



## Complete Summary

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### GUIDELINE TITLE

ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine and Biology, Society of Interventional Radiology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease).

### BIBLIOGRAPHIC SOURCE(S)

Hirsch AT, Haskal ZJ, Hertzner NR, Bakal CW, Creager MA, Halperin JL, Hiratzka LF, Murphy WR, Olin JW, Puschett JB, Rosenfield KA, Sacks D, Stanley JC, Taylor LM Jr, White CJ, White J, White RA. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report [trunc]. Bethesda (MD): American College of Cardiology Foundation; 2005. 192 p. [1308 references]

### GUIDELINE STATUS

This is the current release of the guideline.

**\*\* 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).
- [May 2, 2007, Antidepressant drugs](#): Update to the existing black box warning on the prescribing information on all antidepressant medications to include warnings about the increased risks of suicidal thinking and behavior in young adults ages 18 to 24 years old during the first one to two months of treatment.

## COMPLETE SUMMARY CONTENT

\*\* REGULATORY ALERT \*\*

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## SCOPE

### **DISEASE/CONDITION(S)**

Peripheral arterial disease (PAD) including:

- Lower extremity PAD
- Renal arterial disease
- Mesenteric arterial disease
- Disorders of the abdominal aorta

### **GUIDELINE CATEGORY**

Diagnosis

Evaluation

Management

Prevention

Risk Assessment

Treatment

### **CLINICAL SPECIALTY**

Cardiology

Critical Care

Emergency Medicine

Family Practice

Geriatrics

Internal Medicine

Nephrology

Nursing

Physical Medicine and Rehabilitation

Podiatry

Preventive Medicine

Radiology

Surgery

## **INTENDED USERS**

Advanced Practice Nurses  
Health Care Providers  
Health Plans  
Hospitals  
Managed Care Organizations  
Nurses  
Physical Therapists  
Physician Assistants  
Physicians  
Public Health Departments

## **GUIDELINE OBJECTIVE(S)**

To assist healthcare providers in clinical decision making and care delivery by describing a range of generally acceptable approaches for the prevention, diagnosis, management, and rehabilitation of peripheral arterial disease (PAD), specifically

- To aid in the recognition, diagnosis, and treatment of lower extremity PAD, addressing its high prevalence, impact on quality of life, cardiovascular ischemic risk, and risk of critical limb ischemia (CLI) and amputation
- To aid in the recognition, diagnosis, and treatment of renal and mesenteric arterial diseases
- To improve the detection and treatment of abdominal and branch artery aneurysms

## **TARGET POPULATION**

- Adults with peripheral arterial disease (PAD)
- Adults at risk of PAD

## **INTERVENTIONS AND PRACTICES CONSIDERED**

### **Lower Extremity PAD**

#### **Diagnosis/Evaluation**

1. Medical history and review of symptoms (ROS)
2. Diagnostic methods
  - Ankle-brachial index (ABI) and toe-brachial index
  - Segmental pressure examination
  - Pulse volume recoding
  - Continuous-wave Doppler ultrasound
  - Duplex ultrasound
  - Treadmill exercise testing with and without ankle-brachial index assessments and 6-minute walk test
  - Computed tomographic angiography (CTA)
  - Magnetic resonance angiography (MRA)
  - Contrast angiography

## Management/Treatment/Prevention

1. Cardiovascular risk reduction
  - Lipid-lowering drugs (statins, fibric acid derivatives)
  - Antihypertensive drugs (beta-blockers, angiotensin-converting enzyme [ACE] inhibitors)
  - Diabetes management (foot inspection, skin cleansing, glucose control)
  - Smoking cessation (behavioral therapy, nicotine replacement therapy, bupropion)
  - Antiplatelet and antithrombotic drugs
  - **Note:** The following drugs were considered but not recommended: homocysteine-lowering drugs, such as folic acid, vitamin B<sub>12</sub>
2. Treatment of claudication
  - Supervised exercise programs
  - Pharmacological treatment (cilostazol, pentoxifylline)
  - **Note:** The following agents were considered but not recommended: L-arginine, propionyl-L-carnitine, ginkgo biloba, oral prostaglandins, vitamin E, chelation
  - Endovascular treatment (e.g., stenting, lasers, atherectomy, percutaneous transluminal angioplasty [PTA], thermal angioplasty)
  - Surgery (inflow and outflow procedures)
3. Treatment for limb salvage (critical limb ischemia [CLI])
  - Parenteral prostaglandins (limited efficacy)
  - Angiogenic growth factors (considered but not recommended outside of clinical trials)
  - Endovascular treatment
  - Thrombolysis
  - Surgery
4. Prevention: vascular ROS and prompt use of the ABI test, comprehensive pulse examination, feet inspection, and review of family history of abdominal aortic aneurysm for patients at risk for lower extremity peripheral arterial disease

## Renal Arterial Disease

### Diagnostic Studies

1. Noninvasive imaging (e.g., duplex ultrasound, MRA, CTA)
2. Invasive imaging (e.g., abdominal aortography)

### Treatment

1. Medical treatment (ACE inhibitors, angiotensin-receptor blockers, calcium-channel blockers, beta-blockers)
2. Percutaneous revascularization via renal artery stent placement and balloon angioplasty
3. Vascular surgical reconstruction

## Mesenteric Arterial Disease

1. Management of acute obstructive intestinal ischemia:

- Surgical treatment including revascularization, resection of necrotic bowel, and "second look" operation if appropriate
  - Endovascular treatment including transcatheter lytic therapy, balloon angioplasty, and stenting
2. Management of nonocclusive intestinal ischemia:
    - Arteriography
    - Treatment of the underlying shock state
    - Laparotomy and resection of nonviable bowel
    - Transcatheter administration of vasodilator medications into the area of vasospasm
  3. Management of chronic intestinal ischemia
    - Duplex ultrasound, CTA, MRA, and lateral aortography if needed
    - Percutaneous endovascular treatment
    - Revascularization for patients undergoing aortic/renal artery surgery for other indications

### **Aneurysms of the Abdominal Aorta, Its Branch Vessels, and the Lower Extremities**

1. Management of abdominal aortic and iliac aneurysms
  - Assessment and management of atherosclerotic risk factors
  - Screening high-risk population
  - Open aortic aneurysm repair
  - Endovascular aortic aneurysm repair
  - Prevention of aortic aneurysm rupture
2. Management of visceral artery aneurysms
  - Open repair
  - Catheter-based interventions
3. Management of lower extremity aneurysms
  - Ultrasound, CT, or MR examination
  - Surgical repair
  - Catheter-directed thrombolysis or mechanical thrombectomy or both
  - Antiplatelet medication
4. Management of catheter-related femoral artery pseudoaneurysms
  - Duplex ultrasonography
  - Initial treatment with ultrasound-guided compression or thrombin injection
  - Surgical repair if appropriate
  - Ultrasound re-evaluation

### **MAJOR OUTCOMES CONSIDERED**

- Utility of diagnostic procedures
- Rates of detection of PAD in target populations
- Objective and subjective improvement in claudication symptoms
- Cardiovascular ischemic event rates and cardiovascular mortality
- Operative mortality during vascular surgical procedures
- Primary patency and limb salvage rates after endovascular procedure for peripheral artery disease of the lower extremities
- Procedural success rates (cure, improvement, benefit)
- Four-year survival rates in individuals with renal artery stenosis (RAS)
- Rates of detection of abdominal aortic aneurysm (AAA) in target populations

- Risk factors associated with progression of RAS
- Survival rates in patients with abdominal aortic aneurysms

## METHODOLOGY

### **METHODS USED TO COLLECT/SELECT EVIDENCE**

Hand-searches of Published Literature (Primary Sources)  
Hand-searches of Published Literature (Secondary Sources)  
Searches of Electronic Databases

### **DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE**

The Committee to Develop Guidelines for Peripheral Arterial Disease conducted comprehensive searching of the scientific and medical literature relevant to peripheral arterial disease (PAD). Literature searches were conducted in PubMed/MEDLINE and a clinical trials database. Searches were limited to publications in English and human subjects. The committee reviewed all compiled reports from computerized searches and conducted additional searching by hand. Committee members also recommended applicable articles outside the scope of formal searches.

In addition to broad-based searching on PAD, specific targeted searches were performed on the following subtopics: amputation, aneurysm, ankle-brachial index, antihypertensive drugs, antiplatelet and antithrombotic drugs, arteriography, beta blockade, "blue-toe" syndrome, calcification, catheter-based intervention, chronic limb ischemia, claudication, compression, computed tomography, coprevalance of cardiovascular/carotid disease, diabetes, diagnosis, endovascular treatment, etiology, exercise/rehabilitation, femoral pseudoaneurysms, follow-up, homocysteine lowering, imaging, location and prevalence, lower extremity pulse exam, magnetic resonance angiography, management of ischemia, measurement, medical/pharmacological management, mesenteric, natural history, pathology, pregnancy risk, preoperative assessment/evaluation, prevalence, renal function, smoking cessation, statins, stent, surgical intervention, thrombolysis, ultrasound, vascular surgery. The list of subtopics is not exhaustive.

### **NUMBER OF SOURCE DOCUMENTS**

More than 1300 references were used as the major evidence base in the final Guideline, with many times this number of references reviewed by the Committee.

### **METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE**

Weighting According to a Rating Scheme (Scheme Given)

### **RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE**

#### **Levels of Evidence**

**Level of Evidence A:** Data derived from multiple randomized clinical trials or meta-analyses

**Level of Evidence B:** Data derived from a single randomized trial or nonrandomized studies

**Level of Evidence C:** Only consensus opinion of experts, case studies, or standard-of-care

## **METHODS USED TO ANALYZE THE EVIDENCE**

Review of Published Meta-Analyses  
Systematic Review with Evidence Tables

## **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## **METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Expert Consensus

## **DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS**

Experts in the subject under consideration are selected from the American College of Cardiology (ACC) and American Heart Association (AHA) and charged with examining subject-specific data and writing or updating these guidelines. The process includes additional representatives from other medical practitioner and specialty groups where appropriate. Writing groups are specifically charged to perform a formal literature review, weigh the strength of evidence for or against a particular treatment or procedure, and include estimates of expected health outcomes where data exist. Patient-specific modifiers, comorbidities, and issues of patient preference that might influence the choice of particular tests or therapies are considered, as well as frequency of follow-up and cost-effectiveness. When available, information from studies on cost will be considered; however, review of data on efficacy and clinical outcomes will be the primary basis for preparing recommendations in these guidelines.

This guideline was developed by a writing committee whose members had expertise in vascular medicine and cardiovascular medicine, vascular surgery, vascular and interventional radiology, and hypertension and renal disease, with committee membership derived from the ACC, the AHA, the Society for Vascular Surgery, the Society of Interventional Radiology, the Society for Vascular Medicine and Biology, the Society for Cardiovascular Angiography and Interventions, the ACC Board of Governors, and the ACC/AHA Task Force on Practice Guidelines.

This writing committee recognizes the prodigious effort and international contribution of the "Management of Peripheral Arterial Disease" document developed by the TransAtlantic Inter-Society Consensus (TASC) Working Group (<http://www.tasc-pad.org/>). The TASC is an internationally derived,

collaboratively created consensus that provides an evidence-based, detailed review of the diagnosis and treatment of intermittent claudication, acute limb ischemia, and critical limb ischemia (CLI). The efforts of TASC have defined the standard of excellence in the treatment of peripheral arterial disease. At this writing, the TASC Working Group is in the process of updating its 2000 document. Readers are encouraged to consult, in addition to this guideline, the revised TASC document when it becomes available.

The ACC/AHA Writing Committee was charged with building on the work of TASC to create a guideline for a broader audience to include primary care clinicians as well as vascular specialists.

## **RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS**

**Class I:** Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective

**Class II:** Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment

**Class IIa:** Weight of evidence/opinion is in favor of usefulness/efficacy.

**Class IIb:** Usefulness/efficacy is less well established by evidence/opinion.

**Class III:** Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

## **COST ANALYSIS**

The guideline developers reviewed published cost analyses.

## **METHOD OF GUIDELINE VALIDATION**

External Peer Review  
Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

This document was approved by the American College of Cardiology Foundation Board of Trustees in October 2005 and by the American Heart Association Science Advisory and Coordinating Committee in October 2005.

# **RECOMMENDATIONS**

## **MAJOR RECOMMENDATIONS**

Definitions for the weight of the evidence (A-C) and classes of recommendations (I-III) are provided at the end of the "Major Recommendations" field.



## General Recommendations for Peripheral Arterial Disease

### Vascular History and Physical Examination

#### *Class I*

1. Individuals at risk for lower extremity peripheral arterial disease (PAD) (see the table below) should undergo a vascular review of symptoms to assess walking impairment, claudication, ischemic rest pain, and/or the presence of nonhealing wounds. (*Level of Evidence: C*)
2. Individuals at risk for lower extremity PAD (see the Table below) should undergo comprehensive pulse examination and inspection of the feet. (*Level of Evidence: C*)
3. Individuals over 50 years of age should be asked if they have a family history of a first-order relative with an abdominal aortic aneurysm. (*Level of Evidence: C*)

#### **Table: Individuals at Risk for Lower Extremity Peripheral Arterial Disease**

- Age less than 50 years, with diabetes and one other atherosclerosis risk factor (smoking, dyslipidemia, hypertension, or hyperhomocysteinemia)
- Age 50 to 69 years and history of smoking or diabetes
- Age 70 years and older
- Leg symptoms with exertion (suggestive of claudication) or ischemic rest pain
- Abnormal lower extremity pulse examination
- Known atherosclerotic coronary, carotid, or renal artery disease

### Lower Extremity PAD

#### Clinical Presentation

##### *Asymptomatic*

#### *Class I*

1. A history of walking impairment, claudication, ischemic rest pain, and/or nonhealing wounds is recommended as a required component of a standard review of symptoms (ROS) for adults 50 years and older who have atherosclerosis risk factors and for adults 70 years and older. (*Level of Evidence: C*)
2. Individuals with asymptomatic lower extremity PAD should be identified by examination and/or measurement of the ankle-brachial index (ABI) so that therapeutic interventions known to diminish their increased risk of myocardial infarction (MI), stroke, and death may be offered. (*Level of Evidence: B*)
3. Smoking cessation, lipid lowering, and diabetes and hypertension treatment according to current national treatment guidelines are recommended for individuals with asymptomatic lower extremity PAD. (*Level of Evidence: B*)
4. Antiplatelet therapy is indicated for individuals with asymptomatic lower extremity PAD to reduce the risk of adverse cardiovascular ischemic events. (*Level of Evidence: C*)

### *Class IIa*

1. An exercise ABI measurement can be useful to diagnose lower extremity PAD in individuals who are at risk for lower extremity PAD who have a normal ABI (0.91 to 1.30), are without classic claudication symptoms, and have no other clinical evidence of atherosclerosis. (*Level of Evidence: C*)
2. A toe-brachial index or pulse volume recording measurement can be useful to diagnose lower extremity PAD in individuals who are at risk for lower extremity PAD who have an ABI greater than 1.30 and no other clinical evidence of atherosclerosis. (*Level of Evidence: C*)

### *Class IIb*

1. Angiotensin-converting enzyme (ACE) inhibition may be considered for individuals with asymptomatic lower extremity PAD for cardiovascular risk reduction. (*Level of Evidence: C*)

### *Claudication*

#### *Class I*

1. Patients with symptoms of intermittent claudication should undergo a vascular physical examination, including measurement of the ABI. (*Level of Evidence: B*)
2. In patients with symptoms of intermittent claudication, the ABI should be measured after exercise if the resting index is normal. (*Level of Evidence: B*)
3. Patients with intermittent claudication should have significant functional impairment with a reasonable likelihood of symptomatic improvement and absence of other disease that would comparably limit exercise even if the claudication was improved (e.g., angina, heart failure, chronic respiratory disease, or orthopedic limitations) before undergoing an evaluation for revascularization. (*Level of Evidence: C*)
4. Individuals with intermittent claudication who are offered the option of endovascular or surgical therapies should: (a) be provided information regarding supervised claudication exercise therapy and pharmacotherapy; (b) receive comprehensive risk factor modification and antiplatelet therapy; (c) have a significant disability, either being unable to perform normal work or having serious impairment of other activities important to the patient; and (d) have lower extremity PAD lesion anatomy such that the revascularization procedure would have low risk and a high probability of initial and long-term success. (*Level of Evidence: C*)

#### *Class III*

1. Arterial imaging is not indicated for patients with a normal postexercise ABI. This does not apply if other atherosclerotic causes (e.g., entrapment syndromes or isolated internal iliac artery occlusive disease) are suspected. (*Level of Evidence: C*)

### *Critical Limb Ischemia*

*Class I*

1. Patients with clinical limb ischemia (CLI) should undergo expedited evaluation and treatment of factors that are known to increase the risk of amputation (see table below and discussion in the original guideline document). (*Level of Evidence: C*)
2. Patients with CLI in whom open surgical repair is anticipated should undergo assessment of cardiovascular risk. (*Level of Evidence: B*)
3. Patients with a prior history of CLI or who have undergone successful treatment for CLI should be evaluated at least twice annually by a vascular specialist owing to the relatively high incidence of recurrence. (*Level of Evidence: C*)
4. Patients at risk of CLI (ABI less than 0.4 in a nondiabetic individual, or any diabetic individual with known lower extremity PAD) should undergo regular inspection of the feet to detect objective signs of CLI. (*Level of Evidence: B*)
5. The feet should be examined directly, with shoes and socks removed, at regular intervals after successful treatment of CLI. (*Level of Evidence: C*)
6. Patients with CLI and features to suggest atheroembolization should be evaluated for aneurysmal disease (e.g., abdominal aortic, popliteal, or common femoral aneurysms). (*Level of Evidence: B*)
7. Systemic antibiotics should be initiated promptly in patients with CLI, skin ulcerations, and evidence of limb infection. (*Level of Evidence: B*)
8. Patients with CLI and skin breakdown should be referred to healthcare providers with specialized expertise in wound care. (*Level of Evidence: B*)
9. Patients at risk for CLI (those with diabetes, neuropathy, chronic renal failure, or infection) who develop acute limb symptoms represent potential vascular emergencies and should be assessed immediately and treated by a specialist competent in treating vascular disease. (*Level of Evidence: C*)
10. Patients at risk for or who have been treated for CLI should receive verbal and written instructions regarding self-surveillance for potential recurrence. (*Level of Evidence: C*)

**Table: Factors That Increase Risk of Limb Loss in Patients With Critical Limb Ischemia**

Factors that reduce blood flow to the microvascular bed: <ul style="list-style-type: none"><li>• Diabetes</li><li>• Severe renal failure</li><li>• Severely decreased cardiac output (severe heart failure or shock)</li><li>• Vasospastic diseases or concomitant conditions (e.g., Raynaud's phenomenon, prolonged cold exposure)</li><li>• Smoking and tobacco use</li></ul>
Factors that increase demand for blood flow to the microvascular bed: <ul style="list-style-type: none"><li>• Infection (e.g., cellulitis, osteomyelitis)</li><li>• Skin breakdown or traumatic injury</li></ul>

*Acute Limb Ischemia*

### *Class I*

1. Patients with acute limb ischemia and a salvageable extremity should undergo an emergent evaluation that defines the anatomic level of occlusion and that leads to prompt endovascular or surgical revascularization. (*Level of Evidence: B*)

### *Class III*

1. Patients with acute limb ischemia and a nonviable extremity should not undergo an evaluation to define vascular anatomy or efforts to attempt revascularization. (*Level of Evidence: B*)

### *Prior Limb Arterial Revascularization*

#### *Class I*

1. Long-term patency of infrainguinal bypass grafts should be evaluated in a surveillance program, which should include an interval vascular history, resting ABIs, physical examination, and a duplex ultrasound at regular intervals if a venous conduit has been used. (*Level of Evidence: B*)

#### *Class IIa*

1. Long-term patency of infrainguinal bypass grafts may be considered for evaluation in a surveillance program, which may include conducting exercise ABIs and other arterial imaging studies at regular intervals (see "Duplex Ultrasound" recommendations below). (*Level of Evidence: B*)
2. Long-term patency of endovascular sites may be evaluated in a surveillance program, which may include conducting exercise ABIs and other arterial imaging studies at regular intervals (see "Duplex Ultrasound" recommendations below). (*Level of Evidence: B*)

## **Diagnostic Methods**

### *Ankle- and Toe-Brachial Indices, Segmental Pressure Examination*

#### *Class I*

1. The resting ABI should be used to establish the lower extremity PAD diagnosis in patients with suspected lower extremity PAD, defined as individuals with exertional leg symptoms, with nonhealing wounds, who are 70 years and older or who are 50 years and older with a history of smoking or diabetes. (*Level of Evidence: C*)
2. The ABI should be measured in both legs in all new patients with PAD of any severity to confirm the diagnosis of lower extremity PAD and establish a baseline. (*Level of Evidence: B*)
3. The toe-brachial index should be used to establish the lower extremity PAD diagnosis in patients in whom lower extremity PAD is clinically suspected but in whom the ABI test is not reliable due to noncompressible vessels (usually patients with long-standing diabetes or advanced age). (*Level of Evidence: B*)

4. Leg segmental pressure measurements are useful to establish the lower extremity PAD diagnosis when anatomic localization of lower extremity PAD is required to create a therapeutic plan. (*Level of Evidence: B*)

#### *Pulse Volume Recording*

##### *Class IIa*

1. Pulse volume recordings are reasonable to establish the initial lower extremity PAD diagnosis, assess localization and severity, and follow the status of lower extremity revascularization procedures. (*Level of Evidence: B*)

#### *Continuous-Wave Doppler Ultrasound*

##### *Class I*

1. Continuous-wave Doppler ultrasound blood flow measurements are useful to provide an accurate assessment of lower extremity PAD location and severity, to follow lower extremity PAD progression, and to provide quantitative follow-up after revascularization procedures. (*Level of Evidence: B*)

#### *Treadmill Exercise Testing With and Without ABI Assessments and 6-Minute Walk Test*

##### *Class I*

1. Exercise treadmill tests are recommended to provide the most objective evidence of the magnitude of the functional limitation of claudication and to measure the response to therapy. (*Level of Evidence: B*)
2. A standardized exercise protocol (either fixed or graded) with a motorized treadmill should be used to ensure reproducibility of measurements of pain-free walking distance and maximal walking distance. (*Level of Evidence: B*)
3. Exercise treadmill tests with measurement of preexercise and postexercise ABI values are recommended to provide diagnostic data useful in differentiating arterial claudication from nonarterial claudication ("pseudoclaudication"). (*Level of Evidence: B*)
4. Exercise treadmill tests should be performed in individuals with claudication who are to undergo exercise training (lower extremity PAD rehabilitation) so as to determine functional capacity, assess nonvascular exercise limitations, and demonstrate the *safety of exercise*. (*Level of Evidence: B*)

##### *Class IIb*

1. A 6-minute walk test may be reasonable to provide an objective assessment of the functional limitation of claudication and response to therapy in elderly individuals or others not amenable to treadmill testing. (*Level of Evidence: B*)

#### *Duplex Ultrasound*

##### *Class I*

1. Duplex ultrasound of the extremities is useful to diagnose anatomic location and degree of stenosis of PAD. *(Level of Evidence: A)*
2. Duplex ultrasound is recommended for routine surveillance after femoral-popliteal or femoral-tibial-pedal bypass with a venous conduit. Minimum surveillance intervals are approximately 3, 6, and 12 months, and then yearly after graft placement. *(Level of Evidence: A)*

#### *Class II*

1. Duplex ultrasound of the extremities can be useful to select patients as candidates for endovascular intervention. *(Level of Evidence: B)*
2. Duplex ultrasound can be useful to select patients as candidates for surgical bypass and to select the sites of surgical anastomosis. *(Level of Evidence: B)*

#### *Class IIb*

1. The use of duplex ultrasound is not well established to assess long-term patency of percutaneous transluminal angioplasty. *(Level of Evidence: B)*
2. Duplex ultrasound may be considered for routine surveillance after femoral-popliteal bypass with a synthetic conduit. *(Level of Evidence: B)*

#### *Computed Tomographic Angiography*

##### *Class IIb*

1. Computed tomographic angiography (CTA) of the extremities may be considered to diagnose anatomic location and presence of significant stenosis in patients with lower extremity PAD. *(Level of Evidence: B)*
2. CTA of the extremities may be considered as a substitute for magnetic resonance angiography (MRA) for those patients with contraindications to MRA. *(Level of Evidence: B)*

#### *Magnetic Resonance Angiography*

##### *Class I*

1. MRA of the extremities is useful to diagnose anatomic location and degree of stenosis of PAD. *(Level of Evidence: A)*
2. MRA of the extremities should be performed with gadolinium enhancement. *(Level of Evidence: B)*
3. MRA of the extremities is useful in selecting patients with lower extremity PAD as candidates for endovascular intervention. *(Level of Evidence: A)*

##### *Class IIb*

1. MRA of the extremities may be considered to select patients with lower extremity PAD as candidates for surgical bypass and to select the sites of surgical anastomosis. *(Level of Evidence: B)*
2. MRA of the extremities may be considered for postrevascularization (endovascular and surgical bypass) surveillance in patients with lower extremity PAD. *(Level of Evidence: B)*

## Contrast Angiography

### Class I

1. Contrast angiography provides detailed information about arterial anatomy and is recommended for evaluation of patients with lower extremity PAD when revascularization is contemplated. *(Level of Evidence: B)*
2. A history of contrast reaction should be documented before the performance of contrast angiography and appropriate pretreatment administered before contrast is given. *(Level of Evidence: B)*
3. Decisions regarding the potential utility of invasive therapeutic interventions (percutaneous or surgical) in patients with lower extremity PAD should be made with a complete anatomic assessment of the affected arterial territory, including imaging of the occlusive lesion, as well as arterial inflow and outflow with angiography or a combination of angiography and noninvasive vascular techniques. *(Level of Evidence: B)*
4. Digital subtraction angiography is recommended for contrast angiographic studies because this technique allows for enhanced imaging capabilities compared with conventional unsubtracted contrast angiography. *(Level of Evidence: A)*
5. Before performance of contrast angiography, a full history and complete vascular examination should be performed to optimize decisions regarding the access site, as well as to minimize contrast dose and catheter manipulation. *(Level of Evidence: C)*
6. Selective or superselective catheter placement during lower extremity angiography is indicated because this can enhance imaging, reduce contrast dose, and improve sensitivity and specificity of the procedure. *(Level of Evidence: C)*
7. The diagnostic lower extremity arteriogram should image the iliac, femoral, and tibial bifurcations in profile without vessel overlap. *(Level of Evidence: B)*
8. When conducting a diagnostic lower extremity arteriogram in which the significance of an obstructive lesion is ambiguous, transstenotic pressure gradients and supplementary angulated views should be obtained. *(Level of Evidence: B)*
9. Patients with baseline renal insufficiency should receive hydration before undergoing contrast angiography. *(Level of Evidence: B)*
10. Follow-up clinical evaluation, including a physical examination and measurement of renal function, is recommended within 2 weeks after contrast angiography to detect the presence of delayed adverse effects, such as atheroembolism, deterioration in renal function, or access site injury (e.g., pseudoaneurysm or arteriovenous fistula). *(Level of Evidence: C)*

### Class IIa

1. Noninvasive imaging modalities, including MRA, CTA, and color flow duplex imaging, may be used in advance of invasive imaging to develop an individualized diagnostic strategic plan, including assistance in selection of access sites, identification of significant lesions, and determination of the need for invasive evaluation. *(Level of Evidence: B)*
2. Treatment with *n*-acetylcysteine in advance of contrast angiography is suggested for patients with baseline renal insufficiency (creatinine greater than 2.0 mg per dL). *(Level of Evidence: B)*

## **Treatment**

### *Cardiovascular Risk Reduction*

#### Lipid-Lowering Drugs

##### *Class I*

1. Treatment with a hydroxymethyl glutaryl (HMG) coenzyme-A reductase inhibitor (statin) medication is indicated for all patients with PAD to achieve a target low-density lipoprotein (LDL) cholesterol level of less than 100 mg per dL. (*Level of Evidence: B*)

##### *Class IIa*

1. Treatment with an HMG coenzyme-A reductase inhibitor (statin) medication to achieve a target LDL cholesterol level of less than 70 mg per dL is reasonable for patients with lower extremity PAD at very high risk of ischemic events. (*Level of Evidence: B*)
2. Treatment with a fibric acid derivative can be useful for patients with PAD and low high-density lipoprotein (HDL) cholesterol, normal LDL cholesterol, and elevated triglycerides. (*Level of Evidence: C*)

#### Antihypertensive Drugs

##### *Class I*

1. Antihypertensive therapy should be administered to hypertensive patients with lower extremity PAD to achieve a goal of less than 140 mm Hg systolic over 90 mm Hg diastolic (nondiabetics) or less than 130 mm Hg systolic over 80 mm Hg diastolic (diabetics and individuals with chronic renal disease) to reduce the risk of MI, stroke, congestive heart failure, and cardiovascular death. (*Level of Evidence: A*)
2. Beta-adrenergic blocking drugs are effective antihypertensive agents and are not contraindicated in patients with PAD. (*Level of Evidence: A*)

##### *Class IIa*

1. The use of angiotensin-converting enzyme (ACE) inhibitors is reasonable for symptomatic patients with lower extremity PAD to reduce the risk of adverse cardiovascular events. (*Level of Evidence: B*)

##### *Class IIb*

1. Angiotensin-converting enzyme inhibitors may be considered for patients with asymptomatic lower extremity PAD to reduce the risk of adverse cardiovascular events. (*Level of Evidence: C*)

#### Diabetes Therapies

##### *Class I*



1. Proper foot care, including use of appropriate footwear, chiropody/podiatric medicine, daily foot inspection, skin cleansing, and use of topical moisturizing creams, should be encouraged and skin lesions and ulcerations should be addressed urgently in all diabetic patients with lower extremity PAD. (*Level of Evidence: B*)

#### *Class IIa*

1. Treatment of diabetes in individuals with lower extremity PAD by administration of glucose control therapies to reduce the hemoglobin A<sub>1C</sub> to less than 7% can be effective to reduce microvascular complications and potentially improve cardiovascular outcomes. (*Level of Evidence: C*)

#### Smoking Cessation

##### *Class I*

1. Individuals with lower extremity PAD who smoke cigarettes or use other forms of tobacco should be advised by each of their clinicians to stop smoking and should be offered comprehensive smoking cessation interventions, including behavior modification therapy, nicotine replacement therapy, or bupropion. (*Level of Evidence: B*)

#### Homocysteine-Lowering Drugs

##### *Class IIb*

1. The effectiveness of the therapeutic use of folic acid and B<sub>12</sub> vitamin supplements in individuals with lower extremity PAD and homocysteine levels greater than 14 micromoles per liter is not well established. (*Level of Evidence: C*)

#### Antiplatelet and Antithrombotic Drugs

##### *Class I*

1. Antiplatelet therapy is indicated to reduce the risk of MI, stroke, or vascular death in individuals with atherosclerotic lower extremity PAD. (*Level of Evidence: A*)
2. Aspirin, in daily doses of 75 to 325 mg, is recommended as safe and effective antiplatelet therapy to reduce the risk of MI, stroke, or vascular death in individuals with atherosclerotic lower extremity PAD. (*Level of Evidence: A*)
3. Clopidogrel (75 mg per day) is recommended as an effective alternative antiplatelet therapy to aspirin to reduce the risk of MI, stroke, or vascular death in individuals with atherosclerotic lower extremity PAD. (*Level of Evidence: B*)

##### *Class III*

1. Oral anticoagulation therapy with warfarin is not indicated to reduce the risk of adverse cardiovascular ischemic events in individuals with atherosclerotic lower extremity PAD. (*Level of Evidence: C*)

### *Claudication*

#### Exercise and Lower extremity PAD Rehabilitation

##### *Class I*

1. A program of supervised exercise training is recommended as an initial treatment modality for patients with intermittent claudication. (*Level of Evidence: A*)
2. Supervised exercise training should be performed for a minimum of 30 to 45 minutes, in sessions performed at least 3 times per week for a minimum of 12 weeks. (*Level of Evidence: A*)

##### *Class IIb*

1. The usefulness of unsupervised exercise programs is not well established as an effective initial treatment modality for patients with intermittent claudication. (*Level of Evidence: B*)

#### Medical and Pharmacological Treatment for Claudication

- Cilostazol

##### *Class I*

1. Cilostazol (100 mg orally 2 times per day) is indicated as an effective therapy to improve symptoms and increase walking distance in patients with lower extremity PAD and intermittent claudication (in the absence of heart failure). (*Level of Evidence: A*)
2. A therapeutic trial of cilostazol should be considered in all patients with lifestyle-limiting claudication (in the absence of heart failure). (*Level of Evidence: A*)

- Pentoxifylline

##### *Class IIb*

1. Pentoxifylline (400 mg 3 times per day) may be considered as second-line alternative therapy to cilostazol to improve walking distance in patients with intermittent claudication. (*Level of Evidence: A*)
  2. The clinical effectiveness of pentoxifylline as therapy for claudication is marginal and not well established. (*Level of Evidence: C*)
- Other proposed medical therapies

##### *Class IIb*

1. The effectiveness of L-arginine for patients with intermittent claudication is not well established. (*Level of Evidence: B*)

2. The effectiveness of propionyl-L-carnitine as a therapy to improve walking distance in patients with intermittent claudication is not well established. (*Level of Evidence: B*)
3. The effectiveness of ginkgo biloba to improve walking distance for patients with intermittent claudication is marginal and not well established. (*Level of Evidence: B*)

### *Class III*

1. Oral vasodilator prostaglandins such as beraprost and iloprost are not effective medications to improve walking distance in patients with intermittent claudication. (*Level of Evidence: A*)
2. Vitamin E is not recommended as a treatment for patients with intermittent claudication. (*Level of Evidence: C*)
3. Chelation (e.g., ethylenediaminetetraacetic acid) is not indicated for treatment of intermittent claudication and may have harmful adverse effects. (*Level of Evidence: A*)

## Endovascular Treatment for Claudication

### *Class I*

1. Endovascular procedures are indicated for individuals with a vocational or lifestyle-limiting disability due to intermittent claudication when clinical features suggest a reasonable likelihood of symptomatic improvement with endovascular intervention and (a) there has been an inadequate response to exercise or pharmacological therapy and/or (b) there is a very favorable risk-benefit ratio (e.g., focal aortoiliac occlusive disease). (*Level of Evidence: A*)
2. Endovascular intervention is recommended as the preferred revascularization technique for TransAtlantic Inter-Society Consensus (TASC) type A (see Tables 20 and 21 and Figure 8 in the original guideline document) iliac and femoropopliteal arterial lesions. (*Level of Evidence: B*)
3. Translesional pressure gradients (with and without vasodilation) should be obtained to evaluate the significance of angiographic iliac arterial stenoses of 50% to 75% diameter before intervention. (*Level of Evidence: C*)
4. Provisional stent placement is indicated for use in the iliac arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis greater than 50%, or flow-limiting dissection). (*Level of Evidence: B*)
5. Stenting is effective as primary therapy for common iliac artery stenosis and occlusions. (*Level of Evidence: B*)
6. Stenting is effective as primary therapy in external iliac artery stenoses and occlusions. (*Level of Evidence: C*)

### *Class IIa*

1. Stents (and other adjunctive techniques such as lasers, cutting balloons, atherectomy devices, and thermal devices) can be useful in the femoral, popliteal, and tibial arteries as salvage therapy for a suboptimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis greater than 50%, or flow-limiting dissection). (*Level of Evidence: C*)

### *Class IIb*

1. The effectiveness of stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of femoral-popliteal arterial lesions (except to salvage a suboptimal result from balloon dilation) is not well established. (*Level of Evidence: A*)
2. The effectiveness of uncoated/uncovered stents, atherectomy, cutting balloons, thermal devices, and lasers for the treatment of infrapopliteal lesions (except to salvage a suboptimal result from balloon dilation) is not well established. (*Level of Evidence: C*)

### *Class III*

1. Endovascular intervention is not indicated if there is no significant pressure gradient across a stenosis despite flow augmentation with vasodilators. (*Level of Evidence: C*)
2. Primary stent placement is not recommended in the femoral, popliteal, or tibial arteries. (*Level of Evidence: C*)
3. Endovascular intervention is not indicated as prophylactic therapy in an asymptomatic patient with lower extremity PAD. (*Level of Evidence: C*)

### Surgery for Claudication

- Indications

#### *Class I*

1. Surgical interventions are indicated for individuals with claudication symptoms who have a significant functional disability that is vocational or lifestyle limiting, who are unresponsive to exercise or pharmacotherapy, and who have a reasonable likelihood of symptomatic improvement. (*Level of Evidence: B*)

#### *Class IIb*

1. Because the presence of more aggressive atherosclerotic occlusive disease is associated with less durable results in patients younger than 50 years of age, the effectiveness of surgical intervention in this population for intermittent claudication is unclear. (*Level of Evidence: B*)

#### *Class III*

1. Surgical intervention is not indicated to prevent progression to limb-threatening ischemia in patients with intermittent claudication. (*Level of Evidence: B*)
- Preoperative Evaluation

#### *Class I*

1. A preoperative cardiovascular risk evaluation should be undertaken in those patients with lower extremity PAD in whom a major vascular surgical intervention is planned. *(Level of Evidence: B)*
- Inflow Procedures: Aortoiliac Occlusive Disease

#### *Class I*

1. Aortobifemoral bypass is beneficial for patients with vocational- or lifestyle-disabling symptoms and hemodynamically significant aortoiliac disease who are acceptable surgical candidates and who are unresponsive to or unsuitable for exercise, pharmacotherapy, or endovascular repair. *(Level of Evidence: B)*
2. Iliac endarterectomy and aortoiliac or iliofemoral bypass in the setting of acceptable aortic inflow should be used for the surgical treatment of unilateral disease or in conjunction with femoral-femoral bypass for the treatment of a patient with bilateral iliac artery occlusive disease if the patient is not a suitable candidate for aortobifemoral bypass grafting. *(Level of Evidence: B)*

#### *Class IIb*

1. Axillofemoral-femoral bypass may be considered for the surgical treatment of patients with intermittent claudication in very limited settings, such as chronic infrarenal aortic occlusion associated with symptoms of severe claudication in patients who are not candidates for aortobifemoral bypass. *(Level of Evidence: B)*

#### *Class III*

1. Axillofemoral-femoral bypass should not be used for the surgical treatment of patients with intermittent claudication except in very limited settings (see Class IIb recommendation above). *(Level of Evidence: B)*
- Outflow Procedures: Infringuinal Disease

#### *Class I*

1. Bypasses to the popliteal artery above the knee should be constructed with autogenous vein when possible. *(Level of Evidence: A)*
2. Bypasses to the popliteal artery below the knee should be constructed with autogenous vein when possible. *(Level of Evidence: B)*

#### *Class IIa*

1. The use of synthetic grafts to the popliteal artery below the knee is reasonable only when no autogenous vein from ipsilateral or contralateral leg or arms is available. *(Level of Evidence: A)*

#### *Class IIb*

1. Femoral-tibial artery bypasses constructed with autogenous vein may be considered for the treatment of claudication in rare instances for certain patients (see the original guideline document). (*Level of Evidence: B*)
2. Because their use is associated with reduced patency rates, the effectiveness of the use of synthetic grafts to the popliteal artery above the knee is not well-established. (*Level of Evidence: B*)

### *Class III*

1. Femoral-tibial artery bypasses with synthetic graft material should not be used for the treatment of claudication. (*Level of Evidence: C*)
- Follow-Up after Vascular Surgical Procedures

### *Class I*

1. Patients who have undergone placement of aortobifemoral bypass grafts should be followed up with periodic evaluations that record any return or progression of claudication symptoms, the presence of femoral pulses, and ABIs at rest and after exercise. (*Level of Evidence: C*)
2. Patients who have undergone placement of a lower extremity bypass with autogenous vein should undergo periodic evaluations for at least 2 years that record any claudication symptoms; a physical examination and pulse examination of the proximal, graft, and outflow vessels; and duplex imaging of the entire length of the graft, with measurement of peak systolic velocities and calculation of velocity ratios across all lesions. (*Level of Evidence: C*)
3. Patients who have undergone placement of a synthetic lower extremity bypass graft should, for at least 2 years after implantation, undergo periodic evaluations that record any return or progression of claudication symptoms; a pulse examination of the proximal, graft, and outflow vessels; and assessment of ABIs at rest and after exercise. (*Level of Evidence: C*)

## *Clinical Limb Ischemia and Treatment for Limb Salvage*

### Medical and Pharmacological Treatment for Critical Limb Ischemia (CLI)

#### *Class III*

1. Parenteral administration of pentoxifylline is not useful for the treatment of CLI. (*Level of Evidence: B*)
- Prostaglandins

#### *Class IIb*

1. Parenteral administration of PGE-1 or iloprost for 7 to 28 days may be considered to reduce ischemic pain and facilitate ulcer healing in

patients with CLI, but its efficacy is likely to be limited to a small percentage of patients. (*Level of Evidence: A*)

#### *Class III*

1. Oral iloprost is not an effective therapy to reduce the risk of amputation or death in patients with CLI. (*Level of Evidence: B*)
- Angiogenic Growth Factors

#### *Class IIb*

1. The efficacy of angiogenic growth factor therapy for treatment of CLI is not well established and is best investigated in the context of a placebo-controlled trial. (*Level of Evidence: C*)

### Endovascular Treatment for CLI

#### *Class I*

1. For individuals with combined inflow and outflow disease with CLI, inflow lesions should be addressed first. (*Level of Evidence: C*)
2. For individuals with combined inflow and outflow disease in whom symptoms of CLI or infection persist after inflow revascularization, an outflow revascularization procedure should be performed. (*Level of Evidence: B*)
3. If it is unclear whether hemodynamically significant inflow disease exists, intra-arterial pressure measurements across suprainguinal lesions should be measured before and after the administration of a vasodilator. (*Level of Evidence: C*)

### Thrombolysis for Acute and Chronic Limb Ischemia

#### *Class I*

1. Catheter-based thrombolysis is an effective and beneficial therapy and is indicated for patients with acute limb ischemia (Rutherford categories I and IIa) of less than 14 days' duration. (*Level of Evidence: A*)

#### *Class IIa*

1. Mechanical thrombectomy devices can be used as adjunctive therapy for acute limb ischemia due to peripheral arterial occlusion. (*Level of Evidence: B*)

#### *Class IIb*

1. Catheter-based thrombolysis or thrombectomy may be considered for patients with acute limb ischemia (Rutherford category IIb) of more than 14 days' duration. (*Level of Evidence: B*)

### Surgery for CLI

### *Class I*

1. For individuals with combined inflow and outflow disease with CLI, inflow lesions should be addressed first. *(Level of Evidence: B)*
2. For individuals with combined inflow and outflow disease in whom symptoms of CLI or infection persist after inflow revascularization, an outflow revascularization procedure should be performed. *(Level of Evidence: B)*
3. Patients who have significant necrosis of the weight-bearing portions of the foot (in ambulatory patients), an uncorrectable flexion contracture, paresis of the extremity, refractory ischemic rest pain, sepsis, or a very limited life expectancy due to comorbid conditions should be evaluated for primary amputation of the leg. *(Level of Evidence: C)*

### *Class III*

1. Surgical and endovascular intervention is not indicated in patients with severe decrements in limb perfusion (e.g., ABI less than 0.4) in the absence of clinical symptoms of CLI. *(Level of Evidence: C)*
- Inflow Procedures: Aortoiliac Occlusive Disease

### *Class I*

1. When surgery is to be undertaken, aortobifemoral bypass is recommended for patients with symptomatic, hemodynamically significant, aorto-bi-iliac disease requiring intervention. *(Level of Evidence: A)*
  2. Iliac endarterectomy, patch angioplasty, or aortoiliac or iliofemoral bypass in the setting of acceptable aortic inflow should be used for the treatment of unilateral disease or in conjunction with femoral-femoral bypass for the treatment of a patient with bilateral iliac artery occlusive disease if the patient is not a suitable candidate for aortobifemoral bypass grafting. *(Level of Evidence: B)*
  3. Axillofemoral-femoral bypass is indicated for the treatment of patients with CLI who have extensive aortoiliac disease and are not candidates for other types of intervention. *(Level of Evidence: B)*
- Outflow Procedures: Infringuinal Disease

### *Class I*

1. Bypasses to the above-knee popliteal artery should be constructed with autogenous saphenous vein when possible. *(Level of Evidence: A)*
2. Bypasses to the below-knee popliteal artery should be constructed with autogenous vein when possible. *(Level of Evidence: A)*
3. The most distal artery with continuous flow from above and without a stenosis greater than 20% should be used as the point of origin for a distal bypass. *(Level of Evidence: B)*
4. The tibial or pedal artery that is capable of providing continuous and uncompromised outflow to the foot should be used as the site of distal anastomosis. *(Level of Evidence: B)*



5. Femoral-tibial artery bypasses should be constructed with autogenous vein, including the ipsilateral greater saphenous vein, or if unavailable, other sources of vein from the leg or arm. *(Level of Evidence: B)*
6. Composite sequential femoropopliteal-tibial bypass and bypass to an isolated popliteal arterial segment that has collateral outflow to the foot are both acceptable methods of revascularization and should be considered when no other form of bypass with adequate autogenous conduit is possible. *(Level of Evidence: B)*
7. If no autogenous vein is available, a prosthetic femoral-tibial bypass, and possibly an adjunctive procedure, such as arteriovenous fistula or vein interposition or cuff, should be used when amputation is imminent. *(Level of Evidence: B)*

#### *Class IIa*

1. Prosthetic material can be used effectively for bypasses to the below-knee popliteal artery when no autogenous vein from ipsilateral or contralateral leg or arms is available. *(Level of Evidence: B)*
- Postsurgical Care

#### *Class I*

1. Unless contraindicated, all patients undergoing revascularization for CLI should be placed on antiplatelet therapy (see Sections 2.4.2 and 2.6.1.6 of the original guideline document), and this treatment should be continued indefinitely. *(Level of Evidence: A)*
2. Patients who have undergone placement of aortobifemoral bypass grafts should be followed up with periodic evaluations that record any return or progression of ischemic symptoms, the presence of femoral pulses, and ABIs. *(Level of Evidence: B)*
3. If infection, ischemic ulcers, or gangrenous lesions persist and the ABI is less than 0.8 after correction of inflow, an outflow procedure should be performed that bypasses all major distal stenoses and occlusions. *(Level of Evidence: A)*
4. Patients who have undergone placement of a lower extremity bypass with autogenous vein should undergo for at least 2 years periodic examinations that record any return or progression of ischemic symptoms; a physical examination, with concentration on pulse examination of the proximal, graft, and outflow vessels; and duplex imaging of the entire length of the graft, with measurement of peak systolic velocities and calculation of velocity ratios across all lesions. *(Level of Evidence: A)*
5. Patients who have undergone placement of a synthetic lower extremity bypass graft should undergo periodic examinations that record any return of ischemic symptoms; a pulse examination of the proximal, graft, and outflow vessels; and assessment of ABIs at rest and after exercise for at least 2 years after implantation. *(Level of Evidence: A)*

### **Renal Arterial Disease (RAS)**

#### **Clinical Clues to the Diagnosis of RAS**

### *Class I*

1. The performance of diagnostic studies to identify clinically significant RAS is indicated in patients with the onset of hypertension before the age of 30 years. (*Level of Evidence: B*)
2. The performance of diagnostic studies to identify clinically significant RAS is indicated in patients with the onset of severe hypertension [as defined in The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC-7 report] after the age of 55 years. (*Level of Evidence: B*)
3. The performance of diagnostic studies to identify clinically significant RAS is indicated in patients with the following characteristics: (a) accelerated hypertension (sudden and persistent worsening of previously controlled hypertension); (b) resistant hypertension (defined as the failure to achieve goal blood pressure in patients who are adhering to full doses of an appropriate 3-drug regimen that includes a diuretic); or (c) malignant hypertension (hypertension with coexistent evidence of acute end-organ damage, i.e., acute renal failure, acutely decompensated congestive heart failure, new visual or neurological disturbance, and/or advanced [grade III to IV] retinopathy). (*Level of Evidence: C*)
4. The performance of diagnostic studies to identify clinically significant RAS is indicated in patients with new azotemia or worsening renal function after the administration of an ACE inhibitor or an angiotensin receptor blocking agent (see the original guideline document). (*Level of Evidence: B*)
5. The performance of diagnostic studies to identify clinically significant RAS is indicated in patients with an unexplained atrophic kidney or a discrepancy in size between the 2 kidneys of greater than 1.5 cm. (*Level of Evidence: B*)
6. The performance of diagnostic studies to identify clinically significant RAS is indicated in patients with sudden, unexplained pulmonary edema (especially in azotemic patients). (*Level of Evidence: B*)

### *Class IIa*

1. The performance of diagnostic studies to identify clinically significant RAS is reasonable in patients with unexplained renal failure, including individuals starting renal replacement therapy (dialysis or renal transplantation). (*Level of Evidence: B*)

### *Class IIb*

1. The performance of arteriography to identify significant RAS may be reasonable in patients with multivessel coronary artery disease and none of the clinical clues (refer to Figure 17 in the original guideline document) or PAD at the time of arteriography. (*Level of Evidence: B*)
2. The performance of diagnostic studies to identify clinically significant RAS may be reasonable in patients with unexplained congestive heart failure or refractory angina (see Section 3.5.2.4 of the original guideline document). (*Level of Evidence: C*)

## **Diagnostic Methods**

### *Class I*

1. Duplex ultrasonography is recommended as a screening test to establish the diagnosis of RAS. (*Level of Evidence: B*)
2. Computed tomographic angiography (in individuals with normal renal function) is recommended as a screening test to establish the diagnosis of RAS. (*Level of Evidence: B*)
3. MRA is recommended as a screening test to establish the diagnosis of RAS. (*Level of Evidence: B*)
4. When the clinical index of suspicion is high and the results of noninvasive tests are inconclusive, catheter angiography is recommended as a diagnostic test to establish the diagnosis of RAS. (*Level of Evidence: B*)

### *Class III*

1. Captopril renal scintigraphy is not recommended as a screening test to establish the diagnosis of RAS. (*Level of Evidence: C*)
2. Selective renal vein renin measurements are not recommended as a useful screening test to establish the diagnosis of RAS. (*Level of Evidence: B*)
3. Plasma renin activity is not recommended as a useful screening test to establish the diagnosis of RAS. (*Level of Evidence: B*)
4. The captopril test (measurement of plasma renin activity after captopril administration) is not recommended as a useful screening test to establish the diagnosis of RAS. (*Level of Evidence: B*)

## **Treatment of Renovascular Disease: Renal Artery Stenosis**

### *Medical Treatment*

#### *Class I*

1. Angiotensin-converting enzyme inhibitors are effective medications for treatment of hypertension associated with unilateral RAS. (*Level of Evidence: A*)
2. Angiotensin receptor blockers are effective medications for treatment of hypertension associated with unilateral RAS. (*Level of Evidence: B*)
3. Calcium-channel blockers are effective medications for treatment of hypertension associated with unilateral RAS. (*Level of Evidence: A*)
4. Beta-blockers are effective medications for treatment of hypertension associated with RAS. (*Level of Evidence: A*)

### *Indications for Revascularization*

#### Asymptomatic Stenosis

#### *Class IIb*

1. Percutaneous revascularization may be considered for treatment of an asymptomatic bilateral or solitary viable kidney with a hemodynamically significant RAS. (*Level of Evidence: C*)
2. The usefulness of percutaneous revascularization of an asymptomatic unilateral hemodynamically significant RAS in a viable kidney is not well established and is presently clinically unproven. (*Level of Evidence: C*)

## Hypertension

### *Class IIa*

1. Percutaneous revascularization is reasonable for patients with hemodynamically significant RAS and accelerated hypertension, resistant hypertension, malignant hypertension, hypertension with an unexplained unilateral small kidney, and hypertension with intolerance to medication. *(Level of Evidence: B)*

## Preservation of Renal Function

### *Class IIa*

1. Percutaneous revascularization is reasonable for patients with RAS and progressive chronic kidney disease with bilateral RAS or a RAS to a solitary functioning kidney. *(Level of Evidence: B)*

### *Class IIb*

1. Percutaneous revascularization may be considered for patients with RAS and chronic renal insufficiency with unilateral RAS. *(Level of Evidence: C)*

## Impact of RAS on Congestive Heart Failure and Unstable Angina

### *Class I*

1. Percutaneous revascularization is indicated for patients with hemodynamically significant RAS and recurrent, unexplained congestive heart failure or sudden, unexplained pulmonary edema (see the original guideline document). *(Level of Evidence: B)*

### *Class IIa*

1. Percutaneous revascularization is reasonable for patients with hemodynamically significant RAS and unstable angina (see the original guideline document). *(Level of Evidence: B)*

## *Catheter-Based Interventions*

### *Class I*

1. Renal stent placement is indicated for ostial atherosclerotic RAS lesions that meet the clinical criteria for intervention. *(Level of Evidence: B)*
2. Balloon angioplasty with bailout stent placement if necessary is recommended for fibromuscular dysplasia (FMD) lesions. *(Level of Evidence: B)*

## *Surgery for RAS*

### *Class I*

1. Vascular surgical reconstruction is indicated for patients with fibromuscular dysplastic RAS with clinical indications for interventions (same as for percutaneous transluminal angioplasty [PTA]), especially those exhibiting complex disease that extends into the segmental arteries and those having macroaneurysms. (*Level of Evidence: B*)
2. Vascular surgical reconstruction is indicated for patients with atherosclerotic RAS and clinical indications for intervention, especially those with multiple small renal arteries or early primary branching of the main renal artery. (*Level of Evidence: B*)
3. Vascular surgical reconstruction is indicated for patients with atherosclerotic RAS in combination with pararenal aortic reconstructions (in treatment of aortic aneurysms or severe aortoiliac occlusive disease). (*Level of Evidence: C*)

## **Mesenteric Arterial Disease**

### **Acute Intestinal Ischemia**

#### *Acute Intestinal Ischemia Caused by Arterial Obstruction*

##### Diagnosis

###### *Class I*

1. Patients with acute abdominal pain out of proportion to physical findings and who have a history of cardiovascular disease should be suspected of having acute intestinal ischemia. (*Level of Evidence: B*)
2. Patients who develop acute abdominal pain after arterial interventions in which catheters traverse the visceral aorta or any proximal arteries or who have arrhythmias (such as atrial fibrillation) or recent MI should be suspected of having acute intestinal ischemia. (*Level of Evidence: C*)

###### *Class III*

1. In contrast to chronic intestinal ischemia, duplex sonography of the abdomen is not an appropriate diagnostic tool for suspected acute intestinal ischemia. (*Level of Evidence: C*)

##### Surgical Treatment

###### *Class I*

1. Surgical treatment of acute obstructive intestinal ischemia includes revascularization, resection of necrotic bowel, and, when appropriate, a "second look" operation 24 to 48 hours after the revascularization. (*Level of Evidence: B*)

##### Endovascular Treatment

###### *Class IIb*

1. Percutaneous interventions (including transcatheter lytic therapy, balloon angioplasty, and stenting) are appropriate in selected patients with acute intestinal ischemia caused by arterial obstructions. Patients so treated may still require laparotomy. (*Level of Evidence: C*)

### *Acute Nonocclusive Intestinal Ischemia*

#### Etiology

##### *Class I*

1. Nonocclusive intestinal ischemia should be suspected in patients with low flow states or shock, especially cardiogenic shock, who develop abdominal pain. (*Level of Evidence: B*)
2. Nonocclusive intestinal ischemia should be suspected in patients receiving vasoconstrictor substances and medications (e.g., cocaine, ergots, vasopressin, or norepinephrine) who develop abdominal pain. (*Level of Evidence: B*)
3. Nonocclusive intestinal ischemia should be suspected in patients who develop abdominal pain after coarctation repair or after surgical revascularization for intestinal ischemia caused by arterial obstruction. (*Level of Evidence: B*)

#### Diagnosis

##### *Class I*

1. Arteriography is indicated in patients suspected of having nonocclusive intestinal ischemia whose condition does not improve rapidly with treatment of their underlying disease. (*Level of Evidence: B*)

#### Treatment

##### *Class I*

1. Treatment of the underlying shock state is the most important initial step in treatment of nonocclusive intestinal ischemia. (*Level of Evidence: C*)
2. Laparotomy and resection of nonviable bowel is indicated in patients with nonocclusive intestinal ischemia who have persistent symptoms despite treatment. (*Level of Evidence: B*)

##### *Class IIa*

1. Transcatheter administration of vasodilator medications into the area of vasospasm is indicated in patients with nonocclusive intestinal ischemia who do not respond to systemic supportive treatment and in patients with intestinal ischemia due to cocaine or ergot poisoning. (*Level of Evidence: B*)

### **Chronic Intestinal Ischemia**

#### *Diagnosis*

### *Class I*

1. Chronic intestinal ischemia should be suspected in patients with abdominal pain and weight loss without other explanation, especially those with cardiovascular disease. (*Level of Evidence: B*)
2. Duplex ultrasound, CTA, and gadolinium-enhanced MRA are useful initial tests for supporting the clinical diagnosis of chronic intestinal ischemia. (*Level of Evidence: B*)
3. Diagnostic angiography, including lateral aortography, should be obtained in patients suspected of having chronic intestinal ischemia for whom noninvasive imaging is unavailable or indeterminate. (*Level of Evidence: B*)

### *Interventional Treatment*

#### *Class I*

1. Percutaneous endovascular treatment of intestinal arterial stenosis is indicated in patients with chronic intestinal ischemia. (*Level of Evidence: B*)

### *Surgical Treatment*

#### *Class I*

1. Surgical treatment of chronic intestinal ischemia is indicated in patients with chronic intestinal ischemia. (*Level of Evidence: B*)

#### *Class IIb*

1. Revascularization of asymptomatic intestinal arterial obstructions may be considered for patients undergoing aortic/renal artery surgery for other indications. (*Level of Evidence: B*)

#### *Class III*

1. Surgical revascularization is not indicated for patients with asymptomatic intestinal arterial obstructions, except in patients undergoing aortic/renal artery surgery for other indications. (*Level of Evidence: B*)

## **Aneurysms of the Abdominal Aorta, Its Branch Vessels, and the Lower Extremities**

### **Abdominal Aortic and Iliac Aneurysms**

#### *Etiology*

#### Atherosclerotic Risk Factors

#### *Class I*

1. In patients with abdominal aortic aneurysms (AAAs), blood pressure and fasting serum lipid values should be monitored and controlled as recommended for patients with atherosclerotic disease. (*Level of Evidence: C*)
2. Patients with aneurysms or a family history of aneurysms should be advised to stop smoking and be offered smoking cessation interventions, including behavior modification, nicotine replacement, or bupropion. (*Level of Evidence: B*)

### *Natural History*

#### Aortic Aneurysm Rupture

##### *Class I*

1. Patients with infrarenal or juxtarenal AAAs measuring 5.5 cm or larger should undergo repair to eliminate the risk of rupture. (*Level of Evidence: B*)
2. Patients with infrarenal or juxtarenal AAAs measuring 4.0 to 5.4 cm in diameter should be monitored by ultrasound or computed tomographic scans every 6 to 12 months to detect expansion. (*Level of Evidence: A*)

##### *Class IIa*

1. Repair can be beneficial in patients with infrarenal or juxtarenal AAAs 5.0 to 5.4 cm in diameter. (*Level of Evidence: B*)
2. Repair is probably indicated in patients with suprarenal or type IV thoracoabdominal aortic aneurysms larger than 5.5 to 6.0 cm. (*Level of Evidence: B*)
3. In patients with AAAs smaller than 4.0 cm in diameter, monitoring by ultrasound examination every 2 to 3 years is reasonable. (*Level of Evidence: B*)

##### *Class III*

1. Intervention is not recommended for asymptomatic infrarenal or juxtarenal AAAs if they measure less than 5.0 cm in diameter in men or less than 4.5 cm in diameter in women. (*Level of Evidence: A*)

### *Diagnosis*

#### Symptomatic Aortic or Iliac Aneurysms

##### *Class I*

1. In patients with the clinical triad of abdominal and/or back pain, a pulsatile abdominal mass, and hypotension, immediate surgical evaluation is indicated. (*Level of Evidence: B*)
2. In patients with symptomatic aortic aneurysms, repair is indicated regardless of diameter. (*Level of Evidence: C*)

#### Screening High-Risk Populations



### *Class I*

1. Men 60 years of age or older who are either the siblings or offspring of patients with AAAs should undergo physical examination and ultrasound screening for detection of aortic aneurysms. (*Level of Evidence: B*)

### *Class IIa*

1. Men who are 65 to 75 years of age who have ever smoked should undergo a physical examination and 1-time ultrasound screening for detection of AAAs. (*Level of Evidence: B*)

### *Observational Management*

#### Blood Pressure Control and Beta-Blockade

### *Class I*

1. Perioperative administration of beta-adrenergic blocking agents, in the absence of contraindications, is indicated to reduce the risk of adverse cardiac events and mortality in patients with coronary artery disease undergoing surgical repair of atherosclerotic aortic aneurysms. (*Level of Evidence: A*)

### *Class IIb*

1. Beta-adrenergic blocking agents may be considered to reduce the rate of aneurysm expansion in patients with aortic aneurysms. (*Level of Evidence: B*)

### *Prevention of Aortic Aneurysm Rupture*

#### Management Overview

### *Class I*

1. Open repair of infrarenal AAAs and/or common iliac aneurysms is indicated in patients who are good or average surgical candidates. (*Level of Evidence: B*)
2. Periodic long-term surveillance imaging should be performed to monitor for an endoleak, to document shrinkage or stability of the excluded aneurysm sac, and to determine the need for further intervention in patients who have undergone endovascular repair of infrarenal aortic and/or iliac aneurysms. (*Level of Evidence: B*)

### *Class IIa*

1. Endovascular repair of infrarenal aortic and/or common iliac aneurysms is reasonable in patients at high risk of complications from open operations because of cardiopulmonary or other associated diseases. (*Level of Evidence: B*)

### *Class IIb*

1. Endovascular repair of infrarenal aortic and/or common iliac aneurysms may be considered in patients at low or average surgical risk. *(Level of Evidence: B)*

### **Visceral Artery Aneurysms**

#### *Class I*

1. Open repair or catheter-based intervention is indicated for visceral aneurysms measuring 2.0 cm in diameter or larger in women of childbearing age who are not pregnant and in patients of either gender undergoing liver transplantation. *(Level of Evidence: B)*

#### *Class IIa*

1. Open repair or catheter-based intervention is probably indicated for visceral aneurysms 2.0 cm in diameter or larger in women beyond childbearing age and in men. *(Level of Evidence: B)*

### **Lower Extremity Aneurysms**

#### *Natural History*

#### *Class I*

1. In patients with femoral or popliteal aneurysms, ultrasound (or computed tomography or magnetic resonance) imaging is recommended to exclude contralateral femoral or popliteal aneurysms and AAA. *(Level of Evidence: B)*

#### *Management*

#### *Class I*

1. Patients with a palpable popliteal mass should undergo an ultrasound examination to exclude popliteal aneurysm. *(Level of Evidence: B)*
2. Patients with popliteal aneurysms 2.0 cm in diameter or larger should undergo repair to reduce the risk of thromboembolic complications and limb loss. *(Level of Evidence: B)*
3. Patients with anastomotic pseudoaneurysms or symptomatic femoral artery aneurysms should undergo repair. *(Level of Evidence: A)*

#### *Class IIa*

1. Surveillance by annual ultrasound imaging is suggested for patients with asymptomatic femoral artery true aneurysms smaller than 3.0 cm in diameter. *(Level of Evidence: C)*
2. In patients with acute ischemia and popliteal artery aneurysms and absent runoff, catheter-directed thrombolysis or mechanical thrombectomy (or both) is suggested to restore distal runoff and resolve emboli. *(Level of Evidence: B)*

3. In patients with asymptomatic enlargement of the popliteal arteries twice the normal diameter for age and gender, annual ultrasound monitoring is reasonable. (*Level of Evidence: C*)
4. In patients with femoral or popliteal artery aneurysms, administration of antiplatelet medication may be beneficial. (*Level of Evidence: C*)

### Catheter-Related Femoral Artery Pseudoaneurysms

#### *Class I*

1. Patients with suspected femoral pseudoaneurysms should be evaluated by duplex ultrasonography. (*Level of Evidence: B*)
2. Initial treatment with ultrasound-guided compression or thrombin injection is recommended in patients with large and/or symptomatic femoral artery pseudoaneurysms. (*Level of Evidence: B*)

#### *Class IIa*

1. Surgical repair is reasonable in patients with femoral artery pseudoaneurysms 2.0 cm in diameter or larger that persist or recur after ultrasound-guided compression or thrombin injection. (*Level of Evidence: B*)
2. Re-evaluation by ultrasound 1 month after the original injury can be useful in patients with asymptomatic femoral artery pseudoaneurysms smaller than 2.0 cm in diameter. (*Level of Evidence: B*)

### **Definitions:**

### **Classification of Recommendations**

**Class I:** Conditions for which there is evidence and/or general agreement that a given procedure or treatment is beneficial, useful, and effective.

**Class II:** Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

**Class IIa:** Weight of evidence/opinion is in favor of usefulness/efficacy.

**Class IIb:** Usefulness/efficacy is less well established by evidence/opinion.

**Class III:** Conditions for which there is evidence and/or general agreement that a procedure/treatment is not useful/effective and in some cases may be harmful.

### **Levels of Evidence**

**A:** Data derived from multiple randomized clinical trials or meta-analyses.

**B:** Data derived from a single randomized trial, or nonrandomized studies.

**C:** Only consensus opinion of experts, case studies, or standard-of-care.

## **CLINICAL ALGORITHM(S)**

Clinical algorithms are provided in the original guideline documents (Full-text and Executive Summary) for:

1. Steps toward the diagnosis of peripheral arterial disease (PAD)
2. Diagnosis and treatment of asymptomatic peripheral arterial disease (PAD) and atypical leg pain
3. Diagnosis of claudication and systemic risk treatment
4. Treatment of claudication
5. Diagnosis and treatment of critical limb ischemia (CLI)
6. Diagnosis of acute limb ischemia
7. Treatment of acute limb ischemia
8. Clinical clues to the diagnosis of renal artery stenosis
9. Indications for revascularization
10. Management of abdominal aortic aneurysms
11. Diagnostic and treatment algorithm for popliteal mass
12. Diagnostic and treatment algorithm for femoral pseudoaneurysm

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

### **TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS**

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

## **BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS**

### **POTENTIAL BENEFITS**

- Improved (prompt, accurate, and cost-effective) diagnosis linked to provision of integrated lifelong management of peripheral arterial disease
- Decreased rates of cardiovascular ischemic events (myocardial infarction and stroke) and cardiovascular death
- Decreased rates of critical limb ischemia and amputation
- Decreased rates of ischemic renal failure, and diminished morbidity and mortality due to mesenteric ischemia and aortic aneurysmal rupture
- Improved quality of life

### **POTENTIAL HARMS**

#### **Adverse Effects of Medications**

- Antihypertensive therapy may decrease limb perfusion pressure and potentially exacerbate symptoms of claudication or critical limb ischemia.
- Aspirin and clopidogrel increase the risk of intracranial and gastrointestinal bleeding.
- The most common side effects of cilostazol include headache, diarrhea, abnormal stools, palpitations, and dizziness; cilostazol should not be used in patients with heart failure.

- Adverse effects associated with pentoxifylline include sore throat, dyspepsia, nausea, and diarrhea.

### **Vascular Diagnostic Tools**

- Catheter-based contrast angiography is associated with a low rate of serious adverse outcomes in individuals with normal renal function. However, the risk of contrast-induced acute renal failure is magnified in certain clinical groups, particularly those with diabetes and chronic kidney disease. In general, the incidence of contrast-induced acute renal failure is less than 3% in patients with neither diabetes nor chronic kidney disease; 5% to 10% in those with diabetes; 10% to 20% in those with chronic kidney disease (and greater with more advanced stages), and 20% to 50% in those with both diabetes and chronic kidney disease.
- See Table 15 in the original guideline documents for limitations of noninvasive and invasive vascular diagnostic tools

### **Surgical Procedures**

- Surgical procedures are associated with intraoperative and postoperative complications including an associated cardiovascular ischemic risk and device-related complications and graft-related complications (e.g., pseudoaneurysms, graft thrombosis, enteric fistulas, graft infections, death)
- Mechanical thrombectomy devices are associated with hemorrhage, embolization, acute occlusion, amputation (refer to Table 27 in the original guideline document for more details)

## **CONTRAINDICATIONS**

### **CONTRAINDICATIONS**

- Magnetic resonance angiography is contraindicated in patients with pacemakers, defibrillators, intracranial metallic stents, clips, coils, and other devices
- The history of an allergic reaction to contrast agents may serve as a relative procedural contraindication to angiography.
- Because of bleeding risks, thrombolysis may be con-traindicated in some patients.
- Duplex sonography is contraindicated in patients with suspected acute intestinal ischemia because of the need for emergent treatment and the time required to attempt duplex scanning.

## **QUALIFYING STATEMENTS**

### **QUALIFYING STATEMENTS**

These practice guidelines are intended to assist healthcare providers in clinical decision making by describing a range of generally acceptable approaches for the prevention, diagnosis, and lifelong management of specific diseases or conditions. These guidelines attempt to define practices that meet the needs of most patients

in most circumstances. These guideline recommendations reflect a consensus of expert opinion after a thorough review of the available, current scientific evidence and are intended to improve patient care. If these guidelines are used as the basis for regulatory/payer decisions, the ultimate goal is quality of care and serving the patient's best interests. The ultimate judgment regarding care of a particular patient must be made by the healthcare provider and patient in light of all of the circumstances presented by that patient.

## IMPLEMENTATION OF THE GUIDELINE

### DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

### IMPLEMENTATION TOOLS

Clinical Algorithm  
Pocket Guide/Reference Cards  
Slide Presentation

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  
Staying Healthy

### IOM DOMAIN

Effectiveness

## IDENTIFYING INFORMATION AND AVAILABILITY

### BIBLIOGRAPHIC SOURCE(S)

Hirsch AT, Haskal ZJ, Hertzner NR, Bakal CW, Creager MA, Halperin JL, Hiratzka LF, Murphy WR, Olin JW, Puschett JB, Rosenfield KA, Sacks D, Stanley JC, Taylor LM Jr, White CJ, White J, White RA. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a collaborative report [trunc]. Bethesda (MD): American College of Cardiology Foundation; 2005. 192 p. [1308 references]

### ADAPTATION

The ACC/AHA Writing Committee was charged with building on the work of TransAtlantic Inter-Society Consensus (TASC) to create a guideline for a broader audience.

#### **DATE RELEASED**

2005

#### **GUIDELINE DEVELOPER(S)**

American College of Cardiology Foundation - Medical Specialty Society  
American Heart Association - Professional Association  
Society for Cardiovascular Angiography and Interventions - Medical Specialty Society  
Society for Vascular Medicine and Biology - Medical Specialty Society  
Society for Vascular Surgery - Medical Specialty Society  
Society of Interventional Radiology - Medical Specialty Society

#### **SOURCE(S) OF FUNDING**

The American College of Cardiology Foundation and the American Heart Association. No outside funding accepted.

#### **GUIDELINE COMMITTEE**

Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease

American College of Cardiology/American Heart Association Task Force on Practice Guidelines

#### **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

*Writing Committee Members:* Alan T. Hirsch, MD, FACC, FAHA, *Chair*; Ziv J. Haskal, MD, FAHA, FSIR, *Co-Chair*; Norman R. Hertzler, MD, FACS, *Co-Chair*; Curtis W. Bakal, MD, MPH, FAHA; Mark A. Creager, MD, FACC, FAHA; Jonathan L. Halperin, MD, FACC, FAHA<sup>1</sup>; Loren F. Hiratzka, MD, FACC, FAHA, FACS; William R.C. Murphy, MD, FACC, FACS; Jeffrey W. Olin, DO, FACC; Jules B. Puschett, MD, FAHA; Kenneth A. Rosenfield, MD, FACC; David Sacks, MD, FACR, FSIR<sup>3</sup>; James C. Stanley, MD, FACS, FACR, FSIR<sup>2</sup>; Lloyd M. Taylor, Jr., MD, FACS<sup>2</sup>; Christopher J. White, MD, FACC, FAHA, FESC, FSCAI<sup>4</sup>; John White, MD, FACS<sup>2</sup>; Rodney A. White, MD, FACS<sup>2</sup>

*Task Force Members:* Elliott M. Antman, MD, FACC, FAHA, *Chair*; Sidney C. Smith, Jr., MD, FACC, FAHA, *Vice-Chair*; Cynthia D. Adams, MSN, APRN-BC, FAHA; Jeffrey L. Anderson, MD, FACC, FAHA; David P. Faxon, MD, FACC, FAHA<sup>5</sup>; Valentin Fuster, MD, PhD, FACC, FAHA, FESC<sup>5</sup>; Raymond J. Gibbons, MD, FACC, FAHA<sup>6</sup>; Jonathan L. Halperin, MD, FACC, FAHA; Loren F. Hiratzka, MD, FACC, FAHA<sup>5</sup>; Sharon A. Hunt, MD, FACC, FAHA; Alice K. Jacobs, MD, FACC, FAHA; Rick Nishimura, MD, FACC, FAHA; Joseph P. Ornato, MD, FACC, FAHA; Richard L. Page, MD, FACC, FAHA; Barbara Riegel, DNSc, RN, FAHA

<sup>1</sup>Society for Vascular Medicine and Biology official representative

<sup>2</sup>Society for Vascular Surgery official representative

<sup>3</sup>Society of Interventional Radiology official representative

<sup>4</sup>Society for Cardiovascular Angiography and Interventions official representative

<sup>5</sup>Former Task Force member during this effort

<sup>6</sup>Immediate Past Chair

## **FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST**

The ACC/AHA Task Force on Practice Guidelines makes every effort to avoid any actual, potential, or perceived conflicts of interest that might arise as a result of an outside relationship or personal interest of a member of the writing panel. Specifically, all members of the writing panel are asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements are reviewed by the parent task force, reported orally to all members of the writing panel at each meeting, and updated and reviewed by the writing committee yearly and as changes occur.

**Table: ACC/AHA Writing Committee to Develop Guidelines on Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic)**

<b>Committee Member</b>	<b>Research Grant</b>	<b>Speakers Bureau/Honoraria</b>	<b>Stock Ownership</b>	<b>Consultant</b>	<b>Advisory Board</b>
Dr Curtis W. Bakal	None	None	None	None	Berlex Labs; Abbott Labs
Dr Mark A. Creager	Eli Lilly; Otsuka Pharmaceuticals; Pfizer; Vasogen	Bristol Myers Squibb/Sanofi Partnership; Otsuka Pharmaceuticals	Northport Domain	None	Bristol Myers Squibb/Sanofi; Genvec; Geozyme; Northport Domain; Otsuka; Pharmaceuticals; Pfizer; Vasogen
Dr Jonathan L. Halperin	None	AstraZeneca, LP; Bristol Myers Squibb/Sanofi Partnership	None	AstraZeneca, LP; Bayer AG; Boehringer Ingelheim; Bristol Myers Squibb/Sanofi Partnership	AstraZeneca, LP
Dr Ziv J. Haskal	Bard/Impra; Boston Scientific; Cook; Cordis	TransVascular; W. L. Gore	None	Bard/Impra; Endosurgery; Ethicon;	TransVascular



<b>Committee Member</b>	<b>Research Grant</b>	<b>Speakers Bureau/Honoraria</b>	<b>Stock Ownership</b>	<b>Consultant</b>	<b>Advisory Board</b>
	Endovascular; Genentech; IntraTherapeutics; W. L. Gore			Omnisonics; TransVascular	
Dr Norman R. Hertzner	None	None	None	None	None
Dr Loren F. Hiratzka	None	None	None	None	None
Dr Alan T. Hirsch	Alteon; AstraZeneca Pharmaceuticals; Bristol Myers Squibb/Sanofi Aventis Partnership; Kos Pharmaceuticals; Otsuka America Pharmaceuticals	AstraZeneca Pharmaceuticals; Bristol Myers Squibb/ Sanofi Aventis Partnership; Otsuka America Pharmaceuticals; Pfizer	None	Sonosite; Vasogen	None
Dr William R.C. Murphy	None	None	None	None	None
Dr Jeffrey W. Olin	Bristol Myers Squibb/Sanofi Partnership; Vasogen	None	None	Aventis; Bristol Myers Squibb/Sanofi Partnership; Genzyme; Otsuka; Vasogen	Abbott; Aventis; Bristol Myers Squibb/Sanofi Partnership; Genzyme
Dr Jules B. Puschett	None	None	None	None	None
Dr Kenneth A. Rosenfield	Abbott; Boston Scientific; Cordis; Guidant	Eli Lilly	CryoVascular	Abbott; Boston Scientific; Cordis; CryoVascular; Guidant	Abbott; Boston Scientific; Cordis; Guidant
Dr David Sacks	None	None	Angiotech	None	None
Dr James C. Stanley	None	None	None	None	None
Dr Lloyd M. Taylor, Jr	None	None	None	None	None
Dr Christopher J. White	None	Eli Lilly	None	None	None
Dr John White	None	None	None	None	None
Dr Rodney A. White	AVE; Bard; Baxter; Cordis J &	Multiple relationships with	Several biomedical	None	None

<b>Committee Member</b>	<b>Research Grant</b>	<b>Speakers Bureau/Honoraria</b>	<b>Stock Ownership</b>	<b>Consultant</b>	<b>Advisory Board</b>
	J; EndoLogix; EndoSonics; Medtronic	commercial entities that arise and are met as needed	companies		

Note: This table represents the relationships of committee members with industry that were disclosed at the initial writing committee meeting in November 2002 and that were updated in conjunction with all meetings and conference calls of the writing committee. It does not necessarily reflect relationships with industry at the time of publication.

**Table: External Peer Reviewers for the ACC/AHA 2005 Guideline Update for Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic)\***

<b>Peer Reviewer Name*</b>	<b>Representation</b>	<b>Research Grant</b>	<b>Speakers Bureau/Honoraria</b>	<b>Stock Ownership</b>	<b>Consultant/Advisory Board</b>
Dr Joshua A. Beckman	Content Reviewer -ACC PVD Committee	None	Merck	None	None
Dr James F. Benenati	Official Reviewer - AHA	None	None	None	None
Dr Ralph G. Brindis	Official Reviewer - ACC BOT	None	None	None	None
Dr Alan S. Brown	Official Reviewer - ACC BOG	AstraZeneca; Merck; Merck Schering Plough; Pfizer; Smith Kline Beecham	Merck; Merck Schering Plough; Pfizer	None	AstraZeneca; Merck; Merck Schering Plough
Rita C. Clark	Organizational Reviewer - SVN	None	None	None	None
Dr John P. Cooke	Content Reviewer - Individual	None	None	None	None
Dr Robert T. Eberhardt	Official Reviewer - AHA	None	None	None	None
Dr Brian S. Funaki	Content Reviewer - AHA Committee on PV Imaging and Intervention	None	None	None	None
Dr Bruce Gray	Organizational Reviewer - SVMB	None	None	None	None

<b>Peer Reviewer Name*</b>	<b>Representation</b>	<b>Research Grant</b>	<b>Speakers Bureau/Honoraria</b>	<b>Stock Ownership</b>	<b>Consultant/Advisory Board</b>
Karen Hayden, MSN	Organizational Reviewer - SVN	None	None	None	None
Dr William R. Hiatt	Organizational Reviewer - TASC	None	BMS/Sanofi; Otsuka	None	BMS/Sanofi; Signature
Dr David Holmes, Jr	Content Reviewer - ACC BOG	None	None	None	None
Dr Sharon A. Hunt	Organizational Reviewer - ACC/AHA TF on PGL	None	None	None	None
Dr Michael R. Jaff	Organizational Reviewer - SVMB	None	OtsukaBMS/Sanofi	None	Cordis Endovascular
Dr Matthew S. Johnson	Content Reviewer - AHA Committee on PV Imaging and Intervention	Bard Access Systems; Boston Scientific	None	None	Boston Scientific
Dr John A. Kaufman	Content Reviewer - AHA Atherosclerosis PVD Steering Committee	None	None	None	None
Dr Morton Kern	Content Reviewer - AHA Diag and Interv Cardiac Cath Cmte	None	None	None	None
Dr Lloyd Klein	Content Reviewer - AHA Diag and Interv Cardiac Cath Cmte	TBD	TBD	TBD	TBD
Dr Frank Lederle	Content Reviewer - Individual Review	None	None	None	None
Dr Jonathan Lindner	Official Reviewer - ACCF TF on CECD	None	None	None	None
Dr Mary M. McDermott	Content Reviewer - AHA Athero PVD, PVD Steering Committee	None	None	None	None
Dr Alan	Content	None	Genentech	None	Cordis Endovascular;

<b>Peer Reviewer Name*</b>	<b>Representation</b>	<b>Research Grant</b>	<b>Speakers Bureau/Honoraria</b>	<b>Stock Ownership</b>	<b>Consultant/Advisory Board</b>
Matsumoto	Reviewer - AHA Committee on PV Imaging and Intervention				Medtronic; W. L. Gore
Dr Roxana Mehran	Content Reviewer - Individual Review	Boston Scientific; Cordis; Medtronic	The Medicines Company; Tyco/Mallinckrodt	None	None
Dr Emile R. Mohler III	Content Reviewer - Individual Review	None	None	None	None
Roberta Oka, RN	Content Reviewer - AHA Atherosclerosis PVD Steering Committee	None	None	None	None
Dr Joseph P. Ornato	Official Reviewer - ACC/AHA TF on PGL, Lead Reviewer	None	None	None	Genentech; Meridian; Revivant; Wyeth
Dr Kenneth Ouriel	Content Reviewer - ACC PVD Committee	TBD	TBD	TBD	TBD
Dr William Pearce	Official Reviewer - AHA	None	None	None	None
Carolyn A. Robinson	Organizational Reviewer - SVN	None	None	None	None
Dr Robert D. Safian	Organizational Reviewer - SCAI	None	None	None	Boston Scientific; Cordis/Johnson & Johnson; eV3; Medtronic
Dr Sonia I. Skarlatos	Organizational Reviewer - NHLBI	None	None	None	None
Dr Kimberly A. Skelding	Content Reviewer - AHA Diag and Interv Cardiac Cath Cmte	None	None	None	None
Dr Vincenza Snow	Organizational Reviewer - ACP/ASIM	None	None	None	None
Dr Thomas L. Whitsett	Organizational Reviewer - SVMB	None	None	None	None

**Note:** This table represents the relationships of peer reviewers with industry that were disclosed at the time of peer review of this guideline. It does not necessarily reflect relationships with industry at the time of publication. Participation in the peer review process does not imply endorsement of the document.

\*Names are listed in alphabetical order.

ACCF indicates American College of Cardiology Foundation; ACP, American College of Physicians; AHA Diag and Interv Cardiac Cath Cmte, AHA Diagnostic and Interventional Cardiac Catheterization Committee; ASIM, American Society of Internal Medicine; BOG, Board of Governors; BOT, Board of Trustees; NHLBI, National Heart, Lung, and Blood Institute; PV, peripheral vein; PVD, peripheral vascular disease; SCAI, Society for Cardiovascular Angiography and Interventions; SVMB, Society of Vascular Medicine and Biology; SVN, Society for Vascular Nursing; TBD, to be determined; TF on CECD, Task Force on Clinical Expert Consensus Documents; and TF on PGL, Task Force on Practice Guidelines.

## **ENDORSER(S)**

American Association of Cardiovascular and Pulmonary Rehabilitation - Medical Specialty Society  
National Heart, Lung, and Blood Institute (U.S.) - Federal Government Agency [U.S.]  
Society for Vascular Nursing  
TransAtlantic Inter-Society Consensus - Independent Expert Panel  
Vascular Disease Foundation - Professional Association

## **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the [American College of Cardiology \(ACC\) Web site](#), and from the [American Heart Association \(AHA\) Web site](#).

Print copies: Available from the American College of Cardiology, 9111 Old Georgetown Road, Bethesda, Maryland 20814-1699.

## **AVAILABILITY OF COMPANION DOCUMENTS**

The following are available:

- ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic). A collaborative report from the American Association for Vascular Surgery/Society for Vascular Surgery\*, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society for Vascular Medicine and Biology, and the ACC/AHA Task Force on Practice Guidelines (Writing Committee to Develop Guidelines for the Management of Patients With Peripheral Arterial Disease [Lower Extremity, Renal, Mesenteric,

and Abdominal Aortic])--executive summary. Electronic copies: Available from the [American College of Cardiology \(ACC\) Web site](#).

Print copies: Available from the American College of Cardiology, Resource Center, 9111 Old Georgetown Rd, Bethesda, MD 20814-1699; (800) 253-4636 (US only).

- Slide set. Peripheral arterial disease guidelines: management of patients with lower extremity PAD. Available from the [ACC Web site](#).
- ACC/AHA pocket guideline. Management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic). Electronic copies: Available in Portable Document Format (PDF) from the [American College of Cardiology \(ACC\) Web site](#).

## **PATIENT RESOURCES**

None available

## **NGC STATUS**

This NGC summary was completed by ECRI on February 3, 2006. The information was verified by the guideline developer on May 16, 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. This summary was updated by ECRI Institute on November 9, 2007, following the U.S. Food and Drug Administration advisory on Antidepressant drugs.

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