

**American College of Radiology
ACR Appropriateness Criteria®
Lower Extremity Arterial Claudication-Imaging Assessment for Revascularization**

Variant 1: Lower extremity arterial claudication imaging assessment for revascularization. Initial imaging.

Procedure	Appropriateness Category	Relative Radiation Level
US duplex Doppler lower extremity	Usually Appropriate	○
Arteriography lower extremity	Usually Appropriate	⊗⊗
MRA abdomen and pelvis with bilateral lower extremity runoff with IV contrast	Usually Appropriate	○
CTA abdomen and pelvis with bilateral lower extremity runoff with IV contrast	Usually Appropriate	⊗⊗⊗⊗
CTA abdomen and pelvis with bilateral lower extremity runoff without and with IV contrast	Usually Appropriate	⊗⊗⊗⊗⊗
MRA abdomen and pelvis with bilateral lower extremity runoff without IV contrast	May Be Appropriate	○
MRA lower extremity without and with IV contrast	May Be Appropriate	○
MRA lower extremity without IV contrast	May Be Appropriate	○
CTA lower extremity with IV contrast	May Be Appropriate	⊗⊗⊗
CTA lower extremity without and with IV contrast	May Be Appropriate	⊗⊗⊗

LOWER EXTREMITY ARTERIAL CLAUDICATION-IMAGING ASSESSMENT FOR REVASCULARIZATION

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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 artery disease (PAD), which affects 3% to 7% of the general population and 20% of people >70 years of age [1]. Other disease entities can present similarly with “pseudoclaudication.” 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 [2].

Estimates of the prevalence of claudication in the general population range from 1.6% to almost 8%, depending on age, sex, the geographic location of the population, and the diagnostic criteria used [2,3]. In most studies, fewer than 10% of patients with intermittent claudication progress to chronic limb-threatening ischemia in 5 years [4,5]. However, one large meta-analysis of 16,440 patients demonstrated that 21% of patients with intermittent claudication progressed to chronic limb-threatening ischemia [6].

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 [2].

Noninvasive hemodynamic tests such as the ankle brachial index, toe brachial index, segmental pressures, and pulse volume recordings are considered the first diagnostic modalities necessary to reliably establish the presence and severity of arterial obstructions [2]. Near infrared thermography shows promise as an additional noninvasive examination [7,8]. Once confirmed by noninvasive hemodynamic studies, if intervention beyond medical management is indicated, vascular imaging is used for diagnosing individual lesions and to triage patients for possible percutaneous or surgical intervention [2,9]. 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 [2].

Initial Imaging Definition

Initial imaging is defined as imaging at the beginning of the care episode for the medical condition defined by the variant. More than one procedure can be considered usually appropriate in the initial imaging evaluation when:

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- There are procedures that are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient's care)

OR

- There are complementary procedures (ie, more than one procedure is ordered as a set or simultaneously where each procedure provides unique clinical information to effectively manage the patient's care).

Special Imaging Considerations

CT angiography (CTA) in the tibial arteries is limited by the difficulty in accurately timing the image acquisition with respect to arrival of the iodine bolus: images acquired too late will have problematic venous contamination; images acquired too early will not have adequate contrast enhancement. More common with newer CT technologies is imaging too early either for one leg with slow flow from outflow disease or for both legs secondary to the very fast scanning protocols. Delayed images of the calves can be obtained to catch the bolus in these patients.

Discussion of Procedures by Variant

Variant 1: Lower extremity arterial claudication imaging assessment for revascularization. Initial imaging.

Arteriography Lower Extremity

Catheter angiography is often helpful for imaging the peripheral arteries, providing a dynamic and accurate depiction of the peripheral vascular system [10,11]. 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. Digital subtraction angiography (DSA) allows visualization of the lumen in the presence of densely calcified arteries, especially those in the below knee segment. In addition, DSA allows dynamic assessment of the arteries to evaluate extrinsic compression (as in popliteal artery entrapment). Endovascular treatment of peripheral vascular disease—including angioplasty, stenting, excimer laser, and atherectomy—is commonly used [2].

The presence of diffusely diseased arteries can present challenges during angiography, because 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 are its invasive nature and the known complications from catheterization [2,10]. These difficulties can be avoided by using examinations such as duplex ultrasound (US), MR angiography (MRA), or 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 [12]. 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).

CTA Abdomen and Pelvis with Bilateral Lower Extremity Runoff With IV Contrast

CTA is commonly used for imaging peripheral vascular disease. Multidetector CT scanners, including helical and multistation axial acquisitions, enable rapid scanning of the entire arterial system [13]. When compared with catheter arteriography, CTA offers volumetric as opposed to planar images. The volumetric acquisition enables extensive image postprocessing, including multiplanar reformatted and maximum-intensity projection images to create an arterial road map [13]. With optimized timing of the acquisition, CT images include collaterals and arteries distal to occlusions that may not appear on catheter angiography images. Like MRA, CTA is a cross-sectional technique, which shows nonvascular findings, as well as vascular lesions associated with aneurysms and cystic adventitial disease that are not detected with the projectional technique of catheter arteriography.

Unlike imaging of the peripheral arteries, CTA is considered to have replaced catheter angiography as the reference standard for imaging of the aorta [13,14]. CTA can readily detect stenosis caused by plaque or thrombus in the aorta and iliac arteries that may be contributing to symptoms of claudication.

CTA alone can be used to plan treatment, including assessment of the length, severity, and number of stenoses [15,16]. Compared with catheter angiography, the sensitivity and specificity of CTA for detection of stenoses >50% diameter are 90% to 100% [10,17-20]. Accuracy in patients with bypass grafts is excellent compared with duplex

US [21]. CTA is also more clinically useful than duplex US [21]. However, heavily calcified atheromatous disease can limit the ability to interpret CT images. This drawback is usually more pronounced in tibial arteries. Identification of patients who may be unsuitable candidates for CTA of the tibial arteries (eg, >80 years of age, diabetic, on dialysis) will reduce the number of nondiagnostic studies [22]. Dual-energy CTA can reduce blooming and beam-hardening artifact created by heavily calcified atheromatous disease and metallic stents [23].

Compared with MRA, 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.

CTA Abdomen and Pelvis with Bilateral Lower Extremity Runoff Without and With IV Contrast

CTA is commonly used for imaging peripheral vascular disease. Multidetector CT scanners, including helical and multistation axial acquisitions, enable rapid scanning of the entire arterial system [13]. When compared with catheter arteriography, CTA offers volumetric as opposed to planar images. The volumetric acquisition enables extensive image postprocessing, including multiplanar reformatted and maximum-intensity projection images to create an arterial road map [13]. With optimized timing of the acquisition, CT images include collaterals and arteries distal to occlusions that may not appear on catheter angiography images. Like MRA, CTA is a cross-sectional technique, which shows nonvascular findings as well as vascular lesions associated with aneurysms and cystic adventitial disease that are not detected with the projectional technique of catheter arteriography.

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CTA Lower Extremity Without and With IV Contrast

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MRA Abdomen and Pelvis with Bilateral Lower Extremity Runoff With IV Contrast

Contrast-enhanced MRA (CE-MRA) techniques continue to evolve and improve. Three-dimensional 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 CE-MRA. Its sensitivity and specificity for detection of stenoses >50% are now in the 90% to 100% range [25-27]. Unlike with CTA, the presence of calcium in small vessels does not result in a CE-MRA artifact [28]. Furthermore, dedicated time-resolved CE-MRA of the tibial and pedal arteries significantly increases diagnostic accuracy of tibial and pedal lesions compared with standard multistation CE-MRA. Time-resolved CE-MRA also reduces insufficient arterial filling and venous contamination, which are common limitations of standard multistation CE-MRA [28]. Although CE-MRA has not supplanted angiography as a reference standard, one small study demonstrated that 3T CE-MRA with calf compression (to prevent venous contamination) resulted in better visualization of tibial arteries than DSA [29]. For these reasons, CE-MRA is ideally suited for patients at high risk for calcification of the tibial and pedal arteries, particularly patients with diabetes and patients >80 years of age [28,30].

In comparison with duplex US, CE-MRA is more accurate for detecting and quantifying significant stenoses and for preoperative planning [31]. In a randomized controlled trial comparison with duplex US, CE-MRA for the initial imaging workup of patients with PAD reduced the need for additional imaging [32]. In a meta-analysis comparison with CTA, CE-MRA had equivalent sensitivity and specificity for detecting arterial lesions from the aorta to the tibial arteries in patients with intermittent claudication [26].

Some technical problems limit the utility of CE-MRA for imaging PAD. Challenges may include image quality related to low signal-to-noise ratio, limited spatial resolution, motion artifacts, long acquisition times, 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 newer stent designs.

MRA Abdomen and Pelvis with Bilateral Lower Extremity Runoff Without IV Contrast

Noncontrast MRA techniques predate CE-MRA in their development. However, long acquisition time and motion artifacts limit the use of these techniques in the abdomen and peripheral arteries [33]. To that end, recent

advancements in noncontrast MRA techniques for imaging PAD 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 arterial spin labeling [33]. Two alternative approaches using balanced steady state for peripheral noncontrast MRA applications include flow-sensitive dephasing and quiescent-interval single shot [30,33-35]. When compared with bolus-chase and time-resolved gadolinium-enhanced MRA, initial studies of fresh-blood imaging of the tibial and pedal arteries have provided accurate imaging when technically successful. Overall, these methods are being increasingly adopted for patients with severe renal insufficiency at risk of developing nephrogenic systemic fibrosis.

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MRA Lower Extremity Without and With IV Contrast

MRA of one or both lower extremities can be performed without imaging the abdomen and pelvis when aortoiliac disease is not a concern or the state of the aorta and iliac arteries is already known.

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US Duplex Doppler Lower Extremity

Duplex US of the extremities can be used to identify the location, degree, and extent of stenosis to the level of the knee [37]. Although duplex US includes images in grayscale or in color or power Doppler, the 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% [37-39]. Accuracy of the duplex examination depends on the ability of the technique to visualize the vessel adequately. The use of color improves accuracy [40]. 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 [41].

Duplex US has been established as a useful surveillance tool for arterial bypass grafts with established criteria for graft stenosis and thresholds for reintervention [42]. However, evidence and standards for duplex US surveillance after endovascular treatment are lacking, although duplex US is commonly used for this indication [42]. In comparison with CE-MRA, duplex US is less accurate for detecting significant stenoses and for preoperative planning [31]. In a randomized controlled trial comparison with CE-MRA, duplex US for the initial imaging workup of patients with PAD increased the need for additional imaging [32]. CTA is more clinically useful than duplex US [21].

Advantages of duplex US include its portability and lack of IV contrast agent. Disadvantages include limited sonographic windows resulting in nondiagnostic segments of the aorta and iliac arteries. Duplex US may underestimate the extent of disease when multiple “tandem” stenotic segments are present in series [43]. Patient discomfort during the procedure may limit adequate visualization.

Summary of Recommendations

- Variation 1:** US duplex Doppler lower extremity or arteriography lower extremity or MRA abdomen and pelvis with bilateral lower extremity runoff with IV contrast or CTA abdomen and pelvis with bilateral lower extremity runoff with IV contrast or CTA abdomen and pelvis with bilateral lower extremity runoff without and with IV contrast is usually appropriate for the initial imaging assessment for revascularization in the setting of lower extremity arterial claudication. These procedures are equivalent alternatives (ie, only one procedure will be ordered to provide the clinical information to effectively manage the patient’s care).

Supporting Documents

The evidence table, literature search, and appendix for this topic are available at <https://acsearch.acr.org/list>. The appendix includes the strength of evidence assessment and the final rating round tabulations for each recommendation.

For additional information on the Appropriateness Criteria methodology and other supporting documents go to www.acr.org/ac.

Appropriateness Category Names and Definitions

Appropriateness Category Name	Appropriateness Rating	Appropriateness Category Definition
Usually Appropriate	7, 8, or 9	The imaging procedure or treatment is indicated in the specified clinical scenarios at a favorable risk-benefit ratio for patients.
May Be Appropriate	4, 5, or 6	The imaging procedure or treatment may be indicated in the specified clinical scenarios as an alternative to imaging procedures or treatments with a more favorable risk-benefit ratio, or the risk-benefit ratio for patients is equivocal.
May Be Appropriate (Disagreement)	5	The individual ratings are too dispersed from the panel median. The different label provides transparency regarding the panel’s recommendation. “May be appropriate” is the rating category and a rating of 5 is assigned.
Usually Not Appropriate	1, 2, or 3	The imaging procedure or treatment is unlikely to be indicated in the specified clinical scenarios, or the risk-benefit ratio for patients is likely to be unfavorable.

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, because of both 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 with 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 [44].

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.”

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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.