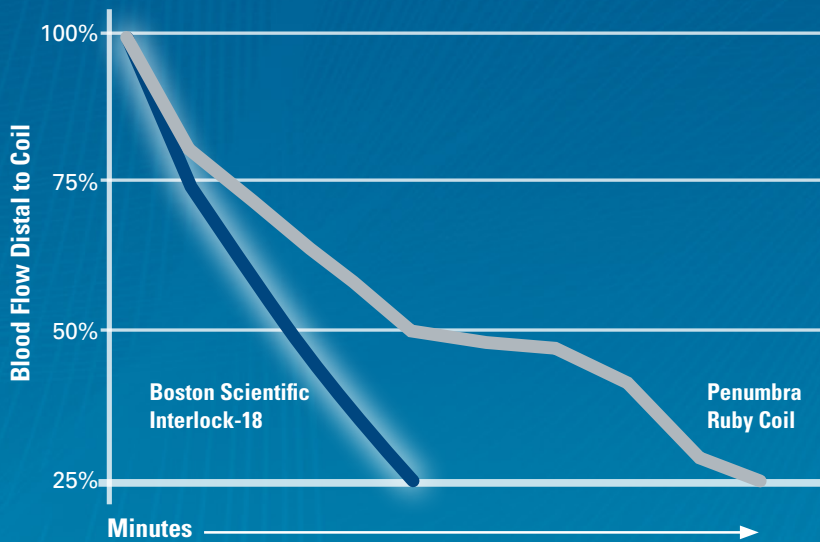
PRECAUTIONS: This device should be used only by physicians thoroughly trained in percutaneous, intravascular techniques and procedures. Do not introduce the microcatheter without guidewire support as this may cause damage to the proximal shaft of the catheter. Because the microcatheter may be advanced into narrow sub-selective vasculature, repeatedly assure that the microcatheter has not been advanced so far as to interfere with its removal.

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)

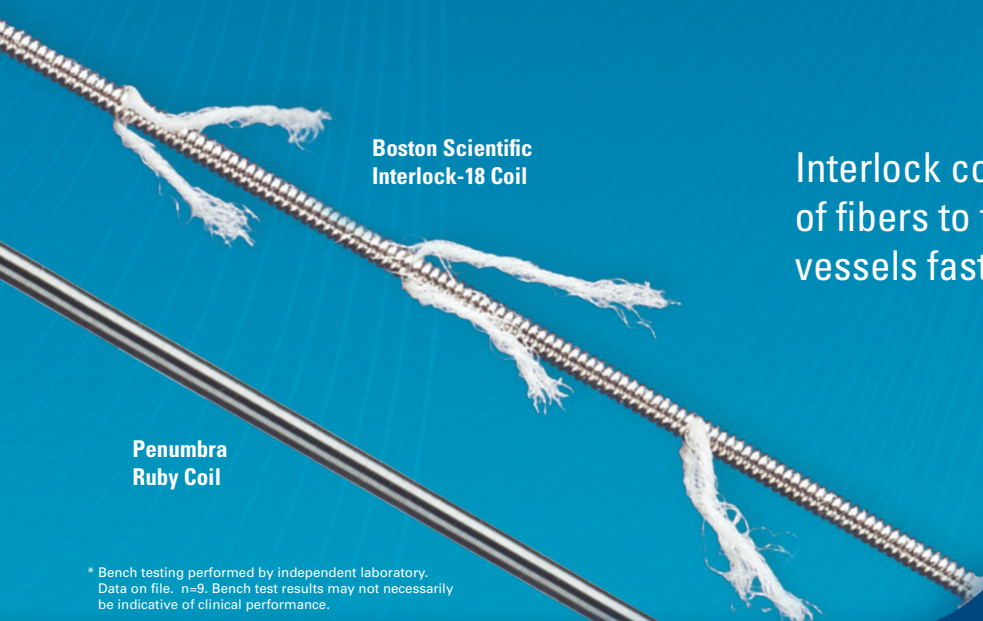
INTERLOCK™ Coils

**MORE FIBER.
MORE POWER.**



**Interlock Coils
PERFORM
FASTER**

Penumbra Ruby™ Coils take over 50% longer to reach an occlusion test endpoint.*



Boston Scientific Interlock-18 Coil

Penumbra Ruby Coil

Interlock coils feature dense networks of fibers to facilitate shutting down vessels faster, with fewer coils.

* Bench testing performed by independent laboratory. Data on file. n=9. Bench test results may not necessarily be indicative of clinical performance.

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device. Information for the use only in countries with applicable health authority product registrations. Information not intended for use or distribution in France.

INTERLOCK™ FIBERED IDC™ OCCLUSION SYSTEM

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE/INDICATIONS FOR USE:** The Interlock 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. **GENERAL PRECAUTIONS:** Do not advance the Interlock Fibered IDC Occlusion System if it becomes lodged within the microcatheter. Determine the cause of the resistance and replace the microcatheter and coil if necessary.

ADVERSE EVENTS: The complications that may result from a peripheral embolization procedure include, but are not limited to: • Complications related to catheterization (e.g., hematoma at the site of entry, vessel injury, etc.) • Death • Emboli • Foreign body reactions necessitating medical intervention • Hemorrhage • Infection necessitating medical intervention • Ischemia • Pain • Recanalization • Temporary neurological deficit • Tissue necrosis • Undesirable clot formation of the vasculature • Vasospasm (REV AA)

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