American College of Radiology
ACR Appropriateness Criteria®
Sudden Onset of Cold, Painful Leg

Variant 1: **Sudden onset of cold, painful leg.**

Radiologic Procedure	Rating	Comments	RRL*
Arteriography lower extremity	8	This procedure is the preferred option if clinical suspicion of acute arterial obstruction is intermediate to high.	☢ ☢ ☢
CTA lower extremity with IV contrast	7	Consider in place of arteriography if clinical suspicion of arterial obstruction is low and patient has a stable baseline eGFR ≥45 mL/min).	☢ ☢ ☢
MRA lower extremity without and with IV contrast	7	This procedure may help reduce total contrast dose. Consider prior to arteriography in patients with mild to moderate chronic kidney disease (GFR 30–89 mL/min).	O
MRA lower extremity without IV contrast	5	This procedure should be considered in patients with eGFR <30 mL/min who are not yet on dialysis.	O
US duplex Doppler lower extremity	5	This procedure may be helpful for problem solving or targeted examinations (eg, bypass graft).	O
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

Introduction/Background

Acute onset of a cold, painful leg, also known as acute limb ischemia (ALI), 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 another cause but much less common. 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.

ALI generally requires urgent treatment. Appropriate care of the patient requires assessing the source (ie, embolic versus thrombotic occlusion) and extent of the underlying arterial obstruction. The available diagnostic studies include invasive catheter angiography and noninvasive testing. Noninvasive imaging modalities include duplex ultrasound (US), magnetic resonance angiography (MRA), and computed tomography angiography (CTA).

The published literature on imaging of peripheral artery disease (PAD) focuses almost exclusively on patients with chronic PAD. This includes asymptomatic PAD, leg pain with exertion (ie, intermittent claudication), and critical limb ischemia (CLI, defined as chronic leg or foot pain at rest, skin ulceration, or gangrene). By comparison, the literature focused on imaging patients with ALI is very limited. Consequently, the following discussion relies heavily on studies of patients with chronic PAD.

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Arteriography

Arteriography (digital subtraction angiography [DSA]) performed with iodinated contrast material remains the diagnostic gold standard for detecting peripheral vascular occlusive disease. However, new and less invasive modalities are gradually replacing it [1-6]. The ability to diagnose and treat disease in a single procedure [7-9] is a major benefit of DSA 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 [10,11]. 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 materials. Most worrisome are the rare fatal systemic reactions and contrast-induced nephropathy. 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 [10]. Carbon dioxide angiography or other imaging modalities that do not use iodinated contrast material should be considered in patients with estimated glomerular filtration rate (eGFR) <45 mL/min/1.73 m^2 [12]. 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 [5,13].

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Magnetic Resonance Angiography

MRA has high sensitivity and specificity for detecting arterial occlusive disease, using DSA as a gold standard [2,3,5,14-17]. Early imaging protocols required 30 minutes or more of acquisition time. However, recent advances, including 3T magnetic fields, parallel imaging, multichannel coils, sequences such as time-resolved MRA, and enhanced acquisition speed, enable rapid assessment of ALI [2,13,18-21]. In addition to decreased total examination times, faster acquisition reduces motion artifact and venous contamination. Motion artifact can also be corrected with automated image registration protocols [22]. Improved spatial resolution translates to thinner slices and clearer depiction of small vessels [2,13,19]. Most information needed for the interventional radiologist 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 [13,18,20,21]. Overestimation of stenosis has been reported in native arteries and in patients with vascular stents secondary to artifacts [23]. Overestimation in native arteries varies among sequences [23] 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.

Another concern with MRA is that most techniques have required the administration of a gadolinium-based contrast material. However, MRA has few associated complications, with the realization of the risk of nephrogenic systemic fibrosis in patients with underlying renal dysfunction [24] who receive these contrast materials. There has been increased interest in using other modalities or limiting the use of gadolinium-based contrast material in such patients. Significantly lower contrast doses can be used at 3T compared to 1.5T without compromising image quality [25]. Noncontrast MRA may prove useful [24,26-30]. However, further improvements will be required, particularly in techniques for assessing pedal circulation [28,31]. Finally, blood-pool gadolinium-chelate contrast materials have prolonged retention in the intravascular space and allow for steady-state imaging [23,32-35] that, in turn, can enable high spatial resolution acquisitions. Additional studies will be needed to confirm potential clinical benefits and cost-effectiveness of such agents.

Computed Tomography Angiography

Multidetector-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 <30 seconds using a single-contrast bolus [11,36]. The use of 64-row or greater MDCT significantly increases the accuracy of stenosis detection, particularly in smaller vessels [6,37-39]. Dynamic, time-resolved "4-D" CTA may improve accuracy even further [37]. However, additional studies are needed before this can be confirmed.

Sophisticated postprocessing tools enable multiplanar visualization in all 3 orthogonal axes as well as in any oblique axis. 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 [40,41]. Volume rendering, including endoluminal reconstruction, 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 [41] and should always be accompanied by an assessment of the raw axial dataset and multiplanar reformatted images.

CTA has proven comparably accurate to MRA in evaluating peripheral arterial diseases [4,6,41]. The advantages of CTA over MRA are its excellent spatial resolution, widespread availability, cost-effectiveness, and usability in patients who have contraindications to MR imaging (MRI), such as those who have pacemakers or defibrillators [42].

One disadvantage of CTA is its limited ability to depict the lumen in heavily calcified arteries. Calcium-induced artifact causes an overestimation of stenosis [41,43]. In theory, dual-energy or spectral CTA can provide image reconstructions at various x-ray energy levels and can be used to distinguish between vascular calcium and iodinated contrast material [44]. Initial studies have shown improved accuracy of stenosis detection and grading with dual-energy CTA compared to conventional CTA [45,46]. However, early studies also suggest dual-energy CTA may still overestimate high-grade vessel stenosis as occlusion [47]. Dual-energy CTA may also correlate

less well with DSA in calcified calf and pedal arteries [48]. Expanded clinical use of dual-energy CTA will require further validation and assessment of relative radiation doses.

Complications related to iodinated contrast material 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 preprocedural planning and postprocedural surveillance. Recent advances in hardware and software, however, have achieved lower radiation dosages for a single CTA examination [40]. 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 [49,50]. Decreasing kVp also has the added advantage of allowing lower doses of iodinated contrast material as kVp approaches the iodine K-edge [50].

Ultrasound Duplex Doppler
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 [3,51,52]. Its advantages are that it can provide useful physiologic as well as anatomic information. Further, it is noninvasive, widely available, and relatively inexpensive.

Echocardiography
Transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) are generally not part of the initial workup but may be useful if patient symptoms could be from cardiac embolization, particularly in patients with known atrial fibrillation [53]. TEE is more invasive and time-consuming than TTE but affords better visualization of the left atrium. TEE may be useful to look for sources of emboli when TTE is indeterminate.

In the acute setting, however, this knowledge is unlikely to influence the immediate evaluation. Similarly, cardiac CT or MRI may 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), segmental blood pressures, Doppler waveforms, handheld Doppler, pulse-volume recordings, transcutaneous oxygen pressure measurement (TcPO2), and exercise treadmill testing. Segmental studies, TcPO2, and exercise treadmill testing are of little use in the diagnosis and management of ALI [54]. However, ABI measurement and handheld Doppler are simple, rapid, and reliable methods to confirm arterial occlusion as the etiology of sudden onset of cold leg when the cause is not obvious. Both ABI and handheld Doppler can also serve as objective baseline tests to follow the patient after intervention [55]. 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.

Summary of Recommendations

- Arteriography (DSA) remains the gold standard for diagnosing acute limb ischemia and continues to be the only modality that allows diagnosis and simultaneous treatment of pathology. This advantage alone will ensure that it continues to be a valuable tool.
- Noninvasive imaging with MRA or CTA before arteriography (DSA) or surgery is accepted and common. Both MRA and CTA can be used for diagnosis and may help surgical or interventional planning.
- Other imaging and noninvasive physiologic tests may prove important for longer-term management but are less recommended in the acute setting.

Summary of Evidence

Of the 55 references cited in the *ACR Appropriateness Criteria® Sudden Onset Cold, Painful Leg* document, 48 are categorized as diagnostic references including 11 well designed studies, 22 good quality studies, and 8 quality studies that may have design limitations. Additionally, 4 references are categorized as therapeutic references including 1 good quality study, and 2 quality studies that may have design limitations. There are 8 references that may not be useful as primary evidence. There are 3 references that are meta-analysis studies.

The 55 references cited in the *ACR Appropriateness Criteria® Sudden Onset Cold, Painful Leg* document were published from 1998-2013.

While there are references that report on studies with design limitations, 34 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**
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 "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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