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**American College of Radiology
ACR Appropriateness Criteria®
Vascular Claudication–Assessment for Revascularization**

Variant 1: Vascular claudication–assessment for revascularization.

Radiologic Procedure	Rating	Comments	RRL*
MRA lower extremity without and with IV contrast	8		O
CTA lower extremity with IV contrast	8	This procedure is the test of choice in patients who cannot have MRA.	☼ ☼ ☼
US duplex Doppler lower extremity	7	This procedure is useful in patients with contrast allergy or renal dysfunction.	O
Arteriography lower extremity	7	This procedure is indicated only if intervention is planned.	☼ ☼ ☼
MRA lower extremity without IV contrast	5	This procedure is appropriate in patients with contraindications to iodinated and gadolinium-based contrast agents.	O
<u>Rating Scale:</u> 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

VASCULAR CLAUDICATION–ASSESSMENT FOR REVASCULARIZATION

Expert Panel on Vascular Imaging: Osmanuddin Ahmed, MD¹; Michael Hanley, MD²; Shelby J. Bennett, MD³; Ankur Chandra, MD⁴; Benoit Desjardins, MD, PhD⁵; Kenneth L. Gage, MD, PhD⁶; Marie D. Gerhard-Herman, MD⁷; Michael Ginsburg, MD⁸; Heather L. Gornik, MD⁹; Isabel B. Oliva, MD¹⁰; Michael L. Steigner, MD¹¹; Richard Strax, MD¹²; Nupur Verma, MD¹³; Frank J. Rybicki, MD, PhD¹⁴; Karin E. Dill, MD.¹⁵

Summary of Literature Review

Introduction/Background

Claudication is a symptom complex characterized by pain and weakness in an active muscle group, reproducibly precipitated by similar amounts of exercise and promptly relieved by rest. Claudication is most commonly a manifestation of peripheral arterial disease (PAD), but other disease entities can present similarly. Nonarterial etiologies represent up to 45% of patients being evaluated for claudication [1]. The most common nonarterial cause is neurogenic disease (especially spinal stenosis), but other diseases, such as compartment syndromes, pelvic tumors, and chronic venous occlusion, have also been associated with symptoms similar to claudication. In addition, most patients with peripheral arterial occlusive disease are asymptomatic, with as few as 6% to 20% of such patients having symptoms of claudication [2].

Estimates of the prevalence of claudication in the general population range from <1% to almost 8%, depending on age, gender, the geographic location of the population, and the diagnostic criteria used [3,4]. The presence of vascular disease in patients with symptoms of claudication is reliably established by a variety of noninvasive hemodynamic tests. In the absence of demonstrable arterial disease, imaging studies of other systems, such as the lumbar spine or soft tissues of the pelvis, may be indicated. If peripheral vascular disease is confirmed, additional studies may be indicated to screen the heart and carotid arteries for involvement [5].

Noninvasive hemodynamic tests such as the ankle brachial index (ABI), toe brachial index (TBI), segmental pressures, and pulse volume recordings (PVR) are considered the first imaging modalities necessary to reliably establish the presence and severity of arterial obstructions. Infrared thermography shows promise as an additional noninvasive examination [6]. Once confirmed by noninvasive hemodynamic studies, vascular imaging is used for diagnosing individual lesions and to triage patients for medical, percutaneous, or surgical intervention [7-9]. The indications for surgical or percutaneous intervention are controversial, and thus specific indications for imaging studies remain ill-defined. Factors that influence this decision include 1) the natural history of limb and patient survival, 2) the patient's tolerance of symptoms and resulting changes in lifestyle, 3) the effectiveness of medical or exercise therapy, 4) the potential risks of invasive tests and treatments, and 5) the short-term and long-term outcomes of surgery or interventional procedures.

Based on natural history studies, the risk of amputation in patients suffering from claudication is approximately 1% per year [10]. Because most of these studies were performed before the era of noninvasive testing, patients who did not truly have peripheral vascular disease may have been included, which could result in the frequency of serious complications to be underestimated. Modern natural history studies using noninvasive hemodynamic tests to confirm the presence of vascular disease show that progression of symptoms occurs in 25% to 60% of surviving patients within 5 years of presentation [10]. Because the risks associated with interventional procedures are low compared with surgery, image-guided interventional studies may be indicated for less severe disease.

¹Principal Author, Rush University Medical Center, Chicago, Illinois. ²Panel Vice-chair, University of Virginia Health System, Charlottesville, Virginia. ³University of Chicago, Chicago, Illinois. ⁴Scripps Green Hospital, La Jolla, California, Society for Vascular Surgery. ⁵University of Pennsylvania, Philadelphia, Pennsylvania. ⁶Moffitt Cancer Center, Tampa, Florida. ⁷Brigham & Women's Hospital, Boston, Massachusetts, American College of Cardiology. ⁸Palos Community Hospital, Palos Heights, Illinois. ⁹Cleveland Clinic Heart and Vascular Institute, Cleveland, Ohio, American College of Cardiology. ¹⁰University of Arizona College of Medicine, Tucson, Arizona. ¹¹Brigham & Women's Hospital, Boston, Massachusetts. ¹²Baylor College of Medicine, Houston, Texas. ¹³University of Florida, Gainesville, Florida. ¹⁴Specialty Chair, Ottawa Hospital Research Institute and the Department of Radiology, The University of Ottawa, Ottawa, Ontario, Canada. ¹⁵Panel Chair, UMass Memorial Hospital, Worcester, Massachusetts.

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Noninvasive Hemodynamic Studies

In combination with the history and physical examination of patients, noninvasive hemodynamic studies have become an important initial tool for evaluating peripheral vascular disease [11-13]. Their importance is related to their ability to provide an objective test for the presence or absence of peripheral vascular disease. They also provide a valuable means of quantifying the severity of vascular disease and are useful in documenting the functional significance of arterial lesions demonstrated by angiography. Noninvasive hemodynamic studies are prerequisite examinations, and if they are positive, then imaging is performed to plan for treatment.

There is no consensus regarding which test is most valuable or accurate because there may be considerable variability depending on clinical circumstances. For instance, patients with stiff, noncompliant arteries (often associated with diabetes) are difficult to study using tests such as the ABI or segmental pressures that depend on measurements of arterial pressure. In these patients, the TBI or PVR may be more helpful. Most laboratories use a combination of tests that increases overall sensitivity and accuracy [14]. The simplicity, reliability, and noninvasive nature of these tests have led to their routine use in screening patients with appropriate symptoms and physical findings. The presence of a normal ABI both at rest and following exercise in a patient with compressible vessels effectively excludes atherosclerotic occlusive disease as a cause of leg claudication and obviates the need for additional arterial imaging [15]. However, the ABI will not evaluate for hypogastric arterial occlusions that may produce buttock claudication. The main limitation of noninvasive testing is that proving the presence of vascular disease does not necessarily exclude the possibility that symptoms are nonetheless caused by neurologic disease. Careful correlation with clinical evaluation is necessary, and in certain cases, tests to rule out neurologic disease (eg, spine or pelvic magnetic resonance imaging [MRI]) may be indicated.

Arteriography

Catheter angiography remains the reference standard for imaging the peripheral arteries, providing a dynamic and accurate depiction of the peripheral vascular system. Multiple views, including oblique projections, are usually necessary for completeness because of overlap from branching vessels, the anteroposterior course of the pelvic vessels, and the tendency of atherosclerotic plaque to develop on the posterior arterial wall [16,17]. The development of digital subtraction has enhanced the ability of contrast angiography to visualize vessels that are poorly opacified and permits multiple views while minimizing the amount of contrast injected. Endovascular treatment of peripheral vascular disease—including angioplasty, stenting, excimer laser, and atherectomy—is increasingly being used.

The presence of diffusely diseased arteries can present challenges during angiography, as stenosis severity can be difficult to determine in the absence of normal arterial segments for comparison. In addition, serial lesions, luminal irregularity, and the degree of collateral development may produce effects on the blood flow that are difficult to quantify angiographically.

The main drawbacks of arteriography in patients with claudication that has a suspected vascular etiology are its invasive nature and the known complications from catheterization [18]. These difficulties can be averted, however, by using examinations such as ultrasound (US), magnetic resonance angiography (MRA), or computed tomography angiography (CTA) to accurately triage patients with confirmed PAD for percutaneous or surgical treatments. For the latter, preoperative arteriography may not be needed.

Finally, arteriography has inconsistent correlation between the hemodynamic or functional effects and the morphology of the arterial lesions [19]. Several studies have reported this problem, but in some of them the problem may be accentuated by less than optimal angiographic technique (eg, single-projection, nonselective injections).

Noninvasive Imaging

Ultrasound duplex Doppler

Duplex US of the extremities can be used to identify the location, degree, and extent of stenosis to the level of the knee [20]. Although duplex US includes images in grayscale or in color or power Doppler, the primary clinically relevant information derived from duplex studies has been validated from analysis of the velocity of blood flow.

The sensitivity and specificity for the diagnosis of stenoses >50% in diameter from the iliac arteries to the popliteal arteries are each approximately 90% to 95% [20-22]. Accuracy of the duplex examination depends on the ability of the technique to visualize the vessel adequately. The use of color improves accuracy [23]. Accuracy is diminished in examinations of the iliac arteries if bowel gas or tortuosity obscures the iliac vessels. Dense

calcification can also obscure flow, particularly if flow is slow. Accuracy of duplex US is also decreased in the setting of multiple sequential lesions [24].

Duplex US can be used for choosing primarily between endovascular and surgical revascularization, although it is not satisfactory for evaluating tibial arteries for distal bypass or choosing specific treatment plans with a high degree of confidence [25]. Duplex US following angioplasty is widely performed to detect recurrent stenoses but has not yet been demonstrated to improve patient outcomes [26-28]. Duplex US is used in specialist centers for preoperative arterial mapping [29,30], but in many centers the diagnostic confidence is low with this technique, and additional studies are often ordered [31]. This renders duplex arterial preoperative mapping a less cost-effective option, as further studies are often ordered [32]. The examination requires a highly skilled sonographer and can require over an hour to perform.

Magnetic resonance angiography

MRA techniques continue to evolve and improve, including the more recent use of noncontrast-only imaging in patients with renal insufficiency [33]. Two-dimensional time of flight, 3-D imaging, contrast enhancement with gadolinium, subtraction, cardiac gating, bolus chase, parallel imaging, optimized K-space filling, 3T magnet strength, and improved coil technology have led to improved temporal resolution, spatial resolution, and signal to noise ratio in MRA. Its sensitivity and specificity for detection of stenoses >50% are now in the 90% to 100% range [24,34-37], which is much better than catheter angiography provides. As a result, MRA is now a first-line technique in many centers for the imaging of peripheral vascular disease [38,39]. Dedicated time-resolved imaging of the calves and pedal arteries provides accurate identification of infrageniculate arteries and pedal arteries as potential touchdown sites for bypass surgeries [40,41].

The majority of MR approaches use noncontrast sequences followed by the intravenous administration of a gadolinium-based agent. In comparison to color duplex US, contrast-enhanced MRA is more accurate for detecting significant stenoses and for preoperative planning [42-44]. Both MRA and CTA are more cost effective than duplex US [32], and MRA is more cost effective and safer than arteriography [45,46]. For postoperative and postangioplasty surveillance, small studies have shown MRA to be helpful in detecting recurrent disease, but improved outcomes for such surveillance have not been documented [47,48]. Regarding comparative studies, MRA typically has not supplanted angiography as a reference standard. However, technology, experience, and protocol optimization have enhanced the use of contrast-enhanced MRA as a replacement for angiography in the initial evaluation. These improvements include 3T field strength, whole-body angiography, reduced gadolinium doses, and contrast agents with improved relaxivity and vascular retention characteristics [49,50].

Recent advancements in noncontrast MRA techniques for imaging peripheral-artery disease have expanded the sequence options from time-of-flight and phase-contrast imaging to include electrocardiogram-gated fresh-blood partial Fourier fast spin echo, balanced steady-state free precession, and spin labeling [51]. Two alternative approaches using balanced steady state for peripheral MRA applications include flow-sensitive dephasing and quiescent-interval single shot [52-54]. When compared to bolus-chase and time-resolved gadolinium-enhanced MRA, initial studies of fresh-blood imaging of the calf and pedal arteries have provided accurate imaging when technically successful. Overall, these methods are being increasingly adopted for patients with renal insufficiency.

Some technical problems limit the utility of MRA for imaging peripheral vascular disease. Challenges may include image quality related to low signal to noise ratio, limited spatial resolution, motion artifacts, long acquisition times, unreliable visualization of lesions with high flow and turbulence (excessive signal loss at regions of high-grade stenoses), nonvisualization of patent vessel segments with reversed blood flow, the need to exclude patients with pacemakers or other metallic implants, and loss of signal in arterial segments within metal stents or adjacent to metallic clips or prosthetic joints. Some of these problems have been addressed successfully with the use of newer imaging sequences and the addition of MR contrast agents. With the newer noncontrast techniques, cardiac arrhythmia can impair image quality, limiting evaluation of the distal calf and pedal arteries. Although useful tools to improve image quality have been suggested, larger-scale trials are required for evaluation of small-vessel peripheral-artery disease with noncontrast MRA [55].

MRA has not yet replaced catheter angiography as the gold standard in comparative studies, but it has largely replaced angiography in some institutions for preintervention planning. This is due to improvements in imaging sequences as well as experience among radiologists. In addition, contrast agents are considered safe in patients with normal renal function. In these patients, MRA is likely to entirely supplant catheter angiography as a pure diagnostic tool.

Computed tomography angiography

Spiral or helical CTA is increasingly used for imaging peripheral vascular disease. Multidetector computed tomography (CT) scanners, including helical and multistation axial acquisitions [56], enable rapid scanning of the entire arterial system. When compared to catheter arteriography, CTA offers volumetric as opposed to planar images and generally requires less radiation exposure with comparable or lower iodine loads. The volumetric acquisition enables extensive image postprocessing including multiplanar reformatted and maximum-intensity projection images to create an arterial road map [57]. Lower radiation and iodine doses have a favorable safety profile. With optimized timing of the acquisition, CT images include collaterals and arteries distal to occlusions that may not appear on arteriogram images. Like MRA, CTA has good soft-tissue contrast and thus shows nonvascular findings as well as vascular lesions associated with aneurysms and cystic adventitial disease that are not detected with the lumen imaging inherent to catheter arteriography.

Although it has been suggested that CT alone can be used to plan treatment, including interventions [58] that require morphological assessment of the lesions, including the length, severity, and number of stenoses [59], its spatial resolution is inferior to that of catheter arteriography. Compared to catheter angiography, the sensitivity and specificity of 4-, 16- and 64-detector-row CTA for detection of stenoses >50% diameter are 90% to 100% [60-67]. Accuracy in patients with bypass grafts is excellent compared to duplex US [68]. CTA is also more clinically useful and is more cost effective than duplex US [32,69]. However, heavily calcified atheromatous disease can limit the ability to interpret CT images. This drawback is usually related to calf arteries. Identification of patients who are unsuitable candidates for CTA (eg, >84 years of age, diabetic, on dialysis, with heart disease) will reduce the number of insensitive studies [70]. Another limitation of CTA that is typically seen in the calf arteries is related to the timing of the acquisition with respect to the iodine bolus. Images acquired too late will have problematic venous contamination. More common with newer CT technologies is imaging too early either for 1 leg with slow flow from outflow disease or for both legs secondary to the very fast scanning protocols. In general, these pitfalls are less problematic in MRI because time-resolved imaging could be used with modern technologies to improve the MR properties of image quality [71]. Some of the aforementioned limitations of CTA, such as vessel calcification, insufficient contrast enhancement of the vasculature, and contrast nephropathy, may soon be mitigated with the advent of dual-energy spectral CT [72].

Compared to MRI, CT has the advantages of more rapid acquisition, better safety in patients with pacemakers or defibrillators, and generally less severe artifacts from metal. Finally, claustrophobia is far less of a problem.

Summary of Recommendations

- Noninvasive hemodynamic tests such as ABI, TBI, segmental pressures, and PVR remain the primary modalities by which a diagnosis of vascular claudication is established and are considered prerequisite to any additional radiographic imaging.
- In conjunction with the noninvasive hemodynamic tests, noninvasive imaging, including US, CTA, and MRA, can reliably confirm or exclude the presence of peripheral vascular disease. All modalities, however, have their own technical limitations when classifying the location, extent, and severity of disease.
- Catheter arteriography remains the gold standard by which the peripheral vasculature is imaged and also allows for a dynamic depiction of the arteries. It is of particular use when endovascular treatment is being considered.
- In patients with limited renal function or planned surgical intervention, noninvasive imaging tests (particularly MRA and CTA) may obviate the need for diagnostic catheter angiography to visualize the location and severity of peripheral vascular disease.

Summary of Evidence

Of the 72 references cited in the *ACR Appropriateness Criteria[®] Vascular Claudication–Assessment for Revascularization* document, all are categorized as diagnostic references, including 6 well-designed studies, 16 good-quality studies, and 12 quality studies that may have design limitations. There are 33 references that may not be useful as primary evidence. There are 5 references that are meta-analysis studies.

The 72 references cited in the *ACR Appropriateness Criteria[®] Vascular Claudication–Assessment for Revascularization* document were published from 1971 to 2016.

Although there are references that report on studies with design limitations, 22 well-designed or good-quality studies provide good evidence.

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.

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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.