

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

Clinical Condition: Sudden Onset of Cold, Painful Leg

Radiologic Procedure	Rating	Comments	<u>RRL</u>*
Arteriography lower extremity	8		☼☼
CTA lower extremity with contrast	7	Distal abdominal aorta should be included.	☼☼☼
MRA lower extremity with contrast	7	Distal abdominal aorta should be included. See statement regarding contrast in text under "Anticipated Exceptions."	O
US segmental Doppler pressures and pulse volume recordings	6	Not required in the acute setting but may provide important physiologic information not obtained on imaging studies to further direct care.	O
US lower extremity with Doppler	5	Limitations include heavily calcified vessels and operator dependency. May be helpful for problem solving.	O
US echocardiography transthoracic resting	4	Generally not part of the initial workup. May be useful to look for source of emboli.	O
US echocardiography transesophageal	3	Generally not part of the initial workup. May be useful to look for source of emboli.	O
MRI heart function and morphology with or without contrast	3	Generally not part of the initial workup. May be useful to look for source of emboli.	O
CT heart function and morphology with contrast	2	Generally not part of the initial workup. May be useful to look for source of emboli.	☼☼☼☼
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			*Relative Radiation Level

SUDDEN ONSET OF COLD, PAINFUL LEG

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Summary of Literature Review

Acute onset of a cold painful leg, although not directly a significant cause of mortality, contributes significantly to morbidity. The etiologies are limited, the most common being arterial occlusion. Total venous outflow occlusion is but another much less common cause. It often results in what is known clinically as “phlegmasia cerulea dolens” (precursor to venous gangrene) with lower-extremity swelling, pain, and a dusky color. It is differentiated from arterial occlusion by the presence of distal arterial pulses. Other causes, such as prolonged exposure to cold and trauma, are rare and usually clinically obvious.

This condition generally requires urgent treatment, regardless of the etiology. Once the etiology is clinically defined, directing appropriate care of the patient requires assessing the source (ie, embolic vs thrombotic occlusion) and extent of the underlying arterial obstruction. The available alternatives include noninvasive testing: duplex ultrasound (US), magnetic resonance angiography (MRA), computed tomography angiography (CTA), and catheter angiography.

Catheter Angiography

Digital subtraction angiography (DSA) remains the diagnostic gold standard for detecting peripheral vascular occlusive disease, but new and less invasive modalities are gradually replacing it [1-7]. Obviously, one of the major benefits is the ability to diagnose and then treat disease with one procedure, that remains unmatched in the treatment of acute ischemic vascular disease. There has been extensive debate regarding the cost-benefit ratios when comparing DSA and MRA. Because of the invasive character of DSA, there is a recovery period

typically lasting 4 hours or more. In some countries, patients remain in the hospital overnight [8-10]. If complications from DSA occur, additional intervention and prolongation of the hospital stay may add cost as well as morbidity or even mortality. To be truly cost-effective, any noninvasive method would have to supplant DSA, not just precede or supplement it.

The reported incidence of complications with DSA varies greatly. There are also risks associated with iodinated contrast agents. Most worrisome are the rare fatal systemic reactions and contrast-induced nephropathy (CIN). The nephrotoxic effects are important to consider, as many patients who present with the sudden onset of a cold, painful leg are elderly, diabetic, and have impaired renal function [8]. Also, many patients will have repeated catheter angiography over the course of their disease, and minimizing patient radiation exposure should always be considered. Angiography has also been criticized for its imperfect evaluation of outflow vessels, specifically for limited visualization of pedal vasculature and patent distal vessels beyond significant obstructive lesions [1,6,11].

Magnetic Resonance Angiography

MRA has high sensitivity and specificity for detecting arterial occlusive disease, using DSA as a gold standard [3,4,6,9,12-14]. Early sequences required protocols with 30 minutes of gradient time or more. However, modern technology — 3 Tesla main fields, parallel imaging, multi-channel coils, and sequences such as time-resolved MRA, and enhance acquisition speed — enables rapid assessment of acute limb ischemia [3,11,15-17]. In addition to decreased total examination times, faster acquisition reduces motion artifact and venous contamination. Improved spatial resolution translates to thinner slices and clearer depiction of small vessels [3,11,16,18]. Most information needed for the interventionalist or vascular surgeon is routinely illustrated with MRA, such as a general road map of arterial anatomy, including runoff vessels and collaterals, as well as the location and extent of significant stenoses and occlusions.

Limitations include less accurate evaluation of smaller arteries, which means that more time-consuming sequences are required to get better results. Also, limited information can currently be obtained on a routine basis regarding the character of vessel walls and detailed flow dynamics, although time-resolved contrast-enhanced MRA techniques are beginning to provide qualitative flow information [11,15,17]. Overestimation of stenosis has been reported in native arteries and in patients with vascular stents secondary to artifacts [14,19]. Overestimation in native arteries varies among sequences [19] and may or may not be a clinical problem in specific cases. This uncertainty highlights the poor consensus on optimal protocols. In part, this is a function of the continuing evolution of technology, both software and hardware.

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Another concern with MRA is that most techniques have required the administration of a gadolinium-based contrast agent. Although MRA has few associated complications, with the realization of the risk of nephrogenic systemic fibrosis (NSF) in patients with underlying renal dysfunction [20] who receive these contrast agents (see Anticipated Exceptions), there has been increased interest in using other modalities or limiting the use of gadolinium-based contrast agent in such patients. Noncontrast MRA may prove useful [20], although there is only anecdotal experience in patients with critical limb ischemia. Further improvements will be required, particularly in techniques for assessing pedal circulation [21,22].

Computed Tomography Angiography

Multi-detector-row technology has dramatically shortened CT acquisition times, improved spatial resolution, and improved vascular image quality depicted with CT. Multidetector CT (MDCT) scanners can image from the diaphragm to the ankles in less than 30 seconds using a single-contrast bolus [10,23]. In theory, dual-energy CTA can provide data from two kV settings which can then be used to distinguish between vascular calcium and iodinated contrast agent [24], although clinical use will require validation and assessment of relative radiation doses.

Sophisticated postprocessing tools enable multiplanar visualization as well as three-dimensional volume rendering. Because of the large data sets, these tools are essential for CTA to be used in patients imaged over large craniocaudal volumes. In addition to multiplanar reconstructions, both volume rendering and maximum-intensity projections can be used, each with advantages and disadvantages. Maximum-intensity projections are very accurate for larger vessels (as distal as the infrapopliteal region) but less accurate for smaller vessels [25,26]. Volume rendering is good for evaluating embolic or vascular endothelial injury. It is also valuable in evaluating heavily calcified vessels. However, interpretation from volume-rendered images or maximum-intensity projections alone is insufficient to characterize vascular lesions [26].

CTA has proven comparably accurate to MRA in evaluating peripheral arterial diseases [5,7,26]. The advantages of CTA over MRA are its excellent spatial resolution, widespread availability, cost-effectiveness, and usability in patients who have contraindications to MRI, such as those who have pacemakers or defibrillators [27,28]. The literature focused on patients with critical limb ischemia is limited, although one study showed that CTA can help ensure correct treatment recommendations [10].

One disadvantage of CTA is to limited ability to depict the lumen in heavily calcified arteries. Calcium-induced artifact causes an overestimation of stenosis [26,29]. Complications related to iodinated contrast are similar to those in catheter-based angiography and have been discussed above. Cumulative radiation dose is also a concern; CTA has been increasingly used for both preprocedure planning and postprocedure surveillance.

Recent advances in hardware and software, however, have achieved lower radiation dosages for a single CTA examination [25]. Also, techniques tailored to the evaluation of lower limb vasculature have been published that allow reduced patient radiation by decreasing kVp, while preserving the ability to evaluate the smaller lower-limb vessels [27,30].

Other Imaging Examinations

In this patient population, Duplex US is limited by the need for operator expertise, by poor accessibility of vessels, by heavy calcification, and often by poor overall accuracy if multilevel disease is present [4,31,32]. Its advantages are that it can provide useful physiologic as well as anatomic information. Further, it is noninvasive, widely available, and relatively inexpensive.

Transthoracic echocardiography (TTE) or the more specific and invasive transesophageal echocardiography (TEE) may be useful if patient symptoms could be from cardiac embolization, particularly in patients with known atrial fibrillation. In the acute setting, however, this knowledge is unlikely to influence the immediate evaluation. Similarly, cardiac MRI can identify or exclude cardiac thrombus or areas of cardiac dysfunction that might be the source of emboli, but this knowledge is not likely to have clinical impact in the acute setting.

Noninvasive Physiologic Testing

Noninvasive physiologic testing includes measurement of ankle-brachial index (ABI), plethysmography, transcutaneous oxygen pressure measurement (TcPO₂) and exercise treadmill testing. ABI measurement is simple and reliable and serves both as confirmation of arterial occlusion as the etiology of sudden onset of cold leg and as a baseline to guide further intervention [33]. Useful physiologic information may also be obtained. In this clinical setting, other noninvasive tests generally are not helpful, as they do not provide specific information that will alter or guide therapy [34].

Summary

DSA remains the gold standard for diagnosing peripheral vascular disease and continues to be the only modality that allows diagnosis and simultaneous treatment of pathology. This alone will ensure that it continues to be a valuable tool. However, noninvasive imaging with MRA or CTA before catheter angiography or surgery is becoming more accepted. Peripheral vascular disease is a significant and growing problem, and continued research and development of current and emerging technologies will ultimately shape the standard of care.

- DSA remains the gold standard in patients with sudden onset of cold, painful leg.
- Both MRA and CTA can be used for diagnosis and can positively influence management into percutaneous or surgical pathways.
- Other imaging may prove important for longer-term management but is less recommended in the acute setting.

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/1.73m²), 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/1.73m². For more information, please see the [ACR Manual on Contrast Media](#) [35].

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
O	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 NS (not specified).

Supporting Document(s)

- [ACR Appropriateness Criteria[®] Overview](#)
- [Procedure Information](#)
- [Evidence Table](#)

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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.