Guidelines for Peripheral and Visceral Vascular Embolization Training

Joint Writing Groups of the Standards of Practice Committees for the Society of Interventional Radiology (SIR), Cardiovascular and Interventional Radiological Society of Europe (CIRSE), and Canadian Interventional Radiology Association (CIRA)

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EMBOLOTHERAPY or embolization has rapidly developed in recent years and now represents an integral part of interventional radiology practice. Embolotherapy is defined as the percutaneous endovascular application of one or more of a variety of agents or materials to accomplish vascular occlusion.

Embolotherapy has evolved since its clinical introduction to include a wide variety of applications that can be grouped into the following categories:

1. Vascular malformations: occlusion of congenital or acquired aneurysms (cerebral, visceral, extremities), pseudoaneurysms, vascular malformations, or other vascular abnormalities that have potential to cause adverse health effects (1–18).
2. Nontraumatic hemorrhage: treatment of acute or recurrent hemorrhage (eg, hemoptysis, gastrointestinal bleeding, postpartum and iatrogenic hemorrhage, and hemorrhagic neoplasms) (18–53).
3. Trauma: for control of dramatic hemorrhage, for example, related to splenic laceration or pelvic fractures.
4. Uterine artery embolization: devascularization of benign uterine leiomyomas and adenomyosis for symptom alleviation or to reduce operative blood loss (3,4,14,54–57).
5. Oncologic embolization: to relieve symptoms, prevent or treat hemorrhage, reduce operative blood loss, or improve survival and quality of life (3,4,14,54–57). Examples include primary and secondary hepatic malignancies, renal cell carcinoma, and primary and secondary bone malignancies.
6. Tissue ablation: ablation of benign neoplastic and nonneoplastic tissue that produces adverse health effects to the patient (eg, hypersplenism, refractory renovascular hypertension, untreatable urine leak, proteinuria in end-stage kidney disease, renal angiomyolipoma, varicocele, pelvic congestion syndrome, priapism, and abdominal pregnancy) (9,10,14,16,58–68).
7. Flow redistribution: to protect normal tissue (eg, gastroduodenal artery and right gastric artery embolization in hepatic artery chemoembolization and radioembolization, or proximal superior gluteal artery coil embolization during particle em-

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bolization of the anterior division of the internal iliac artery for tumor devascularization) (30,69) or to facilitate subsequent other treatments (eg, right portal vein embolization to induce left lobe hypertrophy before surgical resection) (70–71).

8. Endoleak management: including direct sac puncture or collateral vessel embolization for endoleaks (72–76).
9. Regional therapy delivery: vehicle for delivery of drugs or other agents that may include oncolytic viruses, chemotherapy, β-emitting spheres, or other agents used to treat an organ or specific target lesion.
10. Enterocutaneous tracts and lymphatic abnormalities: embolizing abnormal communications between organs, from cavities or organs to the skin surface, thoracic duct leaks, lymphedema.

Embolization has grown dramatically in scope and complexity over the past three decades, and with this growth, there is now a need to define standards for those practicing in this field, including: appropriate training with monitoring of outcomes; provision of pre-, intra-, and postprocedure patient care; and performance of the technical aspects of the procedure.

PHYSICIAN QUALIFICATIONS

Embolization is a complex and demanding endovascular image-guided intervention requiring all of the skills of the interventional radiologist. Interpretation of diagnostic imaging tests is integral to performance of embolization procedures. The interventional radiologist who performs embolization must be competent in diagnostic image interpretation with all modalities of diagnostic imaging including computed tomography (CT), ultrasound (US), magnetic resonance (MR) imaging, fluoroscopy, and radiography. This is demonstrated by the completion of an Accreditation Council of Graduate Medical Education–accredited radiology residency or its equivalent or an international equivalent.

Training in interventional radiology following completion of a diagnostic imaging residency demonstrating essential competency in imaging interpretation is mandatory. The only accredited training pathways to achieve the necessary education to perform embolization procedures in the body is through the Accreditation Council of Graduate Medical Education–accredited fellowship programs in vascular and interventional radiology or its international equivalent. It is recognized that embolization requires a skill set only available through such rigorous and comprehensive American Board of Medical Specialties–accredited medical imaging and intervention training or its international equivalent. The 1-year duration of training is the minimum for attaining competency in embolization catheterization techniques and to acquire sufficient knowledge of the spectrum of diseases that can be served by embolization, including the natural history and risk–benefit analyses associated with provision of the procedures; training on specific aspects of the technical procedures; and the performance characteristics in indications for use for the numerous embolic materials available. This comprehensive training is critical to ensuring that patients receive safe and effective care.

It is expected that, as part of the accredited training process in diagnostic imaging and vascular and interventional radiology, the physician will have a thorough understanding of vascular anatomy including congenital and developmental variants and common collateral pathways, angiographic equipment, radiation safety considerations, and physiologic monitoring equipment. Moreover, it is anticipated that, before the performance of any embolization procedure, the operator will have received specific training, including didactic training as well as hands-on training with a sufficient number of procedures in each of the areas or vascular territories that may be served routinely by embolization (ie, vascular malformations, nontraumatic hemorrhage, trauma embolization, benign tumor embolization, malignant tumor embolization, tissue ablation, flow redistribution, endoleak embolization, regional therapy delivery, and enterocutaneous and lymphatic management). In addition, they must have access to an adequate supply of catheters, guide wires, embolic agents, and personnel to perform the procedures safely. Techniques that should be mastered during training include the use of microcatheters for subselective catheterization and the handling and delivery of particulate agents and embolization coils. The use of embolic agents beyond those described as "basic" may require additional training and proctoring as stipulated by the manufacturer or by the appropriate governing body. Consequences of inadequate training or experience can lead to major adverse events if the disease or imaging and embolization techniques are not fully understood by the operator. These adverse events could include nontarget embolization that can result in major morbidity depending on the territory treated (eg, stroke or blindness for epistaxis embolization, bowel or bladder infarction for uterine artery embolization).

The clinical relationship between a patient who needs an embolization procedure and an interventional radiology physician should be structured so that the physician should see every patient for a preprocedural clinical evaluation and consultation before treatment and for a postprocedure longitudinal clinical follow-up after the procedure. Some of the clinical skills and responsibilities required for patient care particular to embolization procedures include the following:

1. Knowledge of the natural history of the disease;
2. Understanding of the risks of the procedure given the patient's specific presentation and findings;
3. Review of all available diagnostic imaging tests;
4. Knowledge of the acute tumor lysis syndrome;
5. Treatment of the postembolization syndrome;
6. Use of relevant medications including pain medications;
7. Hydration;
8. Treatment failure and potential subsequent interventions;
9. Staging embolization; and
10. Clinical follow-up.

Angiographic and Interventional Skills and Knowledge of Embolic Materials

According to the requirements of American College of Radiology, the operating physician must be capable of accomplishing, with documented

and acceptable success and complication rates, each aspect of embolization procedures, including:

1. Percutaneous arterial access;
2. Manipulation of catheters to selectively access the target vessel and appropriate use of catheters and microcatheters;
3. Understanding and handling of materials used in embolization, including temporary and permanent agents such as particles, coils, plugs, and occluders; and
4. Assessment of the angiographic or imaging to determine the therapeutic endpoint.

There is a wide variety of embolic agents and materials that need to be mastered by the physician performing the embolization procedures. During a single embolization procedure, the interventional radiologist frequently uses a combination of embolic materials to obtain the optimal occlusion of a vessel and optimal clinical result. Specific knowledge of the following characteristics of embolic materials is required: the desired duration of occlusion; the size and shape of the target vessel; the mechanism of occlusion; the understanding of flow changes and distribution before, during, and after embolization; and the mechanical and biologic interaction of the embolic materials with the vessel wall and the target end organ.

Of all the clinical considerations in an embolization procedure, the main factors influencing the selection of a specific embolic agent relate to the size of the vessel, the speed of flow in the vessel, the desired level of occlusion in the vascular tree, and the desired duration of occlusion. For example, when dealing with traumatic bleeding versus hemorrhage caused by a hypervascular tumor, the therapeutic goal, the vascular anatomy, the size of vessels involved, and the level of occlusion will all be different and lead to a completely different selection of embolic materials. It is important to note that the level of occlusion, which is primarily determined by the size of the agent, can also be affected by the occurrence of "clumping" when using particulate agents.

Specific clinical problems can require even more detailed knowledge of occlusion devices. For instance, high-flow arteriovenous fistulas require careful sizing of metallic occlusion devices, knowledge of techniques of packing, and knowledge of techniques to control the delivery of the devices to prevent paradoxic embolization. Techniques of preparation and injection of liquid and particulate agents are very important. For instance, recent studies have demonstrated that the degree of dilution of embolic particles and the use of the proper technique for preparation and injection of the particles can significantly affect the technical and clinical success and the rate of complications of a procedure (77,78). Inappropriate preparation or injection of liquid embolic agents can be a major cause of nontarget embolization. Poor preparation technique and inappropriate dilution can damage embolic materials or create conditions that allow them to clump, which can result in clogging of the catheter or lodging in the incorrect size or location vessel within the vascular tree, resulting in incomplete or nontarget embolization. It is equally important to employ the proper technique of injection. Forceful injection is frequently associated with vessel damage, nontarget embolization, clinical failure, and complications (79).

Knowledge of vascular anatomy, collateral pathways, possible anatomic variants, and the locations where one may encounter small anastomoses that are not seen during angiography (also called "invisible arterial anastomoses") are essential. This requires familiarity with a variety of vascular beds, as the propensity for downstream tissue infarction or distal vascular reconstitution is usually very organ-specific. Anastomoses between arterial beds can be the cause of significant complications if they are not appreciated (80), if an improper technique of injection is used, or if an inappropriate type or size of embolic agent is used.

Radiation Safety Training

Complex embolization procedures require prolonged exposure to radiation to the patient and operator. This frequently occurs in regions where there are radiation-sensitive organs such as the lens of the eyes, thyroid, breast, or gonads (81). The operator needs to be cognizant of that risk and be trained in techniques to reduce radiation exposure to the patient and the staff. This training includes not only the knowledge of radiology physics but also practical training in radiation protection such as is provided during interventional radiology training (82,83).

Physicians, medical physicists, and radiology technologists have a responsibility to minimize the radiation dose to patients, staff, and society as a whole, while maintaining necessary image quality. This concept is known as "as low as reasonably achievable," or "ALARA" (84).

In consultation with a medical physicist, interventional radiology facilities should adhere to the policies and procedures of ALARA. Examination protocols should take into account patient body habitus and use dose reduction devices and techniques to control radiation dose while maintaining image quality. To ensure dose optimization and radiation protection of the staff and the patient, the angiographic suite should at least be able to offer additional tube filtration, pulsed fluoroscopy, last image hold, and fade in/fade out fluoroscopy. Flat-screen digital panels provide another excellent option, as magnification can be achieved without an increase in dose.

Patient radiation doses should be recorded in the medical record for all embolization procedures and should be periodically reviewed by a medical physicist as recommended by the appropriate professional organizations (85,86).

IMAGING AND INTERVENTIONAL TECHNOLOGY

Embolization is an image-intensive intervention. The angiography suite, at a minimum, should have equipment that, independent of the patient's weight, can offer high field of view magnification, the possibility of prolonged fluoroscopy time, and high spatial resolution and contrast resolution to be able to visualize microcatheters, fine 0.010-inch microwires, 2-mm coils, small arteriovenous shunts and fistulas, and contrast agent reflux. Availability of high-quality fluoroscopy and digital subtraction angiograms cannot be overemphasized. Mobile C-arm units do not provide adequate image quality or advanced capabilities available in dedicated angiography suites and therefore should not

be used for these interventions. Advanced imaging technologies available in "modern" or state-of-the-art angiography units include roadmapping, overlay technology, filtration and collimation, semitransparent filters, replay, rotational angiography, and in some cases, cone-beam CT.

Angiographic CT or rotational subtraction is important for selected embolization procedures, including bronchial and pulmonary artery embolization and hepatic chemoembolization. Rotational angiography provides a three-dimensional view of vessels and can be a key tool in certain types of embolization, particularly neurointerventional applications.

The angiographic table must be motorized and able to accommodate large panning movements to move rapidly from one body region to another, especially in the setting of an emergency.

The imaging equipment must have the capacity to store multiple high-resolution images on film, in local digital archives, or on a picture archiving and communication system. The monitoring equipment must have the capacity to store all physiologic data in a paper or electronic form. Full record keeping is necessary to ensure that all patient-related information is maintained in a secure and complete manner so that postprocedural monitoring, patient follow-up, and follow-up interventions are accurately done if needed.

The physician performing embolization must be familiar with the operation of the angiographic system. The physician should also be trained in and comfortable with the interpretation of other imaging studies, including CT, CT angiography, MR imaging, MR angiography, duplex US, and conventional US.

QUALITY ASSURANCE

The physician performing embolization should maintain a permanent record of all patients undergoing embolization and have a system in place to monitor and evaluate outcomes, including complications. All complications should be discussed in a regular morbidity and mortality conference, which should occur at least quarterly, but preferably monthly. The minutes from these conferences should be submitted to the department or hospital quality oversight committee regularly for evaluation.

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