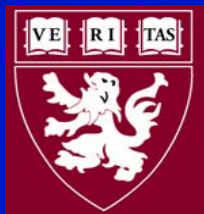


Screening for Peripheral Arterial Disease: Impact on Life and Limb

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Conflicts of Interest

- **Consultant**
 - Cordis Endovascular (Modest)
 - Boston Scientific (Modest)
 - Pathway Medical (Modest)
 - Paragon IP (Modest)
 - Proteon Therapeutics (Modest)
 - X-Tent, Inc (Modest)
 - Harvard Clinical Research Institute (Modest)
 - Bacchus Vascular, Inc (Modest)
- **Equity**
 - Access Closure, Inc (Modest)
 - Square One, Inc (Modest)
 - Vascular Therapies, Inc (Modest)
 - Icon Interventional, Inc (Modest)
 - Setagon (Modest)
- **Speaker's Bureau**
 - Bristol-Myers/Sanofi-Aventis Pharmaceuticals Partnership (Modest)
- **Research Support**
 - Pfizer, Inc.
 - Abbott Vascular
 - Genzyme
 - ActivBiotics

April, 2007

The Prevalence of P.A.D. Increases with Age

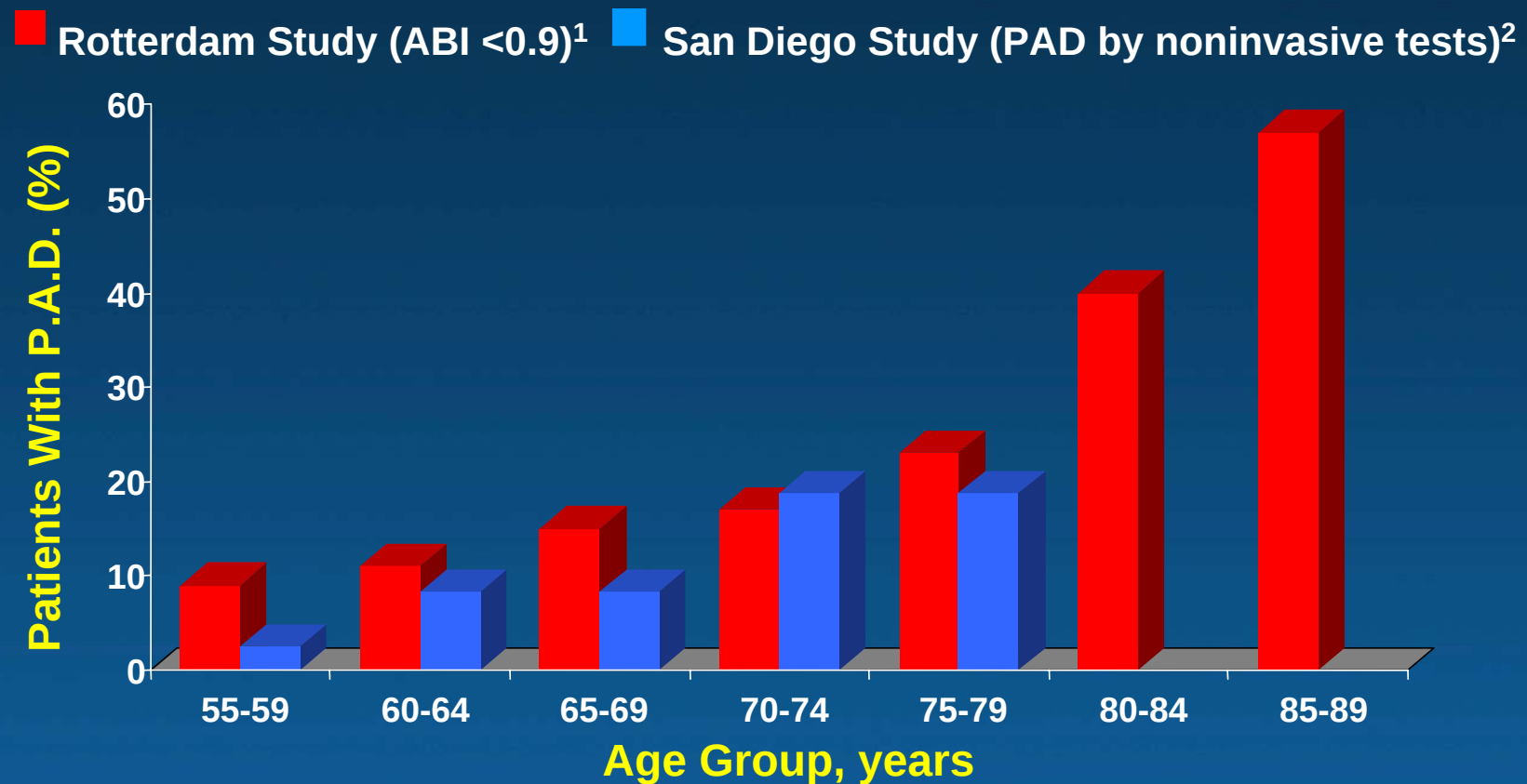
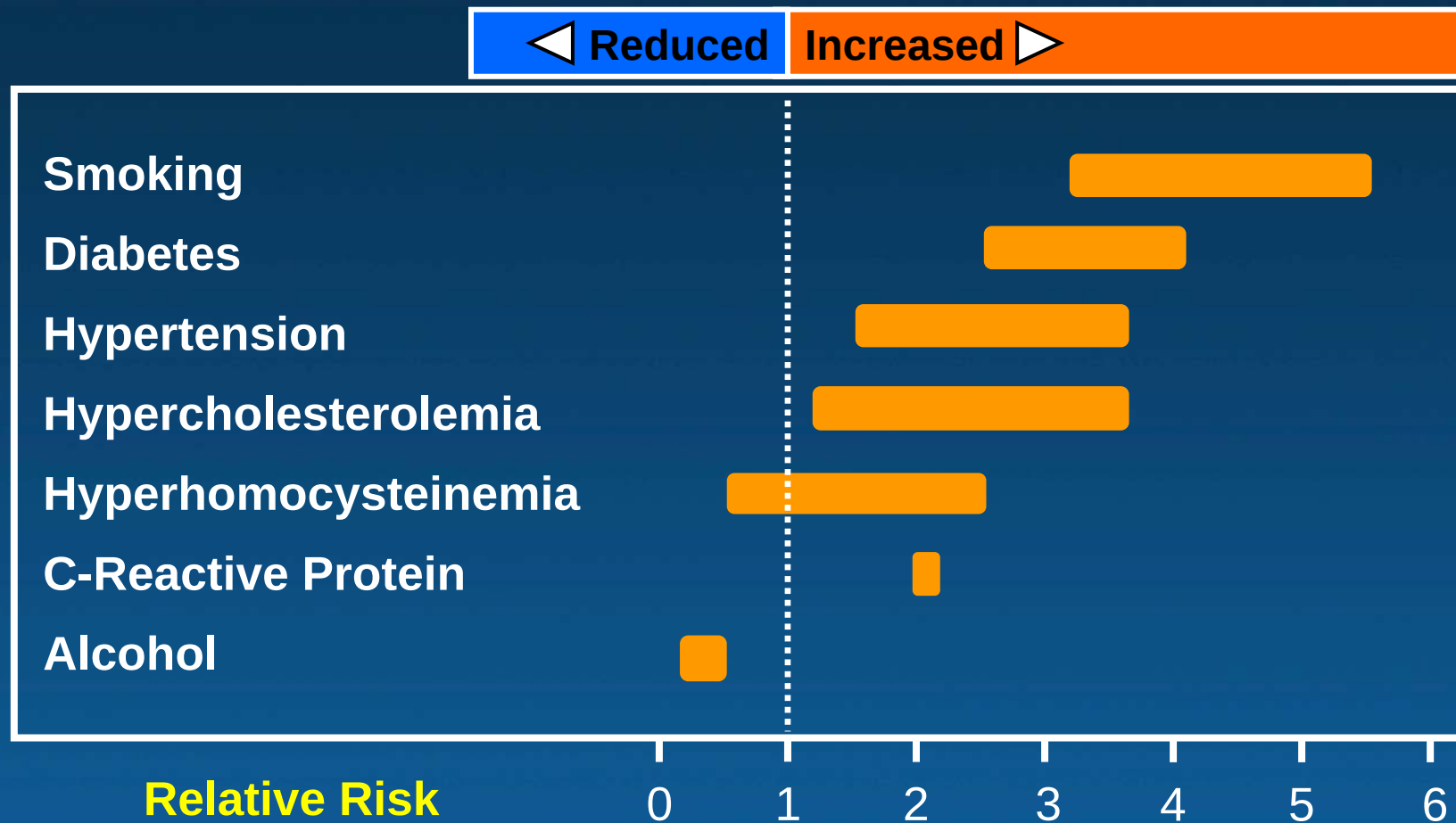


Figure adapted from Golomb BA, Criqui MH, Bundens WP. Epidemiology of peripheral arterial disease. In: Creager MA, ed. *Management of Peripheral Arterial Disease: Medical, Surgical and Interventional Aspects*. London: ReMEDICA Publishing; 2000:1-18.

1. Meijer WT, et al. *Arterioscler Thromb Vasc Biol*. 1998;18:185-192.

2. Criqui MH, et al. *Circulation*. 1985;71:510-515.

Risk Factors for P.A.D.



Newman AB, et al. *Circulation*. 1993;88:837-845; Hiatt WR, et al. *Circulation*. 1995;92:614-621; Graham IM, et al. *JAMA*. 1997;277:1775-1781; TASC Working Group. *J Vasc Surg*. 2000;31(1 pt 2):S1-S288; Ridker PM, et al. *Circulation*. 1998;97:425-428.

Peripheral Arterial Disease: *Why Care about P.A.D.?*

A “Call to Action” to
Recognize, Diagnose, and Treat P.A.D.

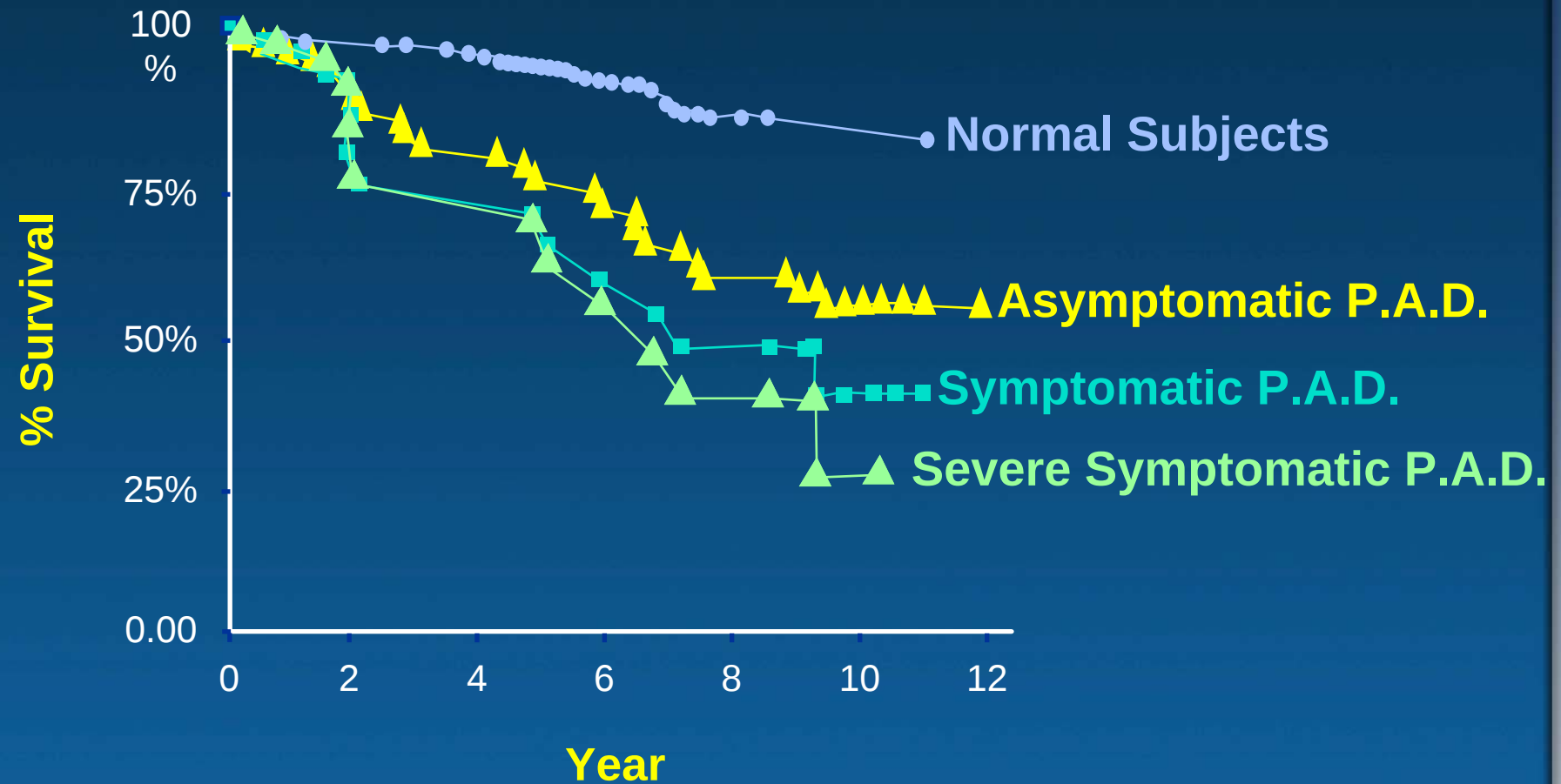
- Major cause of acute and chronic disability
- Limits functional capacity
- Impairs quality of life
- Major cause of limb amputation
- Marked increased risk of nonfatal cardiovascular ischemic events (MI and stroke) and death
- Early detection and treatment decreases risk of MI, stroke and death

Peripheral Arterial Disease:

Consequences of undiagnosed and untreated P.A.D. extend well beyond leg stenosis

The prognosis of patients with lower extremity P.A.D. is characterized by an increased short-term risk for cardiovascular ischemic events due to concomitant coronary artery disease and cerebrovascular disease.

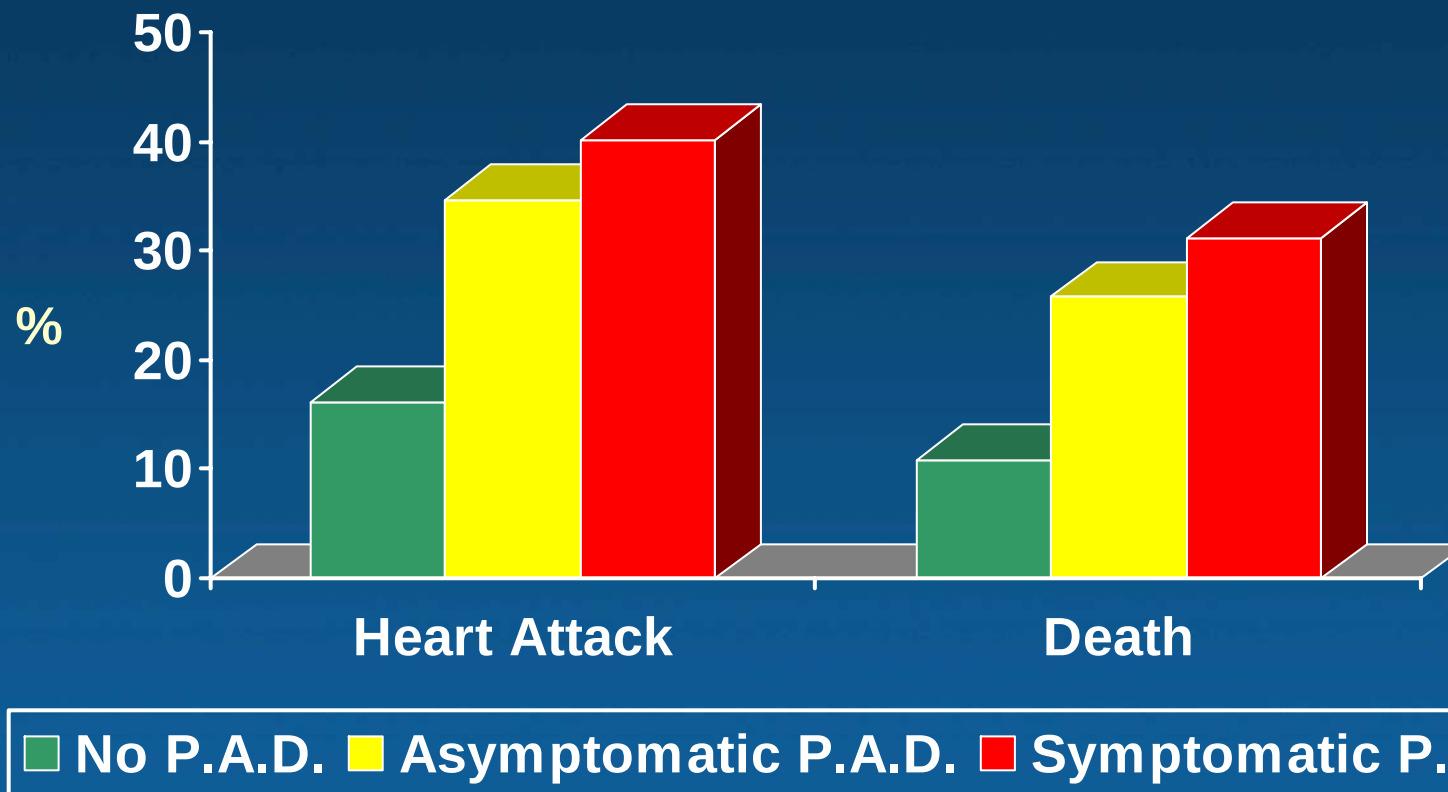
P.A.D. Survival



Criqui MH, et al. *N Engl J Med.* 1992;326:381-386.

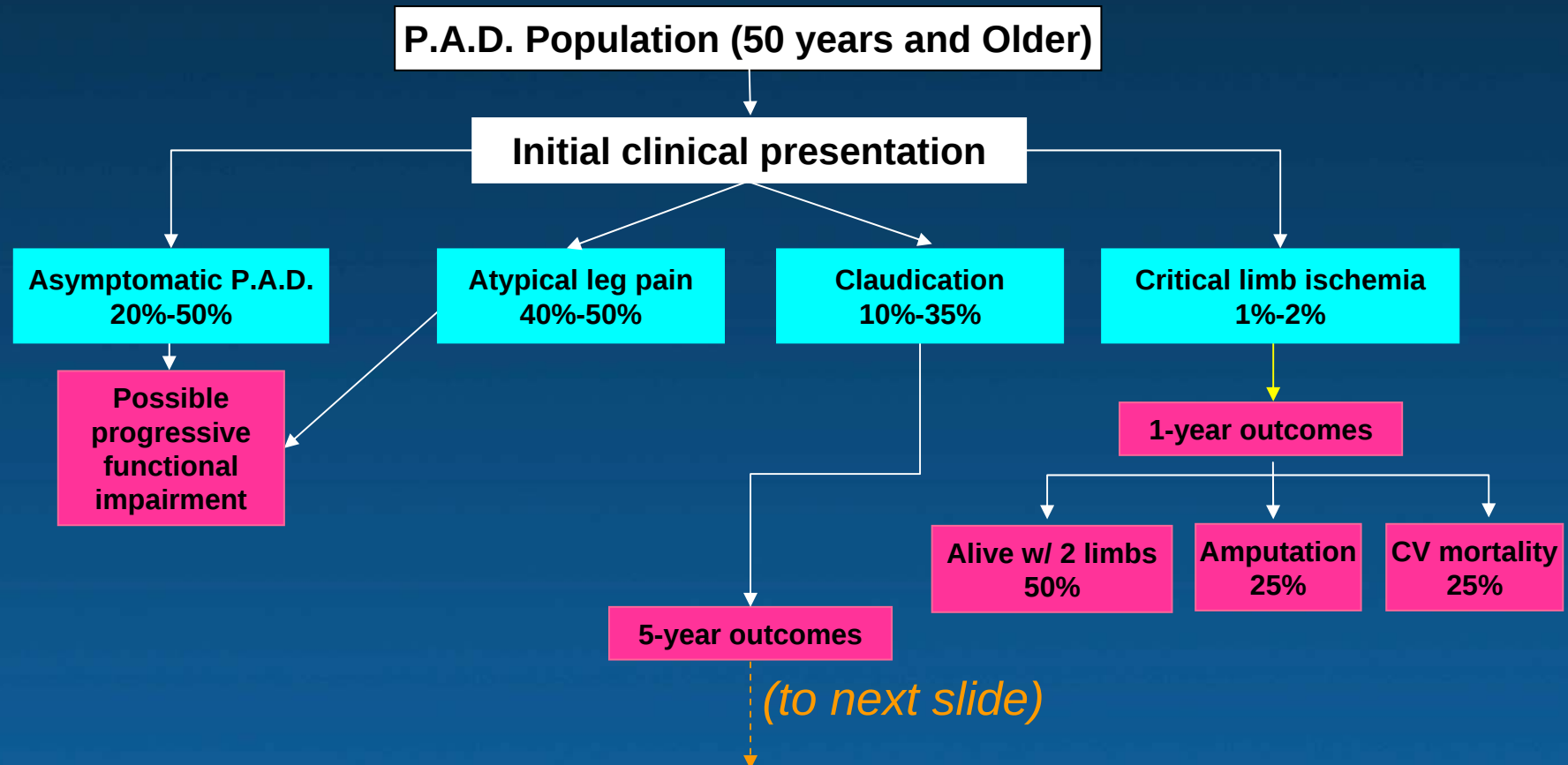
Contemporary P.A.D. Myocardial Infarction and Death

3649 subjects (average age, 64 yrs) followed up for 7.2 years.



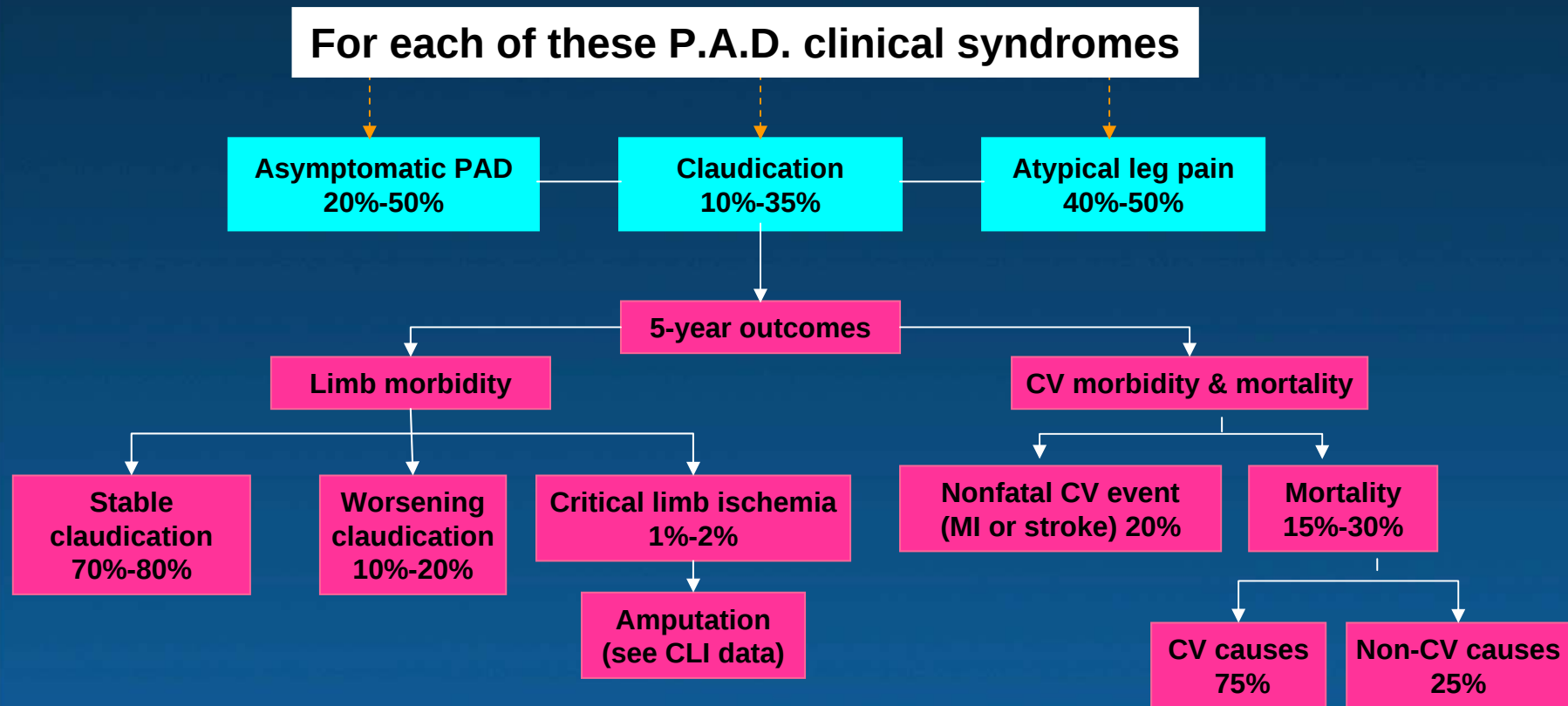
Hooi JD, et al. J Clin Epid 2004;57:294–300.

Natural History of Atherosclerotic Lower Extremity P.A.D.



Hirsch AT, et al. ACC/AHA 2005 guidelines for the management of patients with peripheral arterial disease (lower extremity, renal, mesenteric, and abdominal aortic): a report of the American College of Cardiology/American Heart Association 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]). Available at: J Am Coll Cardiol 2006;47:e1-e192.

Natural History of Atherosclerotic Lower Extremity P.A.D.



“Medical Treatment” is a mandatory component of the health care needs for this fragile population.

Perform a Vascular Exam

- Blood pressure is measured in both arms
- Palpate carotid pulses for carotid upstrokes and amplitude; auscultation for bruits
- Palpate the abdomen (for AAA) and auscultate the abdomen, flank, and femoral arteries for bruits
- Palpate the brachial, radial, femoral, popliteal, dorsalis pedis and posterior tibial pulses
- Evaluate the color, temperature, and integrity of the lower extremity skin

These findings should be charted in the medical record

Perform an Ankle-Brachial Index (ABI)

- An ankle-brachial index exam is a noninvasive test used to assess circulation to the lower extremities. It is the ratio of the ankle pressure to the highest of the brachial (arm) pressures.
- Most cost-effective tool confirming the diagnosis of P.A.D. detection. It should be a routine test in primary care practice:
 - ✓ Individuals at risk for lower extremity P.A.D.
 - ✓ Individuals with classic claudication symptoms or chronic symptoms such as ischemic rest pain, gangrene, non-healing ulcers
- An abnormal ABI is a powerful predictor of increased risk of future atherosclerotic cardiovascular events:
 - ✓ The lower the ABI, the worse the prognosis
- Perform the ABI on individuals who are at risk for P.A.D.!

The ABI Target Population:

Asymptomatic or Symptomatic Individuals at Risk for Lower Extremity P.A.D.

Asymptomatic Individuals

- Age less than 50 years, with diabetes and one other atherosclerosis risk factor
- Age 50 to 69 years and history of smoking or diabetes
- Age 70 years and older regardless of risk factor profile

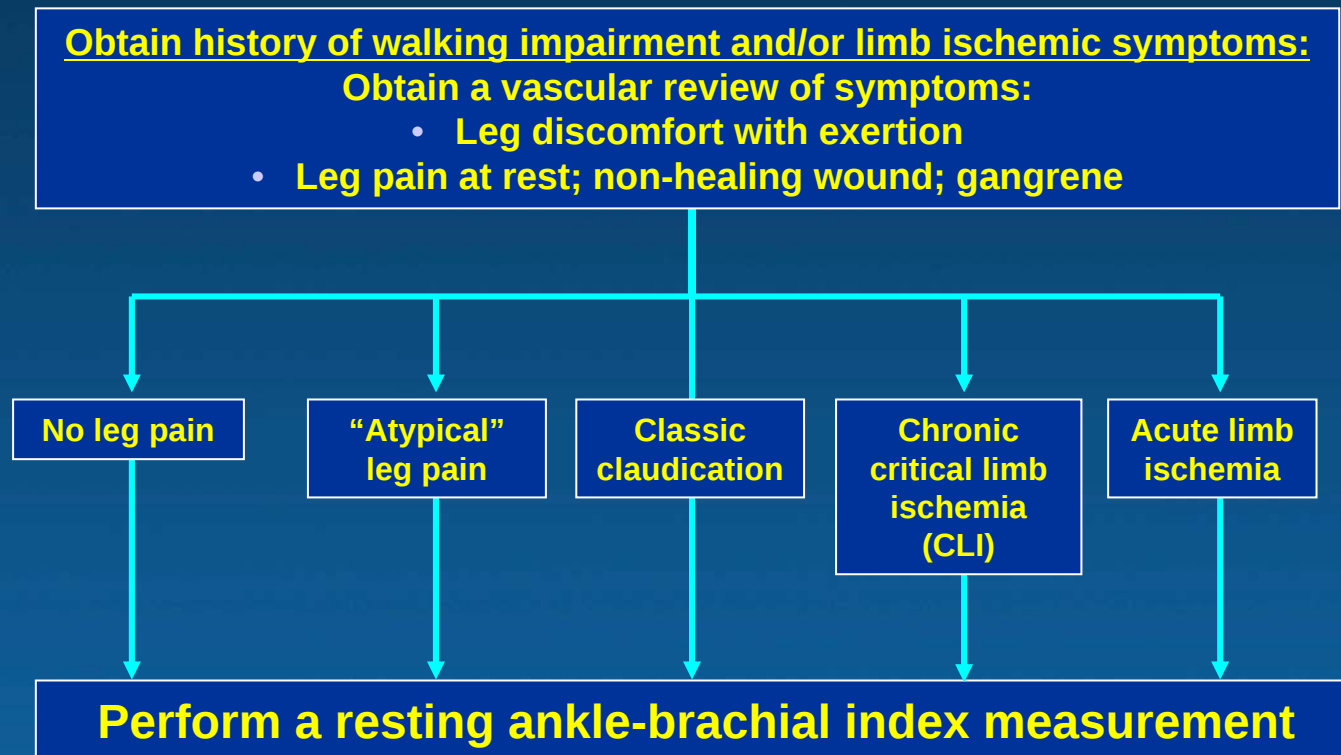
Symptomatic Individuals

- Leg symptoms with exertion (suggestive of claudication) or ischemic rest pain
- Abnormal lower extremity pulse examination
- Non-healing leg wounds or ulcers
- Known atherosclerotic coronary, carotid, or renal arterial disease

Based on a targeted P.A.D. prevalence of > 20-25%

ACC/AHA Guideline for the Management of P.A.D.: *Steps Toward the Diagnosis of P.A.D.*

Recognizing the “at risk” groups leads to recognition of the five main P.A.D. clinical syndromes:

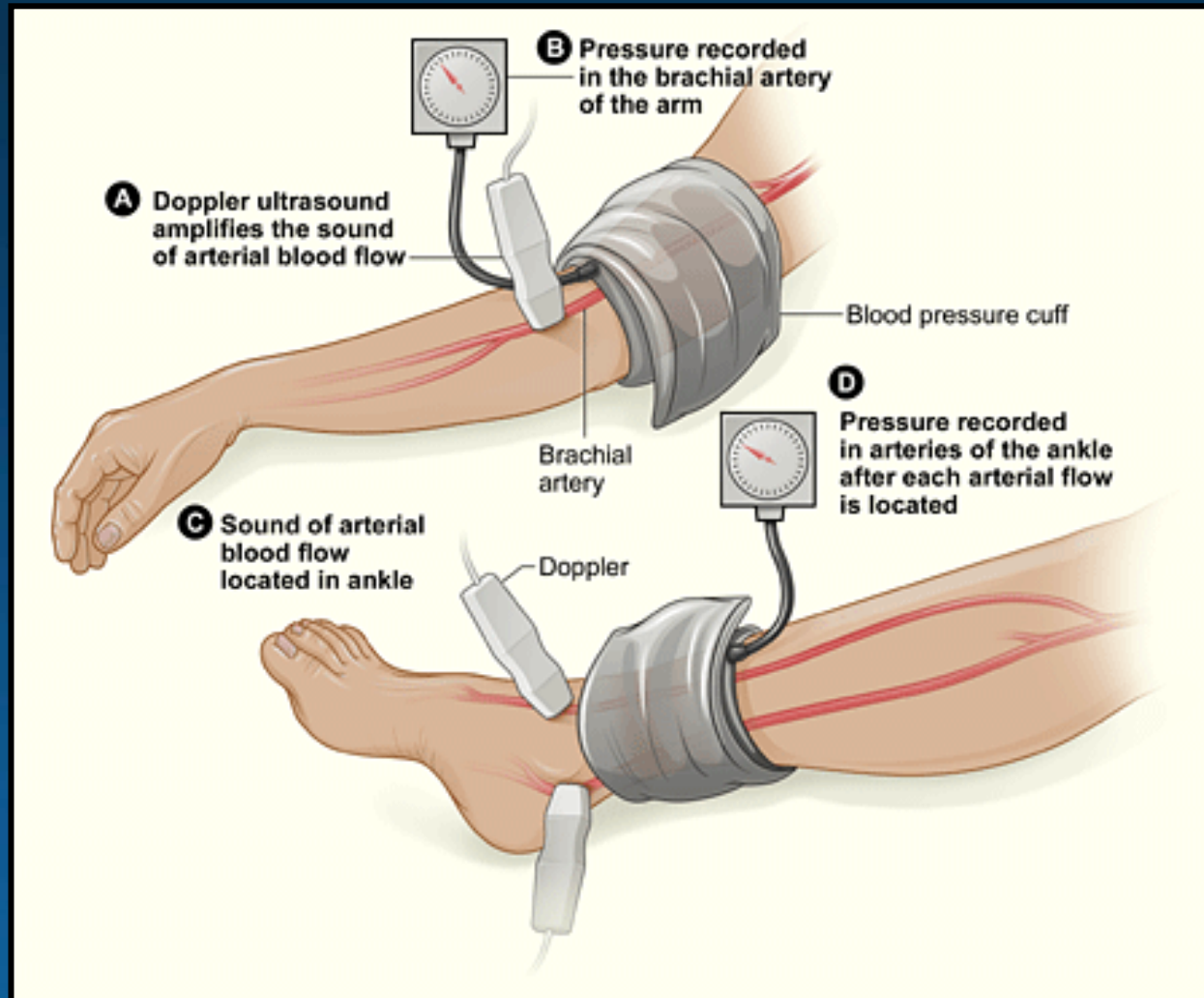


Understanding the ABI

The ratio of the higher systolic brachial pressure and the higher systolic ankle pressure for each leg

$$\text{ABI} = \frac{\text{Ankle systolic pressure}}{\text{Higher brachial artery systolic pressure}}$$

ABI Procedure



Calculate the ABI

1. For the left side, divide the left ankle pressure by the highest brachial pressure and record the result.
2. Repeat the steps for the right side.
3. Record the ABI's and place the results in the medical record.

Right Leg ABI

Left Leg ABI

Right Ankle Pressure

Highest Arm Pressure

Left Ankle Pressure

Highest Arm Pressure

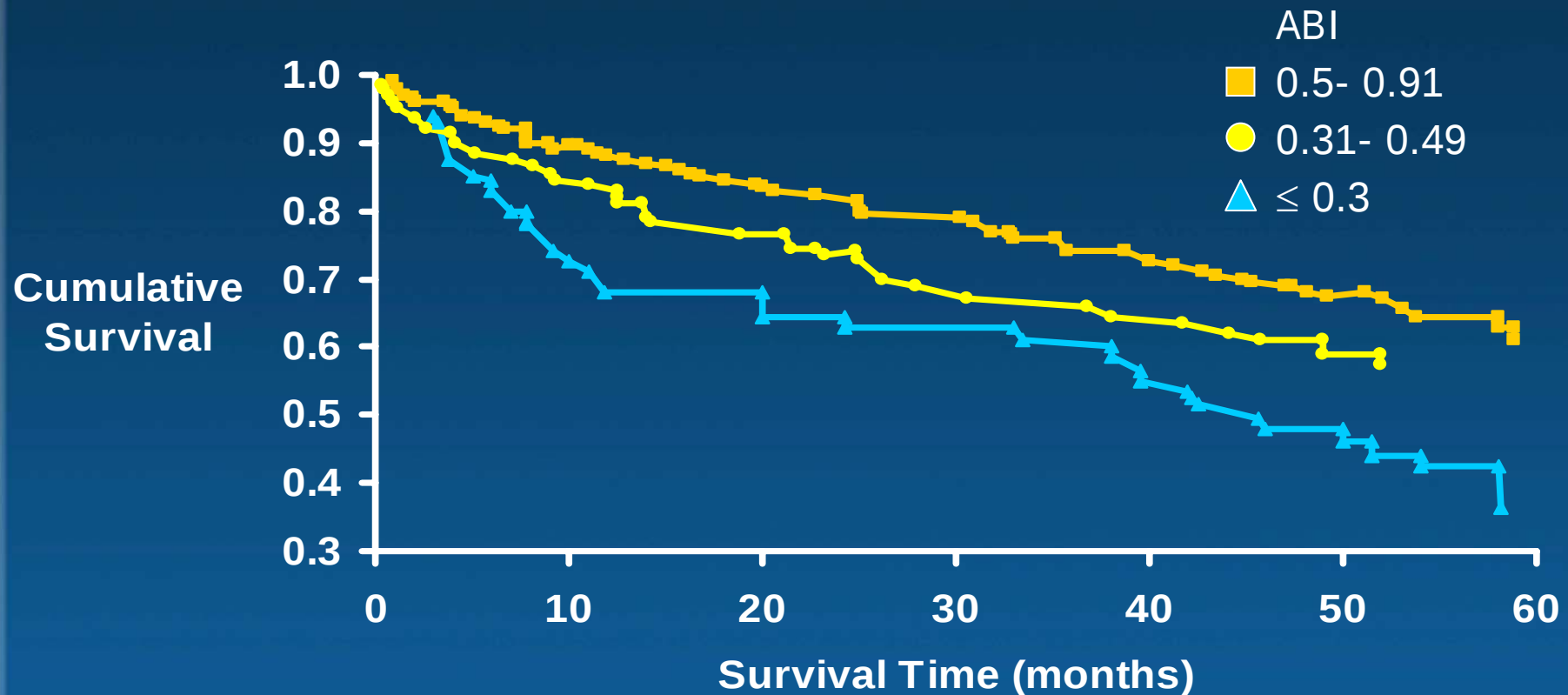
ABI Interpretation

≤ 0.90 is diagnostic of peripheral arterial disease

Interpreting the Ankle-Brachial Index

ABI	Interpretation
1.00–1.29	Normal
0.91–0.99	Borderline
0.41–0.90	Mild-to-moderate disease
≤ 0.40	Severe disease
≥ 1.30	Noncompressible

The ABI as Predictor of Mortality: *Implications for Primary Care*



The lower the ABI, the worse the prognosis

Adapted from McDermott MM et al. *J Gen Intern Med.* 1994;9:445-9.

What do you do in response to an abnormal ABI?

An ABI $\leq$ 0.90 at rest is the threshold for the diagnosis of P.A.D.

Prescribe Effective Evidence-Based Treatments: ***Lower the risk of MI, stroke, limb amputation, and death***

- Smoking cessation counseling and referral
- Lipid lowering targeted to National Cholesterol Education Program (ATPIII) Treatment Guidelines:
 - ✓ Dietary modification
 - ✓ Statin to achieve a target LDL cholesterol of < 100 mg/dl; or to ≤ 70 for patients at “high risk” (P.A.D. and a history of arterial disease in other beds or another risk factor not at goal)
 - ✓ Fibrate and/or niacin for low HDL and increased triglycerides

Prescribe Effective Evidence-Based Treatments: ***Lower the risk of MI, stroke, limb amputation and death***

- Hypertension: For non-DM: < 140/90 mmHg; or to < 130/80 mmHg for individuals with DM or chronic kidney disease
 - ✓ Beta blockers not contraindicated;
 - ✓ ACE-I cardioprotective in P.A.D.
- Diabetes: Blood sugar control (A1C < 7%) and foot care
- Antiplatelet therapy: ASA or clopidogrel

Prescribe Effective Evidence-Based Treatments: ***Lower the risk of MI, stroke, limb amputation and death***

All individuals with P.A.D. should achieve comprehensive risk factor modification.

Then, to improve claudication symptoms:

- Supervised exercise training
- Claudication medication:
 - ✓ Cilostazol (100 mg/bid) unless HF is present
 - ✓ Improves maximal walking distance and symptoms
- Selective use of revascularization (endovascular or surgical)

What do you do in response to an abnormal ABI?

An ABI ≥ 1.30 is not normal, and should be interpreted carefully.

An ABI ≥ 1.30 occurs in less than 2%-5% of the adult population

Resting ABI ≥ 1.3

- Represents “non-compressible” ankle arteries, and is observed most commonly in individuals with long-standing diabetes or renal insufficiency, or the very elderly.
- A “supranormal ABI” is not helpful in ruling out peripheral arterial disease. If symptoms or the physical examination suggest P.A.D., an alternative testing strategy should be considered.
- Recent data suggests that a high ABI may also be associated with an adverse prognostic risk of CVD events.
- Alternative noninvasive P.A.D. tests could include:
 - ✓ toe systolic pressures or toe-brachial index (TBI)
 - ✓ pulse volume recordings (PVR)
 - ✓ duplex ultrasound

– *If these tests are normal, there is no P.A.D.*

What do you do in response to a normal ABI in the presence of limb symptoms?

A normal ABI (0.90 – 1.29) can exist in the presence of leg symptoms.

Are these symptoms claudication or pseudoclaudication?

Resting ABI > 0.90 – 1.29

Typical claudication symptoms or a clinical presentation suggestive of P.A.D.	• Consider exercise ABI • If the post-exercise ABI is normal: – <i>Consider spinal pseudoclaudication</i> • Consider duplex US, MRA, or CTA if there is evidence that the pedal arteries are non-compressible
Atypical symptoms	• Consider other non-arterial causes of leg pain (e.g., neuropathy, DJD, compartment syndrome, etc.)

Indications to Refer Patients to a Vascular Specialist

Individuals who do not improve with comprehensive medical therapy:

- Vocation- or lifestyle-limiting claudication
- Ischemic rest pain
- Non-healing ulcer or gangrene

Critical limb ischemia (ischemic rest pain, non-healing wounds, or gangrene) should be immediately referred for specialty care

How to Implement This P.A.D. GAP/QI Initiative in the Office

1) Meet with all office staff: “Project Kick-off”

- Review slide kit with staff: Science; background; overview; purpose and goals of project; tools and processes
- Assign an office-based staff member to lead project and establish team of all involved in processes
- Define responsibilities and expectations; secure buy-in
- Set target rates for performance measures based on baseline indicator rates

How to Implement This P.A.D. GAP/QI Initiative in the Office (continued)

2) Team Develops An Action Plan

- Review tools and adopt tools/processes appropriate for office practice
- Set timelines for implementation
- Develop strategies to implement and monitor tools and processes; then, embed them into office patient flow
- Key Intervention: Obtain an ABI measurement on all patients with symptoms or at increased risk of P.A.D.

How to Implement This P.A.D. GAP/QI Initiative in the Office (continued)

3) Physician meets with Project Team monthly:

- Provide clinical direction and support
- Review progress of project and data reports of performance measures
- Identify and overcome barriers
- Share successes and lessons learned
- “Learning and Sharing” of new information; updates; insight from collaborative; aggregate results
- Reinforce participation and buy-in

How to Implement this P.A.D. GAP/QI Initiative in the Office (continued)

- 4) Follow-up calls to patients and scheduled visits assessing and reinforcing compliance with prescribed interventions and outcomes
- 5) Explore demonstration projects with industry, payers, and state quality improvement organizations

www.preventiveservices.ahrq.gov

Screening for Peripheral Arterial Disease: Recommendation Statement

U.S. Preventive Services Task Force

Summary of Recommendation

The USPSTF recommends against routine screening for peripheral arterial disease.
D recommendation.

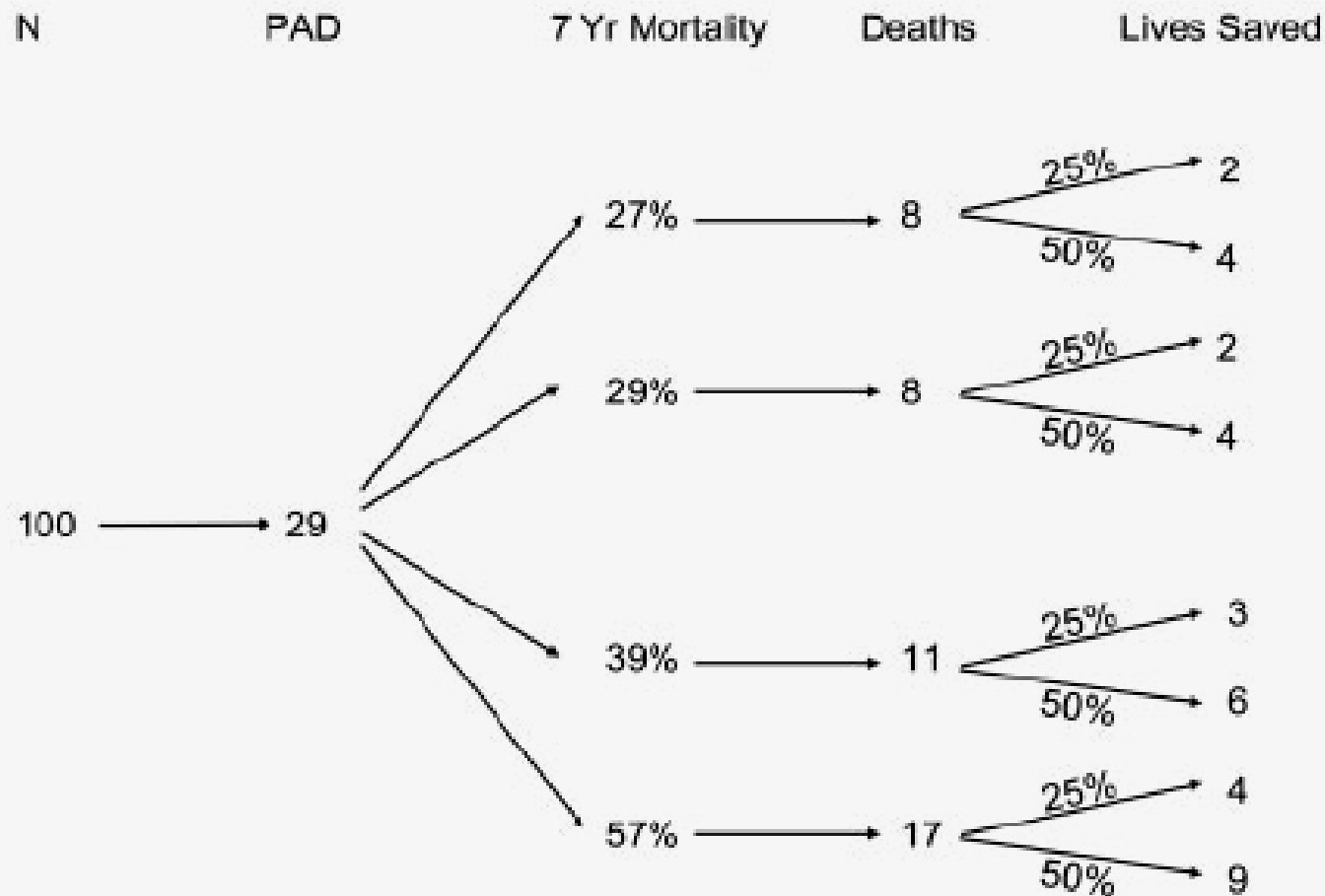
Circulation 2006;114:861-6

Special Report

**The United States Preventive Services Task Force
Recommendation Statement on Screening for
Peripheral Arterial Disease
More Harm Than Benefit?**

Joshua A. Beckman, MD, MS; Michael R. Jaff, DO; Mark A. Creager, MD

Estimated Mortality Reduction with Targeted Screening



Screening for PAD

- Identifies high risk individuals for MI/CVA/CV Death
- Provides early opportunity for risk factor intervention
- Early options to improve quality of life
- Will this save lives?