American College of Radiology
ACR Appropriateness Criteria®

Clinical Condition: **Claudication — Suspected Vascular Etiology**

Radiologic Procedure	Rating	Comments	RRL*
US segmental Doppler pressures and pulse volume recordings	9	Should be performed with exercise in this clinical scenario.	None
Arteriography lower extremity	7	Indicated to guide intervention once vascular diagnosis is established by SDP-PVR, noninvasive imaging, and/or physical exam.	Low
MRA lower extremity with contrast	8	See statement regarding contrast in text under "Anticipated Exceptions."	None
CTA lower extremity	8		Med
US lower extremity with Doppler	6		None
Rating Scale: 1=Least appropriate, 9=Most appropriate			*Relative Radiation Level

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Summary of Literature Review

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 the most common manifestation of peripheral arterial disease, but other disease entities can cause a similar clinical picture. Non-arterial etiologies have been reported as the cause of symptoms in 20%-38% of patients being evaluated for claudication. The most common non-arterial 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; as few as 6%-20% of such patients will have symptoms of claudication [1].

Estimates of the prevalence of claudication in the general population range from less than 1% to almost 8%, depending on the age, gender, geographic location of the population and the diagnostic criteria used [2]. The presence of vascular disease in patients with symptoms of claudication is reliably established by a variety of noninvasive hemodynamic tests. In patients who do not have demonstrable arterial disease, imaging studies of other systems such as the lumbar spine or soft-tissues of the pelvis may be indicated. If the presence of peripheral vascular disease is confirmed, additional studies may be indicated to screen for other commonly associated diseases that may have an important impact on patient survival, such as coronary artery disease.

Since the presence and severity of arterial obstructions are reliably established using noninvasive hemodynamic tests such as the ankle brachial index (ABI), toe brachial index (TBI), segmental pressures, or pulse volume recordings (PVR), imaging studies are reserved for circumstances that warrant consideration for invasive therapy [3-5]. The indications for surgical or interventional procedures in patients with claudication are controversial, and thus specific indications for imaging studies remain ill-defined. Some 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. Since most of these studies were performed before the era of noninvasive testing, many patients who did not actually have vascular disease were probably included, thereby possibly underestimating the frequency of serious complications. Modern natural history studies, using noninvasive hemodynamic tests to confirm the presence of vascular disease, show that progression of symptoms occurs in 25%-60% of surviving patients within 5 years of presentation. Because the risks associated with interventional procedures are low compared with surgery, image-guided interventional studies may be indicated for less severe disease than if surgery were the only option for treatment.

Noninvasive Hemodynamic Studies

In combination with the history and physical examination of patients, noninvasive hemodynamic studies have become an important tool for the evaluation of peripheral vascular disease [6-8]. 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.

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 [9]. 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

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disease as a cause of leg claudication and obviates the need for additional arterial imaging [10]. 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 MRI) may be indicated.

Contrast Angiography

Once the decision has been made that invasive therapy is indicated, an accurate and complete assessment of the peripheral arteries is essential for adequate planning of the procedure. Digital subtraction angiography (DSA) remains the gold standard for imaging the peripheral arteries. Multiple projections including oblique views, are usually necessary for a complete study because of the overlapping of branching vessels, the anteroposterior course of the pelvic vessels, and the tendency of atherosclerotic plaque to develop on the posterior arterial wall [11,12]. The development of digital subtraction has enhanced the ability of contrast angiography to visualize poorly opacifying distal vessels, and permits multiple views while minimizing the amount of contrast injected. Endovascular treatment of peripheral vascular disease including stenting, embolization, and arthrectomy is increasingly being utilized and DSA provides dynamic and accurate depiction of the peripheral vascular system.

Although contrast angiography remains the diagnostic standard for peripheral vascular disease, it does have shortcomings that limit its usefulness. The main diagnostic limitation of angiography is inconsistent correlation between the hemodynamic or functional effects and the morphology of the arterial lesions [13]. Several studies have reported this poor correlation, but in some of these studies the problem may be accentuated by less than optimal angiographic technique (eg, single projection, nonselective injections).

Other factors are also involved, however, such as diffusely diseased arteries that make it difficult to estimate stenosis severity (no normal arterial segments are available 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 other main drawback of contrast angiography is the low but not insignificant incidence of complications, due to arterial catheterization or injection of contrast material [14]. Currently, with improved noninvasive imaging, contrast angiography's role in patients with claudication is limited to situations in which a therapeutic intervention is expected to be undertaken.

Noninvasive Imaging

Duplex Ultrasound

Duplex ultrasound (US) of the extremities can be used to diagnose the location, degree, and extent of stenosis to the level of the knee [15]. Although duplex US includes images, in either black and white or color format, 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 greater than 50% diameter from the iliac arteries to the popliteal arteries are each approximately 90%-95% [15-17]. Accuracy of the duplex exam depends on the ability of the technique to visualize the vessel adequately. The use of color improves accuracy [18]. 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 [19].

Duplex US can be used for selection of endovascular vs. surgical revascularization, although it is not satisfactory for evaluation of tibial arteries for distal bypass. Duplex US following angioplasty is widely performed to detect recurrent stenoses but has not yet been demonstrated to improve patient outcomes [20-22]. Duplex US is used in specialist centers for pre operative arterial mapping [23,24], but in many centers the diagnostic confidence is low with this technique and additional studies are often ordered [25]. This renders duplex arterial pre operative mapping a less cost effective option as further studies are often ordered [26]. The examination requires a highly skilled sonographer and can require over an hour to perform.

Magnetic Resonance Angiography

Magnetic resonance angiography (MRA) techniques continue to evolve and improve. Two-dimensional time of flight, 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 lead to improved temporal resolution, spatial resolution and signal to noise in MRA. The sensitivity and specificity for detection of stenoses >50% diameter compared to catheter angiography is now 90%-100% [19,27-29]. As a result, MRA is now a first line technique in many centers for the imaging of peripheral vascular disease [30,31]. Dedicated time resolved imaging of the calves and pedal arteries provides accurate identification of infra geniculate arteries and pedal arteries as potential touch-down sites for bypass surgeries [32,33].

Compared to color duplex US, MRA is more accurate for detecting significant stenoses and for preoperative planning [34-36]. The cost effectiveness of both MRA and CTA (discussed below) is greater than duplex US [26]. MRA is more cost effective and safer than DSA [37,38]. For postoperative and post-angioplasty surveillance, small studies have shown MRA to be helpful in detecting recurrent disease, but improved outcomes for such surveillance have not been documented [39,40].

Some technical problems persist regarding the use of MRA for peripheral vascular disease; and may include:

marginal image quality related to low signal/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.

The risk of nephrogenic systemic fibrosis (NSF) requires careful selection of patients for contrast MRA [41,42]. If contrast enhanced MRA is deemed clinically necessary in a patient at risk of NSF, protocol optimization using low dose gadolinium, time resolved imaging, parallel imaging techniques, compression, high field strength magnets and contrast agents with high relaxivity is indicated. Noncontrast MRA techniques that use ECG-gated sequences to create signal dependant on arterial and venous flow velocities are showing potential and are currently being further developed and tested. However, to date these methods have not been proven effective [43,44].

MRA has not yet replaced catheter angiography as the gold standard in comparative studies, but it has largely replaced angiography in some institutions for pre-intervention 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 CT angiography (CTA) is increasingly used for peripheral vascular disease. Multidetector CT scanners allow rapid, helical scanning from the aorta to the feet. CTA has the advantage of offering three-dimensional images with lower radiation dose than catheter angiography and with no need for an arterial puncture. Iodinated contrast material is necessary, but in doses comparable to or in some cases less than contrast angiography. The intravenous injection of contrast during CTA fills all collateral vessels and opacifies arteries distal to occlusions that may be occult by catheter angiography. CTA images tissues surrounding the opacified lumen of the artery and has demonstrated that some popliteal stenoses and occlusions are due to aneurysms, popliteal entrapment, and cystic adventitial disease that are not detected with catheter angiography. Spatial resolution, although excellent overall, is lower than that of catheter angiography. Current voxel sizes are approximately 0.3-0.5 mm, including CT performed with wide area detectors. An advantage of CT with respect to conventional angiography is that the volumes from CT can be rendered in any plane, and maximum intensity projection (MIP) images can be used in conjunction with the thin slice axial images to develop the arterial road map preoperatively [45]. CT can also meet the requirement of the surgeon to accurately provide morphological assessment of the lesions including the length, severity and number of stenoses [46].

Compared to catheter angiography the sensitivity and specificity of 4, 16 and 64 detector row CTA for detection of stenoses >50% diameter is 90%-100% [47-54]. Accuracy in patients with bypass grafts is excellent compared to duplex US [55]. It has been shown that CTA is clinically more useful than duplex US and is more cost effective [26]. Significant calcified atheromatous disease is a limitation of CTA and identification of patients who are unsuitable candidates for CTA will reduce the number of insensitive studies (elderly >84 years of age), diabetic, dialysis, cardiac disease) [56].

CTA has potential advantages compared to MRA. Patients with pacemakers or defibrillators, who are excluded from MRI, may be safely imaged with CTA. Metal clips, stents, and prostheses usually do not cause significant CTA artifacts. CTA has higher resolution and can provide images of calcification in the vessel wall. As with MRA, extensive calcification may obscure the opacified lumen with CTA. Scan times are significantly faster with CTA than MRA. Claustrophobia is far less of a problem. CTA should also be considered in patients for whom Gadolinium is contraindicated.

Summary

- Multiple clinical and technical factors are involved in determining the proper timing and technique for imaging the lower extremity arterial system in patients with claudication.
- The purpose of imaging studies is to define the location and extent of vascular lesions before a percutaneous or surgical revascularization procedure.
- The clinical success of these vascular procedures depends to a large extent on accurate and complete visualization of the entire lower extremity arterial system, or at least of the entire symptomatic extremity and the pelvic vasculature.
- Several noninvasive vascular imaging methods have been shown to be useful in certain clinical situations. All, however, currently have important practical limitations.
- Although the role of these techniques in evaluating patients with peripheral vascular disease continues to evolve, contrast angiography must still be considered the gold standard even though it is rarely necessary for diagnosing claudication or assessing the severity of arterial obstruction causing claudication.
- The noninvasive imaging modalities, supplemented by physical examination and history, usually provide all the information needed to confirm or exclude the presence of peripheral vascular disease as the cause of claudication. Further, they can provide sufficient information to accurately plan medical, surgical, or catheter-directed treatment.

- The choice of noninvasive imaging modality will depend on local expertise and experience.

Anticipated Exceptions

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (ie, <30 mL/min/1.73m^2), and almost never in other patients. There is growing literature regarding NSF. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73m^2. For more information, please see the ACR *Manual on Contrast Media* [57].

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. 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	**Effective Dose Estimate Range**
None	0
Minimal	< 0.1 mSv
Low	0.1-1 mSv
Medium	1-10 mSv
High	10-100 mSv

Supporting Document(s)

- ACR Appropriateness Criteria® Overview
- Evidence table under review

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