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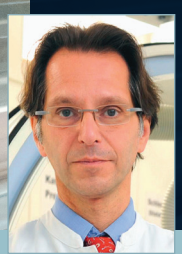

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EXPANDING HORIZONS IN EMBOLIZATION

What Does the Future Hold for Interventional Radiologists?

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EXPANDING HORIZONS IN EMBOLIZATION

What Does the Future Hold for Interventional Radiologists?

EIGHT LEADERS IN THE INTERVENTIONAL RADIOLOGY FIELD SHARE THEIR THOUGHTS.

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Disclosures: None.

Interventional radiologists (IRs) are always searching for the next big thing into which to expand. In the past 5 years, IRs have explored prostate artery embolization, gastric artery embolization, and genicular artery embolization—even hemorrhoidal artery embolization.

The inventiveness of interventional radiology is one of the specialty's most attractive qualities. IRs' inherent desire to reduce morbidity and mortality by developing minimally invasive solutions is commendable as long as we are able to adequately demonstrate improved outcomes; just because we *can* embolize something does not mean that we *should*.

IRs should remain committed to perfecting what we have developed. Let's consider transarterial chemoembolization (TACE) for hepatocellular carcinoma (HCC). With the advent of microcatheters and advanced imaging, outcomes have improved over the past decades, but complete response rates (for intermediate-stage disease) are still low, and the overall response rate is 52%. Drug-eluting embolics (DEEs) are not as disruptive as we had hoped. However, did the DEE fail, or is it the drug we use? Doxorubicin is not very effective against HCC, yet we use it. We still do not know whether hypoxia, drugs, or both are responsible for the antitumoral effect. Moreover, a predominant hypothesis of TACE failure is the release of hypoxia-inducible factor 1-alpha and vascular endothelial growth factor (VEGF); however, all trials combining an anti-VEGF agent with TACE have failed. Clearly, our understanding of the actual mechanism of action and failure for TACE is deficient and needs to be corrected. Oncologic therapeutic options are expanding, and unless we improve our results, we will be outperformed by noninvasive infusions. That being said, better systemic options can be an opportunity for IRs to expand into new indications with better drugs.

The quantity of prospective randomized trials has significantly increased in our specialty, and IRs must remember to follow the evidence, even if it is not where we hoped it would lead—eventually, we will reach our goal.

Finally, a consistent message is that IRs have to be more clinical and keep patients as their top priority. Most understand that message, as IRs see patients before and after procedures and are involved in tumor boards. However, the desire for efficiency has to be replaced by the desire for efficacy. Indeed, cone-beam CT and superselective TACE have been shown to improve outcomes, but segmental or lobar TACE are still being performed for the sake of speed. Standardizing the technique to maximize outcomes is essential. With the new Medicare reimbursement centered on quality rather than fee for service, IRs are positioned to succeed.

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Disclosures: None.

Liver embolization represents one of the primary effective localized therapies against cancer, thanks to the huge amount of data supporting its clinical value. Developed from the basic concept of producing ischemic damage to the cancerous environment, embolization is now increasingly considered as a platform for carrying and delivering therapies to the target. Following this concept, the future will see developments in new and more efficient carriers (eg, beads) and drugs against cancer cells. A deeper knowledge of tumor mechanisms will enhance the development of drugs that are effective for specific cancers.

It is now clear that every tumor has its own specific biological characteristics that define a certain sensitivity (and resistance) to some drugs. Eventually, anticancer molecules to the tumor will be selected according to their tested and proven effectiveness, as has occurred for some of the new systemic therapies. Hence, percutaneous biopsies of the target tumor will be a crucial step in planning embolization therapy.

Moreover, immunology seems to play an essential role in cancer therapy, and it is also related to the emerging concept of tumor-infiltrating lymphocytes. The mechanism of immune activation against cancer is based on the infiltration of tumor by lymphocytes, which damage the tumor mass in some way. Embolization, ablation, and radiation may cause tumor damage, which can activate the immune system against the same cancer cells, even if located in a distant organ or tissue. With embolization, beads could be loaded with certain molecules that could enhance this mechanism.

Last but not least, embolization will play a crucial role in therapy beyond the liver. As we know, every tissue needs blood for survival. The same blood feeders theoretically can be used to affect any organ or tissue. The only limit we have today is how to reach some targets due to the complexity of vascular anatomy. It is also well known in this field how improvements to imaging technology will allow delivery of embolics almost everywhere.

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Disclosures: None.

In 1972, Josef Rösch, MD, and colleagues reported the first case of catheter-based arterial embolization on a 43-year-old woman in hemorrhagic shock secondary to a bleeding gastric ulcer.[1] During the initial angiogram, active contrast extravasation from the right gastroepiploic artery was identified. After a failed arterial epinephrine infusion, 2 mL of the patient's venous blood was drawn and allowed to clot. This clot was then injected through the catheter in the right gastroepiploic artery, with subsequent resolution of the patient's hemorrhage.

Since then, the field of embolization has flourished to encompass a wide range of indications with a profound impact on patient care. With the advent of smaller-caliber microcatheters and a wider variety of embolic devices, the field of embolization can now be used in a vast array of disease states. The primary intent of embolization has been to stop patients from ongoing hemorrhage. This includes the patient involved in significant trauma, when gelatin slurry or coils are deployed in the internal iliac artery for an unstable pelvic fracture. Coil embolization for diverticular hemorrhage, bleeding ulcers, or ruptured varices continues to play a major role for patients with gastrointestinal hemorrhage. Detachable coils and liquid embolics now allow us to perform embolization in potentially high-risk regions, with a wider margin of safety and greater degree of efficacy. Liver cancer therapy has advanced dramatically with the widespread use of radioactive and DEE agents. Due to these advances, liver-directed therapy for cancer has shifted to an outpatient therapy with vastly improved quality of life for patients.

Where do we go from here? The field of embolic agents will continue to expand down multiple paths. Currently, only two chemotherapy agents are actively used for DEEs. The development of novel and potentially more cytotoxic DEEs over the next several years may result in greater and more durable tumor response. The advent of smaller calibrated microspheres could potentially be used for more distal penetration into tumors, with eventual adoption of nanoparticle technology. Although the current embolic agents are typically permanent,

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biodegradable particles used for tumor therapy may maintain vessel patency for future interventions. A wider array of liquid embolics, perhaps with controlled polymerization rates, will allow more versatility in terms of treating both high- and low-flow lesions.

The advent of new embolic technologies will be coupled with potentially expanding applications for embolization. Although embolization for cancer has focused on the liver, malignancy in other organs, such as the pancreas, kidneys, and musculoskeletal system, may be candidates for catheter-directed embolization. Research is currently underway using particle embolization to treat inflammatory disorders, which could potentially change the treatment paradigm for these patients.

Although evolving technology always brings excitement to interventional radiology, our challenge is to tailor therapy for each individual patient. With this comes the increasing necessity of producing high-quality safety and outcomes data to prove the effectiveness of our therapy. Nevertheless, the future of embolization shows great promise for our patients.

1. Rösch J, Dotter CT, Brown MJ. Selective arterial embolization. A new method for control of acute gastrointestinal bleeding. Radiology. 1972;102:303-306.

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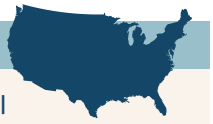

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Disclosures: None.

The future of embolization in the interventional radiology space is brighter than ever. This is bolstered by the advances in melding fluoroscopic and cross-sectional imaging, the leaps forward in catheter/wire technology, and the flexibility of use with newer detachable and liquid embolics. The latter is supported by several well-performed studies that have assessed recanalization rates for agents in certain clinical scenarios. These factors have led to substantial advancement in embolotherapy. Whether the vessel is large or small, or whatever the length of vessel occlusion, the progression in coil technology has also allowed for IRs to have a better understanding of what will occur to the tissue that this vessel is supplying, allowing for more predictable outcomes.

IRs, with their superior knowledge and understanding of the cross-sectional space, now have added liquid embolics to their armamentarium. Taking advantage of vessel flow dynamics, liquid embolics provide deeper penetration to the distal vessel, which is not always accessible by coils. However, this is still an area of intense research, as the ideal material has yet to be developed. We now have agents for any clinical scenario—large or small vessels or temporary or permanent occlusions.

The evolution of detachable coils, their materials, and the dynamics of their deployment have made vessel takedown significantly easier and more efficient. Plugs deployed in the right circumstances can hasten procedures and has made the learning curve a bit less steep for our trainees and more junior physicians. All of this has allowed IRs to not only treat more varied and complex medical conditions, but most importantly also has improved patient care.

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Disclosures: None.

Despite the enormous amount of progress made since the 1970s on embolic materials, the potential for future improvements remains infinite. Our research strategies must focus on one clear objective: to peacefully gain new territory through new arms. In recent years, after prostatic artery embolization, bariatric embolization, musculoskeletal pain embolization, emborrhoid, and other spaces, there remain unknown territories.

The development of new microcatheters and very precise guidance tools will enable us to reach these unknown territories. There will be an ability to catheterize very small vessels (< 300 µm) for ultraselective drug delivery, along with a less-invasive (< 3 F) arterial approach to improve patient safety and comfort.

I anticipate the toolbox of the future having custom-made embolic agents: beads loaded with specific

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molecules and coated with surface antigens, liquids with viscosity and cohesion that are modifiable according to the target, and embolic agents that are excitable and directed by external sources. Imagine, for example, a liquid embolic agent that becomes solid under the excitation of an external field focused on a target.

These technologies already exist in our imagination, and some already exist in our research laboratories. This exciting story of interventional radiology continues to evolve with embolization, and now is the time to think outside the box and reveal new clinical applications that are calling out to us. Embolization also protects IRs with its high technology that resonates with radiology.

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Disclosures: None.

A wide variety of indications, techniques, and compounds for embolization have evolved over time. Beyond the long-established indications for controlling bleeding, various embolization techniques were developed to enhance transarterial tumor treatment. These therapies encompass both benign (eg, uterine fibroids, prostatic hyperplasia) and, perhaps on a larger global scale, malignant conditions, where embolization complements other tumor therapies for enhanced precision. When utilizing embolization technologies, IRs and oncologists could gain an important position in supporting hepatic treatments. Many questions regarding "which, when, and how" embolization techniques should be used are not answered comprehensively, and some answers are still not satisfying.

Inconsistent results remain a challenge with embolic therapies, leaving room for future improvements. Ongoing studies will provide more insight into the pathophysiologic effects of embolization techniques. A better understanding of the currently available embolic compounds and compositions (eg, loaded and unloaded particles, liquids, emulsions, suspensions, permanent or transient embolization) will help to enhance specific treatment needs. Consequently, interventional oncologists may be able to apply embolizing compounds more deliberately in terms of size and loadability. Moreover, because tumor perfusion and humoral (immunologic) parenchymal factors determine tumor growth and influence potential therapy response in the vast majority of tumors, this fuels expectations that the combination of highly precise, transvascular angiographic techniques and various embolization compounds, along with immunologic or targeted therapies, may enhance therapeutic efficacy, precision of addressing tumor tissue, and reduce side effects.

Based on an already existing substantial body of evidence, numerous oncologic guidelines have appreciated the role of embolization in complex treatment regimens, especially in primary and secondary hepatic tumors. This provides ground for a broader acceptance and further development of multimodality treatment, where the multifaceted nature of embolization will play an important role.

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Disclosures: None.

Embolization procedures have been performed for many years by IRs all over the world. Compared to relatively old embolization techniques, we also have a wide variety of "younger" nonembolization techniques available to us, such as branched and fenestrated stent grafts for the treatment of abdominal aortic aneurysms, drug-eluting techniques for the treatment of peripheral artery occlusive disease, and ablation techniques for locoregional tumor treatment. Nevertheless, embolization techniques have shown a dramatic improvement in the last several years—the basis of this improvement is a huge variety of newly developed technical devices for different embolization procedures.

With high-quality devices such as microwires and microcatheters, almost every region of the human body can be reached, and with a variety of available embolization materials, different benign and malignant

lesions can be treated. The treatment is, in most cases, minimally invasive with almost no side effects for the patient. In many fields of medicine, these techniques have become the standard of care and should be available in every state-of-the-art hospital.

New embolization therapies such as prostate artery embolization, bariatric embolization, or embolization of hemorrhoids have been developed recently by IRs. In cancer treatments, techniques such as radioembolization or embolization with drug-eluting beads are becoming more common—and I am sure this is not the end. With the upcoming development and evaluation of different new drugs including immunotherapy, new fields of minimally invasive therapies will open up for IRs.

The most important task for all IRs will be to produce good evidence based on randomized multicenter trials to make these new therapies valuable for our clinical partners. Moreover, it will be very important to take care of our patients not only during the interventional procedure, but also in the pre- and postinterventional setting. IRs should not only be excellent technicians in terms of the procedures they perform, but also excellent clinicians in taking care of their patients.

Last but not least, we have to work hard to stay at the forefront in modern hospitals. For that reason, IRs have to be a central part of tumor boards and other hospital decision-making institutions in order to promote our highly advanced diagnostic and therapeutic possibilities.

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Disclosures: None.

Interventional radiology is a clinical specialty that combines correct clinical judgment and technical skills to use devices under imaging guidance to achieve expected patient outcome. Embolization as a therapeutic modality was introduced more than 40 years ago, but has had a revolutionary growth in terms of indications and success in the last decade. Embolization for fibroids, prostate, and some types of liver tumors, combined with chemotherapy or radiotherapy agents, have been recently introduced and have become standard of care in selected patients. Future improvement in technology, devices, and imaging quality will probably result in new indications of embolization and better patient outcomes in different diseases and territories. As the population is aging, an increased incidence of diabetes and obesity will further affect current and potential new interventional radiology treatments throughout the body.

Cancer care through interventional oncology foresees a great future with the development of new biologic drugs, radio sensitizers, immunotherapy, and other antitumor agents that could be easily delivered inside the tumor under imaging guidance. Longer survival of patients is turning cancer into a chronic disease; thus, secondary complications of cancer such as hemorrhage or vascular occlusions will further involve interventional radiology with oncology.

The future seems bright for those interventional radiologists who commit to patient care and are involved in both outpatient and in-hospital management and follow-up. Recognition of interventional radiology by patients, managers, and hospital administration as a clinical specialty and not as a technical service is a must to expand its horizons. As a minimally invasive discipline with short hospital stay and excellent results in appropriate candidates, IRs may have a great impact in value-based medicine. IRs should be encouraged to move from a simple technical specialty to becoming a well-recognized specialty aligned with other key stakeholders to deliver enhanced value to patients through quality, safety, efficiency, and patient satisfaction. ■

In the U.S., no embolic microspheres are FDA indicated for use as a drug-eluting microsphere.

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CASE REPORT

Transarterial Embolization of Neuroendocrine Tumor Liver Metastases With Embozene™ Microspheres via Extrahepatic Collateral Arteries

BY R. JUSTIN KNEBEL, MD; DANNY CHENG, MD; AND CATHERINE VU, MD

A 54-year-old woman presented with a history of small bowel carcinoid neuroendocrine tumor metastatic to the liver. She had undergone multiple radiofrequency ablation and transarterial embolization (TAE) procedures since 2006, with hepatic arterial access complicated by dissection/chronic occlusion of the common hepatic artery. Systemic therapy was limited by allergy to octreotide. She developed worsening carcinoid symptoms of diarrhea, nausea, flushing, and abdominal pain. Her chromogranin A level was persistently elevated (124 ng/mL). Liver and renal function were preserved (total bilirubin, 0.6 mg/dL; creatinine, 0.66 mg/dL). She elected to undergo repeat bland embolization of liver metastases for palliation of hormonal and bulk symptoms.

PROCEDURE

Preprocedure MRI of the abdomen (Figure 1) demonstrated multifocal liver metastases measuring up to 5.4 cm (solid arrows) showing progression by RECIST criteria and prior ablation sites (dotted arrows). The main portal vein was patent. The MRI and prior angiographic studies were reviewed for procedural planning.

Vascular access was achieved at the right common femoral artery with ultrasound guidance, and a 5-F sheath was placed. The celiac artery was selected with a 5-F diagnostic catheter. Digital subtraction angiography (Figure 2) demonstrated chronic dissection/occlusion of the common hepatic artery with extrahepatic collateral arterial supply to the right (solid arrows) and left (dotted arrows) hepatic lobes.

A small arterial collateral extending from the dorsal pancreatic artery to a tumor in the right hepatic lobe (Figure 3) was selected with a 2.4-F microcatheter over a 0.014-inch Transend™ Microwire (Boston Scientific Corporation). It was not possible to advance the microcatheter beyond an inferior branch (dotted arrow), but flow in this branch was retrograde and there was preferential

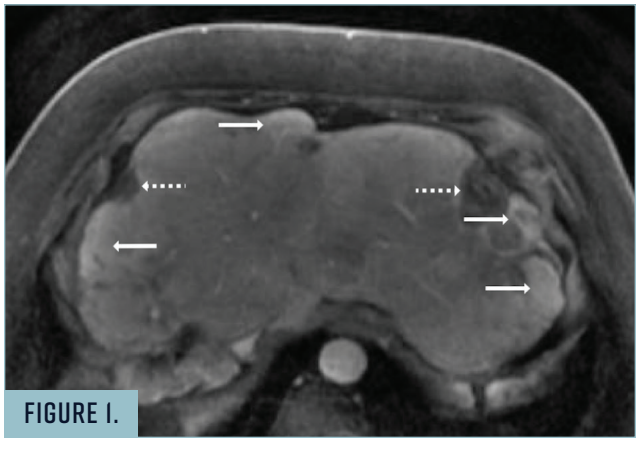

FIGURE 1.

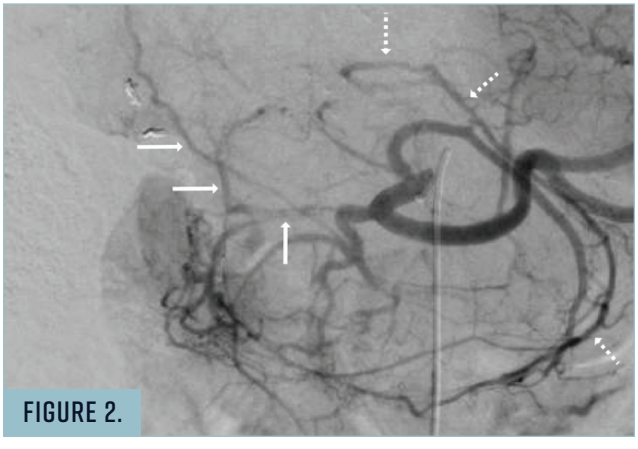

FIGURE 2.

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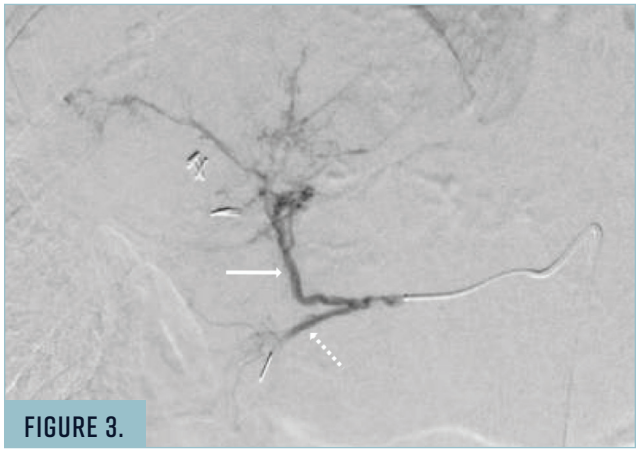

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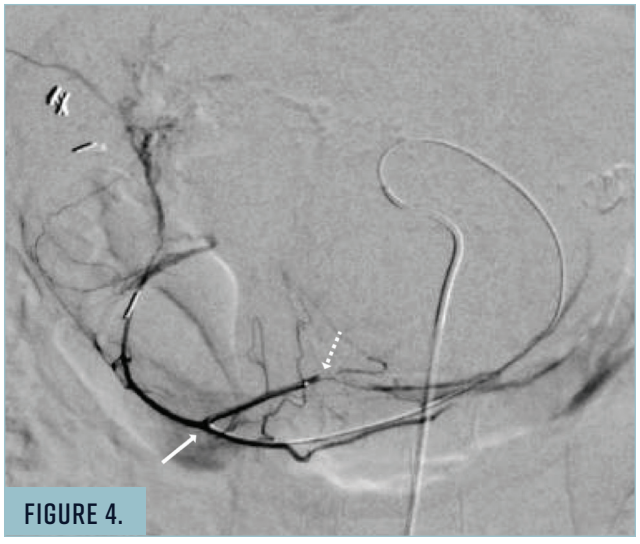

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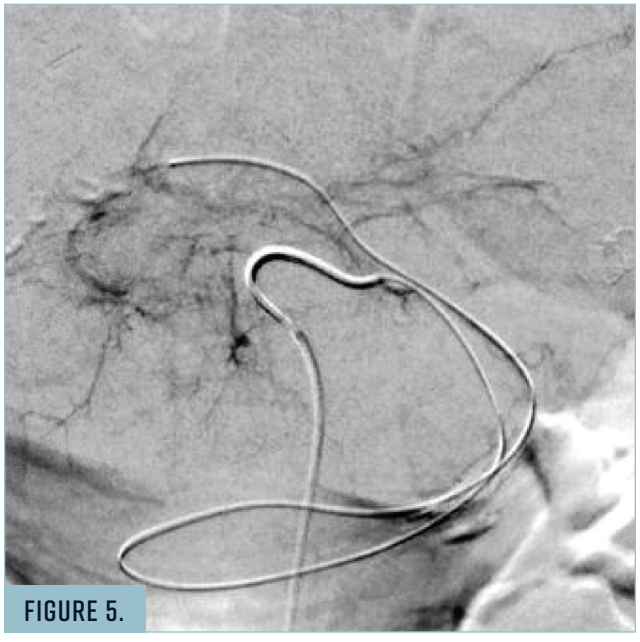

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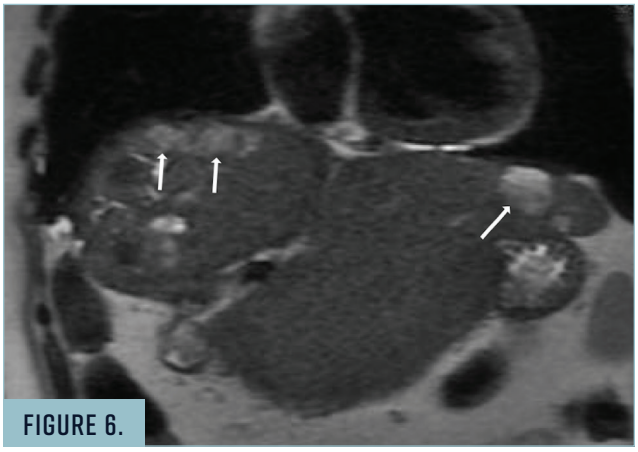

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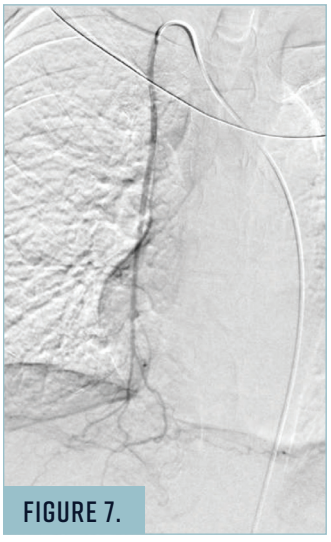

FIGURE 7.

flow to the liver (solid arrow). Embolization was performed to near stasis with one vial of 100-µm Embozene™ Microspheres (Boston Scientific Corporation).

The base catheter was repositioned into the left gastric artery. The microcatheter was advanced through the left gastric artery to an accessory left hepatic artery originating from the left gastric/right gastric arcade (Figure 4). A 0.018-inch hydrophilic guidewire was helpful in selecting the acute origin of the accessory left hepatic artery (solid arrow) but resulted in vessel spasm (dotted arrow) that resolved after 15 min with intra-arterial administration of 100 µg of nitroglycerin and 5 mg of verapamil. The microcatheter was successfully advanced into the accessory left hepatic artery (Figure 5) over the Transend™ Microwire. Embolization was performed to near stasis with one syringe of 100-µm Embozene™ Microspheres.

Based upon prior angiographic imaging and coronal MRI demonstrating metastases in the liver dome (Figure 6, solid arrows), the right internal thoracic artery was selected with a 5-F diagnostic catheter (Figure 7), and the microcatheter was advanced inferiorly. Angiography demonstrated arterial supply to the liver dome from a medial branch (Figure 8, solid arrow) and to the abdominal wall from lateral branches (dotted arrow). The medial branch was selected (Figure 9), with angiography demonstrating multifocal tumor blush (Figure 10, solid arrows). Embolization was performed to near stasis with one syringe of 100-µm Embozene™ Microspheres.

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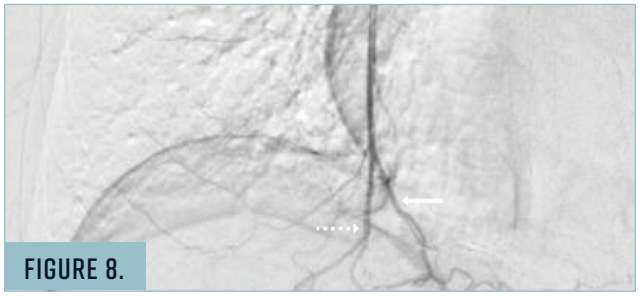

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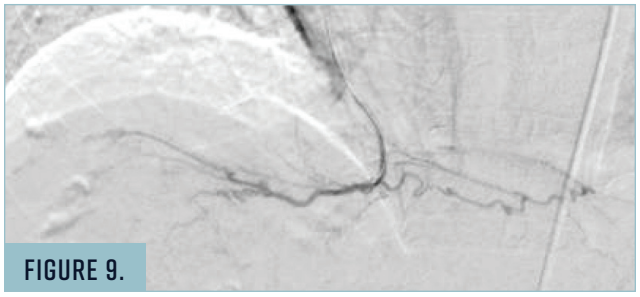

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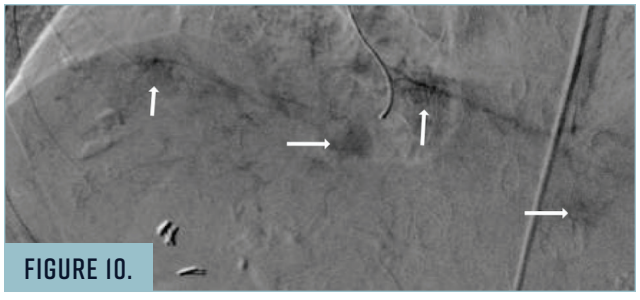

FIGURE 10.

Intraprocedure, 10 mg of dexamethasone, 30 mg of ketorolac, and 4 mg of ondansetron were administered intravenously for control of inflammation, pain, and nausea, in addition to moderate sedation with fentanyl and midazolam. Postprocedure, the patient experienced fatigue, nausea, flushing, and pain. Additionally, transient retiform erythema was noted over the abdominal right upper quadrant, likely representing inadvertent nontarget embolization (although microcatheter positioning was superselective, and no nontarget vessel pruning was apparent angiographically). She was admitted to the hospital for management of postembolization syndrome and carcinoid exacerbation (somatostatin analogue therapy was contraindicated due to history of octreotide allergy) with hydromorphone patient-controlled analgesia pump and intravenous antiemetics, later transitioned to oral formulations. Transaminitis occurred as expected with embolization and began to downtrend at 48 hours. The patient was discharged to home 4 days later. At 3-week clinical follow-up, she reported persistent fatigue but no carcinoid symptoms since discharge. Follow-up imaging with Gallium-68 DOTATATE PET/CT is pending at the time of this report.

CONCLUSION

Up to 75% of patients with small bowel neuroendocrine tumors develop liver metastases over the course of the disease.[1] These may result in significant morbidity due to hormonal hypersecretion and tumor bulk. TAE has been demonstrated to be effective in the management of hormonal symptoms and tumor burden.[1,2] This report illustrates the use of TAE for treatment of neuroendocrine tumor liver metastases, with embolization from three different extrahepatic arterial collateral vessels. The shapeable tip of the Transend® Microwire (Boston Scientific Corporation) was helpful in navigating the small, tortuous collateral vessels. Embozene™ Microspheres provided consistent, reliable penetration into the tumors, resulting in good angiographic and clinical results, with palliation of carcinoid symptoms (after the expected initial exacerbation and postembolization syndrome). Repeat transarterial embolization may be performed as needed for recurrent symptoms. Additional treatments including peptide receptor radionuclide therapy may also be used in the future. ■

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2. Kennedy A, Bester L, Salem R, et al. Role of hepatic intra-arterial therapies in metastatic neuroendocrine tumours (NET): guidelines from the NET-Liver-Metastases Consensus Conference. HPB (Oxford). 2015;17:29–37.

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CASE REPORT

Bland Hepatic Embolization for Metastatic Rectal Neuroendocrine Tumors

BY VENU VADLAMUDI, MD

A 41-year-old woman with a history of rectal neuroendocrine tumors underwent primary resection several years ago. She presented to the interventional oncology clinic following referral from her medical oncologist due to bulk symptoms from newly diagnosed hepatic metastatic tumors (biopsy-proven grade I neuroendocrine tumors; Figure 1). Due to the size of the tumors, the decision was made to proceed with bland embolization for devascularization/debulking of the largest tumors.

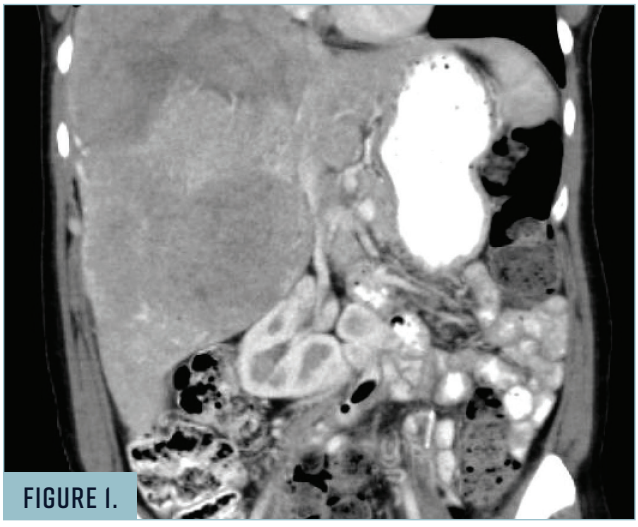

FIGURE 1.

Preoperative CT abdomen demonstrated large vascular tumors throughout the right lobe of the liver. Note the mass effect on the medially/inferiorly displaced right kidney.

PROCEDURE

A left radial approach was used with a 5-F sheath. Using a 5-F X 110-cm radial catheter, a celiac arteriogram was performed; it showed standard anatomy but hypertrophied hepatic branches, especially the right hepatic branches (Figure 2). Through the radial catheter, bland embolization of the right hepatic arterial supply to the largest tumors was performed utilizing 100-µm Embozene™ Microspheres (Boston Scientific Corporation). During embolization of the segment 7-8 supply, there was intratumoral hemorrhage from a branch near the dome, which was embolized through a 2.4-F X 150-cm microcatheter utilizing 4:1 n-BCA glue. Final angiography demonstrated good pruning of the distal tumoral supply with preservation of the main arterial branches for potential future liver-directed therapy (Figure 3).

The patient was discharged home the same day with methylprednisolone. She reported initial abdominal discomfort for a

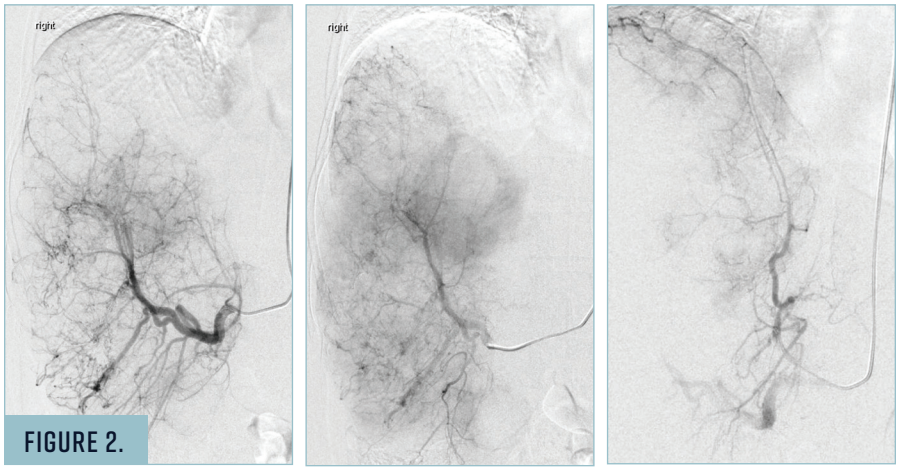

FIGURE 2.

Hepatic angiograms (segments 4-6 and segments 7-8) confirm supply to multiple hypervascular neuroendocrine metastases.

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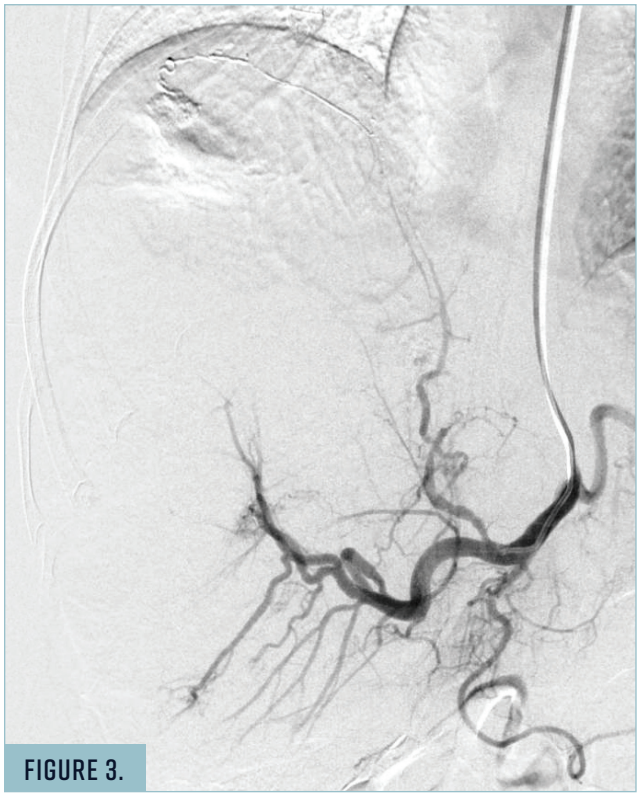

FIGURE 3.

Final celiac angiogram demonstrated good pruning of the distal tumoral supply with preservation of major arterial branches. Note the glue cast in the distal segment 7-8 branch.

few days, which slowly improved. She was seen at 6 weeks, and an MRI of the abdomen demonstrated good devascularization of the largest right hepatic tumors and an approximate 15% decrease in overall volume compared to preoperative imaging (Figure 4). She reported improvement in her original bulk symptoms.

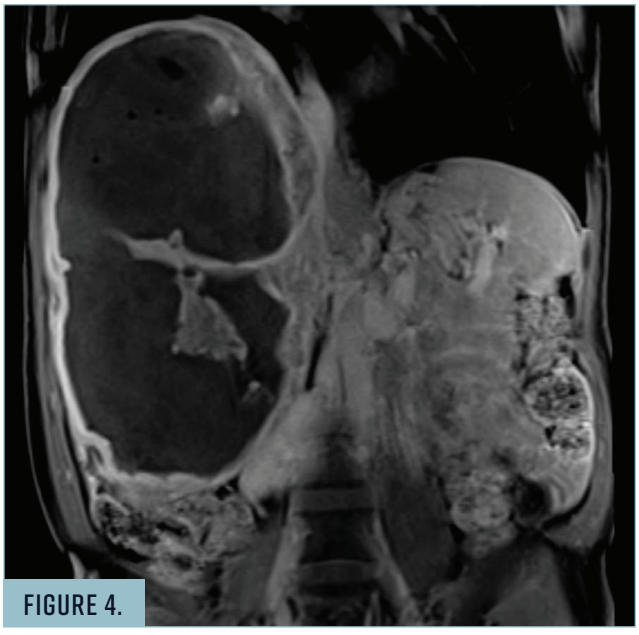

FIGURE 4.

Follow-up MRI at 6 weeks demonstrated good devascularization of the large right hepatic tumors.

CONCLUSION

Embozene™ Microspheres allow for calibrated bland embolization of distal vasculature while preserving larger proximal branches. ■

VENU VADLAMUDI, MD

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Disclosures: None.

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CASE REPORT

Yttrium-90 Mapping Via a Radial Approach in a Patient With an Occluded Celiac Artery

BY VINCENT L. FLANDERS, MD

A 55-year-old man with a history of metastatic colorectal cancer was being mapped for yttrium-90 (Y-90) therapy. Previous chemotherapy treatment proved unsuccessful, and the patient was referred to the interventional radiology department because his disease was slowly progressing.

The initial CT scan demonstrated complete occlusion of the celiac artery with a hypertrophied arc of Buhler (AOB). The AOB is a rare anastomotic branch between the 10th and 13th ventral segmental arteries, resulting in a connection between the celiac and the superior mesenteric artery (SMA). It is present in 1% to 4% of individuals. The initial attempt from a femoral approach was not accessible (Figure 1).

Because of this occlusion, a left radial approach was chosen, given the angle of origin of the SMA. A 4-F long angled glide catheter was manipulated into the proximal SMA through which a 0.021-inch J-shaped Direxion™ Microcatheter (Boston Scientific Corporation) and a 0.014-inch microwire were advanced through the tortuous AOB into the common hepatic artery (Figure 2). Given that the celiac artery origin was occluded, the flow within the splenic artery resulted in reversal of flow within the proper hepatic artery.

The splenic artery was then coil embolized to stasis using a number of Interlock™-18 Fibered Platinum Coils (Boston Scientific Corporation) allowing for proper mapping of the liver (Figure 3). The patient underwent Y-90 and had an uneventful recovery. The final result is shown using 3D spin imaging (Figure 4). ■

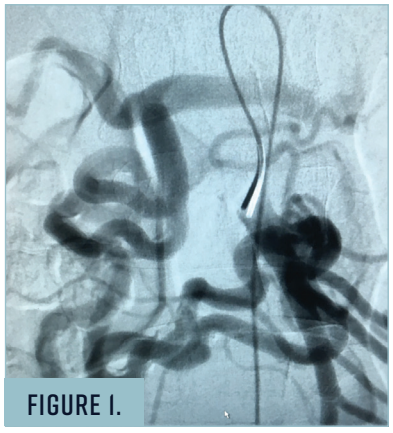

FIGURE 1.

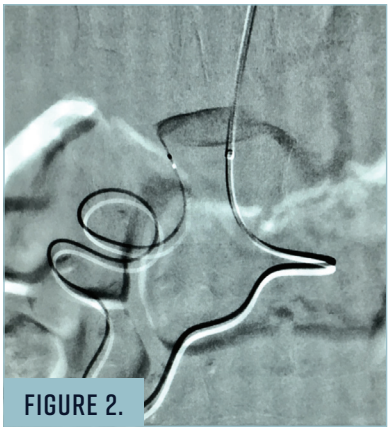

FIGURE 2.

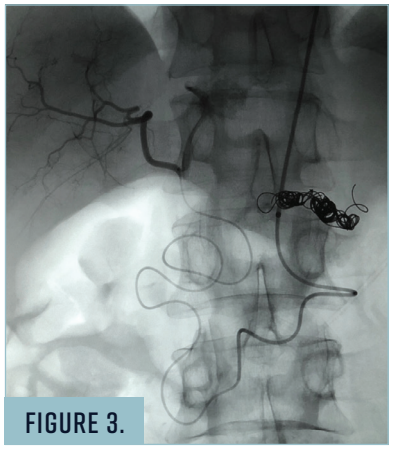

FIGURE 3.

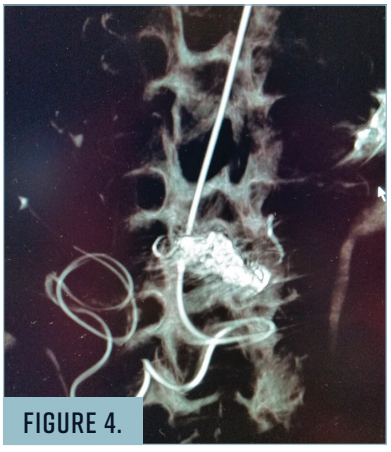

FIGURE 4.

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Disclosures: None.

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)

Embozene Microspheres

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.*

INDICATIONS
Embozene Microspheres are indicated for the embolization of hypervascular tumors and arteriovenous malformations (AVMs).

CONTRAINDICATIONS
Embolization procedures shall not be performed if:
- Patient is unable to tolerate vascular occlusion procedures.
- Vascular anatomy precludes correct catheter placement or embolic injection.
- Presence or likely onset of vasospasm.
- Presence of a blood coagulation disorder that would prohibit arterial punctures.
- Presence of severe atheromatous disease that would preclude correct catheter placement.
- Presence of patent extra-to-intra-cranial anastomoses or shunts from the arterial to the venous circulation.
- Presence of collateral vessel pathways which could potentially endanger non-targeted tissue during an embolization procedure.
- Presence of any vasculature where Embozene Microspheres could pass directly into the central nervous system, central circulatory system or other nontarget territories.
- Patient has high-flow arteriovenous shunt with diameter greater than the selected Embozene Microspheres.
- Patient is pregnant.
- Patient has known allergies to barium sulfate, 3-aminopropyltrialkoxysilane, polyphosphazene or IV radiopaque contrast agent.

WARNINGS
Vascular embolization is a high risk procedure. The procedure should be performed by specialized physicians trained in vascular embolization procedures. Complications can occur at any time during or after the procedure, and may include, but not limited to:
• Undesirable reflux or passage of Embozene Microspheres into normal arteries adjacent to the targeted lesion or through the lesion into other arteries or arterial beds.
- Embolization of the wrong artery or migration of the microspheres to other parts of the body, which may necessitate further treatment.
- Hematoma, or bruising, at the incision site for arterial access.
- Arterial aneurysm at the incision site for arterial access.
- Deep vein thrombosis, or clotting of a deep vein in patient's leg(s).
- Thrombosis of the artery at the incision site for arterial access.
- Pulmonary embolization.
- Ischemia at an undesirable location.
- Capillary bed saturation and tissue damage.
- Ischemic stroke or ischemic infarction.
- Vessel or lesion rupture and hemorrhage.
- Neurological deficits including cranial nerve palsies.
- Vasospasm.
- Recanalization.
- Foreign body reactions necessitating medical intervention.
- Infection necessitating medical intervention.
- Clot formation at the tip of the catheter and subsequent dislodgement.
- Allergic reaction.
- Risks of radiation from angiography and fluoroscopy used to visualize the blood vessels during embolization, which may include a radiation burn and risks to future fertility.
- Death.

Do not use Embozene Microspheres in conjunction with embolization devices based on organic solvents such as ethyl alcohol or dimethyl sulfoxide (DMSO) at the same embolization site.
Do not use ionic contrast agent with this product. Ionic contrast agents could alter the microsphere characteristics resulting in microsphere deformation and procedure failure.

PRECAUTIONS
To maintain safety, the following precautions shall be considered:

- Safety and effectiveness of Embozene Microspheres in the treatment of uterine fibroids has not been established
- Safety and effectiveness of Embozene Microspheres for hepatic and renal embolization uses has not been established.
- The physician should carefully select the size and quantity of Embozene Microspheres according to the lesion to be treated based on the physician's education and training and currently available scientific evidence.
- Physicians must decide the most appropriate time to stop the infusion of Embozene Microspheres. Typically the artery will accept fewer Embozene Microspheres as the treatment progresses. Proximal slowing or termination of flow may indicate that the vessel or the target area is occluded by Embozene Microspheres. Careful fluoroscopic monitoring is required.
- Microparticle embolization must be performed slowly. The injection speed and manner must be controlled. Excessive injection rate may result in retrograde flow in the vessel leading to embolization of other non-target healthy tissue or organs
- The color of the Embozene Microspheres may be visible through the skin if injected into superficial arteries.
- If arteriovenous anastomoses, branch vessels which lead away from the targeted embolization area, or emergent vessels not evident prior to embolization are present, it can lead to non-targeted embolization and cause severe complications for the patient.
- Microspheres smaller than 100 µm can migrate to distal anastomotic feeders and embolize circulation to distal tissue. For this reason, smaller microspheres have a greater likelihood of causing unwanted ischemic injury. This should be considered prior to starting the embolization procedure. Possible consequences include, but are not limited to, paralysis, necrosis, swelling, abscess formation and more severe post-embolization syndrome.
- Ischemia of tissue adjacent to the targeted area may result from post-embolization swelling. Therefore, special care should be taken to avoid such ischemia of non-tolerant, non-targeted tissue such as the nervous system.
- Consider upsizing Embozene Microspheres if angiographic appearance of embolization does not quickly appear during injection of the microspheres.
- If there are any symptoms of unwanted embolization during injection, consider stopping the procedure to evaluate the possibility of shunting. Such symptoms may include changes in patient vital signs, such as hypoxia or central nervous system changes.

Transend Guidewire with ICE Coating

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 Transend Guidewire is intended for general intravascular use, including the peripheral vasculature. The wire can be torqued to facilitate the selective placement of diagnostic or therapeutic catheters.

CONTRAINDICATIONS
This device is not intended for use in coronary arteries.

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

ADVERSE EVENTS
Complications attributed to guidewire applications are the following:
- Procedural related complications including but not limited to:
  - Vessel trauma
  - Vessel damage
  - Air embolism, thromboembolism
  - Post embolization syndrome (abdominal pain, fever, and nausea/vomiting)
  - Hematoma at the puncture site
  - Infection
  - Perforation of the vessel
  - Vessel spasm
  - Hemorrhage
  - Vascular thrombosis
  - Death
  - Bleeding
- Failed treatment
- Inability to position guidewire
- Damage to catheter
- Excessive force against resistance may result in separation of the guidewire tip

Fibered IDC
Interlock Fibered IDC Occlusion System
IDC Interlocking Detachable Coil

CAUTION: *FFederal 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 IDC Occlusion System is a modified interlocking detachable coil. The Interlock IDC Occlusion Systems are indicated for obstructing or reducing blood flow in the peripheral vasculature during embolization procedures. These devices are 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 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

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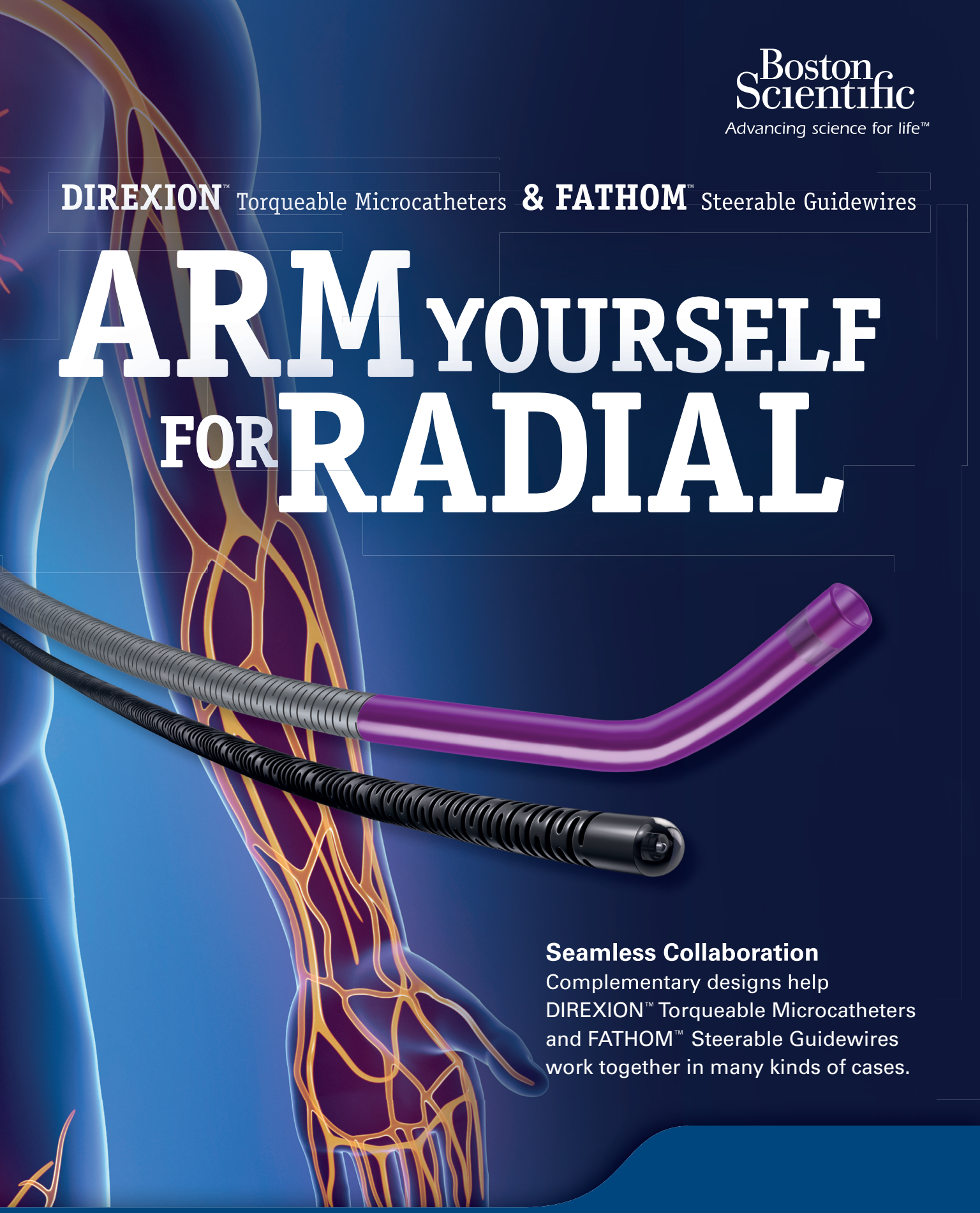
Advancing science for life™

DIREXION™ Torqueable Microcatheters **& FATHOM™** Steerable Guidewires

ARM YOURSELF FOR RADIAL



Seamless Collaboration
Complementary designs help DIREXION™ Torqueable Microcatheters and FATHOM™ Steerable Guidewires work together in many kinds of cases.