

# Lower Extremity PAD: Underdiagnosed and Undertreated

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# Disclosures

Joshua Beckman:

- Consultant: Merck, Novartis, AstraZeneca, Bristol-Myers Squibb
- Research Grant: Bristol-Myers Squibb
- Ownership Interest: Janacare, EMX
- Neither AHA nor I received funding to participate in today's meeting

# The American Heart Association

## *Life is Why*

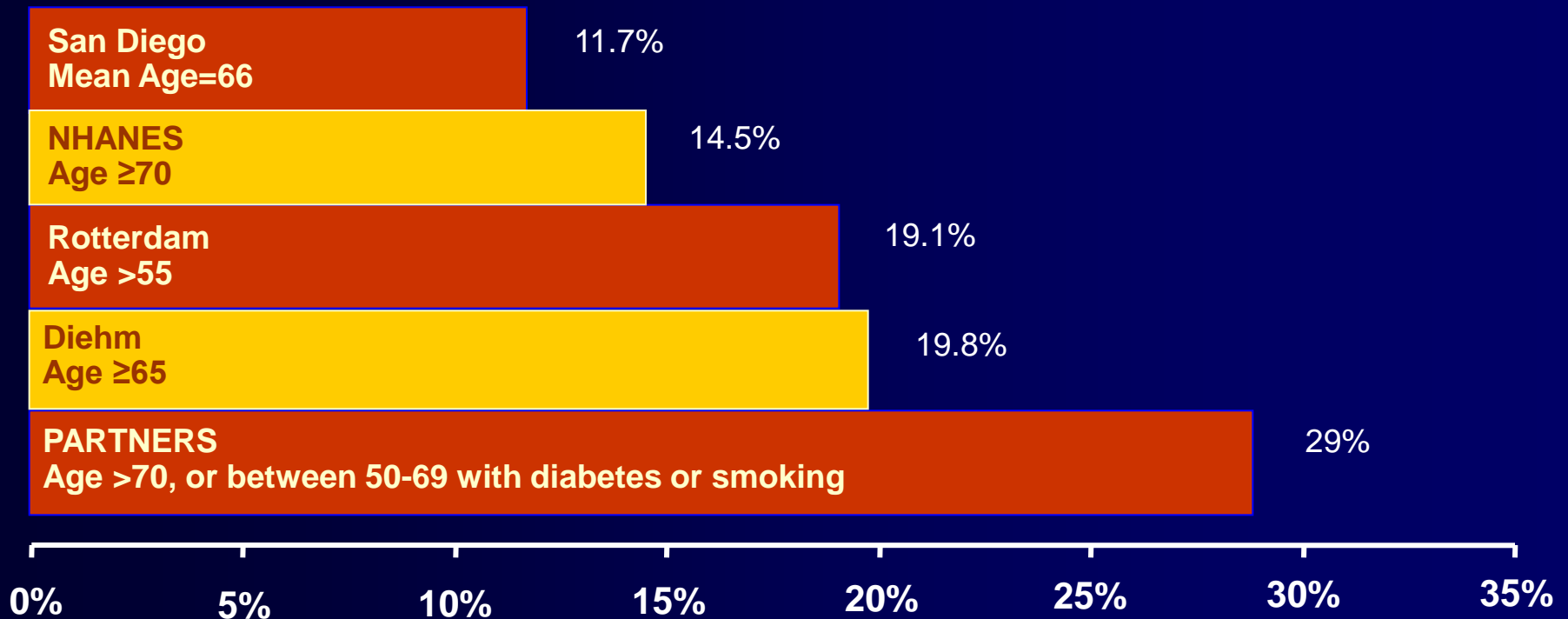
- **Who We Are:** The American Heart Association is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. Our organization now includes more than 22.5 million volunteers and supporters. We fund innovative research, fight for stronger public health policies, and provide critical tools and information to save and improve lives.
- **What We Do:** To improve the lives of all Americans, we provide public health education in a variety of ways. We're the nation's leader in CPR education training. We help people understand the importance of healthy lifestyle choices. We provide science-based treatment guidelines to healthcare professionals to help them provide quality care to their patients. We educate lawmakers, policymakers and the public as we advocate for changes to protect and improve the health of our communities.

# Identifying Patients with PAD

- This meeting is focused on what happens after a patient is diagnosed with PAD
  - The appropriate *interventions* to improve health outcomes
- Should also consider how patients with PAD are first identified
  - Especially patients with asymptomatic PAD or PAD with atypical pain
- Problem: Patients with PAD
  - Are under-diagnosed and under-treated
  - Have excess mortality from inadequate treatment

# We Know In Whom To Diagnose PAD

## *Documented Presence of PAD*



Selvin E et al. *NHANES*. *Circulation*. 2004;110:738-743.

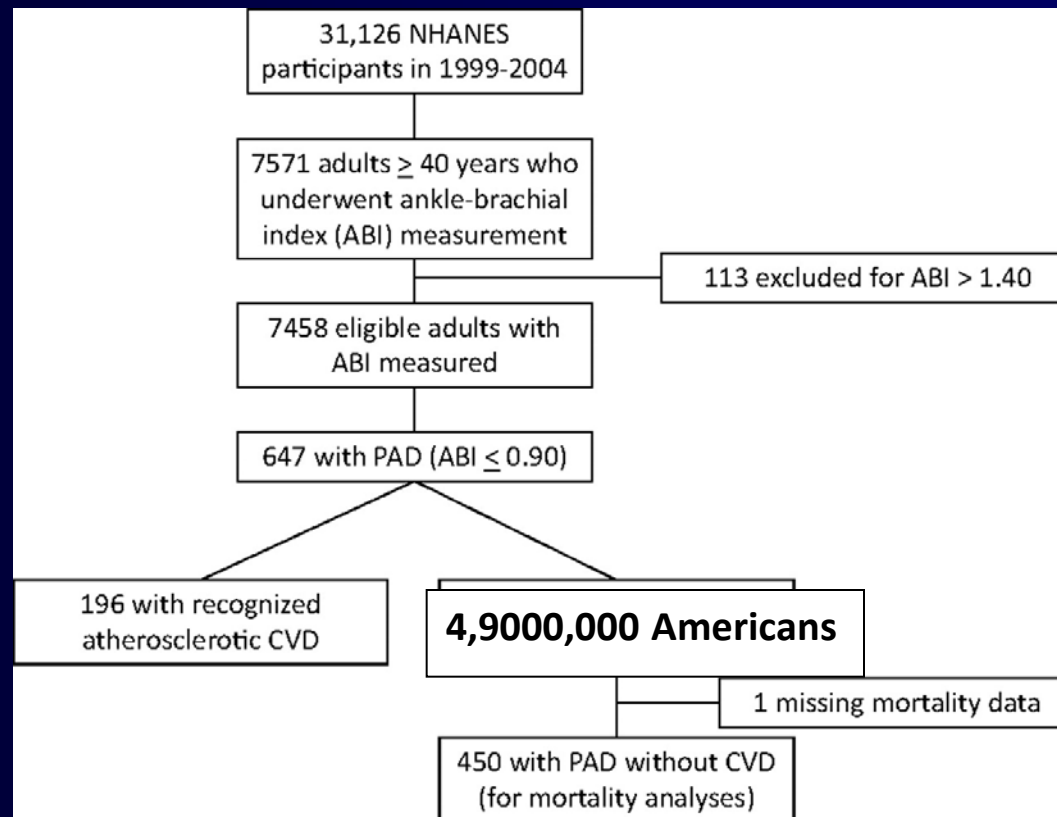
Criqui MH et al. *Circulation*. 1985;71:510-515.

Diehm C et al. *Atherosclerosis*. 2004;172:95-105.

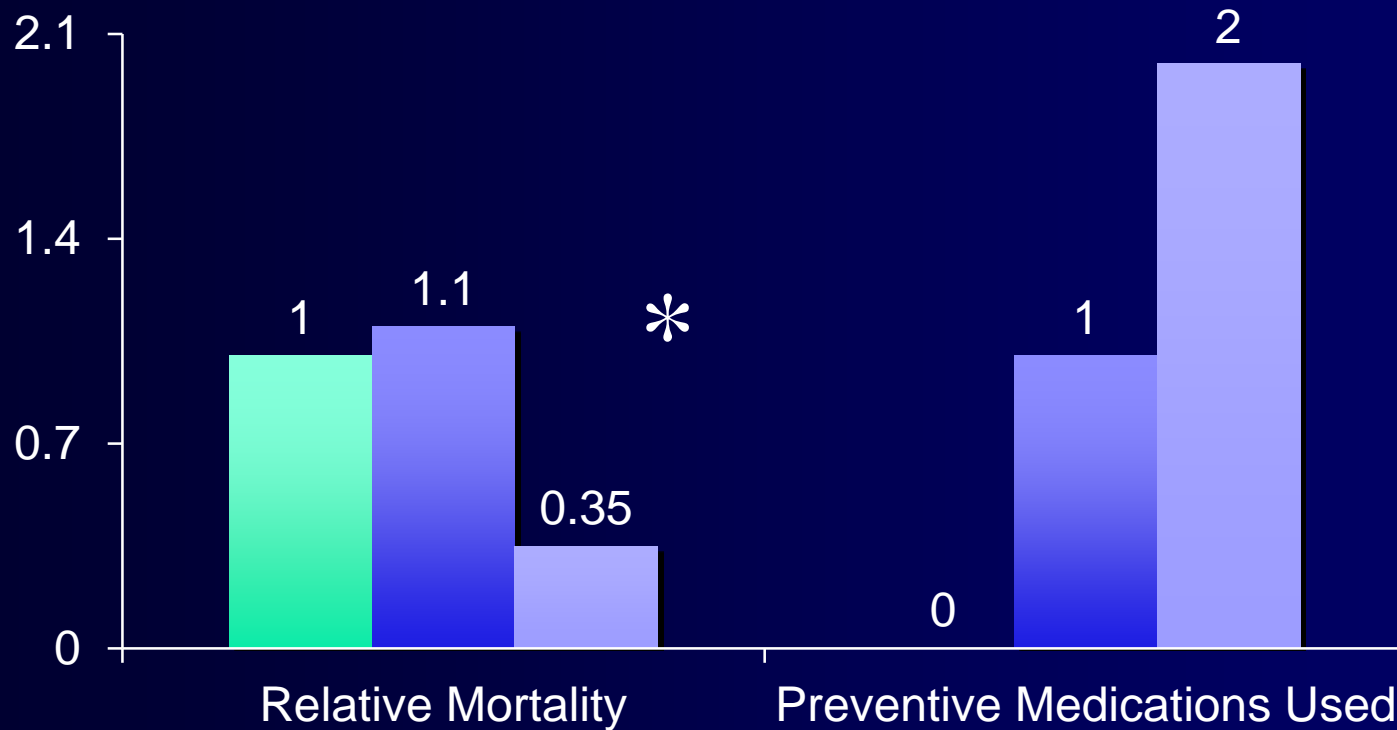
Meijer WT et al. *Arterioscler Thromb Vasc Biol*. 1998;18:185-192.

Hirsch AT et al. *JAMA*. 2001;286:1317-1324.

# Most PAD Patients Do Not Get Recognized



# Patients With PAD Have Increased Mortality Because They Don't Get Treated



Adjusted for age, sex, race/ethnicity, atherosclerosis risk factors, prior heart disease, insurance, education, socioeconomic status

# **PAD Is Treated Less Well Than Atherosclerosis Discovered in Other Vascular Beds**

- There are millions of patients either undiagnosed or untreated in the United States.
- Inadequate treatment increases mortality.
- Recently approved medications may reduce the need for future revascularization.



# The ABI is a *Diagnostic Test*

- CMS Definition of a Diagnostic Test (Medicare Benefits Policy Manual, Chapter 6)
  - A service is “diagnostic” if it is an examination or procedure to which the patient is subjected...to obtain information to aid in the **assessment of a medical condition or the identification of a disease**. Among these examinations and tests are diagnostic laboratory services such as hematology and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, **and other tests given to determine the nature and severity of an ailment or injury**.
- In contrast, CMS defines preventive services (Your Guide to Medicare’s Preventive Services )
  - Tests that “can find health problems **early**, when treatment works best, and **can keep you from getting certain diseases**.”

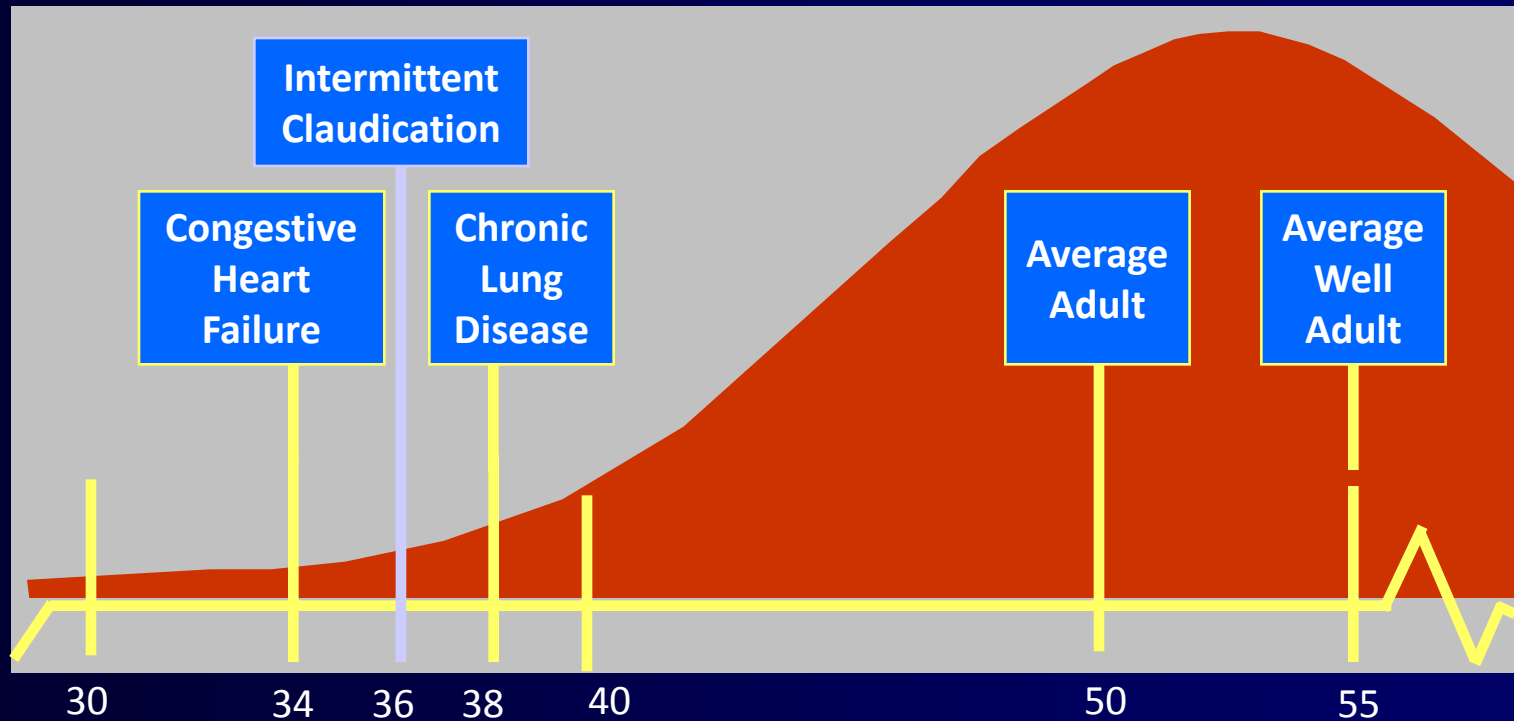
# Recommendation

- All patients in the Medicare population should have a one-time screening ankle-brachial index covered by CMS.
  - As currently performed with the same criteria for reimbursement for patients with leg pain

# Under-treatment of PAD

- Once diagnosed with PAD, patients are frequently undertreated
- Problem: Patients with Intermittent Claudication do not have access to supervised exercise rehabilitation; an effective therapeutic option that is well established and proved.
  - The availability of intervention is immaterial to the need for supervised exercise rehabilitation.

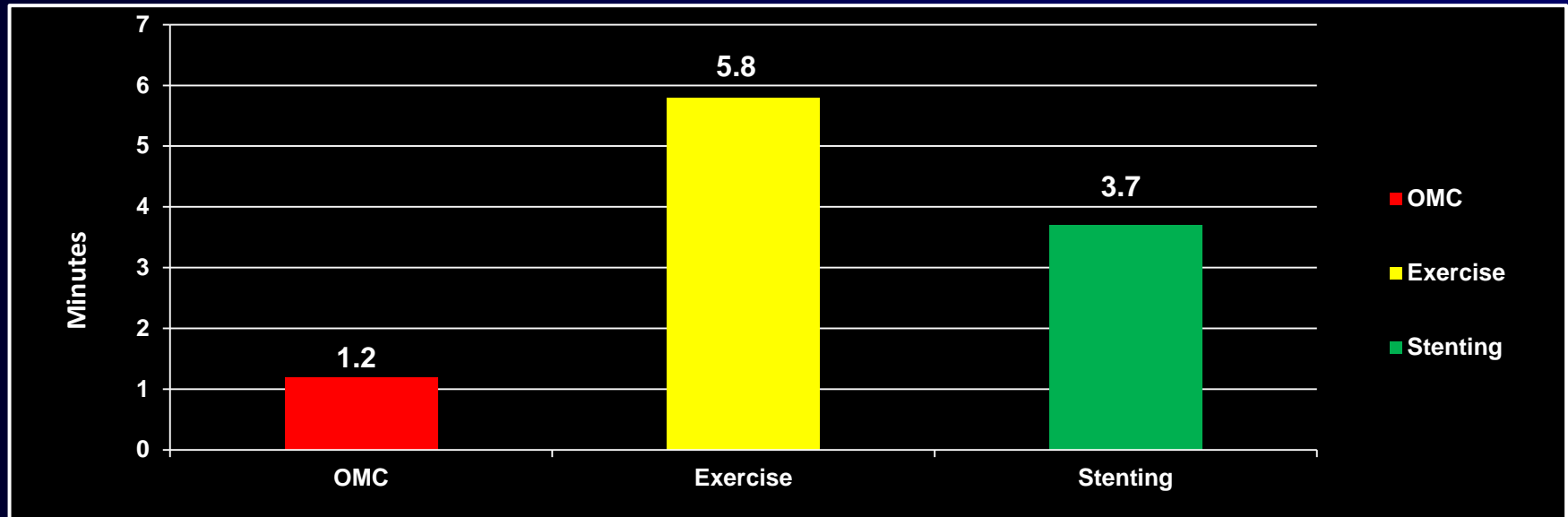
# Comparing Physical Health for Chronically ill U.S. Adults



Physical Component Summary (PCS)

# CLEVER Trial: Peak Walking Time

111 patients with aortoiliac PAD randomized to optimal medical care (OMC), OMC plus Supervised Exercise, or OMC plus stenting.



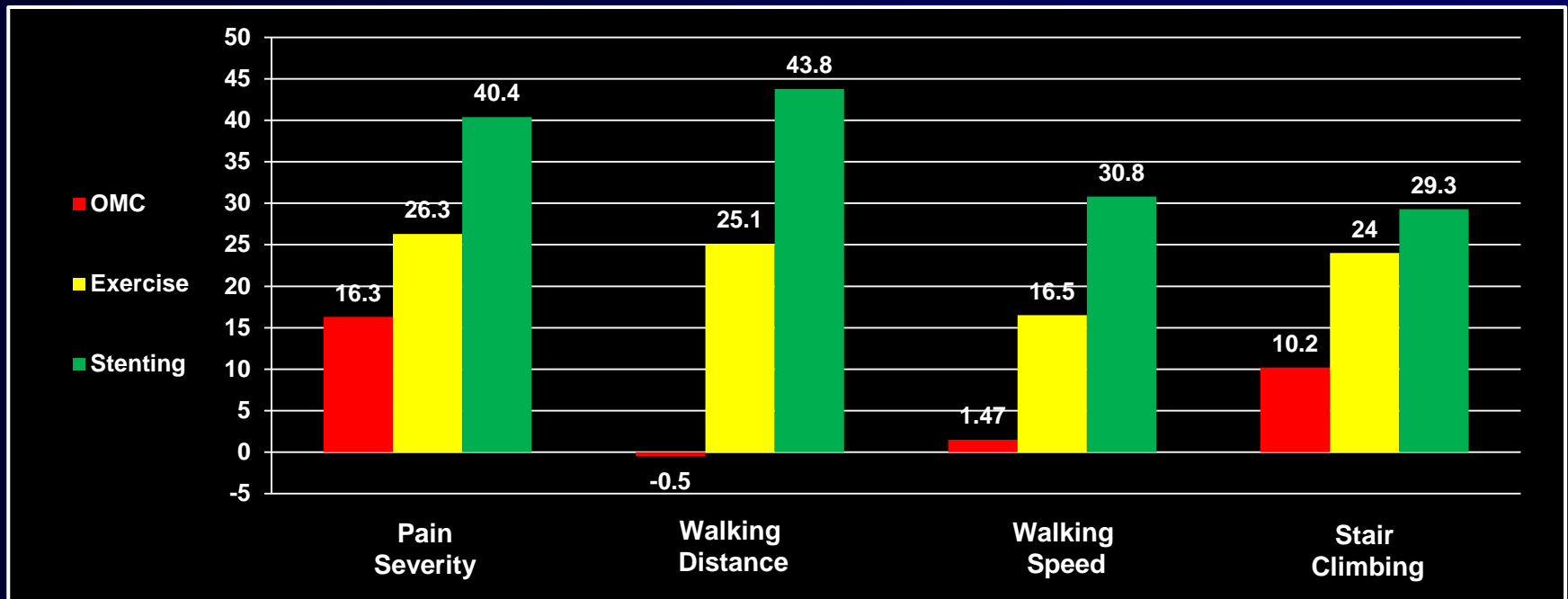
## Pair-Wise Comparisons

	Difference (minutes)	P Value
Exercise vs. OMC	4.6 (95% CI, 2.7-6.5)	<0.001
Stenting vs. OMC	2.5 (95% CI, 0.6-4.4)	0.02
Exercise vs. Stenting	2.1 (95% CI, 0.0-4.2)	0.04

# CLEVER Trial:

## Walking Impairment Questionnaire

111 patients with aortoiliac PAD randomized to optimal medical care (OMC), OMC plus Supervised Exercise, or OMC plus stenting.



	P Value	P Value	P Value	P Value
SE vs. OMC	0.25	0.007	0.007	0.07
ST vs. OMC	<0.001	<0.001	<0.001	0.05
ST vs. SE	0.01	0.03	0.007	0.53

# Efficacy of Supervised Exercise: The “Gardner 21-Study Meta-Analysis”

	Exercise	Control	Change
Pain-Free Walking Distance	<b>180% *</b>	40%	2 blocks
Maximal Walking Distance	<b>130% *</b>	30%	3 blocks
			1 block = 80 m

- **Predictors of improvement**
  - Moderate claudication pain
  - Walking exercise
  - > 3 (or 6) months exercise training
  - Supervised exercise

# Recommendation

- All patients in the Medicare population with intermittent claudication should be offered exercise rehabilitation like patients after PCI, CABG, or heart valve surgery.
- Patients with claudication deserve coverage of all established and proved therapies



# What Does Coverage Mean?

- These services should be covered because CMS has a vested interest in
  - Diagnosing atherosclerosis
    - The ABI is as reasonable as an ETT or carotid ultrasound
  - Reducing mortality from atherosclerosis
  - Improving functional capacity
    - As it does after MI, CABG, or with stable angina