

**American College of Radiology  
ACR Appropriateness Criteria®**

**Clinical Condition:**      **Recurrent Symptoms Following Lower-Extremity Angioplasty**

**Variant 1:**                      **Claudication.**

Radiologic Procedure	Rating	Comments	RRL*
Segmental Doppler pressures and pulse volume recordings	9	Usual first tests.	O
MRA lower extremity without and with IV contrast	8	Able to triage between catheter and surgical management and thus may substitute for other noninvasive studies.	O
US lower extremity with Doppler	8	May be useful to identify focal lesions amenable to percutaneous intervention.	O
Arteriography lower extremity	7	Used for a lesion amenable to percutaneous intervention (eg, restenosis).	☼ ☼ ☼
CTA lower extremity with IV contrast	7	Can be an alternative to MRA. Heavy calcification, especially in calf arteries, can limit evaluation of outflow disease.	☼ ☼ ☼
MRA lower extremity without IV contrast	6		O
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

**Variant 2:**                      **Threatened limb.**

Radiologic Procedure	Rating	Comments	RRL*
Arteriography lower extremity	9	Allows most timely diagnosis and treatment.	☼ ☼ ☼
Segmental Doppler pressures and pulse volume recordings	8		O
MRA lower extremity without and with IV contrast	5	Useful if angiography is not performed (ie, surgical treatment is necessary).	O
CTA lower extremity with IV contrast	5	Useful if angiography is not performed, with limitations as described above.	☼ ☼ ☼
US lower extremity with Doppler	4	May be useful to identify focal lesions amenable to percutaneous intervention.	O
MRA lower extremity without IV contrast	4		O
<b>Rating Scale:</b> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			<b>*Relative Radiation Level</b>

# RECURRENT SYMPTOMS FOLLOWING LOWER-EXTREMITY ANGIOPLASTY

Expert Panel on Vascular Imaging: Matthew P. Schenker, MD<sup>1</sup>; Frank J. Rybicki, MD, PhD<sup>2</sup>; Karin E. Dill, MD<sup>3</sup>; Benoit Desjardins, MD, PhD<sup>4</sup>; Scott D. Flamm, MD<sup>5</sup>; Christopher J. Francois, MD<sup>6</sup>; Marie D. Gerhard-Herman, MD<sup>7</sup>; Sanjeeva P. Kalva, MD<sup>8</sup>; M. Ashraf Mansour, MD<sup>9</sup>; Emile R. Mohler III, MD<sup>10</sup>; Isabel B. Oliva, MD<sup>11</sup>; Clifford Weiss, MD.<sup>12</sup>

## **Summary of Literature Review**

### **Introduction/Background**

Endovascular therapy has supplanted bypass surgery as the primary invasive treatment modality for patients with peripheral arterial obstructive disease (PAOD). The Bypass versus Angioplasty in Severe Ischemia of the Limb (BASIL) trial showed that patients with critical limb ischemia (CLI) presenting with rest pain, ulceration, and gangrene of the leg due to infrainguinal disease had similar amputation-free survival and quality of life outcomes whether they were randomized to a surgery-first or an angioplasty-first treatment strategy. Furthermore, first-year costs associated with the bypass surgery were about one-third higher than with angioplasty [1]. In the United States, endovascular therapy is now far more common than bypass surgery for the management of patients with severe claudication and CLI, and the number of surgical bypass procedures has fallen accordingly [2].

Restenosis after endovascular therapy is a pervasive issue, however. Restenosis is a manifestation of the reparative response to vessel injury and is characterized by late elastic recoil, smooth muscle cell proliferation, neointimal hyperplasia, and positive vessel wall remodeling. Stents have traditionally been used to bail out a failed angioplasty, as in cases of acute thrombosis, flow-limiting dissection, or significant residual stenosis >30%. Increasingly, however, stents are used as primary implants to inhibit positive vessel wall remodeling and prolong target lesion patency rates. However, stents also suffer from neointimal hyperplasia, so identifying those patients with restenosis requiring target lesion revascularization is of obvious interest. Nevertheless, relatively few studies have focused on the importance of patient follow-up after lower-extremity intervention [3]. Recurrent symptoms of claudication usually precede the onset of limb- or life-threatening events in patients with lower extremity arterial disease, and it is the recurrence of these symptoms that typically drives patient assessment.

Clinical examination with periodic evaluation of the peripheral pulses and a determination of the resting and, if possible, postexercise ankle-brachial indices (ABIs) should be a standard part of the surveillance program after revascularization [3,4]. However, restenosis is often undetected clinically, and the natural progression of PAOD frequently leads to the development of new lesions at different sites. Thus, radiographic imaging is essential for the accurate diagnosis and subsequent treatment of the recurrent stenoses that develop after initial endovascular therapy.

### **Noninvasive Hemodynamic Studies**

Segmental limb pressures (SLP) and pulse volume recordings (PVR, also known as segmental plethysmography) are the most commonly performed noninvasive tests for evaluating peripheral arterial disease. Deterioration of SLP from previous levels by  $\geq 15\%$  has been accepted as indicative of restenosis [5-7]. However, this measurement does not clearly specify the site or length of the lesion beyond general terms, such as “femoropopliteal” or “inflow” disease, and it is of little value in patients with noncompressible arteries, as often occurs in diabetics and patients with renal insufficiency. Similarly, segmental PVR, a useful adjunct in calcified arteries, is not accurate with regard to location or length of lesions, nor does it provide specific enough information for treatment decision-making in patients with symptomatic recurrent peripheral vascular disease [8]. In conjunction with ABIs, however, it does provide a useful guide to the overall clinical severity of the obstructive disease.

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<sup>1</sup>Principal Author, Brigham and Women’s Hospital, Boston, Massachusetts. <sup>2</sup>Panel Chair, Brigham and Women’s Hospital, Boston, Massachusetts. <sup>3</sup>Panel Vice-chair, University of Chicago, Chicago, Illinois. <sup>4</sup>University of Pennsylvania, Philadelphia, Pennsylvania. <sup>5</sup>Cleveland Clinic, Cleveland, Ohio. <sup>6</sup>University of Wisconsin, Madison, Wisconsin. <sup>7</sup>Brigham and Women’s Hospital, Boston, Massachusetts, American College of Cardiology. <sup>8</sup>Massachusetts General Hospital, Boston, Massachusetts. <sup>9</sup>Vascular Associates, Grand Rapids, Michigan, Society of Vascular Surgeons. <sup>10</sup>University of Pennsylvania, Philadelphia, Pennsylvania, American College of Cardiology. <sup>11</sup>Yale University School of Medicine, New Haven, Connecticut. <sup>12</sup>Johns Hopkins Bayview Medical Center, Baltimore, Maryland.

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## **Ultrasound Imaging**

Duplex ultrasound (US) is the least expensive cross-sectional imaging modality and has widespread usage and acceptance in this patient population, although some uncertainty exists regarding its utility and cost-effectiveness following endovascular therapy [9]. Nevertheless, early duplex US after infrainguinal endovascular therapy for CLI has been shown to be predictive of primary lesion patency and subsequent limb loss and may even help identify residual stenotic lesions missed by conventional angiography [10]. In patients with CLI, duplex US surveillance can be used to ensure high limb salvage rates after infrapopliteal angioplasty as well [11].

Duplex US is highly operator dependent, but in expert hands, there is a high, although not perfect, correlation with catheter angiography, especially for infrainguinal disease. While preoperative duplex US can be used to establish an appropriate revascularization strategy [12], the Diagnostic Imaging of Peripheral Arterial Disease (DIPAD) study [13] showed that duplex US was less clinically useful than magnetic resonance angiography (MRA) or computed tomography angiography (CTA), and since more patients undergo additional vascular imaging after an initial duplex US, the total diagnostic costs per patient after an initial duplex US are higher than those after an initial CTA and similar to those after an initial MRA. As discussed below, when compared to duplex US, contrast-enhanced MRA (CE-MRA) is more sensitive and specific for PAOD [14].

## **Catheter Angiography**

Digital subtraction angiography (DSA) is still considered the gold standard for imaging of PAOD. DSA can localize and quantify obstructive lesions with an accuracy exceeded only by intravascular US. Moreover, it permits physiological evaluation by determining pressure gradients. In addition to its diagnostic capabilities, DSA allows for intervention at the time of diagnosis, which can prove invaluable in patients with a threatened limb. In high-acuity settings, such as a thrombosed bypass graft, where immediate catheter-based intervention is likely to be indicated, direct referral to catheter angiography is the preferred option. However, DSA is an invasive technique with a small but definite risk in every patient and a variable higher risk in patients with severe widespread vascular disease, diabetes, renal insufficiency, or other contraindications to the use of iodinated contrast media. Carbon dioxide angiography may be of value in these patients. In light of the risk of nephrogenic systemic fibrosis in patients with severe renal disease, gadolinium chelates serve a very limited role as DSA contrast agents.

## **Computed Tomography Angiography**

Early multidetector computed tomography (MDCT) had insufficient spatial resolution, temporal resolution, and volume coverage per gantry rotation to adequately evaluate the lower-extremity arterial system. With improvements in MDCT technology, CTA has become much more relevant in the imaging of peripheral vascular disease [15-20]. CTA now has several advantages over DSA, including shorter examination times, lower complication rates, direct visualization of mural plaque and calcium, and 3D volumetric display and analysis. Although relatively noninvasive compared with catheter angiography, CTA has similar relative limitations related to radiation exposure and the use of iodinated contrast medium. Furthermore, if used as the initial imaging modality, CTA can significantly reduce diagnostic costs compared to DSA and MRA in patients with PAOD [13].

Several studies have demonstrated the excellent diagnostic accuracy of CTA in evaluating aortoiliac and peripheral vascular disease [16,19,21-23]. CTA findings can reliably lead to correct treatment recommendations in patients with intermittent claudication and with CLI [24,25]. Although it is particularly useful for evaluating a defined vascular segment, CTA is still somewhat limited in its ability to grade the severity of stenotic lesions accurately when the volume of calcified plaque in a vessel is high with respect to the diameter of the vessel [26-28], which is an important limitation when using CTA to plan interventions in the foot and calf. Metal artifacts also limit the role of CTA in stent surveillance, although image interpretability and diagnostic accuracy continue to improve with advances in MDCT technology [29].

One potential advance in the noninvasive imaging of PAOD over conventional CTA is dual-energy (DE) CTA. DE-CTA can take advantage of element-specific attenuations to differentiate between calcium and iodine [30]. Automated bone and plaque subtraction can therefore be applied with considerable time savings over conventional postprocessing techniques and more accurate generation of CTA-luminograms, although plaque subtraction is less reliable below the knee [31,32].

## **Magnetic Resonance Angiography**

CE-MRA is a widely used modality for imaging of PAOD [33-37]. It is noninvasive and low-risk and can image the entire vascular system, including tibial and pedal arteries [38-40]. Recent work at 3 Tesla with parallel imaging and multichannel coils has shown nearly isotropic submillimeter voxels throughout the entire peripheral

arterial tree [41-43]. Time-resolved MRA may correlate more accurately with catheter angiography, especially in the calf vessels where minimizing venous contamination is essential [44-46]. Moreover, in a patient with total occlusion, CE-MRA more reliably defines the reconstituted vessels. Metallic stents, especially stainless steel, cause signal intensity dropout, which can be indistinguishable from an occlusion. This is less of a problem with nitinol stents. CE-MRA is now widely available, and its use, especially in conjunction with duplex US, allows for reliable determination of appropriate intervention when symptoms occur after angioplasty [47-56].

There are several important limitations of MRA. Patients with defibrillators, spinal cord stimulators, intracerebral shunts, cochlear implants, and other devices are excluded, as are patients affected by claustrophobia that is not amenable to sedation. It takes longer to acquire images with MRA as compared to CTA, and the studies themselves are considerably more expensive. However, with MRA, patients are not exposed to ionizing radiation, and the nephrotoxicity of gadolinium-based contrast is generally considered less than that of iodinated contrast agents.

A serious concern with CE-MRA and the use of gadolinium-based contrast agents is the risk of NSF in patients with impaired renal function [57-59] (see Anticipated Exceptions). This has revitalized interest in noncontrast MRA for the imaging of PAOD. Advances in MR technology along with the application of parallel imaging have reduced acquisition times sufficiently to render several new techniques clinically relevant. Recently developed electrocardiogram (ECG)-gated 3D partial Fourier fast spin-echo techniques (also known as “fresh blood imaging” or FBI) allow for shorter acquisition times than previous time-of-flight (TOF) or phase-contrast techniques [60,61]. Further improvements, in particular for the depiction of pedal circulation [62,63], will be required. An important limitation of FBI is that it requires preparatory scans to determine acquisition windows, optimal trigger delays, and spoiler gradients, adding time to the study and potentially introducing operator variability. Compared to other noncontrast imaging methods, quiescent-interval single-shot (QISS), a balanced steady-state free-precession-based technique, may offer a more consistent signal over a wider range of flow velocities, which is relevant in the imaging of small arteries and vessel stenoses [64]. The diagnostic performance of QISS MRA is nearly equivalent to that of CE-MRA and DSA [65]. Further investigation of these techniques and others at 3 Tesla is required.

## Summary

A complete vascular physical examination, including measurement of the ABIs, is always the first step in assessing a patient with recurrent symptoms after an initially successful endovascular intervention. With this information, appropriate imaging studies can be ordered. If it is clear that reintervention is necessary, as is often the case with a threatened limb, proceeding directly to catheter angiography is timely and appropriate. Preliminary duplex US imaging in less urgent cases may be helpful to define the problem by confirming a recurrence at the previously treated site or suggesting progression elsewhere.

Both MRA and CTA continue to develop and assume a greater role in patient evaluation. Some of the development is evolutionary, such as the use of time-resolved sequences in CE-MRA or the techniques of noncontrast MRA. Additional early work includes imaging the graft vessel wall in addition to the lumen to give further information towards understanding the biology of recurrent disease after intervention in patients with PAOD [63,66,67]. In parallel with developments in imaging technology, new gadolinium-based MR contrast agents with improved properties for vascular imaging have been developed. The Food and Drug Administration (FDA) recently approved gadofosveset trisodium, a molecule that binds more strongly to serum albumin than other gadolinium agents, resulting in a better visualization of vascular system [38,39,68]. Gadobenate dimeglumine also has advantages in vascular depiction in comparison to other conventional gadolinium-based agents [40,69].

Another fundamental development is CT scanners with two keV settings (DE CTA), in theory allowing separation between calcium and iodinated contrast material. However, plaque subtraction is still challenging, particularly for infrapopliteal lesions [31,32].

At present there is only anecdotal experience with the new techniques and contrast agents discussed above, and thus while they are extremely promising, their use must ultimately be supported by scientific evidence. Current MRI and CT protocols are robust, but they are somewhat limited in practice by the meager distribution of high-end MRI and MDCT equipment and the limited number of professionals trained to use them. However, where this equipment and expertise are more available, the improved accuracy, comprehensiveness, and reproducibility of MRI and CT make them appropriate first examinations after clinical examination. The choice of modality is usually related to the expertise of the imager. MRA still has the advantage of more easily visualizing lesions obscured by overlying bone cortex in the calf, in particular the anterior tibial artery. In properly screened patients

or in patients who are at risk for significant reactions to iodinated contrast agents, MRA is the procedure of choice.

- Clinical examination and measurement of the ABI is an essential first step in assessing patients with recurrent symptoms after prior lower-extremity revascularization.
- Catheter-based angiography is the gold standard in patients with a threatened limb, allowing for intervention at the time of diagnosis.
- Both MRA and CTA can be used to triage between endovascular and open surgical management.
- Newer noncontrast MRA techniques provide a reasonable alternative to CE-MRA in patients with renal insufficiency or other contraindication to the administration of gadolinium-based contrast agents.

### Relative Radiation Level Information

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults (see Table below). Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® [Radiation Dose Assessment Introduction](#) document.

Relative Radiation Level Designations		
Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
○	0 mSv	0 mSv
⊛	<0.1 mSv	<0.03 mSv
⊛ ⊛	0.1-1 mSv	0.03-0.3 mSv
⊛ ⊛ ⊛	1-10 mSv	0.3-3 mSv
⊛ ⊛ ⊛ ⊛	10-30 mSv	3-10 mSv
⊛ ⊛ ⊛ ⊛ ⊛	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (eg, region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as “Varies”.		

### Supporting Documents

For additional information on the Appropriateness Criteria methodology and other supporting documents go to [www.acr.org/ac](http://www.acr.org/ac).

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The ACR Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the FDA have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.