Complete Summary

GUIDELINE TITLE

Recurrent symptoms following lower extremity angioplasty.

BIBLIOGRAPHIC SOURCE(S)

Grollman JH, Bettmann MA, Boxt LM, Casciani T, Gomes AS, Holtzman SR, Polak JF, Sacks D, Stanford W, Jaff M, Moneta GL, Expert Panel on Cardiovascular Imaging. Recurrent symptoms following lower extremity angioplasty. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 6 p. [34 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: American College of Radiology (ACR), Expert Panel on Cardiovascular Imaging. Recurrent symptoms following lower extremity angioplasty: claudication and threatened limb. Reston (VA): American College of Radiology (ACR); 2002. 5 p. (ACR appropriateness criteria).

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).

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SCOPE

DISEASE/CONDITION(S)

Recurrent symptoms following lower extremity angioplasty: claudication and threatened limb

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Radiology
Surgery

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for recurrent symptoms following lower extremity angioplasty: claudication and threatened limb

TARGET POPULATION

Patients with recurrent symptoms following lower extremity angioplasty: claudication and threatened limb

INTERVENTIONS AND PRACTICES CONSIDERED

1. Ankle-brachial indices (ABI)
2. Invasive (INV), peripheral arteriography
3. Other physiologic noninvasive tests
4. Ultrasound (US)
    - Duplex Doppler with color
    - Lower extremity, intravascular (in conjunction with angiography)

- Lower extremity, venous

5. Magnetic resonance angiography (MRA)
6. Computed tomography angiography (CTA), multi-detector

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 to reach 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 the 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: Recurrent Symptoms Following Lower Extremity Angioplasty

Variant 1: Claudication

Radiologic Exam Procedure	Appropriateness Rating	Comments
Ankle-brachial indices (ABI)	9	Usual first test.
INV, peripheral arteriography	8	Use when it is thought there is likely a lesion amenable to percutaneous intervention (e.g., restenosis).
Other physiologic noninvasive tests	8	Used to clarify ABI.
US, Duplex Doppler with color	8	Useful screen to define location and extent of lesions.
MRA	8	May substitute for other non-invasive studies.
CTA, multi-detector	6	Although extensive data are not yet available, experience suggests that this may be or become equivalent to MRA.
US, lower extremity, intravascular	2	May be useful in conjunction with angiography to determine the significance of a lesion, but is not indicated alone.
US, lower extremity, venous	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

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

Variant 2: Threatened limb

Radiologic Exam Procedure	Appropriateness Rating	Comments
INV, peripheral arteriography	9	Allows diagnosis and treatment.
Ankle-brachial indices	8	Always useful as a baseline.

Radiologic Exam Procedure	Appropriateness Rating	Comments
(ABI)		
MRA	6	An adjunct usually useful only if angiography is not to be done (i.e., surgical treatment is necessary).
CTA, multi-detector	6	Although extensive data are not yet available, experience suggests that this may be or become equivalent to MRA.
Other physiologic noninvasive tests	4	
US, Duplex Doppler with color	4	
US, lower extremity, intravascular	2	May be useful in conjunction with angiography to determine the significance of a lesion, but is not indicated alone.
US, lower extremity, venous	2	
Appropriateness Criteria Scale **1 2 3 4 5 6 7 8 9** **1 = Least appropriate 9 = Most appropriate**		

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

Endovascular interventions for lower extremity arterial obstructive disease, both for lifestyle-limiting claudication and for critical ischemia with threatened limb, have become accepted treatment modalities. The availability of these techniques has reduced the numbers of surgical reconstructive procedures. But in spite of their very high initial technical success rates, restenosis after angioplasty with recurrent symptoms is frequent, especially with infrainguinal lesions. The use of nitinol stents appears to decrease restenosis in the peripheral arteries. The status of drug-eluting stents in decreasing restenosis is not clear and is still under investigation. The literature has not clarified the importance of the follow-up of patients who have had such interventions. Recurrent symptoms usually precede the onset of limb- or life-threatening events, in contrast to what may occur with coronary artery disease. Close surveillance of these patients, therefore, is often not routine; follow-up has often been driven by recurrence of symptoms. The imaging approach to patients with claudication or with acute limb ischemia after angioplasty is the same.

Clinical examination with evaluation of the peripheral pulses and determination of the ABI is the obvious and accepted first step in evaluating these patients. However, restenosis is not always clinically discernible, since the natural

progression of the patient's disease process is often characterized by development of new lesions at different sites. Thus definitive diagnosis is important for therapeutic planning, whether for repeat endovascular intervention, for reconstructive vascular surgery, or for medical management.

Noninvasive Hemodynamic Studies

The ABI is the accepted, most commonly performed noninvasive technique for evaluating peripheral vascular disease. Deterioration from previous levels by 0.15 or more has been accepted as indicative of restenosis. However, this measurement is not specific as to site and is of little value in patients with noncompressible arteries, as often occurs in diabetics and patients with renal insufficiency. Similarly, segmental pulse volume recordings, although more site-specific, are not accurate nor do they provide specific enough information for treatment decision-making in patients with symptomatic recurrent peripheral vascular disease.

Ultrasound Imaging

Duplex Doppler color flow vascular US imaging has achieved widespread usage and acceptance in the evaluation of patients with peripheral vascular obstructive disease. It has the ability to localize the site(s) of involvement and assess the hemodynamic significance of the lesions. A major limitation, however, is that it is operator-dependent, requiring a meticulous and compulsive ultrasonographer (either technologist or physician) for accurate results. In good hands, there is a high, although not perfect, correlation with conventional catheter angiography. US is especially appropriate for infrainguinal arterial disease but can also be helpful in evaluating aortoiliac disease in suitable patients (obesity and bowel gas can significantly degrade the quality of the study). Some authorities recommend duplex Doppler scanning as the best screening imaging tool in the initial evaluation of symptomatic peripheral vascular disease. It is also recommended by most of them for routine surveillance, evaluation, or recurrent symptoms following surgical or percutaneous intervention.

Catheter Angiography

Although MRA, CTA, and US have now generally supplanted catheter angiography (CA), CA is still the "gold standard" for peripheral arterial imaging. Its ability to localize and quantify obstructive lesions accurately is exceeded only by intravascular US imaging. It also may allow physiological evaluation by determining pressure gradients. However, it is an invasive technique that has a small but definite risk in every patient and a variable higher risk in patients with severe widespread vascular disease, diabetes, renal insufficiency, or other contraindications to the use of contrast media. CO_2-negative contrast angiography may be of value in certain patients at high risk for receiving iodinated contrast medium. Gadolinium contrast agents are thought to be less nephrotoxic and may be used for CA, but their use is limited by the relatively large volumes needed to complete the study and the high cost of the various available agents. Only qualified angiographers should perform CA.

Computed Tomography Angiography

Multidetector CTA (MDCTA) is rapidly evolving in its ability to image peripheral vascular obstructive disease. It has the advantage of allowing very rapid evaluation of a large portion of the arterial tree (for example, from the level of the diaphragm to the foot vessels), noninvasively and in a matter of minutes. Although it is particularly useful for evaluating a defined vascular segment, it is still somewhat limited in the ability to grade the severity of stenotic lesions accurately. Its resolution, however, is improving dramatically with a significant reduction in examination time. It can be used to study segmented arterial components and is particularly good for evaluating aortoiliac disease, especially with its ability to view the image in coronal and sagittal views in addition to the conventional axial projection. Large calcified plaques currently remain a significant problem in quantifying the degree of stenosis. Although it is relatively noninvasive as compared with CA, it has a similar disadvantage in requiring iodinated contrast medium.

Magnetic Resonance Angiography

MRA has become an accepted method of imaging arterial obstructive disease, particularly with gadolinium-enhanced MRA. This modality has the benefit of being totally noninvasive and without any significant risk. It can image the entire vascular system, including difficult-to-visualize tibial and pedal arteries. With specialized techniques it also may be able to assess hemodynamic significance. MRA is challenging conventional CA, although there is a tendency to overestimate stenoses. On the other hand, when there are total occlusions, MRA more reliably defines reconstituted vessels. Metallic stents, especially stainless steel, cause signal intensity dropout, which can be indistinguishable from an occlusion. This is less of a problem with nitinol stents. MRA is now widely available, and its use, especially in conjunction with duplex vascular US, allows reliable determination of appropriate intervention when symptoms occur after angioplasty. It takes longer to acquire images with MRA than with CTA, and reconstruction and interpretation may be more complex. It is, however, similarly noninvasive and has the advantages of not requiring iodinated contrast agents and not using ionizing radiation.

Radionuclide Imaging

Isotopic arterial blood flow measurement has been described as a technique for evaluating the hemodynamic significance of peripheral vascular disease and for evaluating patients who have had endovascular interventions. However, this method is not widely available and does not have anatomic imaging capabilities.

Summary

A complete vascular physical examination, including measurement of the ABI, is obviously the first step in assessing a patient with recurrent symptoms after an initially successful endovascular intervention. With this knowledge the clinician/angiographer can decide on appropriate imaging studies. Duplex Doppler US is generally the first imaging study, and it is followed by one of the angiographic contrast modalities. If it is clear that reintervention (whether endovascular or surgical) is necessary, and the site of the problem is certain, then proceeding directly to catheter angiography (CA) may be appropriate. Preliminary Duplex Doppler US imaging is usually an appropriate starting point as it may more

clearly define the problem, confirming a recurrence at the previously treated site or suggesting progression elsewhere. Duplex Doppler scanning is also currently considerably cheaper than CA, MRA, and CTA.

MRA and MDCTA are increasingly promising and available imaging techniques but have several limitations: 1) lack of available room time because of high demand for other examinations; 2) poor ability to distinguish mild and moderate degrees of restenosis; 3) limitation of field of view, a problem only with older CT and MR equipment, that may prevent visualization of the entire vascular tree from the abdominal aorta to the pedal arches; 4) artifacts caused by calcification and metallic devices such as stents and surgical clips; and 5) poor ability to evaluate the condition of the more "normal" adjacent vessel segments. On the other hand, when equipment and expertise are available, with improved accuracy, comprehensiveness, and reproducibility, it may be appropriate to proceed from the clinical examination directly to MRA or MDCTA. MRA has been shown to be able to image potentially by-passable infrapopliteal and pedal vessels that may not be visualized by CA. MRA and MDCTA may more easily visualize lesions obscured by overlying bone cortex in the calf. In patients who are at risk for renal function deterioration and significant reactions to iodinated contrast medium, MRA may be the procedure of choice and even warrant sending a patient to another institution with MRA capability.

Anticipated Exceptions

Patients presenting with critical recurrent ischemia with motor and sensory deficit occurring shortly after a percutaneous intervention (<7-10 days), and in whom the anatomy is well understood, may proceed directly to surgical revascularization by bypass or thrombectomy.

Abbreviations

- ABI, ankle-brachial indices
- 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 recurrent symptoms following lower extremity angioplasty: claudication and threatened limb sagittal views

POTENTIAL HARMS

Catheter angiography (CA) is an invasive technique that has a small but definite risk in any patient.

Subgroups Most Likely to be Harmed

Catheter angiography (CA) has a variable higher risk in patients with severe widespread vascular disease, diabetes, renal insufficiency, and other contraindications to the use of contrast media.

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
Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Grollman JH, Bettmann MA, Boxt LM, Casciani T, Gomes AS, Holtzman SR, Polak JF, Sacks D, Stanford W, Jaff M, Moneta GL, Expert Panel on Cardiovascular Imaging. Recurrent symptoms following lower extremity angioplasty. [online publication]. Reston (VA): American College of Radiology (ACR); 2005. 6 p. [34 references]

ADAPTATION

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

DATE RELEASED

1998 (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

Panel Members: Julius H. Grollman, MD (*Principal Author*); Michael A. Bettmann, MD (*Panel Chair*); Lawrence M. Boxt, MD; Thomas Casciani, MD; Antoinette S. Gomes, MD; Stephen R. Holtzman, MD; Joseph F. Polak, MD, PH; David Sacks, MD; 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.

This guideline updates a previous version: American College of Radiology (ACR), Expert Panel on Cardiovascular Imaging. Recurrent symptoms following lower extremity angioplasty: claudication and threatened limb. Reston (VA): American College of Radiology (ACR); 2002. 5 p. (ACR appropriateness criteria).

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 31, 2003. The updated information was verified by the guideline developer on April 21, 2003. This summary was updated by ECRI on March 20, 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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