Complete Summary

GUIDELINE TITLE

Claudication.

BIBLIOGRAPHIC SOURCE(S)

Sacks D, Bettmann MA, Casciani T, Gomes AS, Grollman J, Holtzman SR, Polak JF, Stanford W, Jaff M, Moneta GL, Expert Panel on Cardiovascular Imaging. Claudication. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 6 p. [56 references]

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previously published version: Bettmann MA, Boxt LM, Gomes AS, Grollman J, Henkin RE, Higgins CB, Kelley MJ, Needleman L, Pagan-Marin H, Polak JF, Stanford W, Levin DC, Gardiner GA. Diagnostic imaging in patients with claudication. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):61-5. [44 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- May 23, 2007, Gadolinium-based Contrast Agents: The addition of a boxed warning and new warnings about the risk of nephrogenic systemic fibrosis (NSF) to the full prescribing information for all gadolinium-based contrast agents (GBCAs).

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **
SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Claudication

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Cardiology
Family Practice
Internal Medicine
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for patients with claudication

TARGET POPULATION

Patients with claudication

INTERVENTIONS AND PRACTICES CONSIDERED

1. Physiological noninvasive tests
2. Invasive (INV) tests
    - Lower extremity angiography
    - Cine angiography
3. Lower extremity magnetic resonance angiography (MRA)
4. Lower extremity computed tomography angiography (CTA)

5. Ultrasound (US)
    - Lower extremity, Duplex, spectral and color
    - Lower extremity, Doppler, spectral only
    - Lower extremity, venous, duplex
    - Heart, echocardiography
6. X-ray, lumbosacral spine

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals, and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible. If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Diagnostic Imaging in Patients with Claudication

Radiologic Exam Procedure	Appropriateness Rating	Comments
Physiological noninvasive tests	9	
INV, lower extremity, angiography	8	If noninvasive tests are abnormal.
MRA, lower extremity	8	
CTA, lower extremity	6	
US, lower extremity, Duplex, spectral and color	6	
US, lower extremity, Doppler, spectral only	5	
X-ray, lumbosacral spine	3	
US, heart, echocardiography	2	
US, lower extremity, venous, duplex	2	
INV, Cine angiography	1	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

Note: Abbreviations used in the table are listed at the end of the "Major Recommendations" field.

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.

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. 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. 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. 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. 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. 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 (e.g., 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. In most circumstances a complete survey of the arterial system from the abdominal aorta to the pedal arch is helpful. The gold standard for imaging the peripheral arteries is multiprojection contrast angiography. 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. 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.

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. Several studies have reported this poor correlation, but in some of these studies the problem may be accentuated by less than optimal angiographic technique (e.g., 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. 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 US of the extremities can be used to diagnose the anatomic location and degree of stenosis. 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%. Accuracy of the duplex exam depends on the ability of the technique to visualize the vessel adequately. The use of color improves accuracy. 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. The examination requires a highly skilled sonographer and can require over an hour to perform.

Duplex US can be used for pre-intervention decision making, although duplex may be inferior to angiography for evaluation of tibial arteries for distal bypass. It is the standard technique for post-revascularization surveillance of vein graft patency leading to improved long-term graft patency. Duplex US surveillance of synthetic grafts is of questionable value. Duplex US following angioplasty is widely performed to detect recurrent stenoses but has not yet been demonstrated to improve patient outcomes.

Magnetic Resonance Angiography

MRA techniques continue to evolve and improve. Techniques employed include two-dimensional time of flight, three-dimensional imaging, contrast enhancement with gadolinium, subtraction, cardiac gating, and bolus chase. These techniques may be used in combination, as each has advantages and disadvantages. The clinical use of these techniques for peripheral vascular disease has met with considerable success. The sensitivity and specificity for detection of stenoses >50% diameter compared to catheter angiography is 90-100%. Compared to color duplex US, MRA is more accurate for detecting significant stenoses and for preoperative planning. Studies have demonstrated that MRA can be effectively used to plan interventional or surgical procedures, eliminating the necessity for conventional angiography. For post-operative 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.

Some technical problems persist regarding the use of MRA for peripheral vascular disease. These 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.

MRA has not yet replaced catheter angiography as the gold standard, but it has replaced angiography in some institutions as a pre-intervention planning study. As contrast agents and MR imaging sequences improve, MRA is likely to entirely supplant catheter angiography as a pure diagnostic tool.

Computed Tomography Angiography

Spiral or helical CTA is increasingly used for peripheral vascular disease. Multidetector CT scanners with up to 64 slices obtained simultaneously allows scanning from the aorta to the feet in less than 1 minute. 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 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. In general, however, this is not an important clinical consideration.

Results of relatively small series of patients studied with CTA have been excellent. Compared to catheter angiography the sensitivity and specifity of CTA for detection of stenoses >50% diameter is 90-100%. However, diagnostic certainty is lower with CTA compared to catheter angiography, leading to more recommendations for additional imaging. Accuracy in patients with bypass grafts is excellent compared to duplex ultrasound.

At this time, studies of CTA are fewer and smaller than those of MRA in evaluating peripheral arteries. However, 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.

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.

Abbreviations

- CTA, computed tomography angiography
- INV, invasive
- MRA, magnetic resonance angiography
- US, ultrasound

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for evaluation of patients with claudication

POTENTIAL HARMS

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. 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.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (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

exams 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 U.S. Food and Drug Administration (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.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Sacks D, Bettmann MA, Casciani T, Gomes AS, Grollman J, Holtzman SR, Polak JF, Stanford W, Jaff M, Moneta GL, Expert Panel on Cardiovascular Imaging. Claudication. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 6 p. [56 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1995 (revised 2005)

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Cardiovascular Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Names of Panel Members: David Sacks, MD (*Principal Author*); Michael A. Bettmann, MD (*Panel Chair*); Thomas Casciani, MD; Antoinette S. Gomes, MD; Julius Grollman, MD; Stephen R. Holtzman, MD; Joseph F. Polak, MD, MPH; William Stanford, MD; Michael Jaff, MD; Gregory L. Moneta, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

It updates a previously published version: Bettmann MA, Boxt LM, Gomes AS, Grollman J, Henkin RE, Higgins CB, Kelley MJ, Needleman L, Pagan-Marin H, Polak JF, Stanford W, Levin DC, Gardiner GA. Diagnostic imaging in patients with claudication. American College of Radiology. ACR Appropriateness Criteria. Radiology 2000 Jun;215(Suppl):61-5. [44 references]

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® *Anytime*, *Anywhere*™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 20, 2001. The information was verified by the guideline developer on March 14, 2001. This summary was updated by ECRI on March 6, 2006. This summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents.

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