A stylized graphic on the left side of the page. It features a white, 3D-style heart shape with a red outline, positioned at the bottom left. Above it, a large, flowing red shape resembling a flame or a ribbon curves upwards and to the right. The background is a dark grey color with a dotted white line curving from the bottom left towards the center.

A Clinical Assessment of Peripheral Artery Disease for Those on the Primary Care Spectrum

American Heart Association



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RN-BC, FAHA**

College of Nursing, *University of Toledo*

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Ownership Interest-Flexlife Health*

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Learning Objectives

Recognize PAD as a common vascular disease that is associated with functional impairment and increased risk of major cardiovascular events and amputation.

Review the diagnostic approach to PAD: history and physical examination, the ankle-brachial index (ABI), and when and which additional diagnostic testing is recommended.

Review medical therapy for the patient with PAD.



2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease

Developed in collaboration with the American Association of Cardiovascular and Pulmonary Rehabilitation, Inter-Society Consensus for the Management of Peripheral Arterial Disease, Society for Cardiovascular Angiography and Interventions, Society for Clinical Vascular Surgery, Society of Interventional Radiology, Society for Vascular Medicine, Society for Vascular Nursing, and Vascular and Endovascular Surgery Society



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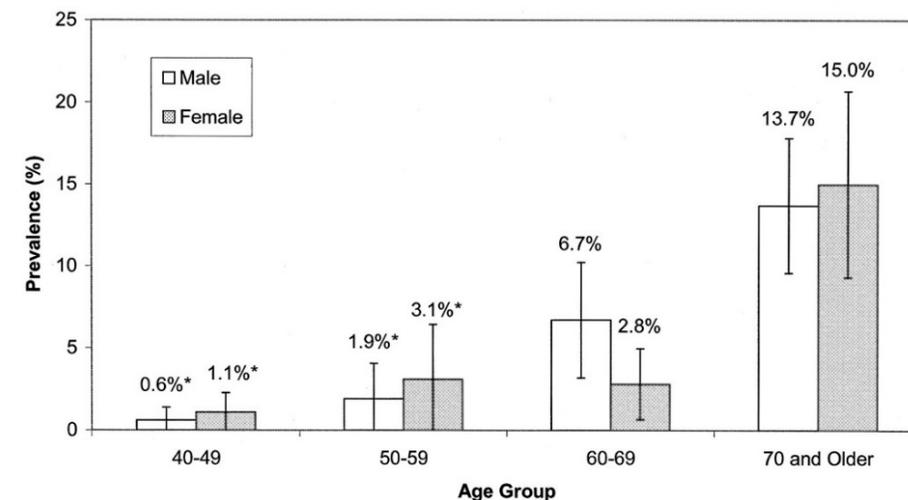
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Why These Guidelines?

Concept 1: PAD is a Highly Prevalent Disease

Prevalence varies depending on characteristics of population sampled:

- **NHANES¹ U.S. general population:** 14.5% of individuals age 70+ have PAD
- **GetABI²:** 21% prevalence of PAD in German ambulatory care population age 65+
- **PARTNERS³:** 29% prevalence of PAD in at risk U.S. ambulatory care population
 - Age 70+ years
 - Ages 50–69 with diabetes or tobacco use history



Per 2016 AHA Heart Disease and Stroke Statistical Update

**PAD Effects ~ 8.5 Million
Americans Ages 40+**



Why These Guidelines?

Concept 2: PAD is a High CV Risk, High Mortality Condition

San Diego Population Study:

PAD Increases Risk of Death

3x↑ All Cause Mortality

~6x↑ CV Related Mortality

Criqui MH et al. N Engl J Med. 1992;326:386.

ABI Collaboration:

For each Framingham Risk Category,

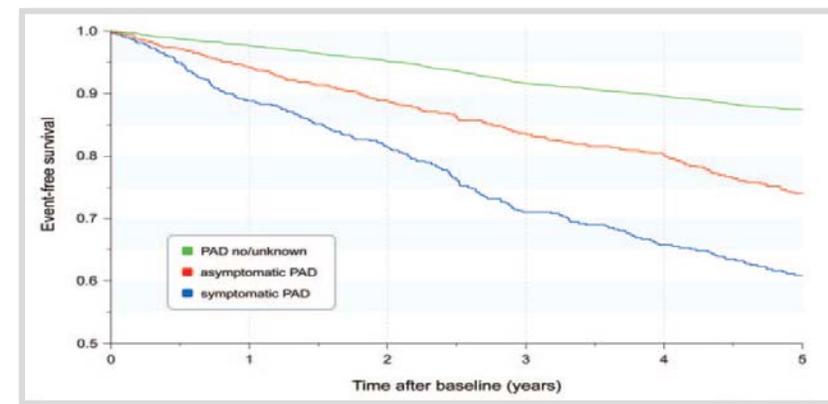
**ABI <0.91 doubles
CV event & death rate**

ABI Collaboration. JAMA 2008;300:197.

Get ABI:

PAD Predicts CV Events Regardless of Symptoms

Diehm C, et al. German Epidemiological Trial on ABI Study Group. Circulation. 2009; 120:2053.



REACH Registry:

**~1 in 5 PAD patients has MI, Stroke,
CV hospitalization or dies of CV cause each year**

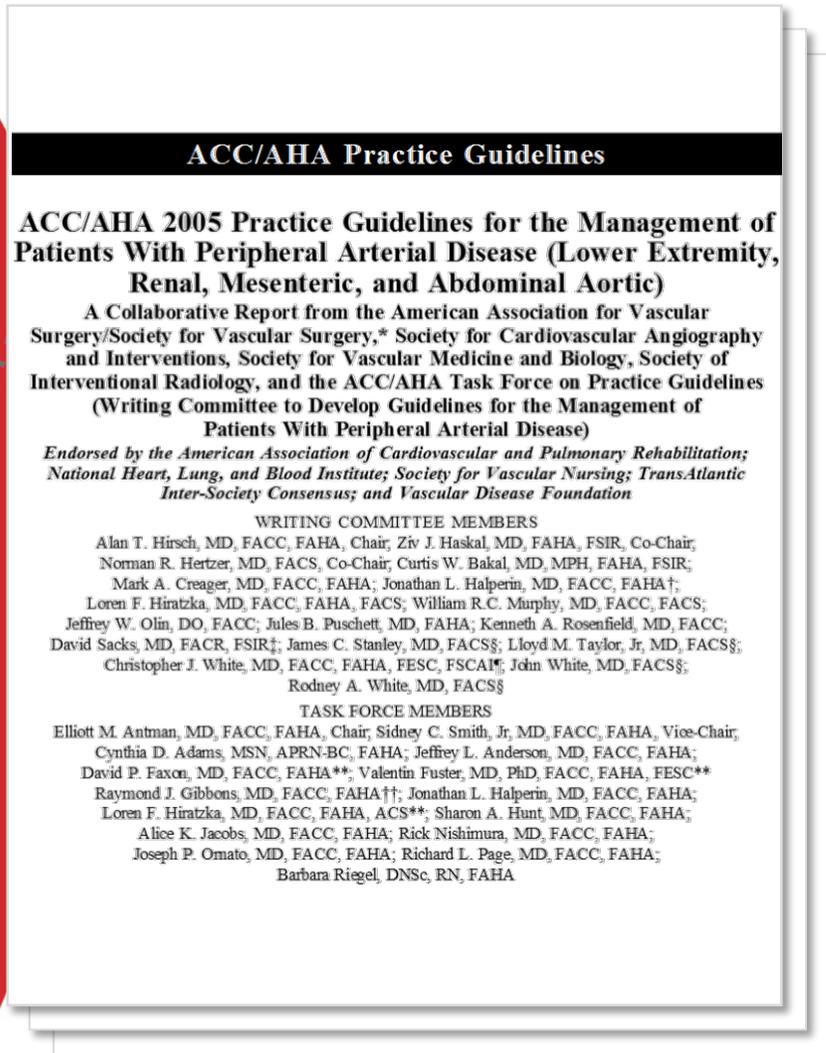
Steg PG, et al. REACH Registry. JAMA 2007.

Why These Guidelines?

Concept 3: PAD is a Morbid Disease

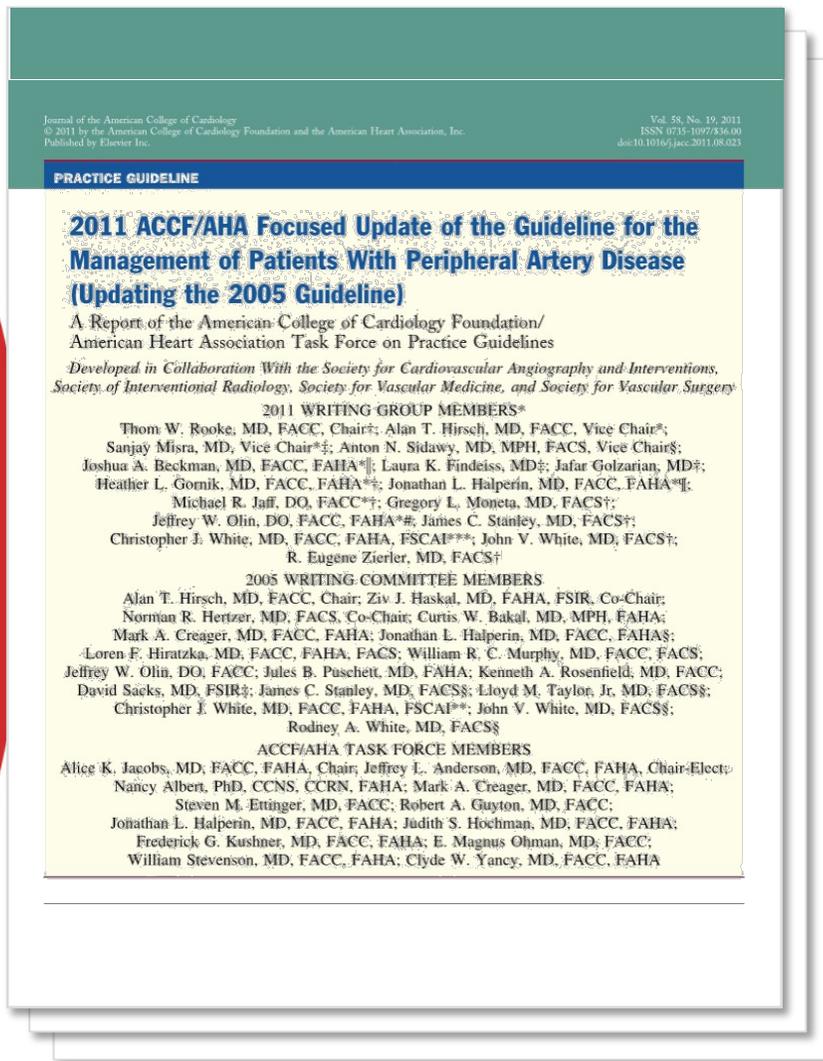
- **PAD a major risk factor for lower extremity amputation**
 - < 5% at 5 years among stable patients with claudication¹
 - However, risk increases dramatically among those with critical limb ischemia (as high as 30–40%/year)²
- **QoL impairment of PAD more severe than CHF or recent MI³**
- **Functional impairment is common, even among patients with atypical leg symptoms⁴⁻⁷**
 - Decreased walking distance
 - Decreased walking velocity
- **Patients with PAD are at increased risk of depression^{8,9}**

First a Little History: 2005 “PAD” Guideline



- 2005 “PAD” guideline truly a noteworthy publication
- Groundbreaking interprofessional collaboration
- Covered all arterial disease below diaphragm
 - PAD, AAA, peripheral aneurysms, renal/mesenteric disease, FMD, femoral pseudoaneurysms
 - 198 pages long, 1308 references
- Achieved national impact in improving public and health professional PAD awareness

2011 PAD Guideline Update



- Focused on guideline areas with new evidence since 2005
- Provided new recommendations to replace specific 2005 recs:
 - ABI for PAD
 - PAD Med Rx: smoking cessation, anti-platelet, anticoagulant therapies
 - Revascularization for CLI
 - Approach to AAA repair

2016 ACC/AHA Lower Extremity PAD Guideline

- Scope of document limited to atherosclerotic lower extremity PAD
- **Goal:** to provide a contemporary guideline for diagnosis and management of patients with lower extremity PAD
- Supersedes the lower extremity PAD recommendations in the 2005 and 2011 guidelines
- Used updated ACC/AHA Guidelines Taskforce methodology for evidence review, guideline writing and rating, voting, and peer review

Guideline Writing Committee (GWC)

- Developed with attention to the interdisciplinary nature of PAD care as well as Relationships with Industry (RWI)
 - Rigorous RWI policy followed throughout documented development process
 - GWC members with relevant RWI did not vote on recommendations in any section in any section in which their RWI applied
- Participants nominated from ACC/AHA and all collaborating organizations
- Highly interdisciplinary GWC
 - Vascular medicine, vascular surgery, IR, interventional cardiology, nursing, wound care, vascular research, anesthesiology, exercise physiology, lay member

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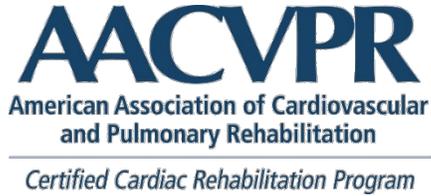
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Collaborating Organizations



Inter-Society Consensus for the Management of PAD (TASC)



ACC/AHA Guidelines Methodology

What Has Changed?

- The look and format of the guideline – less text, evidence/summary tables required *“KNOWLEDGE BYTES RATHER THAN A TEXTBOOK”*
- Scientific rigor has increased and an explicit review and analysis of the evidence is required, published in online data supplement
- ALL Level of Evidence A, B, and C recommendations must have references and supporting tables

Scope of the 2016 PAD Guideline

- Clinical Assessment for PAD
- Diagnostic Testing for the Patient With Suspected Lower Extremity PAD (Claudication or CLI)
- Screening for Atherosclerotic Disease in Other Vascular Beds for the Patient With PAD
- Medical Therapy for the Patient With PAD
- Structured Exercise Therapy
- Minimizing Tissue Loss in Patients With PAD
- Revascularization for Claudication
- Management of CLI
- Management of Acute Limb Ischemia
- Longitudinal Follow-Up
- Evidence Gaps and Future Research Directions
- Advocacy Priorities



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ACC/AHA Clinical Practice Guidelines

Class of Recommendation & Level of Evidence

CLASS (STRENGTH) OF RECOMMENDATION	
CLASS I (STRONG)	Benefit >>> Risk
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> ■ Is recommended ■ Is indicated/useful/effective/beneficial ■ Should be performed/administered/other ■ Comparative-Effectiveness Phrases†: <ul style="list-style-type: none"> ○ Treatment/strategy A is recommended/indicated in preference to treatment B ○ Treatment A should be chosen over treatment B 	
CLASS IIa (MODERATE)	Benefit >> Risk
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> ■ Is reasonable ■ Can be useful/effective/beneficial ■ Comparative-Effectiveness Phrases†: <ul style="list-style-type: none"> ○ Treatment/strategy A is probably recommended/indicated in preference to treatment B ○ It is reasonable to choose treatment A over treatment B 	
CLASS IIb (WEAK)	Benefit ≥ Risk
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> ■ May/might be reasonable ■ May/might be considered ■ Usefulness/effectiveness is unknown/unclear/uncertain or not well established 	
CLASS III: No Benefit (MODERATE)	Benefit = Risk
<i>(Generally, LOE A or B use only)</i>	
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> ■ Is not recommended ■ Is not indicated/useful/effective/beneficial ■ Should not be performed/administered/other 	
CLASS III: Harm (STRONG)	Risk > Benefit
Suggested phrases for writing recommendations:	
<ul style="list-style-type: none"> ■ Potentially harmful ■ Causes harm ■ Associated with excess morbidity/mortality ■ Should not be performed/administered/other 	

LEVEL (QUALITY) OF EVIDENCE‡	
LEVEL A	
<ul style="list-style-type: none"> ■ High-quality evidence‡ from more than 1 RCT ■ Meta-analyses of high-quality RCTs ■ One or more RCTs corroborated by high-quality registry studies 	
LEVEL B-R	(Randomized)
<ul style="list-style-type: none"> ■ Moderate-quality evidence‡ from 1 or more RCTs ■ Meta-analyses of moderate-quality RCTs 	
LEVEL B-NR	(Nonrandomized)
<ul style="list-style-type: none"> ■ Moderate-quality evidence‡ from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies ■ Meta-analyses of such studies 	
LEVEL C-LD	(Limited Data)
<ul style="list-style-type: none"> ■ Randomized or nonrandomized observational or registry studies with limitations of design or execution ■ Meta-analyses of such studies ■ Physiological or mechanistic studies in human subjects 	
LEVEL C-EO	(Expert Opinion)
Consensus of expert opinion based on clinical experience	

Class (Strength) of Recommendation

Magnitude of Benefit in Relation to Risk

Class I (Strong): Benefit \gg Risk

Is recommended, should be performed/administered

Class IIa (Moderate): Benefit $>$ Risk

Is reasonable, can be useful/effective/beneficial

Class IIb (Weak): Benefit \geq Risk

May/might be reasonable, usefulness/effectiveness is unknown/uncertain/not well established

Class III: No Benefit (Moderate): Benefit = Risk

Is not recommended, is not useful/effective

Class III: Harm (Strong): Risk $>$ Benefit

Potentially harmful, should not be performed or administered

Level (Quality) of Evidence

Degree of Confidence in the Assessment

LEVEL A

- High-quality evidence from more than 1 RCT
- Meta-analyses of high-quality RCTs
- 1 or more RCTs corroborated by high-quality registry studies

LEVEL B-R (Randomized)

- Moderate-quality evidence[†] from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

LEVEL B-NR (Nonrandomized)

- Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

Level (Quality) of Evidence

Degree of Confidence in the Assessment

C-LD (Limited Data)

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

C-EO (Expert Opinion)

- Consensus of expert opinion, based on clinical experience

2016 ACC/AHA Lower Extremity PAD Guideline

Clinical Assessment for PAD

- **History and Physical Examination**
- **Ankle-Brachial Index (ABI)**
- **Physiological Testing (Vascular Lab)**
- **Anatomic Imaging Assessment**
- **Assessing PAD Patients for Disease in Other Vascular Beds**

STEP #1: Identify Patients at Increased Risk of PAD

Patients at Increased Risk of PAD

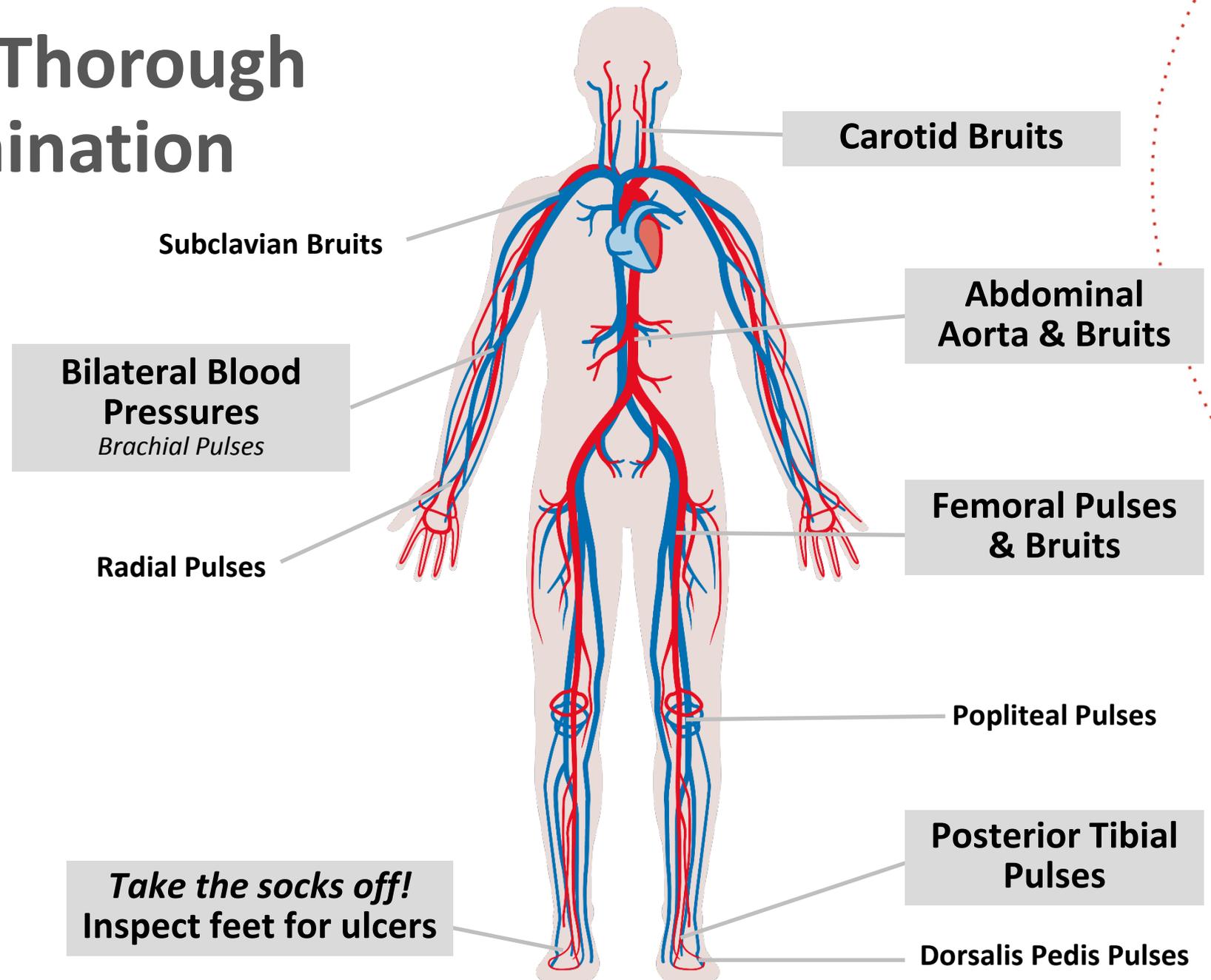
- Age ≥ 65 years
- Age 50–64 years, with risk factors for atherosclerosis (*e.g., diabetes mellitus, history of smoking, hyperlipidemia, hypertension*) or family history of PAD
- Age < 50 years, with diabetes mellitus and 1 additional risk factor for atherosclerosis
- Individuals with known atherosclerotic disease in another vascular bed (*e.g., coronary, carotid, subclavian, renal, mesenteric artery stenosis, or AAA*)

Recommendations:

History & Physical Examination

COR	LOE	Recommendations
I	B-NR	Patients at increased risk of PAD should undergo a comprehensive medical history and a review of symptoms to assess for exertional leg symptoms, including claudication or other walking impairment, ischemic rest pain, and nonhealing wounds.
I	B-NR	Patients at increased risk of PAD should undergo vascular examination, including palpation of lower extremity pulses (<i>e.g., femoral, popliteal, dorsalis pedis, and posterior tibial</i>), auscultation for femoral bruits, and inspection of the legs and feet.

Incorporate a Thorough Vascular Examination



***Inter-arm blood pressure gradient >15-20 mm Hg suggests subclavian stenosis**

Take the socks off!
Inspect feet for ulcers

Take the Socks Off! Inspect the Feet



Photo from www.youtube.com/watch?v=0_OVILSTAAE

- Allows for pedal pulse assessment
- Assess for bony foot deformity, callous formation that may predispose to ulcers, peripheral neuropathy
- Assess for signs of tissue loss (*e.g.*, wounds, gangrene) or foot infection
- Important to evaluate for suspected PAD and in routine care of patients with established diagnosis of PAD

A Word About Pulses



Photo from www.angiologist.com

- All clinicians should use the same grading system
- Grading system recommended by the ACC/AHA PAD guidelines:
 - 0** - *Absent*
 - 1** - *Diminished*
 - 2** - *Normal*
 - 3** - *Bounding*

Physical Examination for PAD: Summary of Evidence¹⁻³

- Presence of a non-healing LE wound should raise concern for possible CLI
- Presence of abnormal physical findings **↑**likelihood of PAD
 - Any femoral/popliteal/DP/PT pulse abnormality (reduced/absent vs. normal)
 - Femoral bruit
 - Multiple abnormal physical findings further **↑**likelihood of PAD
- Entirely normal pulse exam and absence of femoral bruits **↓**likelihood of PAD
- PT pulse assessment has higher SENS/SPEC for PAD than DP pulse assessment
 - DP congenitally absent in significant % of population
- Normal capillary refill and normal skin temperature cannot “rule out PAD”

Physical Examination for PAD: Summary of Evidence¹⁻³

- Presence of physical findings is associated with PAD
- Presence of physical findings is associated with PAD
 - Ankle-brachial index (ABI)
 - Femoral brachial index (FBI)
 - Ankle-skin temperature
- Entire physical examination is not sufficient to rule out PAD
- PT pulse examination is not sufficient to rule out PAD
 - Capillary refill
- Normal capillary refill and normal skin temperature cannot “rule out PAD”

Bottom line: physical examination is imperfect to diagnose PAD:

- *Abnormal physical findings should be confirmed with ABI/TBI*
- *Normal physical exam does not completely rule out PAD if there is high clinical suspicion based on symptoms*

STEP #2

Identify PAD “Red Flags”

History and/or Physical Examination Findings Suggestive of PAD

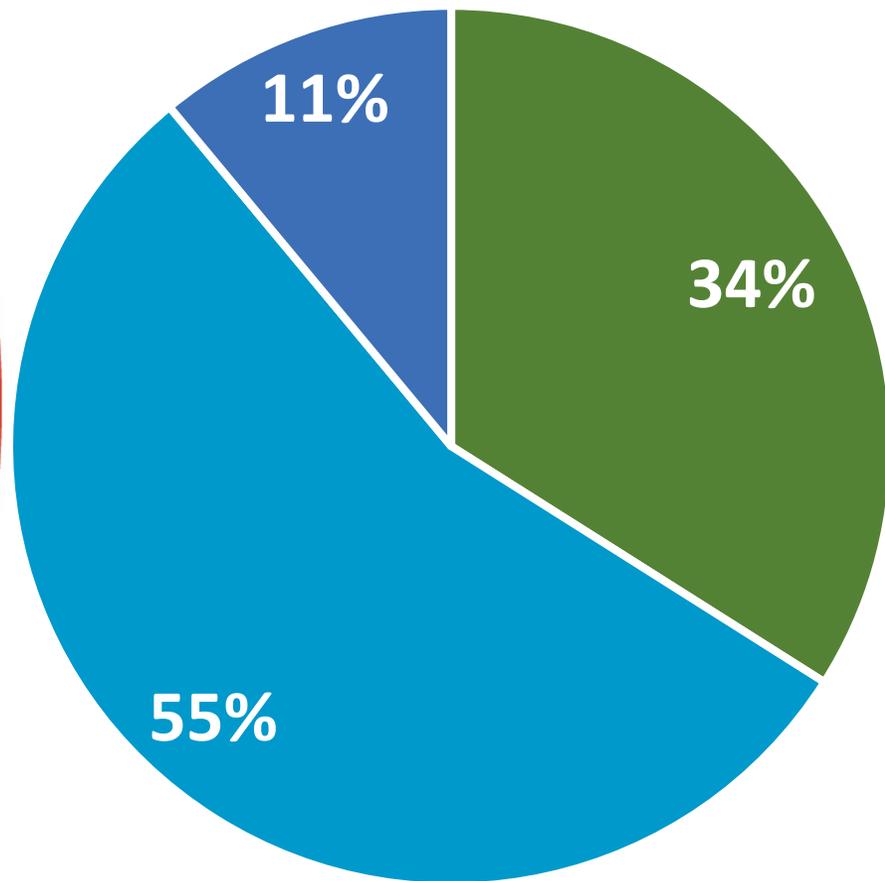
History

- Claudication
- Other non-joint-related exertional lower extremity symptoms
(not typical of claudication)
- Impaired walking function
- Ischemic rest pain

Physical Examination

- Abnormal lower extremity pulse examination
- Vascular bruit
- Nonhealing lower extremity wound
- Lower extremity gangrene
- Other suggestive lower extremity physical findings
(e.g., elevation pallor/dependent rubor)

Reminder: *Classic Claudication Is the Exception Rather than the Rule for Patients with PAD*



N=1857 Patients with ABI <0.9

- No Pain
- Atypical Leg Pain
- Classic Claudication



Classic Claudication:

Fatigue, discomfort, cramping, or pain of vascular origin in the muscles of the lower extremities that is consistently induced by exercise and consistently relieved by rest (within 10 minutes)

STEP #3: The Resting ABI

$$\text{ABI} = \frac{\text{Ankle systolic pressure}}{\text{Brachial systolic pressure}}$$

Right Arm:
Systolic Pressure mmHg

Left Arm:
Systolic Pressure mmHg

Right Ankle: Systolic Pressure
Posterior Tibial (PT) mmHg
Dorsalis Pedis (DP) mmHg

Left Ankle: Systolic Pressure
Posterior Tibial (PT) mmHg
Dorsalis Pedis (DP) mmHg

Right ABI equals Ratio of:
Higher of the Right Ankle Pressure (PT or DP) $\frac{\text{68 mmHg}}{\text{120 mmHg}} = 0.57^*$
Higher Arm Pressure (right or left arm)

Left ABI equals Ratio of:
Higher of the Left Ankle Pressure (PT or DP) $\frac{\text{136 mmHg}}{\text{120 mmHg}} = 1.13^*$
Higher Arm Pressure (right or left arm)

*The lower of these numbers is the patient's overall ABI. Overall ABI (lower ABI) = 0.57

- Cornerstone of PAD diagnosis
- Ankle and brachial systolic pressures in all extremities taken using Doppler device
- Supine position after 5+ minutes of rest
- Higher brachial pressure is used as denominator for both legs
- Higher ankle pressure (DP or PT) is used as numerator for the index leg
- Segmental leg pressures and Doppler or plethysmographic waveforms may be performed concurrently to localize disease

Recommendations:

Resting ABI for Diagnosis of PAD

COR	LOE	Recommendations
I	B-NR	In patients with history or physical examination findings suggestive of PAD, the resting ABI, with or without segmental pressures and waveforms, is recommended to establish the diagnosis.
I	C-LD	Resting ABI results should be reported as abnormal (ABI ≤ 0.90), borderline (ABI 0.91–0.99), normal (1.00–1.40), or noncompressible (ABI > 1.40).
IIa	B-NR	In patients at increased risk of PAD but without history or physical examination findings suggestive of PAD, measurement of the resting ABI is reasonable.
III: No Benefit	B-NR	In patients not at increased risk of PAD and without history or physical examination findings suggestive of PAD, the ABI is not recommended.

AHA Scientific Statement

Measurement and Interpretation of the Ankle-Brachial Index

A Scientific Statement From the American Heart Association

Victor Aboyans, MD, PhD, FAHA, Chair; Michael H. Criqui, MD, MPH, FAHA, Co-Chair; Pierre Abraham, MD, PhD; Matthew A. Allison, MD, MPH, FAHA; Mark A. Creager, MD, FAHA; Curt Diehm, MD, PhD; F. Gerry R. Fowkes, MBChB, PhD, FAHA; William R. Hiatt, MD, FAHA; Björn Jönsson, MD, PhD; Philippe Lacroix, MD; Benoît Marin, MD; Mary M. McDermott, MD, FAHA; Lars Norgren, MD, PhD; Reena L. Pande, MD, MSc; Pierre-Marie Preux, MD, PhD; H.E. (Jelle) Stoffers, MD, PhD;

Diane Treat-Jacobson, PhD, RN, FAHA; on behalf of the American Heart Association Council on Peripheral Vascular Disease, Council on Epidemiology and Prevention, Council on Clinical Cardiology, Council on Cardiovascular Nursing, Council on Cardiovascular Radiology and Intervention, and Council on Cardiovascular Surgery and Anesthesia

The ankle-brachial index (ABI) is the ratio of the systolic blood pressure (SBP) measured at the ankle to that measured at the brachial artery. Originally described by Winsor¹ in 1950, this index was initially proposed for the noninvasive diagnosis of lower-extremity peripheral artery disease (PAD).^{2,3} Later, it was shown that the ABI is an indicator of atherosclerosis at other vascular sites and can serve as a prognostic marker for cardiovascular events and functional impairment, even in the absence of symptoms.

brachial artery and at the ankles, whether the arm and ankle pressures were measured bilaterally, which ankle pulses were used, and whether a single or replicate measures were obtained.¹⁰

There is controversy about what ABI threshold should be used to diagnose PAD. The ABI threshold most commonly used is ≤ 0.90 based on studies reporting $>90\%$ sensitivity and specificity to detect PAD compared with angiography.^{2,3} These studies were limited in that they included mostly older

Rationale for

The current lack of the ABI leads to diagnostic, clinical, public health, and economic consequences. The estimated prevalence of PAD is 12.5% in the United States. The current mode of ABI measurement is not standardized, and selected reports used for diagnosis were identified. In the current measurement, the cuff on the ext

The American Heart Association does not have a relationship or a personal or professional relationship with any of the individuals or organizations mentioned in this statement. This statement was prepared by the American Heart Association and is available for additional reprints, e



For More Detail About the ABI

Measurement and Interpretation of the Ankle-Brachial Index

Diagnostic Testing for the Patient With Suspected Lower Extremity PAD (Claudication or CLI)

Physiological Testing (Vascular Laboratory)

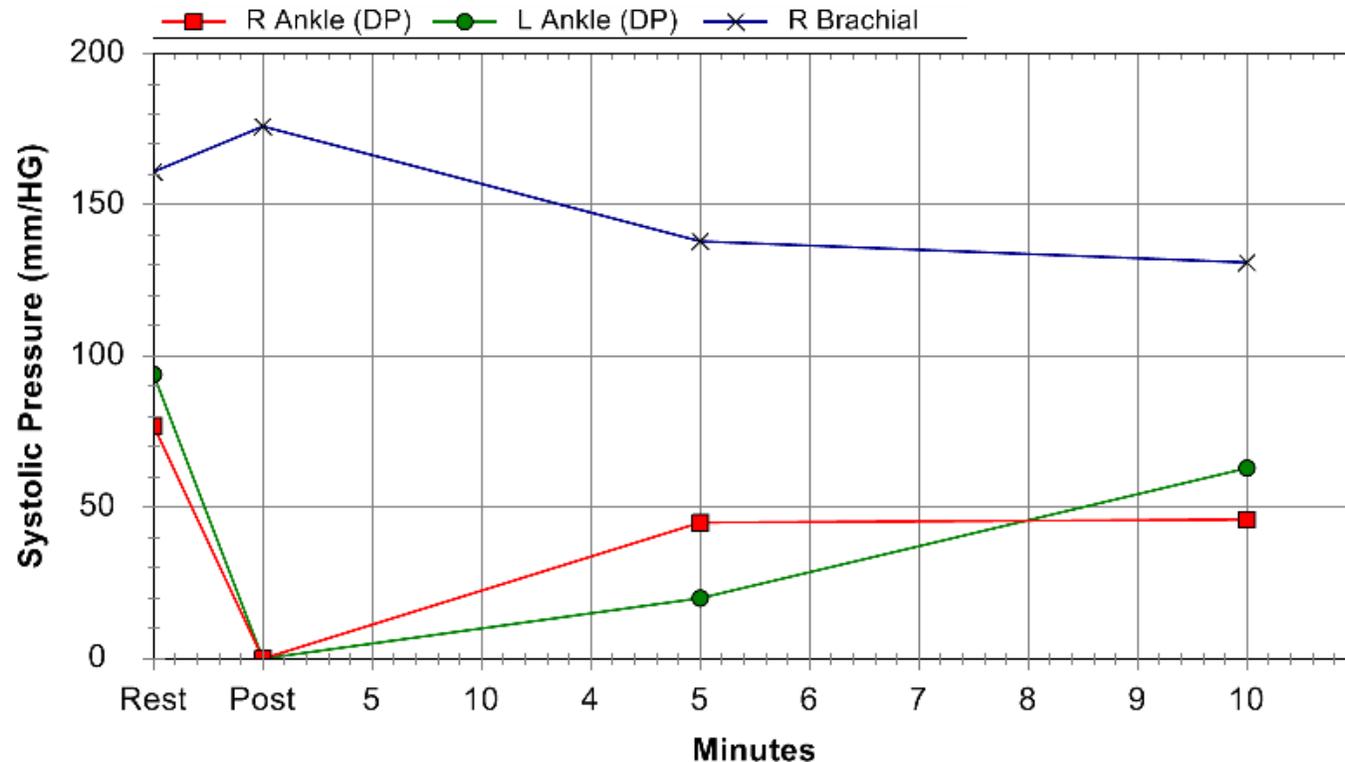
Recommendations: *Physiological Testing*

COR	LOE	Recommendations
I	B-NR	Patients with exertional non-joint-related leg symptoms and normal or borderline resting ABI (>0.90 and ≤ 1.40) should undergo exercise treadmill ABI testing to evaluate for PAD.
IIa	B-NR	In patients with PAD and an abnormal resting ABI (≤ 0.90), exercise treadmill ABI testing can be useful to objectively assess functional status.

Exercise ABI Testing

	Rest	Post	5	10
R Ankle (DP):	77	0	45	46
L Ankle (DP):	94	0	20	63
R Brachial:	161	176	138	131
R ABI:	0.48	0.00	0.33	0.35
L ABI:	0.58	0.00	0.14	0.48

Exercise Pressures



Resting ABIs

Right=0.48 Left=0.58

Immediate Post ABIs

Right=0.00 Left=0.00

Patient walked full 5 minutes of protocol but experienced moderately severe bilateral “calf burning.”



Critical Limb Ischemia (CLI)

A condition characterized by chronic (≥ 2 wk) ischemic rest pain, nonhealing wound/ulcers, or gangrene in 1 or both legs attributable to objectively proven arterial occlusive disease. The term CLI implies chronicity and is to be distinguished from ALI.

- The diagnosis of CLI is a constellation of both symptoms and signs. Arterial disease can be proved objectively with ABI, TBI, TcPO₂, or skin perfusion pressure. Supplementary parameters, such as absolute ankle and toe pressures and pulse volume recordings, may also be used to assess for significant arterial occlusive disease.
- However, a very low ABI or TBI does not necessarily mean the patient has CLI.

Toe-Brachial Index (TBI)

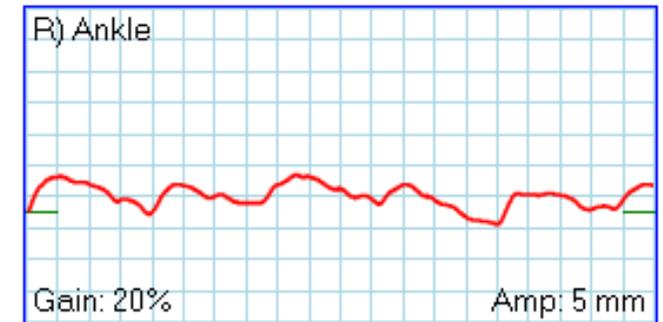


- Can be used to diagnose PAD with ABI > 1.4 or partially noncompressible vessels
- Great toe pressure measured using small digit cuff and a flow sensor
- Room must be warm to avoid vasoconstriction
- Digital vessels almost always compressible
- Compute ratio of toe pressure to brachial pressure
- Normal TBI > 0.7

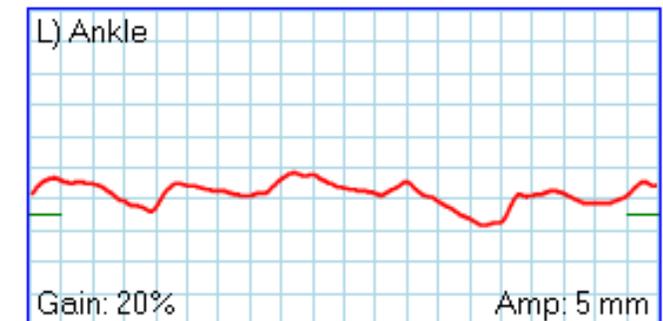
Partially Noncompressible Vessels or Why ABI Is Flawed in Suspected CLI

- 73-year-old man with diabetes and multiple bilateral leg wounds
- Ankle-brachial indices
 - Right ABI = 0.73 (mild)
 - Left ABI = 0.90 (borderline)
- BUT: PVR tracings don't match pressures at all!
 - Moderate-to-severe PAD bilaterally
- Due to partially noncompressible vessels
- Arterial duplex confirmed severe multi-vessel occlusive disease

Right ABI = 0.73



Left ABI = 0.90

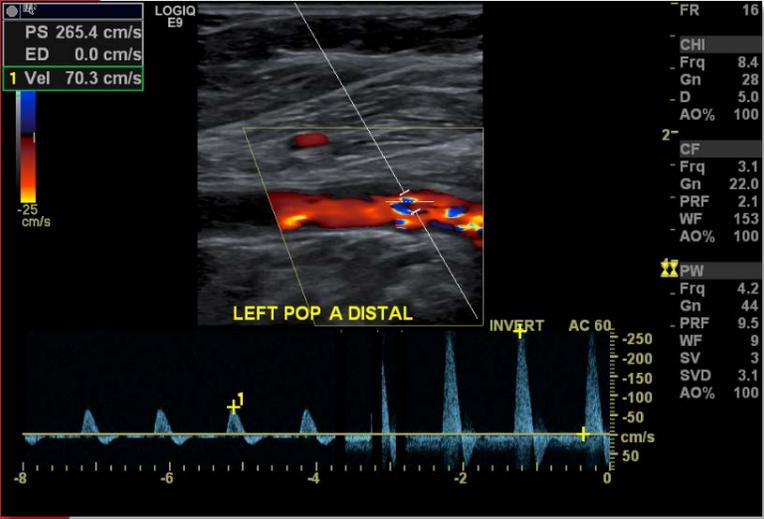


Recommendations: *Physiological Testing*

COR	LOE	Recommendations
I	B-NR	TBI should be measured to diagnose patients with suspected PAD when the ABI is greater than 1.40.
IIa	B-NR	In patients with normal (1.00–1.40) or borderline (0.91–0.99) ABI in the setting of nonhealing wounds or gangrene, it is reasonable to diagnose CLI by using TBI with waveforms, TcPO ₂ , or SPP.
IIa	B-NR	In patients with PAD with an abnormal ABI (≤ 0.90) or with noncompressible arteries (ABI > 1.40 and TBI ≤ 0.70) in the setting of nonhealing wounds or gangrene, TBI with waveforms, TcPO ₂ , or SPP can be useful to evaluate local perfusion.

Diagnostic Testing for the Patient With Suspected Lower Extremity PAD (Claudication or CLI)

Imaging for Anatomic Assessment



Anatomic Imaging Options for PAD

Duplex Ultrasound

- + Least expensive
- + No dye, no ionizing radiation
- Labor intensive for complete studies
- Not a perfect road map
- Generally reserved for f/u

MRA

- + Angiographic projections
- + No ionizing radiation
- Requires high degree of expertise
- May overestimate % stenosis
- Pacemaker contraindication
- Stent drop-out
- Risk of gadolinium related nephrogenic systemic fibrosis (GSF)

CT Angiography

- + Angiographic projections
- + Readily available at most institutions
- Requires IV contrast
- Ionizing radiation exposure

Digital Subtraction Arteriography (DSA)

- + The gold standard
- + Efficient if intervention is definitely needed
- Invasive
- Requires IV contrast
- Ionizing radiation exposure



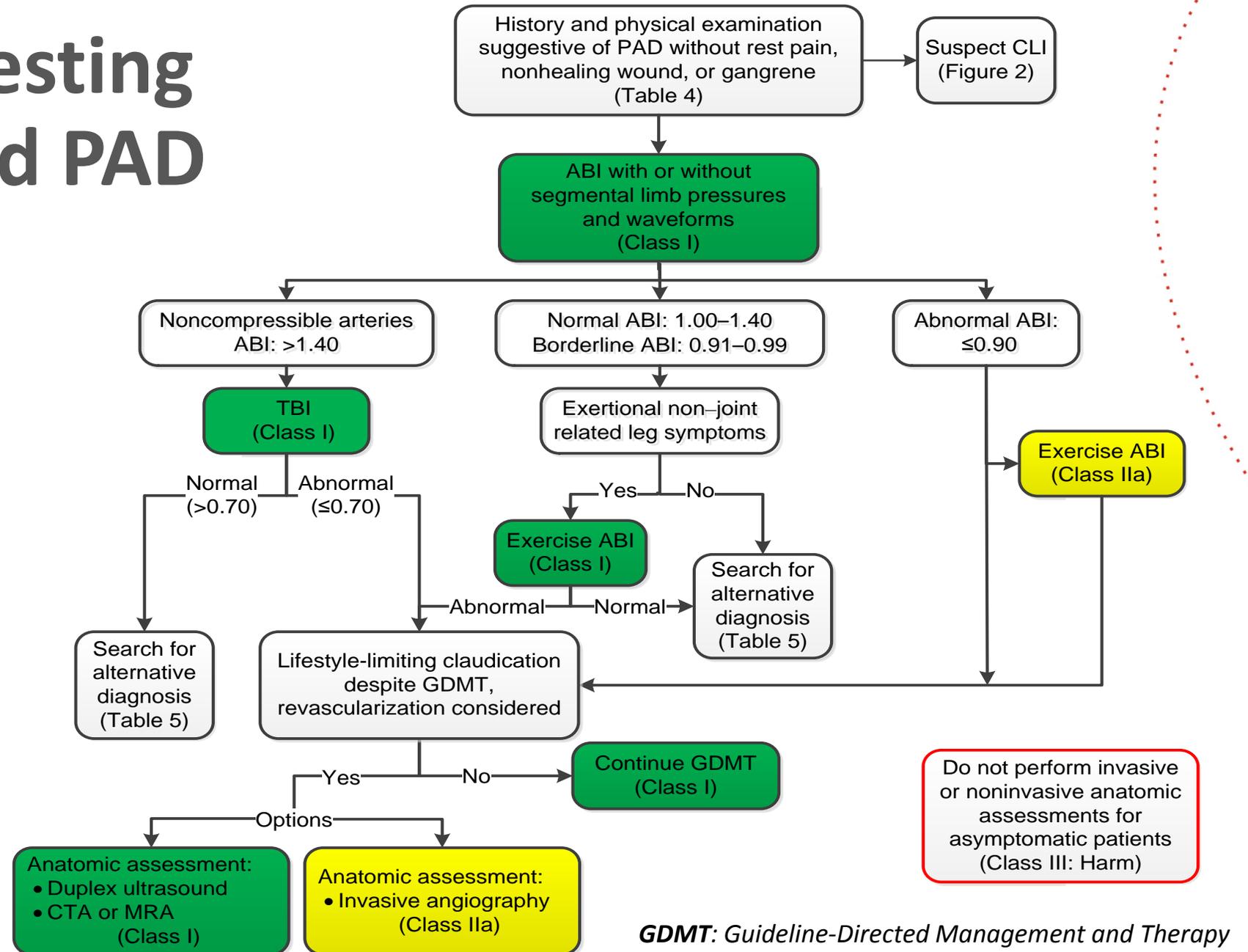
Recommendations:

Imaging for Anatomic Assessment

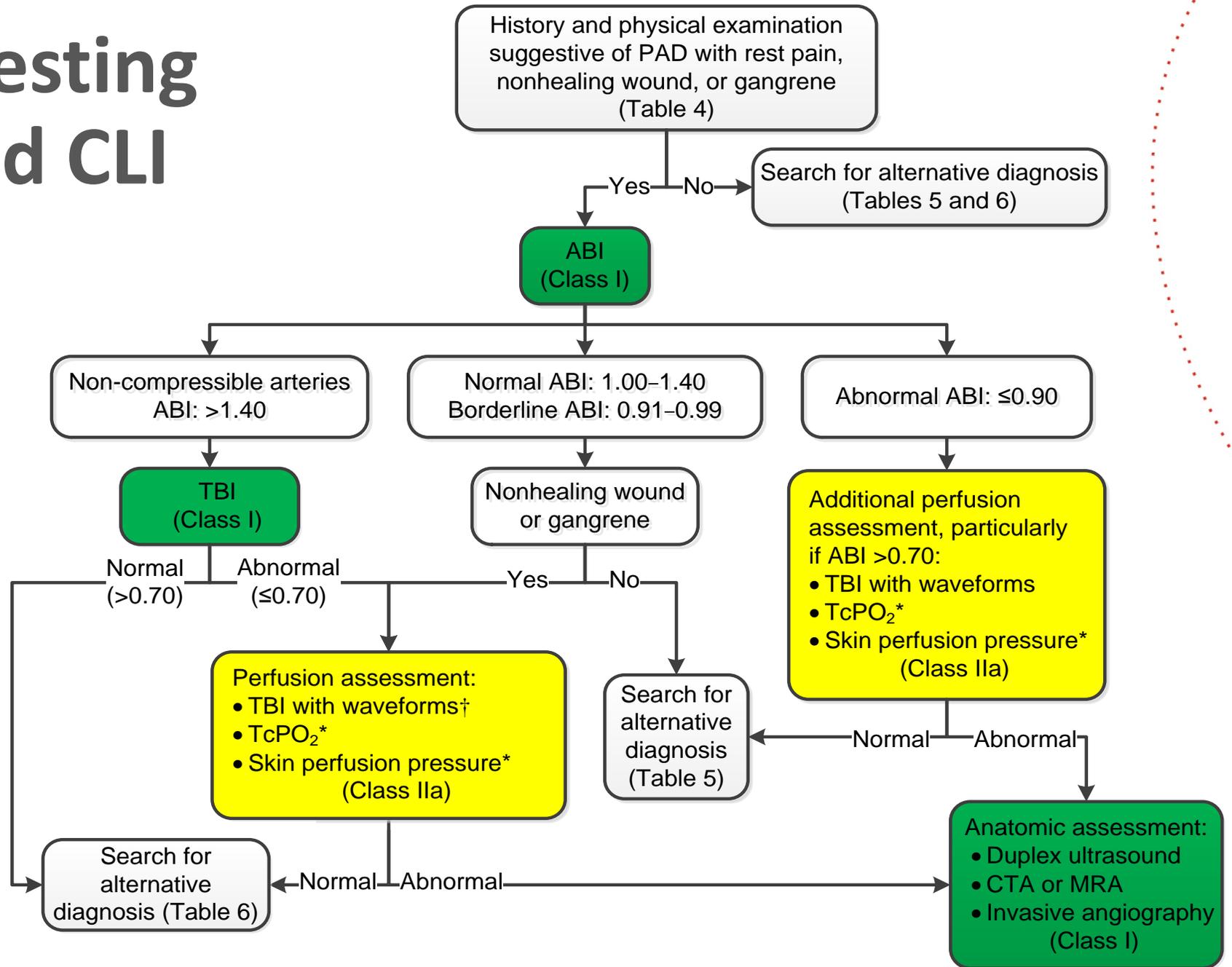
COR	LOE	Recommendations
I	B-NR	Duplex ultrasound, CTA, or MRA of the lower extremities is useful to diagnose anatomic location and severity of stenosis for patients with symptomatic PAD in whom revascularization is considered.
I	C-EO	Invasive angiography is useful for patients with CLI in whom revascularization is considered.
IIa	C-EO	Invasive angiography is reasonable for patients with lifestyle-limiting claudication with an inadequate response to GDMT for whom revascularization is considered.
III: Harm	B-R	Invasive and noninvasive angiography (<i>e.g.</i> , CTA, MRA) should not be performed for the anatomic assessment of patients with asymptomatic PAD.

GDMT: Guideline-Directed Management and Therapy

Diagnostic Testing for Suspected PAD (not CLI)



Diagnostic Testing for Suspected CLI





Medical Therapy for the Patient With PAD

Antiplatelet Agents

COR	LOE	Recommendations
I	A	Antiplatelet therapy with aspirin alone (range 75–325 mg per day) or clopidogrel alone (75 mg per day) is recommended to reduce MI, stroke, and vascular death in patients with symptomatic PAD.
IIa	C-EO	In asymptomatic patients with PAD (ABI ≤ 0.90), antiplatelet therapy is reasonable to reduce the risk of MI, stroke, or vascular death.
IIb	B-R	In asymptomatic patients with borderline ABI (0.91–0.99), the usefulness of antiplatelet therapy to reduce the risk of MI, stroke, or vascular death is uncertain.
IIb	B-R	The effectiveness of dual-antiplatelet therapy (aspirin and clopidogrel) to reduce the risk of cardiovascular ischemic events in patients with symptomatic PAD is not well established.
IIb	C-LD	Dual-antiplatelet therapy (aspirin and clopidogrel) may be reasonable to reduce the risk of limb-related events in patients with symptomatic PAD after lower extremity revascularization.
IIb	B-R	The overall clinical benefit of vorapaxar added to existing antiplatelet therapy in patients with symptomatic PAD is uncertain.

Oral Anticoagulation



COR	LOE	Recommendations
IIb	B-R	The usefulness of anticoagulation to improve patency after lower extremity autogenous vein or prosthetic bypass is uncertain.
III: Harm	A	Anticoagulation should not be used to reduce the risk of cardiovascular ischemic events in patients with PAD.

Statin Agents

COR	LOE	Recommendations
I	A	Treatment with a statin medication is indicated for all patients with PAD.

Antihypertensive Agents

COR	LOE	Recommendations
I	A	Antihypertensive therapy should be administered to patients with hypertension and PAD to reduce the risk of MI, stroke, heart failure, and cardiovascular death.
IIa	A	The use of angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers can be effective to reduce the risk of cardiovascular ischemic events in patients with PAD.

Glycemic Control

COR	LOE	Recommendations
I	C-EO	Management of diabetes mellitus in the patient with PAD should be coordinated between members of the healthcare team.
IIa	B-NR	Glycemic control can be beneficial for patients with CLI to reduce limb-related outcomes.

Smoking Cessation



COR	LOE	Recommendations
I	A	Patients with PAD who smoke cigarettes or use other forms of tobacco should be advised at every visit to quit.
I	A	Patients with PAD who smoke cigarettes should be assisted in developing a plan for quitting that includes pharmacotherapy (<i>i.e.</i> , <i>varenicline</i> , <i>bupropion</i> , and/or <i>nicotine replacement therapy</i>) and/or referral to a smoking cessation program.
I	B-NR	Patients with PAD should avoid exposure to environmental tobacco smoke at work, at home, and in public places.

Cilostazol, Pentoxifylline, and Chelation Therapy

COR	LOE	Recommendations
Cilostazol		
I	A	Cilostazol is an effective therapy to improve symptoms and increase walking distance in patients with claudication.
Pentoxifylline		
III: No Benefit	B-R	Pentoxifylline is not effective for treatment of claudication.
Chelation Therapy		
III: No Benefit	B-R	Chelation therapy (<i>e.g., ethylenediaminetetraacetic acid</i>) is not beneficial for treatment of claudication.

Homocysteine Lowering

COR	LOE	Recommendation
III: No Benefit	B-R	B-complex vitamin supplementation to lower homocysteine levels for prevention of cardiovascular events in patients with PAD is not recommended.

Minimizing Tissue Loss in Patients With PAD



COR	LOE	Recommendations
I	C-LD	Patients with PAD and diabetes mellitus should be counseled about self-foot examination and healthy foot behaviors.
I	C-LD	In patients with PAD, prompt diagnosis and treatment of foot infection are recommended to avoid amputation.
IIa	C-LD	In patients with PAD and signs of foot infection, prompt referral to an interdisciplinary care team (Table 8) can be beneficial.
IIa	C-EO	It is reasonable to counsel patients with PAD without diabetes mellitus about self-foot examination and healthy foot behaviors.
IIa	C-EO	Biannual foot examination by a clinician is reasonable for patients with PAD and diabetes mellitus.

Structured Exercise Therapy



COR	LOE	Recommendations
I	A	In patients with claudication, a supervised exercise program is recommended to improve functional status and QoL and to reduce leg symptoms.
I	B-R	A supervised exercise program should be discussed as a treatment option for claudication before possible revascularization.
IIa	A	In patients with PAD, a structured community- or home-based exercise program with behavioral change techniques can be beneficial to improve walking ability and functional status.
IIa	A	In patients with claudication, alternative strategies of exercise therapy, including upper-body ergometry, cycling, and pain-free or low-intensity walking that avoids moderate-to-maximum claudication while walking, can be beneficial to improve walking ability and functional status.

2016 ACC/AHA Lower Extremity PAD Guideline

Screening for Atherosclerotic Disease
in Other Vascular Beds for the Patient With PAD

Screening for Atherosclerotic Disease in Other Vascular Beds for the Patient With PAD

Subclavian Stenosis



COR	LOE	Recommendations
I	B-NR	Patients with PAD should undergo noninvasive blood pressure measurement in both arms at least once during the initial assessment.

- PAD is a risk factor for subclavian stenosis.¹
- Inter-arm blood pressure difference of >15 to 20 mm Hg suggestive of subclavian (or innominate) artery stenosis.
- Identification of unequal blood pressures in the arms allows for more accurate measurement of blood pressure in the treatment of hypertension (*e.g., blood pressure is taken at the arm with higher measurements*).
- In the absence of symptoms (*e.g., arm claudication or symptoms of vertebral artery steal*), no further imaging or intervention is warranted.

Screening for Atherosclerotic Disease in Other Vascular Beds for the Patient With PAD

Abdominal Aortic Aneurysm (AAA)

COR	LOE	Recommendations
Ia	B-NR	A screening duplex ultrasound for AAA is reasonable in patients with symptomatic PAD.

- PAD demonstrated as a risk factor for AAA.
- Recommendation refers to screening patients with symptomatic PAD for AAA regardless of patient age, sex, smoking history, or family history of AAA.
- Recommendations for screening the general population with these risk factors for AAA have been previously published.



Screening for Atherosclerotic Disease in Other Vascular Beds for the Patient With PAD

Prevalence of atherosclerosis in the coronary, carotid, and renal arteries higher in patients with PAD than in those without PAD.

- However, intensive atherosclerosis risk factor modification in patients with PAD justified regardless of the presence of disease in other arterial beds.
- Only justification for screening for disease in other arterial beds is if revascularization results in a reduced risk of MI, stroke, or death, and this has never been shown.
- Thus, no evidence to demonstrate that screening all patients with PAD for asymptomatic atherosclerosis in other arterial beds improves clinical outcome.
- Intensive treatment of risk factors through GDMT is the principle method for preventing adverse cardiovascular ischemic events from asymptomatic disease in other arterial beds.

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Evidence Gaps and Future Research
Directions Identified by the GWC



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PAD Evidence Gaps & Future Research Directions

- Basic science and translational studies to better understand the vascular biology of endovascular therapies and bypass grafting and to develop new methods for preventing restenosis after revascularization
- Determination of risk factors for progression from asymptomatic PAD to symptomatic disease, including CLI
- RCTs to determine the value of using the ABI to identify asymptomatic patients with PAD for therapies to reduce cardiovascular risk (*e.g., antiplatelet agents, statins, and other therapies*)
- Advancement in PAD diagnostics
- Comparative-effectiveness studies to determine the optimal antiplatelet therapy for prevention of cardiovascular and limb-related events in patients with PAD
- Development of additional medical therapies for claudication—an area of unmet medical need with a currently limited research pipeline

PAD Evidence Gaps & Future Research Directions

- Studies to investigate the role of dietary intervention, in addition to statin therapy, to improve outcome and modify the natural history of PAD
- Additional research to identify the best community- or home-based exercise programs for patients with PAD to maximize functional status and improve QoL, as well as the role of such exercise programs before or in addition to revascularization
- Development and validation of improved clinical classification systems for PAD that incorporate symptoms, anatomic factors, and patient-specific risk factors and can be used to predict clinical outcome and optimize treatment approach
 - *Example: SVS Wifi limb classification system for CLI*
- Comparative- and cost-effectiveness studies of the different endovascular technologies for treatment of claudication and CLI
- Additional studies to demonstrate the impact of multisocietal registries on clinical outcomes and appropriate use

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Advocacy Priorities
Identified by the GWC

Advocacy Priorities

1. Availability of the ABI as the initial diagnostic test to establish the diagnosis of PAD in patients with history or physical examination findings suggestive of PAD
2. Insuring access to supervised exercise programs for patients with PAD
 - Exciting update: Medicare coverage issued 3.2.2017.
3. Incorporation of patient-centered outcomes into the process of regulatory approval of new medical therapies and revascularization technologies
 - *Not only safety and target-lesion patency but also patient-centered outcomes, such as functional parameters and QoL which are so important for patients with PAD*

Summary: Scope of the 2016 PAD Guideline

- Clinical Assessment for PAD
- Diagnostic Testing for the Patient With Suspected Lower Extremity PAD (Claudication or CLI)
- Screening for Atherosclerotic Disease in Other Vascular Beds for the Patient With PAD
- Medical Therapy for the Patient With PAD
- Structured Exercise Therapy
- Minimizing Tissue Loss in Patients With PAD
- Revascularization for Claudication
- Management of CLI
- Management of Acute Limb Ischemia
- Longitudinal Follow-Up
- Evidence Gaps and Future Research Directions
- Advocacy Priorities



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