Recognizing and Diagnosing Peripheral Arterial Disease (P.A.D.)

A Clinical Introduction

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This presentation was co-authored with Ofstead & Associates, Inc., Dr Alan Hirsch and ev3 Inc.

A Clinical Introduction to P.A.D.

- This presentation covers the following P.A.D. topics:
  - Overview
  - Risk factors and epidemiology
  - Clinical presentation
  - Clinical outcomes and comorbid conditions
  - Early detection and diagnosis
  - Treatment options
  - Economic costs
  - Specialty concerns
  - Call to action

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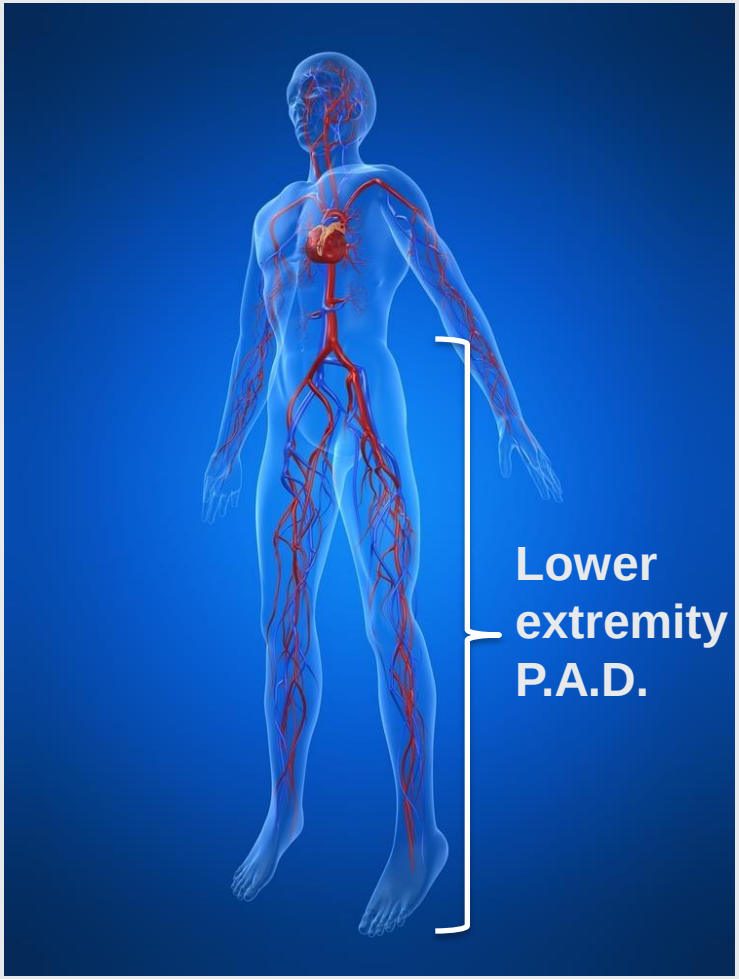
Overview of Peripheral Arterial Disease (P.A.D.)



- All non-coronary arterial diseases
- P.A.D.:
  - Causes acute and chronic illness
  - Reduces functional capacity and quality of life
  - Causes limb amputations
  - Increases risk of death

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P.A.D. Nomenclature

- P.A.D. is Peripheral Arterial Disease
- P.A.D. is a disease that has been called many names:
  - PVD (peripheral vascular disease)
  - PAOD (peripheral arterial occlusive disease)
  - LEP.A.D. (lower extremity peripheral arterial disease)
  - Arteriosclerosis obliterans

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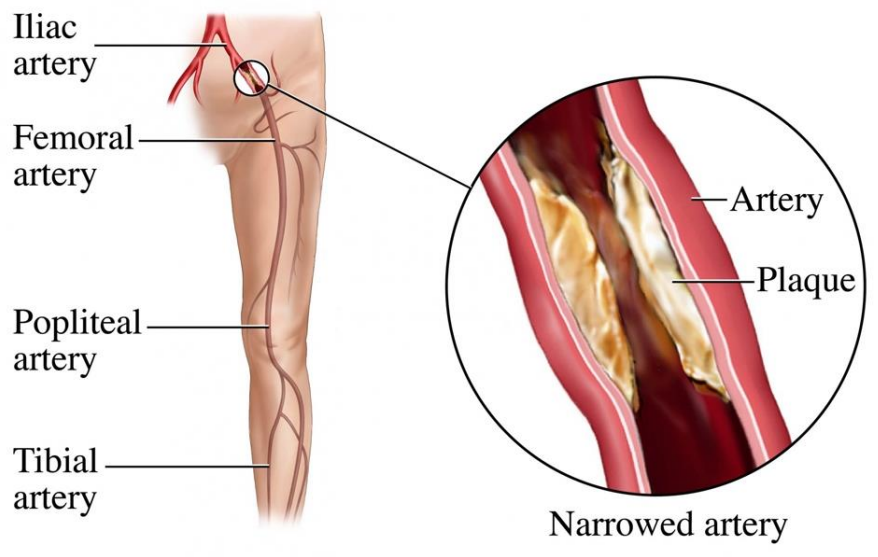
Atherosclerosis and P.A.D.

- Manifestation of a systemic disease
- Buildup of plaque
  - Cholesterol and other fats
  - Calcium
  - Fibrous tissue
  - Other substances
- Arterial stenosis or occlusion
- Reduced blood flow
- Increased risk of cardiovascular events and death



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Risk Factors for P.A.D.

- Lifestyle
  - **Smoking**
  - Obesity
- Health conditions
  - **Diabetes**
  - Cardiovascular disease
  - Erectile dysfunction
  - Chronic kidney disease
  - Hypertension
  - Hyperlipidemia
- Demographics
  - **Older age**
  - Black race

More than half of the attributable risk of P.A.D. is due to smoking and diabetes

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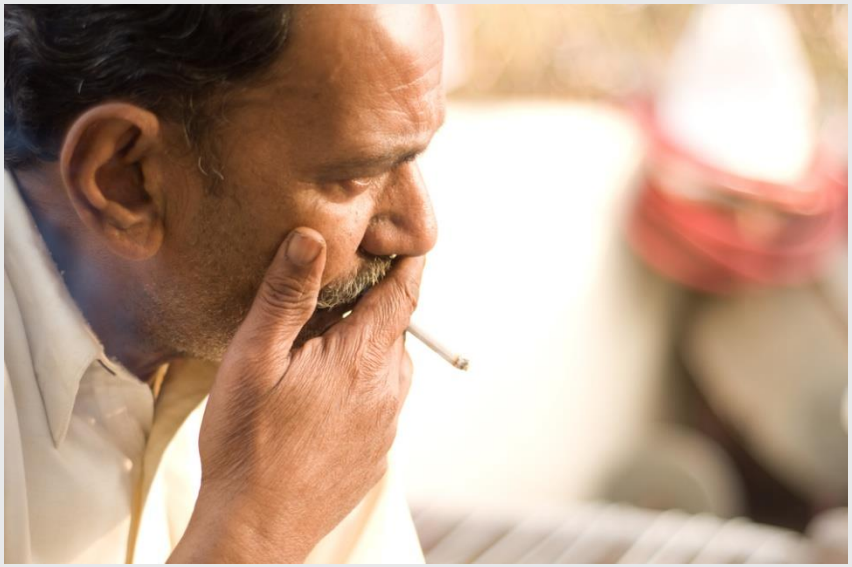
Smoking and P.A.D.



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"Smoking is the single most important modifiable risk factor for prevention of P.A.D."

- More than 80% of persons with P.A.D. are current or former smokers
- Smoking increases the risk of P.A.D. 4-fold
- P.A.D. in smokers:
  - Develops 10 years earlier
  - More likely to progress
  - Worse outcomes
    - Double the risk of amputation
    - Poor survival rates

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Smoking and P.A.D.

Smoking introduces lead and cadmium into the body

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Higher levels of these metals increase the risk of P.A.D. almost 3 times

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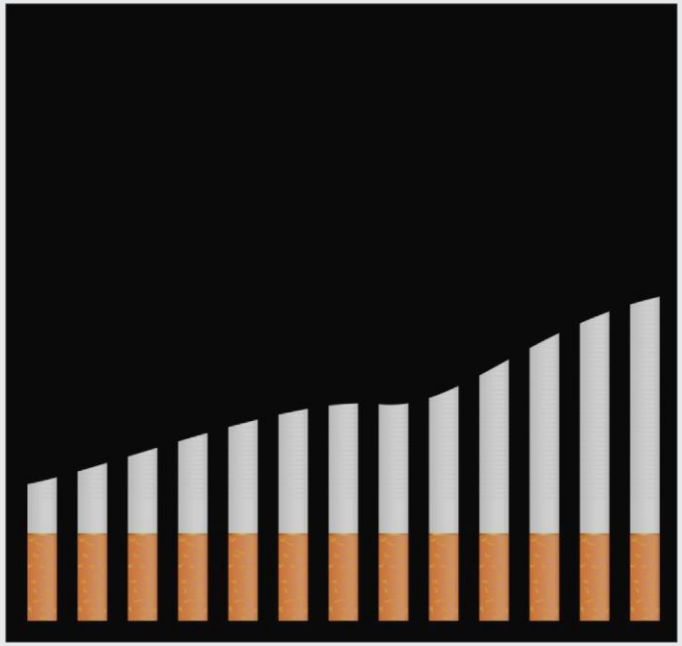
Smoking and P.A.D.

The risk of P.A.D. is dose-dependent



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Risk and severity of P.A.D. increase with the number of cigarettes and years smoked

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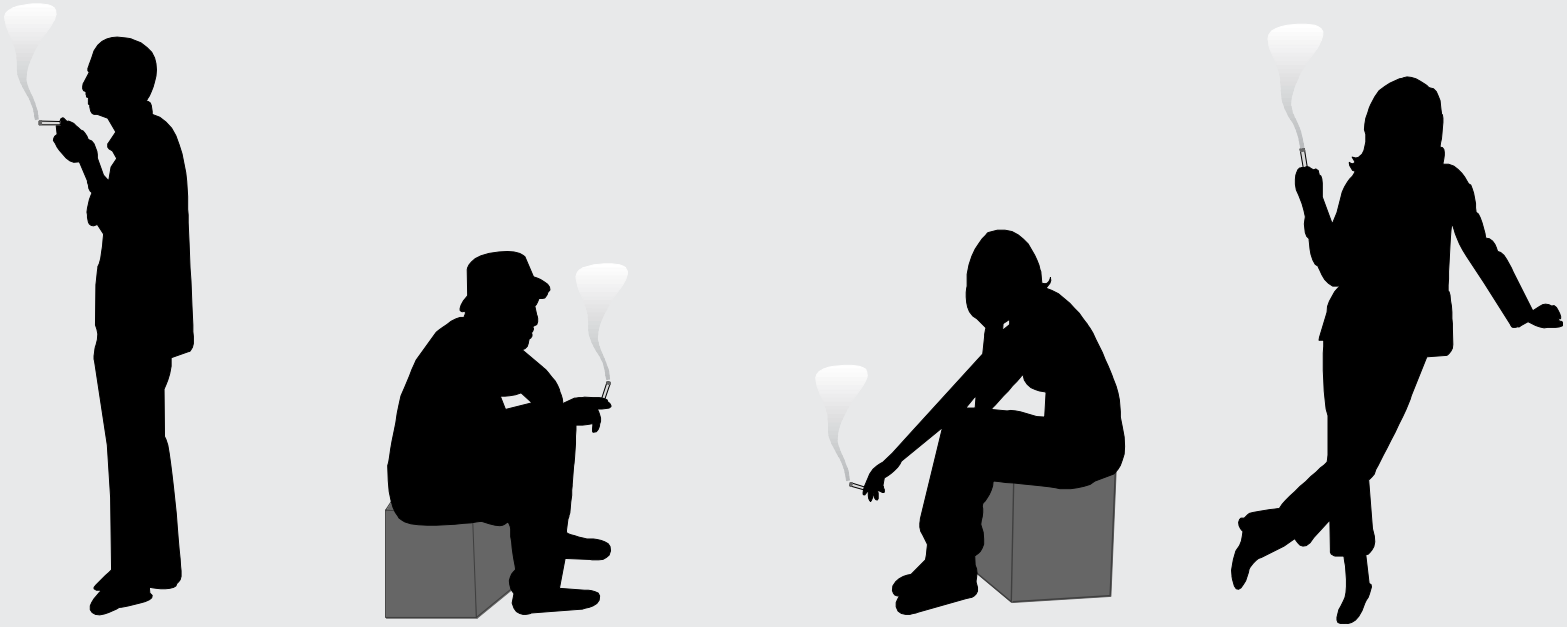
P.A.D. and Current Smokers

30%-40% of persons with P.A.D. are current smokers



80%-90% of persons with P.A.D. who require revascularization are current smokers

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Diabetes and P.A.D.

- 25%-40% of persons with P.A.D. have diabetes
- Risk of P.A.D. is 2-4 times higher
- Risk increases in proportion to diabetes severity and duration
- P.A.D. in persons with diabetes:
  - Commonly asymptomatic
  - More severe and progresses rapidly
  - Worse outcomes
    - Ulceration and gangrene
    - Amputation
    - Cardiovascular events

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Diabetes and P.A.D.

1 in 3 persons over age 50 with diabetes is likely to have P.A.D.



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Diabetes, P.A.D., and Amputation

- Diabetes alone does not cause amputation—it increases the risk of P.A.D.
- P.A.D. and diabetes are the leading cause of non-traumatic, lower limb amputations
- P.A.D. patients with diabetes have a 7-15 times higher risk of amputation

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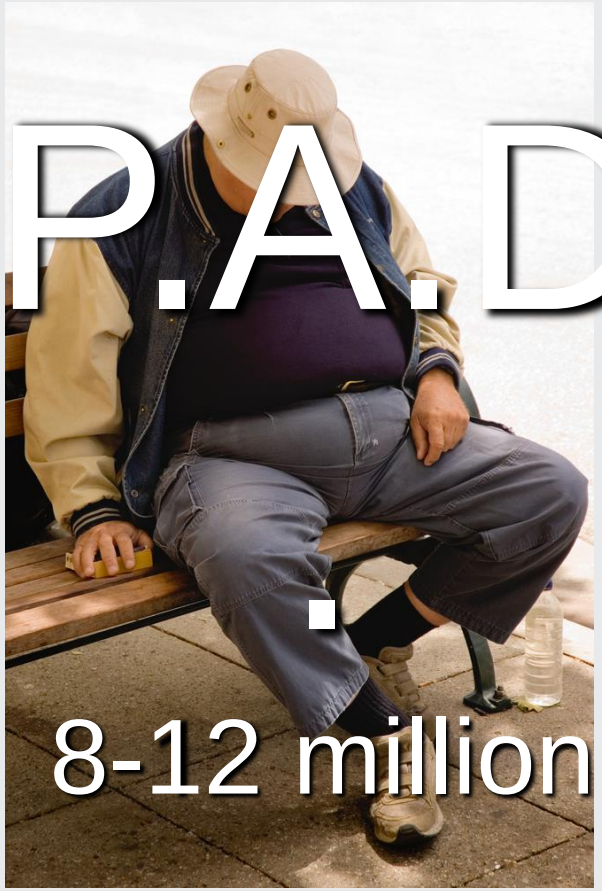
Prevalence of P.A.D. and Cancer in the U.S.



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P.A.D. affects the same number of Americans as cancer

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5-Year Mortality Rates for P.A.D. and Breast Cancer in the U.S.

P.A.D.
15%-30%

Breast Cancer
11%

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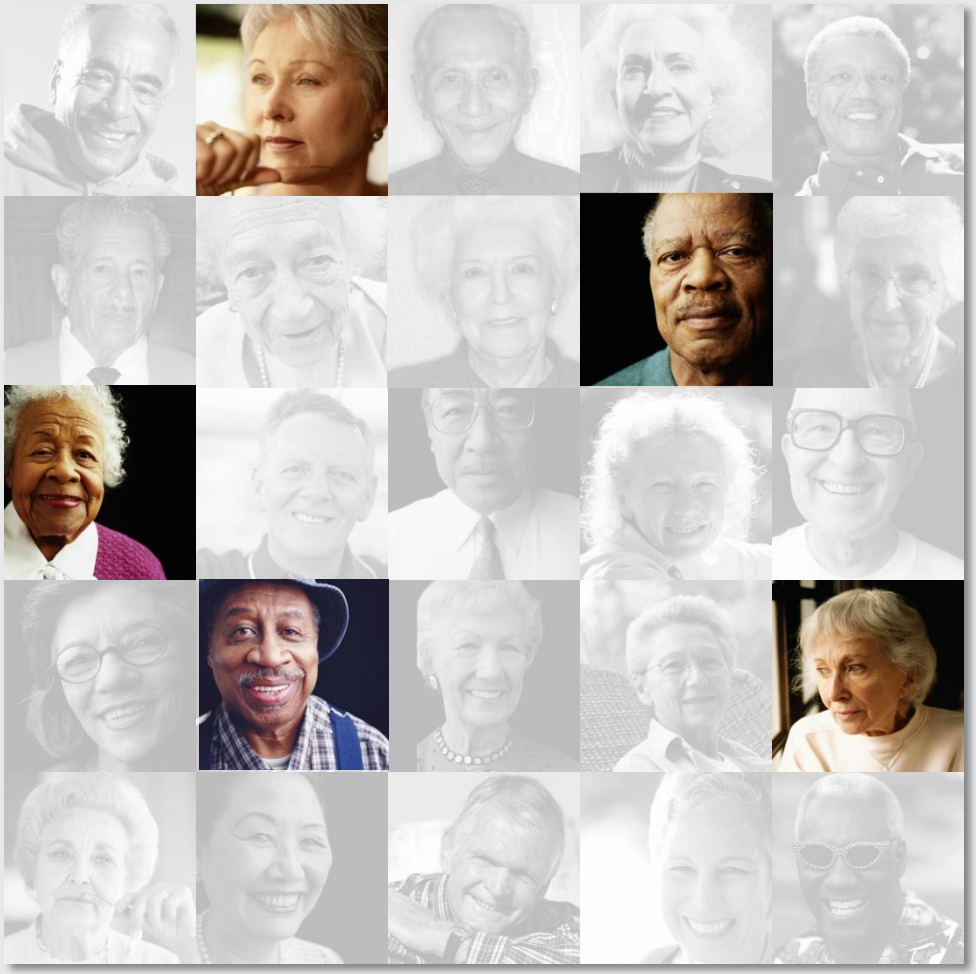
Prevalence of P.A.D. Among Older Adults



- The prevalence of P.A.D. increases dramatically with age
- 12%-20% of persons aged 65 or older have P.A.D.

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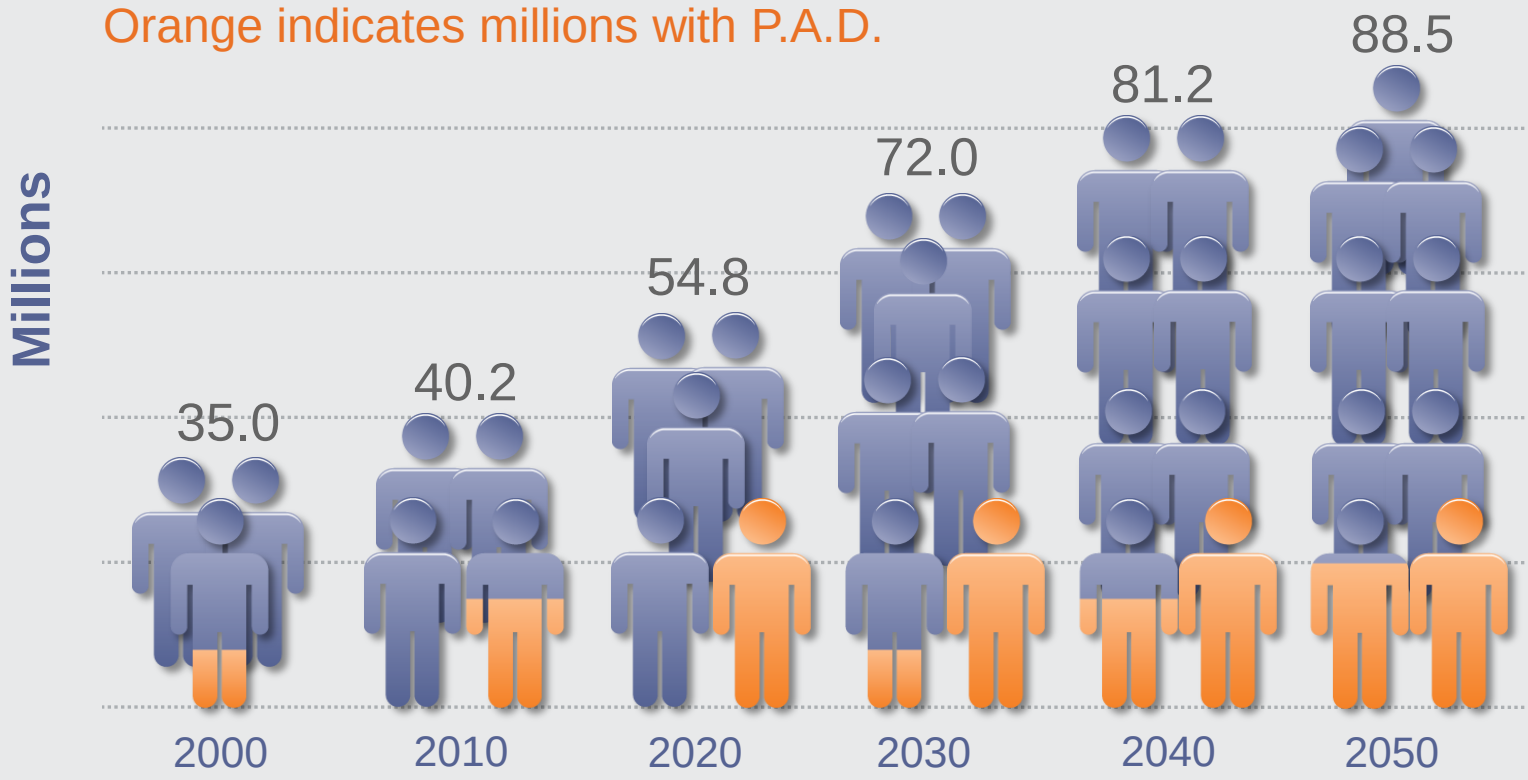
Expansion of the Older Population

Millions of Americans aged 65 and older by year

Orange indicates millions with P.A.D.



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Clinical Presentation of P.A.D.

P.A.D. Status	Rate of Clinical Presentation (%)
Asymptomatic ▪ No leg pain	20%-50%
Atypical leg pain ▪ Leg discomfort with exertion	40%-50%
Claudication ▪ Leg muscle discomfort with exertion	10%-35%
Critical limb ischemia (CLI) ▪ Chronic leg pain at rest ▪ Nonhealing ulcers and gangrene	1%-2%
Acute limb ischemia (ALI) ▪ Sudden onset of leg pain	NA

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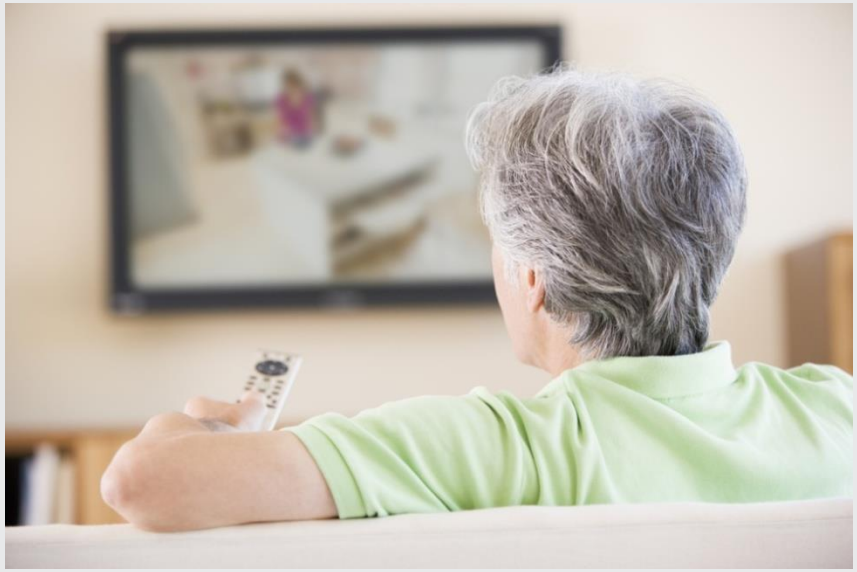
Asymptomatic P.A.D.

- More than 50% do not have classical signs or symptoms
- Asymptomatic patients:
  - Subtle impairments of limb function
  - Risk factors and comorbidities comparable to symptomatic patients
- Symptoms may not occur in patients who do not perform sufficient activity to produce them



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Claudication and P.A.D.

- Claudication is the most common symptom of P.A.D.
  - Cramping, aching, fatigue, weakness, or pain
  - Involving the muscles of the buttocks, legs, or feet
  - Occurs with activity
  - Quickly relieved by rest
- Present in only about 10% of P.A.D. patients
- Claudication alone does not define the presence or absence of P.A.D.

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Clinical Signs of Limb Ischemia

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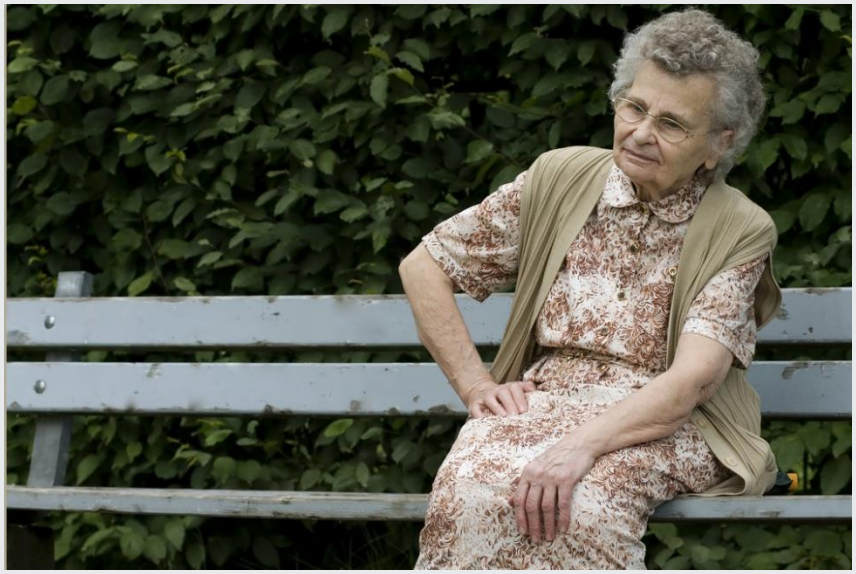
P.A.D. Patient are at Increased Risk

- Impaired function and quality of life
- Progressive disease severity
- Amputation
- Cardiovascular ischemic events
- Cardiovascular mortality



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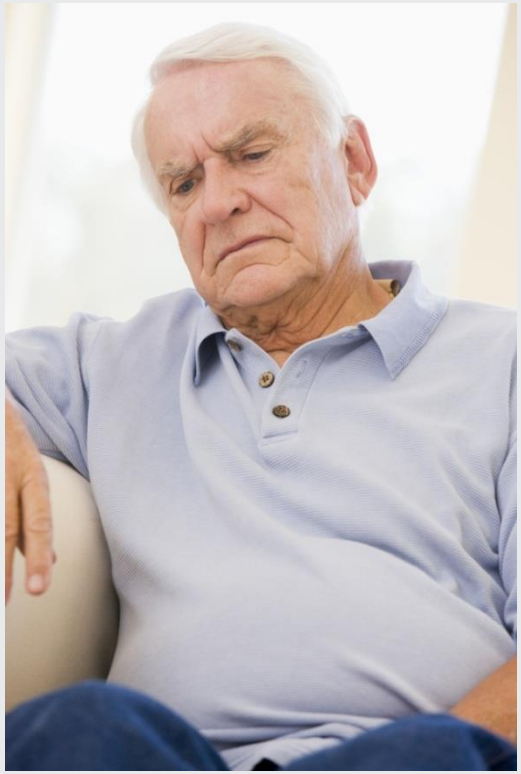
Loss of Functional Independence with P.A.D.

Independence is valued in all stages of life and in all cultures



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P.A.D. limits physical activity and can result in isolation

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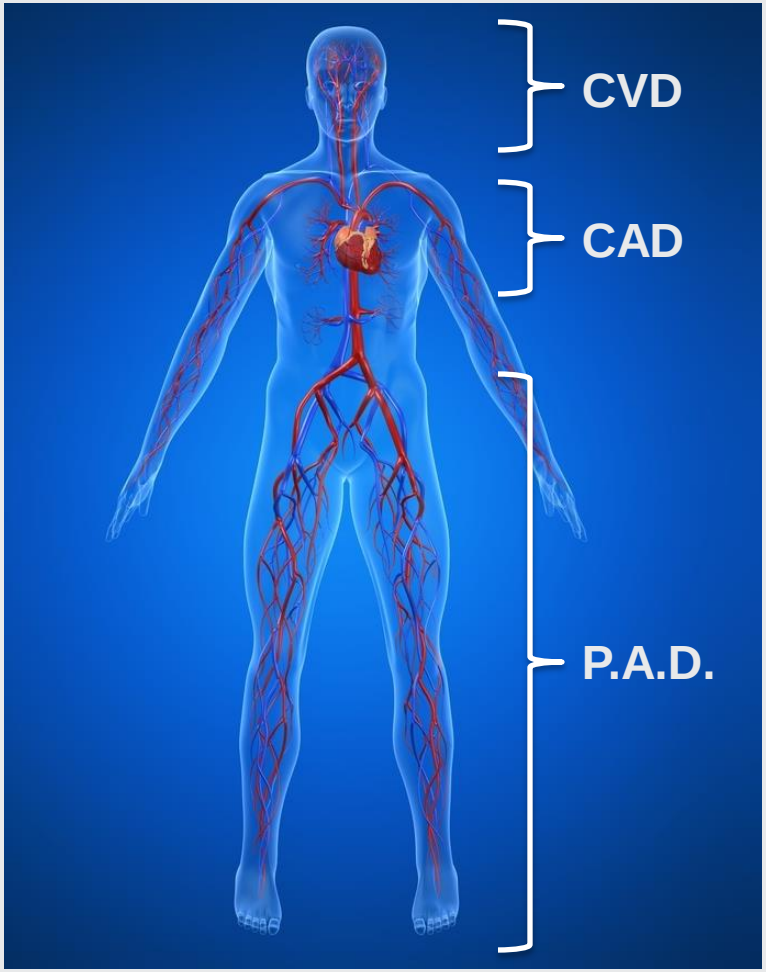
Comorbid Conditions Associated with P.A.D.

- Atherosclerotic diseases:
  - Coronary artery disease (CAD; MI)
  - Cerebrovascular disease (CVD; stroke)
  - Aortic aneurysmal disease (rupture)
  - Erectile dysfunction
- Chronic kidney disease (CKD)
- Diabetes



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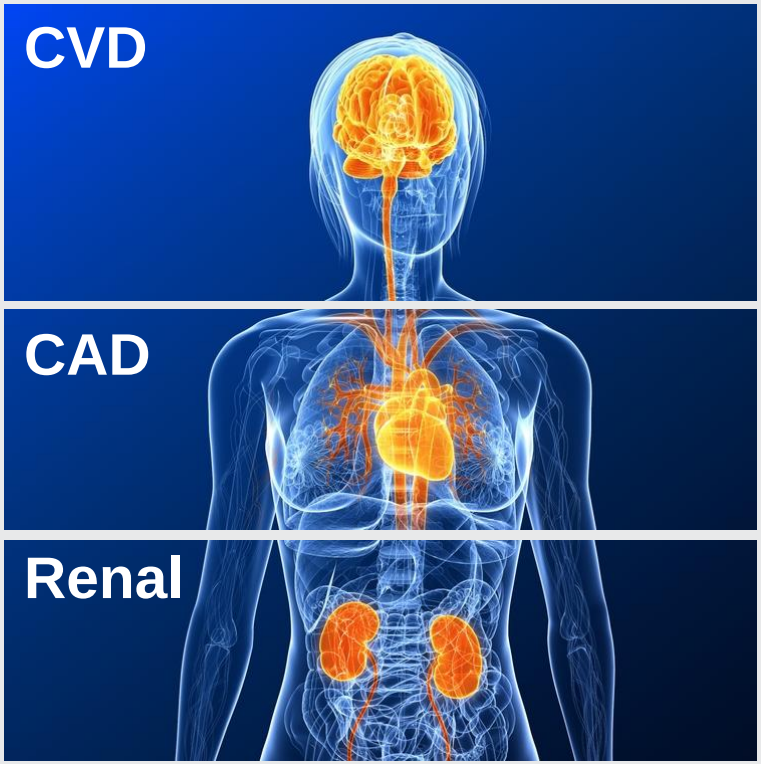
Cardiovascular Disease and P.A.D.

- Coprevalence of cardiovascular disease among P.A.D. patients:



25%-50%

50%-80%

25%-40%

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Cardiovascular Events and P.A.D.

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- P.A.D. patients have:
  - 40% increased risk of a cerebrovascular event (stroke)
  - 20%-60% increased risk of a heart attack (MI)
  - 2-6-fold increased risk of death due to coronary events

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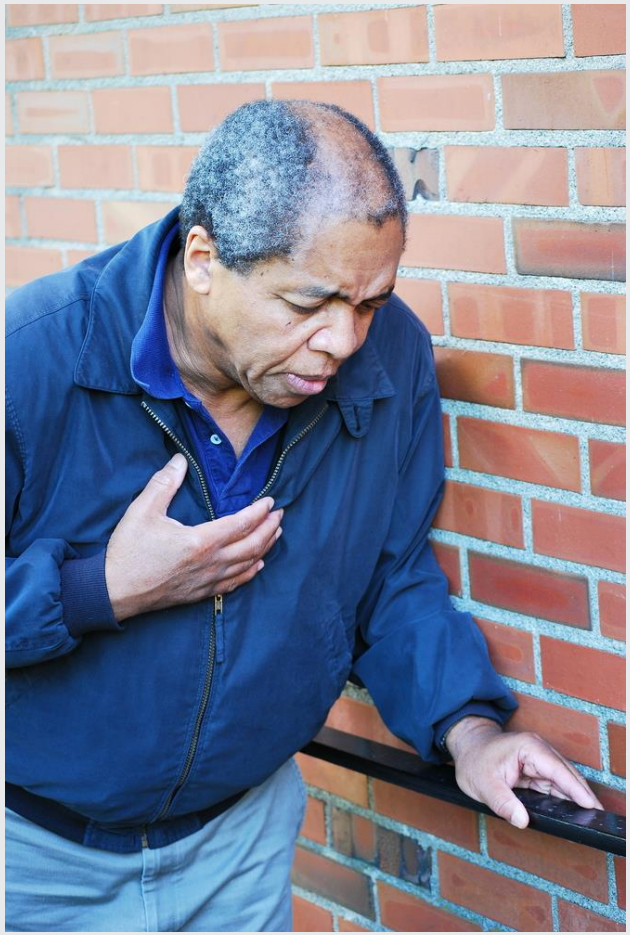
Mortality Among P.A.D. Patients



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70%-80% of P.A.D. patients die of cardiovascular causes

P.A.D. Status	Annual mortality rate
All patients with P.A.D.	4%-6%
Acute limb ischemia (ALI)	15%-20%
Critical limb ischemia (CLI)	20-25%
CLI & amputation	45%

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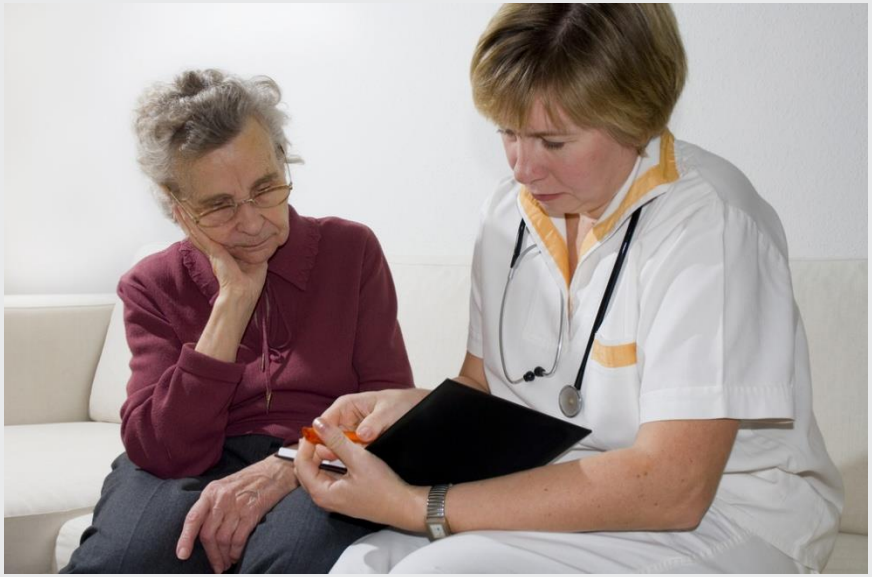
Importance of Early Detection

- P.A.D. is underdiagnosed
  - Over ⅔ are asymptomatic or have atypical symptoms
  - ½ have not yet suffered a major cardiovascular event
- Early detection can identify individuals:
  - Without claudication
  - With atypical leg symptoms
  - At high cardiovascular risk
- Initiate risk reduction treatment



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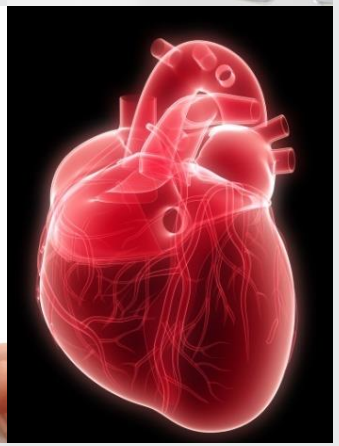
Target Your Efforts

Identify Persons at High Risk	
Age	>70 years
Lifestyle	Smokers • >50 years
Comorbidities	Diabetes • >50 years • Other risk factors Cardiovascular disease Chronic kidney disease
Symptoms	Leg pain with exertion Leg pain at rest Walking impairment Nonhealing wounds



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Clinical Assessment for P.A.D.

- Clinical History & Vascular Review
  - Vascular history
  - Limb symptoms
  - Atherosclerotic risk factors
  - Comorbid conditions
- Physical examination of the legs, feet, and toes
  - Weak or absent peripheral pulses
  - Signs of limb ischemia
- Laboratory testing and ABI

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Noninvasive Diagnostic Tests for P.A.D.

- Universally indicated diagnostic tests:
  - Ankle-brachial index (ABI)
  - Toe-brachial index (TBI)
    - Substitute or supplement for ABI
- Reimbursement for the ABI depends on using appropriate:
  - Equipment
  - Coding

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Measuring the ABI

1. Take 6 measurements with patient in supine position

Systolic blood pressure (mm Hg)

2. Select higher values for calculating ABI

1. Left arm
2. Right arm

Left ankle:

3. Dorsalis pedis
4. Posterior tibial

Right ankle:

5. Dorsalis pedis
6. Posterior tibial

To perform the ABI, use a 10-12 cm blood pressure cuff and a handheld 5- or 10-mHz Doppler probe

Sources: Hirsch et al. (2006) ACC/AHA Practice Guidelines for P.A.D.; Norgren et al (2007) TASC II Guidelines for P.A.D.

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Calculating and Interpreting the ABI

ABI Calculation

Left ABI:

Higher left ankle pressure ÷ Higher arm pressure = ____

Right ABI:

Higher right ankle pressure ÷ Higher arm pressure = ____

ABI	Interpretation (Arterial Status)
>1.30	Noncompressible
1.00-1.29	Normal
0.91-0.99	Borderline (equivocal)
0.41-0.90	Mild to Moderate P.A.D.
0.00-0.40	Severe P.A.D.

P.A.D. is defined as an ABI of ≤0.90

Sources: Hirsch et al. (2006) ACC/AHA Practice Guidelines for P.A.D.; Norgren et al. (2007) TASC II Guidelines for P.A.D.

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Value of the ABI Test

- Detects P.A.D. at all stages
- 95% sensitive and nearly 100% specific
- Confirms the diagnosis of P.A.D.
- Lower ABIs:
  - Higher cardiovascular risk
  - Greater disease severity
  - Worse prognosis for limb and life
- Most cost-effective tool for P.A.D. detection

The ABI is the gold standard for diagnostic P.A.D. testing

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ACC/AHA and TASC II Guidelines on P.A.D.

- Current guidelines endorsed by the American Heart Association (AHA), the American College of Cardiology (ACC), and international vascular societies recommend:
  - ABI testing for all patients with a history or exam indicative of P.A.D. (i.e., high risk patients)

Patients at High Risk for P.A.D.	
Age	>70 years
Lifestyle	Smokers • >50 years
Comorbid conditions	Diabetes • >50 years • Other risk factors Cardiovascular disease Chronic kidney disease
Symptoms	Leg pain with exertion Leg pain at rest Walking impairment Nonhealing wounds

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Noninvasive Diagnostic Tests for P.A.D.

- Supportive diagnostic tests to determine anatomy, physiology, or functional status:
  - Segmental pressure measurements
  - Pulse volume recordings (PVR)
  - Doppler waveform measurements
  - Transcutaneous oxygen tension
  - Exercise ABI testing
  - Vascular imaging
    - Duplex ultrasound
    - Angiography (CTA, MRA)

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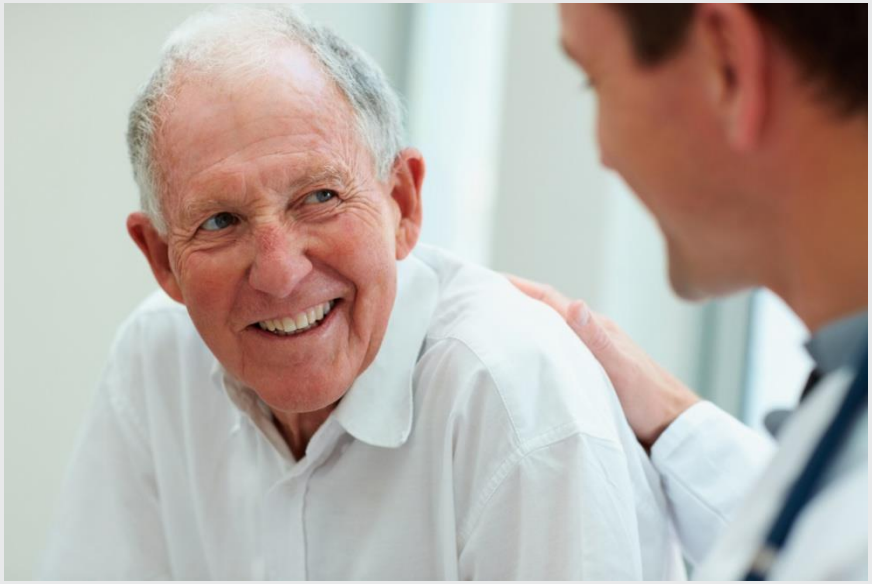
Treatment of P.A.D.

- Treatment goals are to:
  - Reduce the risk of death and cardiovascular events
  - Prevent limb loss
  - Relieve symptoms
  - Improve function and quality of life
- Cardiovascular risk reduction therapy is indicated for all patients
  - Risk factor modification
  - Antiplatelet therapy
- Symptomatic treatment is individualized



Only 20%-30% of patients with P.A.D. are receiving treatment

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Lifestyle Modifications to Treat P.A.D.

- Risk reduction:
  - Smoking cessation
  - Risk factor modification:
    - Lipid control
    - Blood pressure control
    - Diabetes control
    - Weight reduction
  - Exercise
  - Nonatherogenic diet
- Lifelong treatment

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Medications for Treating P.A.D.

- Risk reduction
  - Statins
  - ACE inhibitors
  - Antiplatelet therapy
    - Aspirin
    - Clopidogrel
- Symptom relief
  - Claudication
    - Cilostazol
  - CLI
    - Pain medication
    - Antibiotics

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Lifelong antiplatelet therapy is recommended for patients with P.A.D.

You need to decide what is best for your patient.

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Exercise Therapy to Treat P.A.D.

- Exercise program
  - Walking is most effective
  - Exercise-rest-exercise
- Sessions performed for:
  - Minimum of 30-45 minutes
  - At least 3 times per week
  - Minimum of 3 months
- Walking outcomes:
  - Relief from claudication
  - Increase in walking ability and daily activity
  - Risk reduction

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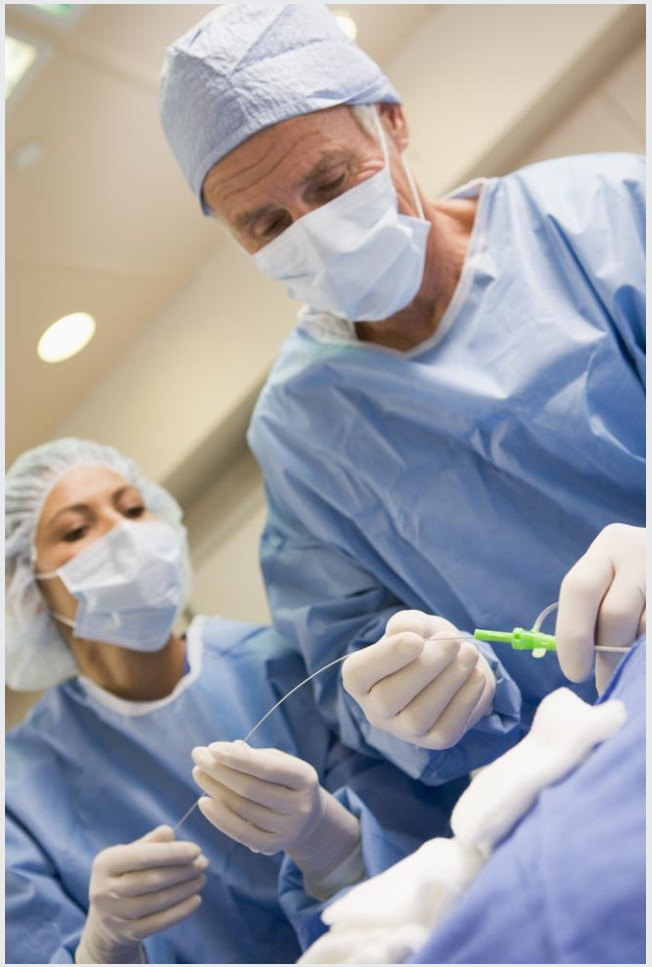
Revascularization and P.A.D.

- Indications:
  - Failure with exercise and drug therapy
  - Lifestyle-limiting symptoms and function
  - Nonhealing wound
  - Risk of amputation
- Requires a favorable risk/benefit ratio
- Less invasive endovascular procedures:
  - Preferred over surgery
  - Preserve options for fall-back surgical procedures



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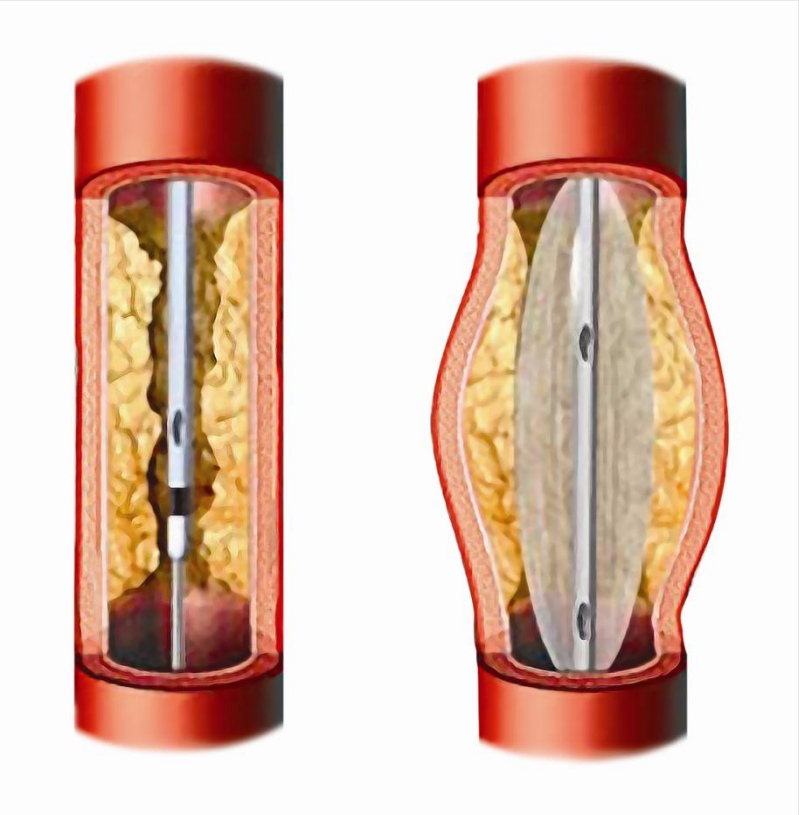
Endovascular P.A.D. Treatment –Angioplasty

- Mechanism:
  - Catheter-guided balloon
  - Balloon dilation
  - Plaque displacement into the artery wall
  - Vessel stretch and expansion



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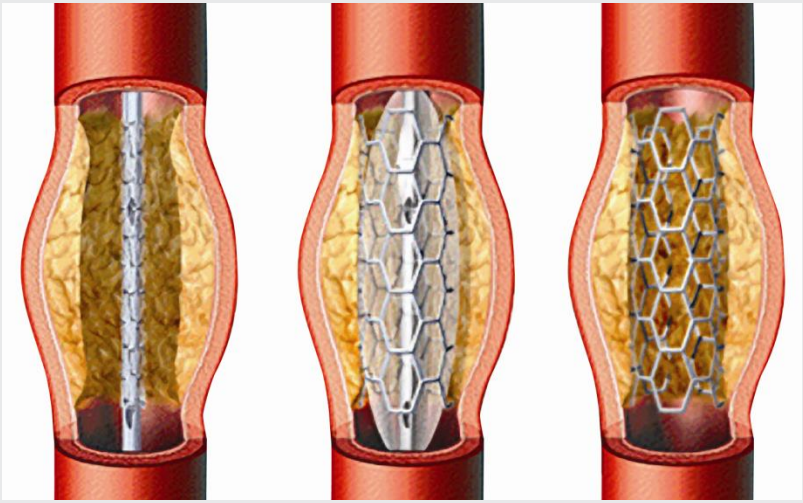
Endovascular P.A.D. Treatment – Stents and Stent-Grafts

- Mechanism:
  - Balloon-expandable or self-expanding
  - Plaque displacement into the artery wall
  - Vessel stretch and expansion
- Indications:
  - Prevent recoil of the artery wall
  - Repair complications resulting from angioplasty



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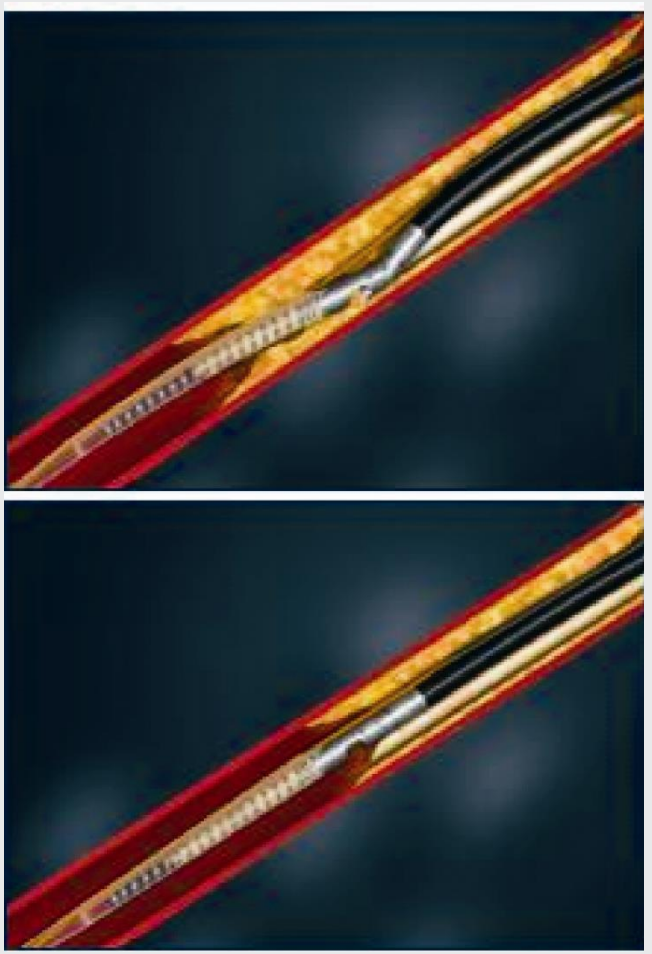
Endovascular P.A.D. Treatment – Atherectomy

- Mechanism:
  - Debulk plaque
    - Cut
    - Pulverize
    - Shave
  - Remove or excise plaque
- Types:
  - Directional or excisional
  - Rotational or orbital
  - Photoablative (excimer laser)



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Surgical Treatment for P.A.D.

- Types:
  - Surgical bypass
    - Venous or synthetic bypass graft
  - Endarterectomy
    - Surgical removal of plaque
  - Intra-operative hybrid procedure
- Not recommended as prophylactic therapy
- Increased risk of operative mortality

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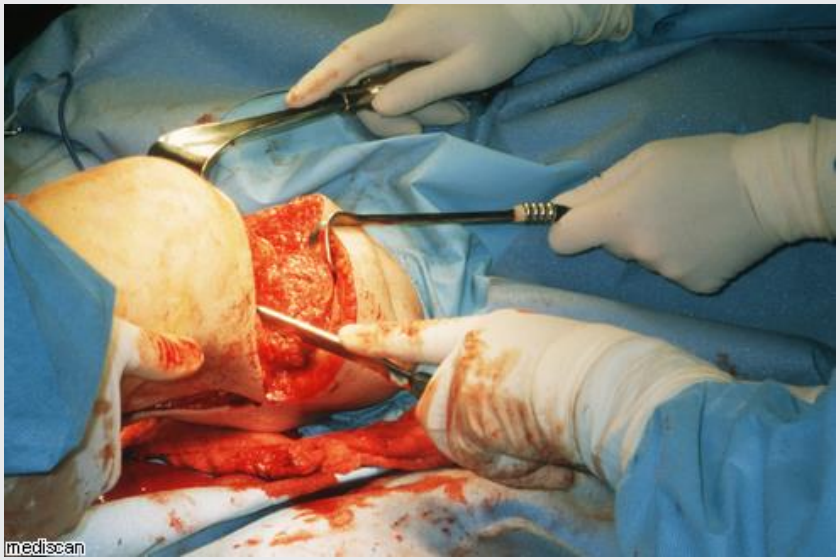
Amputation and P.A.D.

- About 5% undergo amputation
- Indications:
  - Failed revascularization (~60%)
  - Refractory ischemic rest pain
  - Gross infection
  - Extensive necrosis
- High incidence in persons with diabetes
- Significant risk of morbidity and mortality
- Up to 85% of amputations are preventable



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Personal Costs of Major Amputation

- Less than half of amputees regain the ability to walk
- 15% require amputation of the other limb within 2 years
- Amputees have a 20%-35% risk of MI, stroke, and infection
- Less than half of amputees survive more than 2-3 years

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Economic Costs of Major Amputation

- Annual costs associated with amputation are $10-20 billion in the U.S.
- Post-amputation care costs $50,000 per patient annually
- Nursing home care costs $100,000 per patient

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Annual Economic Burden of P.A.D.

- P.A.D. accounts for approximately:
  - 750,000 office visits
  - 63,000 hospitalizations
- Total hospitalization costs in excess of $21 billion
  - 57% of costs due to revascularization and amputation
- Average annual costs of P.A.D. are greater than CAD and CVD:
  - $4,000 for hospitalization
  - $2,800 for medication
- Costs increase with additional cardiovascular disease

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Treatment Costs for P.A.D.

Treatment	Cost
PTA	$10,000
PTA & thrombolysis	$20,000
Bypass grafting	$20,000
Amputation	$40,000
Adding rehabilitation	Cost x2
Failed procedure	Cost x2-4

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P.A.D. Costs and Medicare

- 98% of U.S. adults over age 65 are covered by Medicare
- 6.8% of beneficiaries received P.A.D. treatment
  - Accounts for only 1/3 of estimated P.A.D. population
- Medicare expenditures for P.A.D.:
  - $1,868 average annual treatment cost per patient
  - 88% of costs due to inpatient care
  - 2.3% of total Medicare budget
- $4.37 billion in treatment costs

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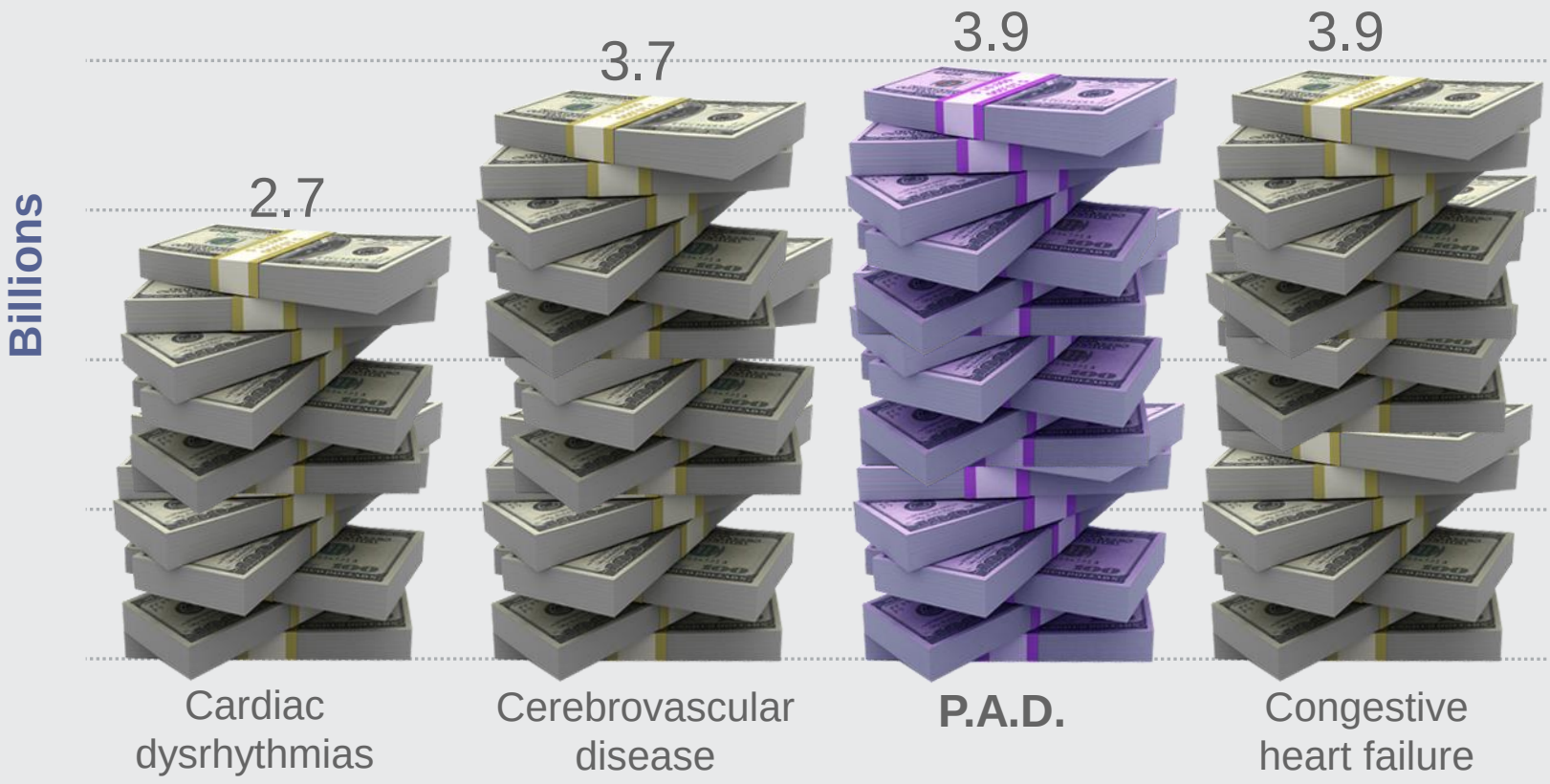
Medicare Expenditures for Disease Care

Billions in Medicare Expenditures



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Call to Action for Leaders and Administrators

1. Increase awareness of P.A.D. and its consequences (amputation, MI, stroke, and death)
2. Determine coding and reimbursement for diagnostic P.A.D. testing
3. Promote ABI testing and risk reduction therapy to improve patient outcomes
4. Develop a list of referral physicians including vascular specialists and podiatrists

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Call to Action for Clinicians

1. Use medical history and recognize risk factors
2. Perform ABI testing on high risk patients to increase early diagnosis
3. Manage risk factors promptly and aggressively
4. Implement multidisciplinary care or make the appropriate referrals
5. Maintain the continuity of care

Peripheral artery disease (P.A.D.) is underrecognized, underdiagnosed, and undertreated in the U.S.

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