2018 MID-ATLANTIC
CONFERENCE

8th ANNUAL CURRENT CONCEPTS IN
VASCULAR THERAPIES

2018

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April 27th, 2018

Claudication – Is Vascular Rehab for Real?

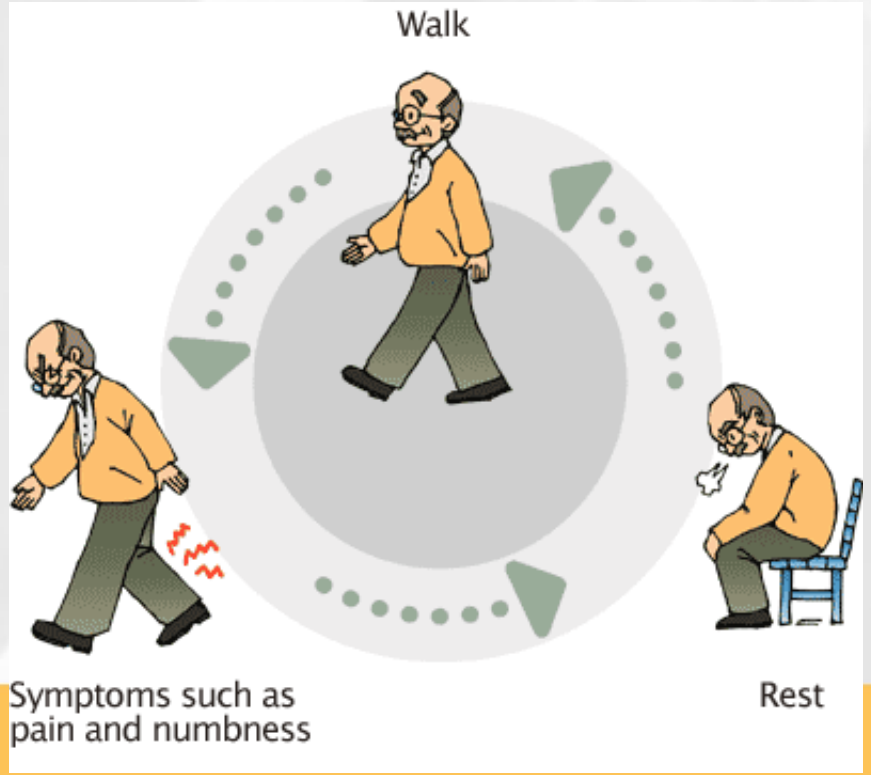
Peripheral Arterial Disease

Asymptomatic

Definition of Claudication

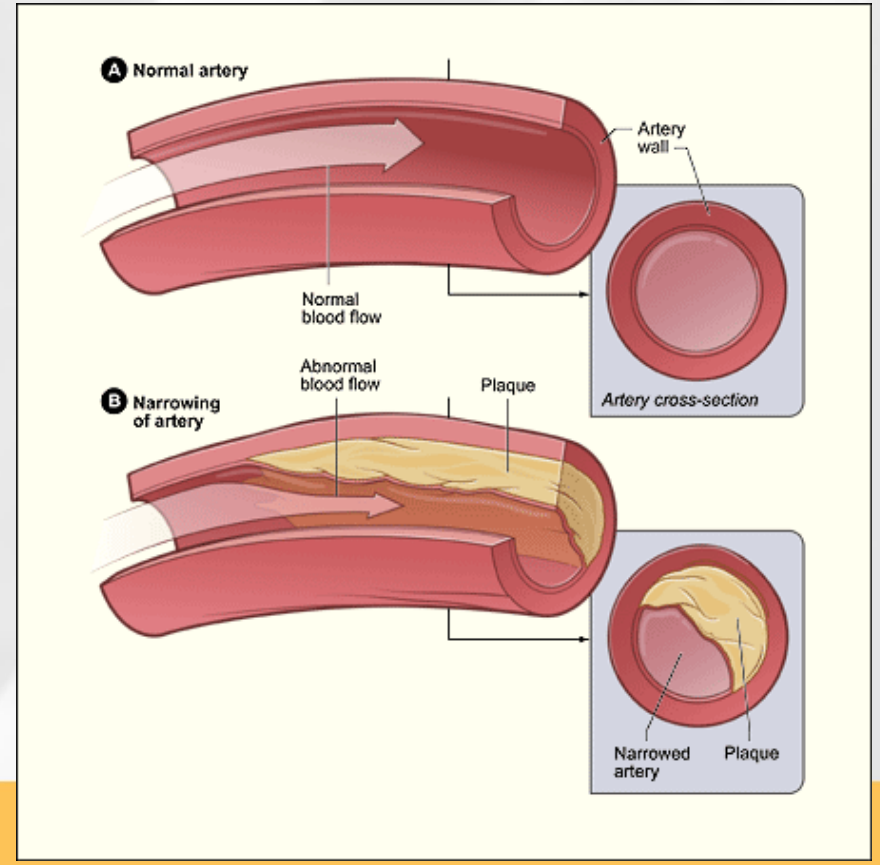
- Pain – most commonly in calves – with ambulation which resolves with rest

- Disease progression:
  - decreased distance
  - increased frequency



Pathophysiology

- Progressive atherosclerosis
- Decreased blood flow
- Muscle ischemia with exertion
- pain

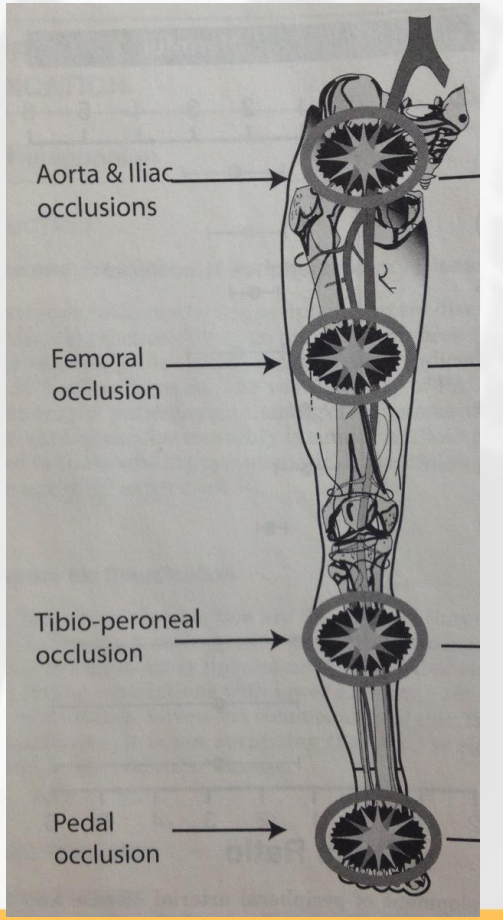


Patterns of Disease

- Usually single level of occlusion
  -> symptoms in muscle group below site of occlusion
- Distal flow through collaterals
- 3 major patterns:
  1) inflow disease
  2) outflow disease
  3) combined disease

inflow

outflow



Buttock/Thigh, Calf claudication

Most common, Calf claudication

In DM, associated with limb-threatening ischemia

Prevalence

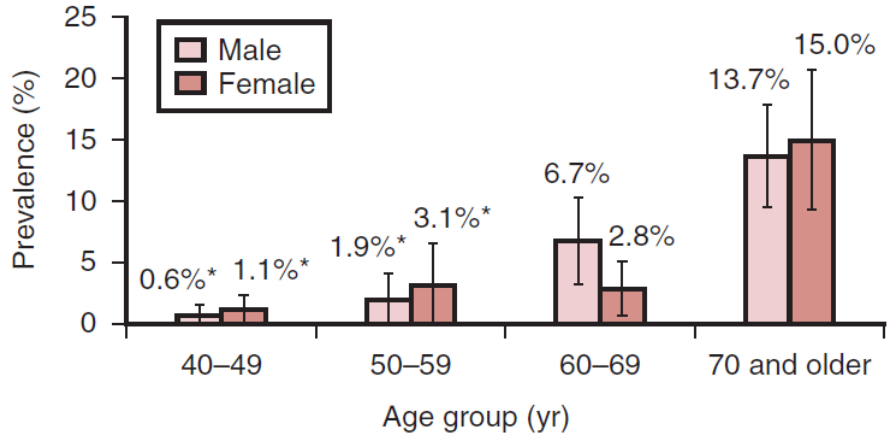


Figure 103-2 Prevalence of peripheral arterial disease by age and gender in adults 40 years and older, United States, 1999–2000 (n = 2174). *(Redrawn from Selvin E, Erlinger TP. Prevalence of and risk factors for peripheral arterial disease in the United States: results from the National Health and Nutrition Examination Survey, 1999-2000.* Circulation. *2004;110:738-43.)*

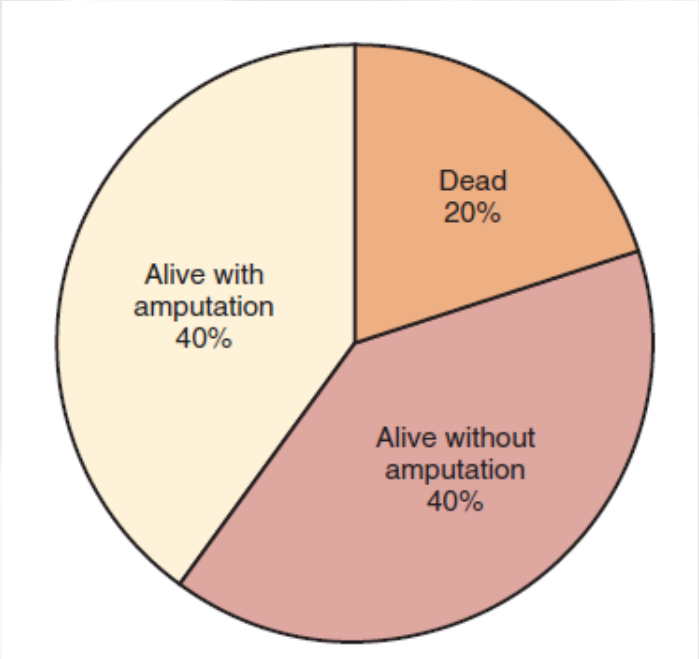
- National Health and Nutrition Examination Survey (NHANES)
- 9000 participants, >40yo ABIs recorded for 2381
- PAD defined as ABI <0.9
- Significant associations with
  - HTN
  - DM
  - HLD
  - smoking
- Affects ~ 10 million, >100,000/year undergo revascularization

Natural History

Claudication

- Slow progression to shorter walking distances
- Rarely limb threatening
- 5yr rate of amputation: <5%
- Clinical deterioration: 25%
- BUT:
  1) profound impact on quality of life
  2) high risk of death – marker for systemic atherosclerosis
  -- 42%, 65% mortality at 5, 10yrs
  -- 66% due to MI

Critical Limb Ischemia



At 6 months after diagnosis

Treatment Approach

- **Risk Factor Identification and Modification**
  -- ASA for MI/CVA prevention
  -- smoking cessation (delays progression, decreases risk of death, decreases graft failure rates)
  -- tight glucose control
  -- normotension (ACE inhibitor)
  -- statin (stabilize existing plaque, reduce vascular inflammation)

- **Pharmacological Therapy**
  -- cilostazol

- **Structured Exercise Therapy**

- **Endovascular or Surgical Intervention**

Treatment for Claudication

- MEDICAL FIRST!
  - Risk of CV event >> risk of limb loss

- Intervention is reserved for
  - Severe, non-remitting, life style-limiting disease

Exercise Therapy for Claudication

- Benefits of exercise in claudicants have been recognized for 30 years

Benefit of Exercise Conditioning for Patients With Peripheral Arterial Disease

William F

Exercise Rehabilitation Programs for the Treatment of Claudication Pain

A Meta-analysis

Andrew W. Gardner, Phl

JAMA. 1995;274(12):975

Exercise Training for Claudication

Kerry J. Stewart, Ed.D., William R. Hiatt, M.D., Judith G. Regensteiner, Ph.D., and Alan T. Hirsch, M.D.

December 12, 2002

N Engl J Med 2002;347:1941-1951

Benefits of supervised exercise therapy

- Reduced cardiovascular risk, decreased XOL, SBP and improved glycemic control
- Improved maximal treadmill walking distance
  - By approx. 200m
- Improved pain-free walking distance
  - By approx. 130m
- Improved 6 min walk test
- Improved QoL scores
- Greater benefit to older patients
- Supervised seems to be superior

Selected References:
Hageman et al, Cochrane review. 2018
Gardner et al, JAMA. 1995
Stewart et al, N Engl J Med. 2002
Vemulapalli et al, Am Heart J. 2015
Wind et al, Eur J Vasc Endovasc Surg. 2007

Key Components of a Structured Exercise Program

- 30-60 min of supervised exercise, at least 3x/week for at least 12 weeks
- Treadmill or track walking
- Walk to point of maximal pain before rest
- Program should have complementary educational components
- Administered by an individual trained in exercise therapy

Challenges of supervised exercise therapy

- Patient compliance
- Requires commitment
- ***No insurance coverage until now***

CMS.gov
Centers for Medicare & Medicaid Services

Decision Memo for Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD) (CAG-00449N)

Decision Summary

A. The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is sufficient to cover supervised exercise therapy (SET) for beneficiaries with intermittent claudication (IC) for the treatment of symptomatic peripheral artery disease (PAD). Up to 36 sessions over a 12 week period are covered if all of the following components of a SET program are met:

The SET program must:

- consist of sessions lasting 30-60 minutes comprising a therapeutic exercise-training program for PAD in patients with claudication;
- be conducted in a hospital outpatient setting, or a physician's office;
- be delivered by qualified auxiliary personnel necessary to ensure benefits exceed harms, and who are trained in exercise therapy for PAD; and
- be under the direct supervision of a physician (as defined in 1861(r)(1)), physician assistant, or nurse practitioner/clinical nurse specialist (as identified in 1861(aa)(5)) who must be trained in both basic and advanced life support techniques.

Beneficiaries must have a face-to-face visit with the physician responsible for PAD treatment to obtain the referral for SET. At this visit, the beneficiary must receive information regarding cardiovascular disease and PAD risk factor reduction, which could include education, counseling, behavioral interventions, and outcome assessments.

B. Medicare Administrative Contractors (MACs) have the discretion to cover SET beyond 36 sessions over 12 weeks and may cover an additional 36 sessions over an extended period of time. A second referral is required for these additional sessions.

C. SET is non-covered for beneficiaries with absolute contraindications to exercise as determined by their primary physician.

May 25, 2017

Treatment Approach

- **Risk Factor Identification and Modification**
  -- ASA for MI/CVA prevention
  -- smoking cessation (delays progression, decreases risk of death, decreases graft failure rates)
  -- tight glucose control
  -- normotension (ACE inhibitor)
  -- statin (stabilize existing plaque, reduce vascular inflammation)
- **Pharmacological Therapy**
  -- cilostazol
- **Structured Exercise Therapy – can now actually be prescribed**
- **Endovascular or Surgical Intervention**

Intervention for Claudication

- Has remained controversial
- Traditional teaching has been risk factor modification and exercise
  "stop smoking and keep walking"
- Surgical intervention reserved for severe symptoms - "life-style limiting" – in low risk patients
- Advent of endovascular therapies has led to more liberal indications

But are we serving this patient population by increasing intervention rate?

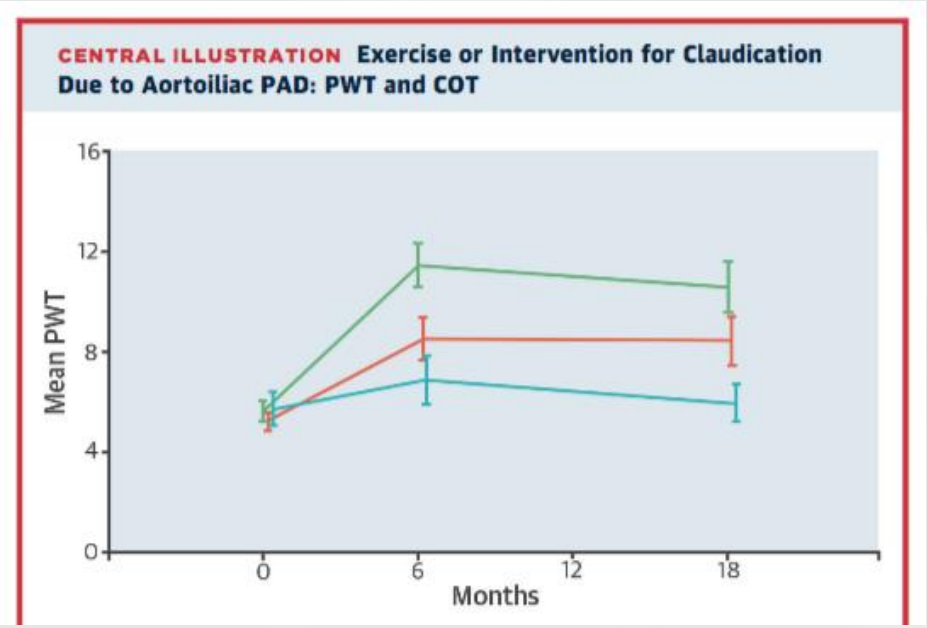
Supervised Exercise, Stent Revascularization, or Medical Therapy for Claudication Due to Aortoiliac Peripheral Artery Disease

The CLEVER Study

Timothy P. Murphy, MD,* Donald E. Cutlip, MD,†‡ Judith G. Regensteiner, PhD,§ Emile R. Mohler III, MD,‖ David J. Cohen, MD, MSc,¶ Matthew R. Reynolds, MD,‡ Joseph M. Massaro, PhD,‡# Beth A. Lewis, PhD,** Joselyn Cerezo, MD,* Niki C. Oldenburg, DrPH,†† Claudia C. Thum, MA,‡ Michael R. Jaff, DO,‡‡ Anthony J. Comerota, MD,§§ Michael W. Steffes, MD,†† Ingrid H. Abrahamsen, MS,‡ Suzanne Goldberg, MSN, Alan T. Hirsch, MD††

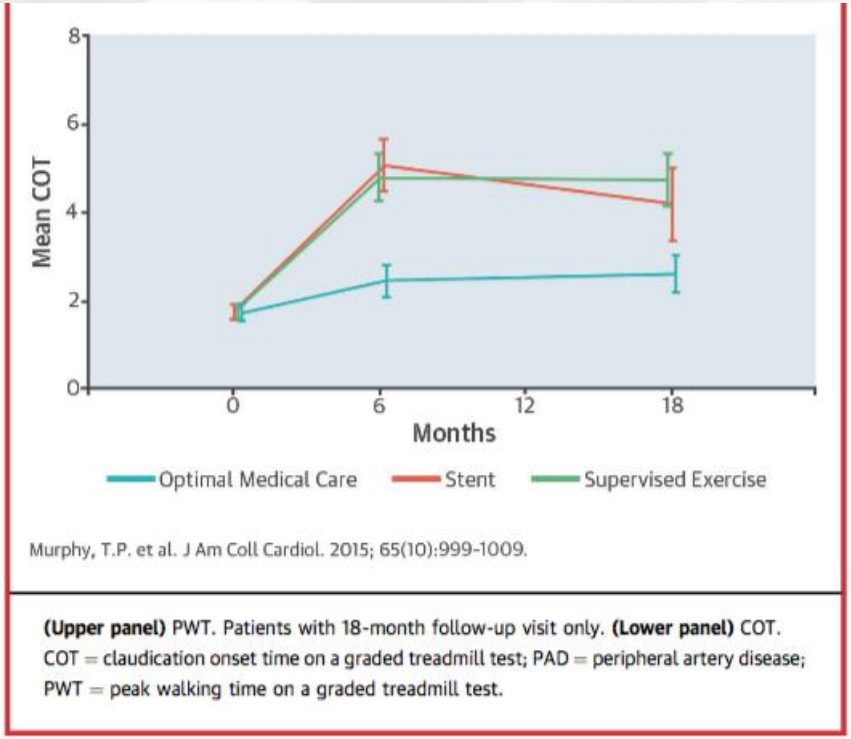
(J Am Coll Cardiol 2015;65:999-1009)

- Prospective, multicenter, randomized, controlled, comparative effectiveness trial
- 111 patients with IC due to aorto-iliac disease
  - Supervised exercise
  - Primary stenting
  - Optimal medical management (cilostazol)
- 6 months and 18 months outcomes
- Outcome measures
  - Peak walking time
  - Claudication onset time
  - Quality of Life measures



Peak walking time

Claudication onset time



SET is

- superior to endovascular intervention for peak walking time
- equivalent for claudication onset time

Pivotal study in obtaining CMS coverage for SET

Comparative Efficacy of Endovascular Revascularization Versus Supervised Exercise Training in Patients With Intermittent Claudication

Meta-Analysis of Randomized Controlled Trials

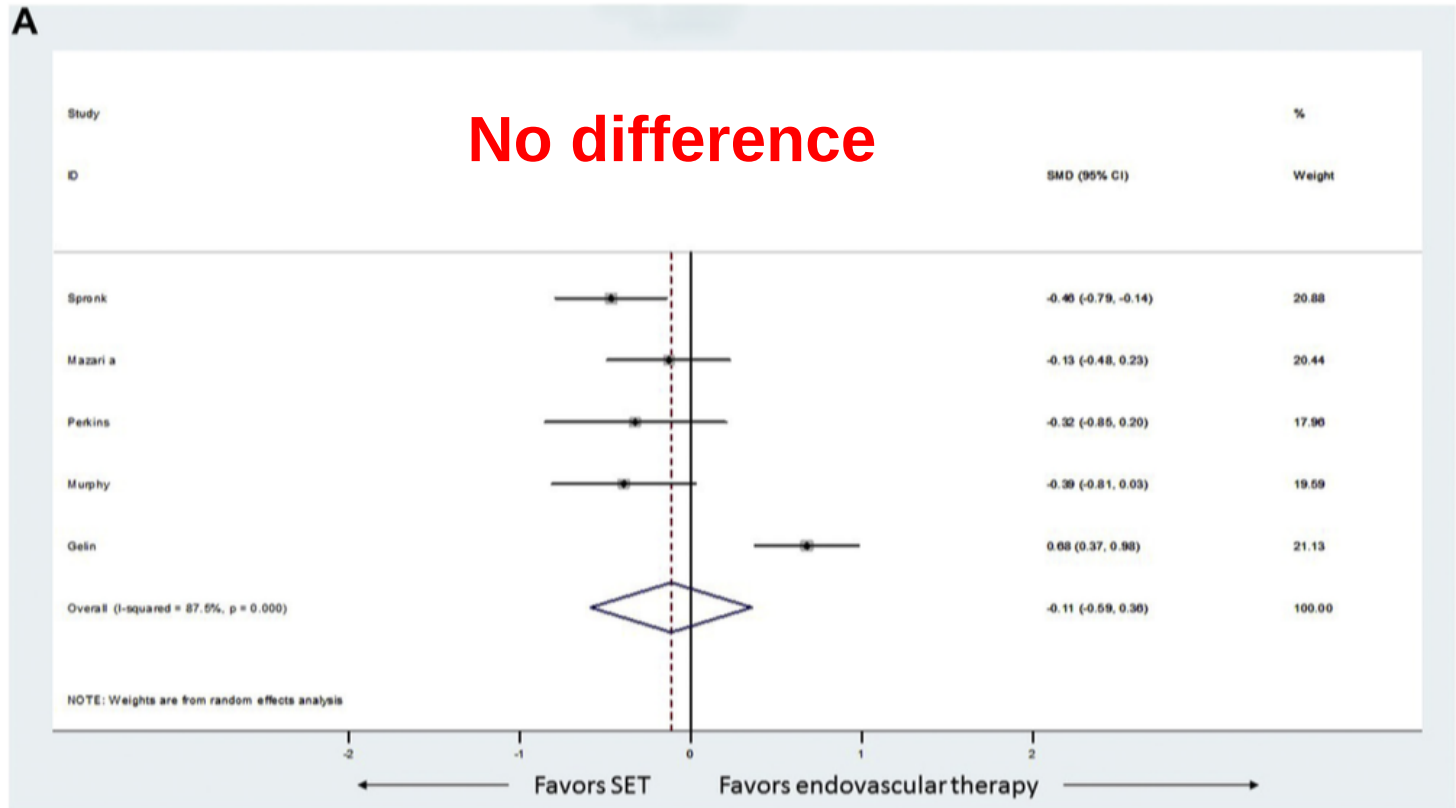
Ambarish Pandey, MD,[a] Subhash Banerjee, MD,[a] Christian Ngo, MD,[a] Purav Mody, MD,[a] Steven P. Marso, MD,[a] Emmanouil S. Brilakis, MD, PhD,[a] Ehrin J. Armstrong, MD, MS,[b] Jay Giri, MD, MPH,[c] Marc P. Bonaca, MD, MPH,[d] Aruna Pradhan, MD, MPH,[d] Anthony A. Bavry, MD, MPH,[e] Dharam J. Kumbhani, MD, SM[a]

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 10, NO. 7, 2017
APRIL 10, 2017:712–24

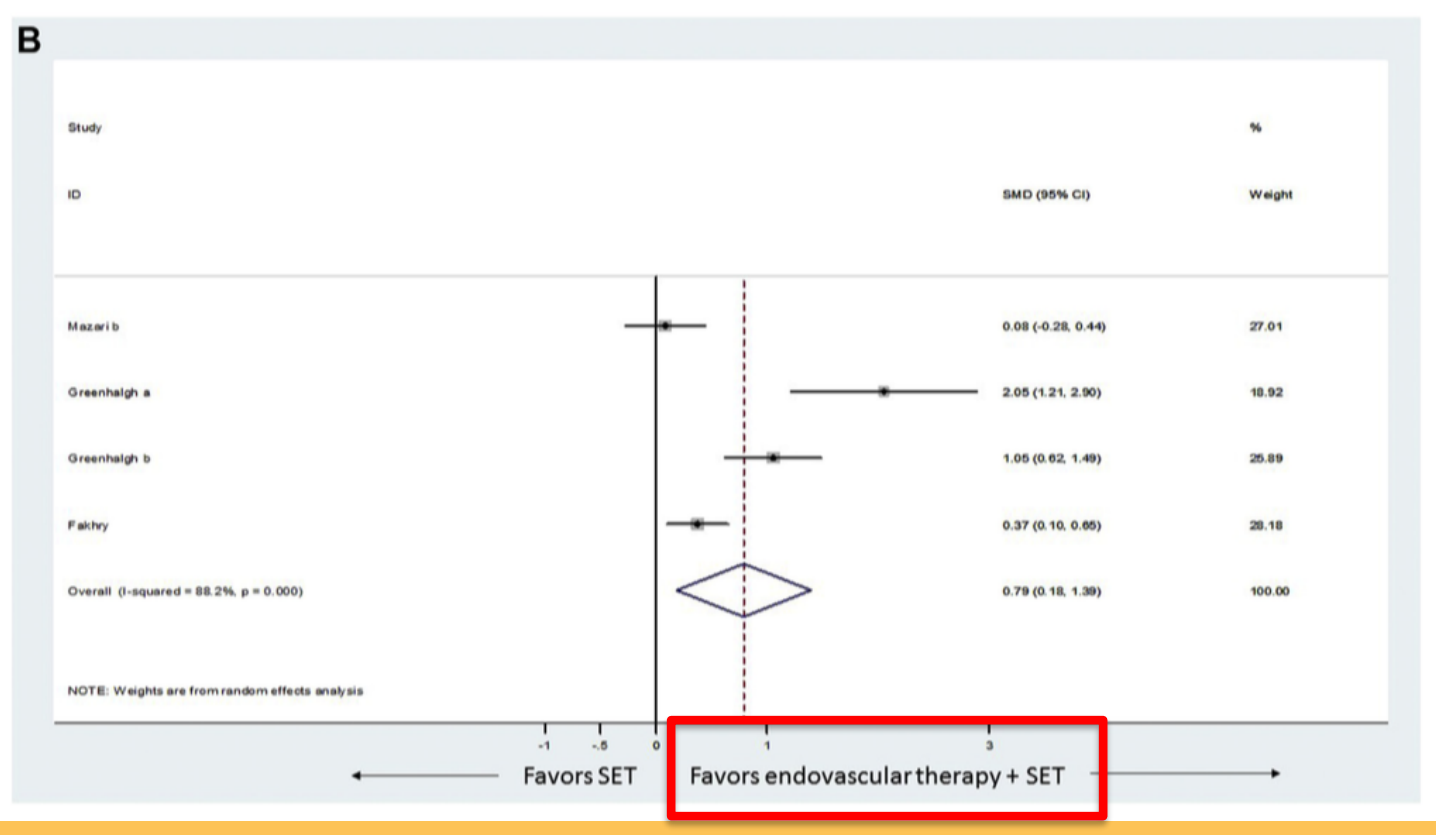
- Meta-analysis assessing endovascular revascularization with or without SET
- 7 trials, 987 patients. Aortoiliac and femoropopliteal Dz
- Outcome Measures:
  - max treadmill walking distance at 12 months
  - Need for revascularization or amputation at follow up

- Results:
  - Maximal walking distance SET vs. endo only

FIGURE 2 Forest Plot for Maximal Walking Distance on Follow-Up

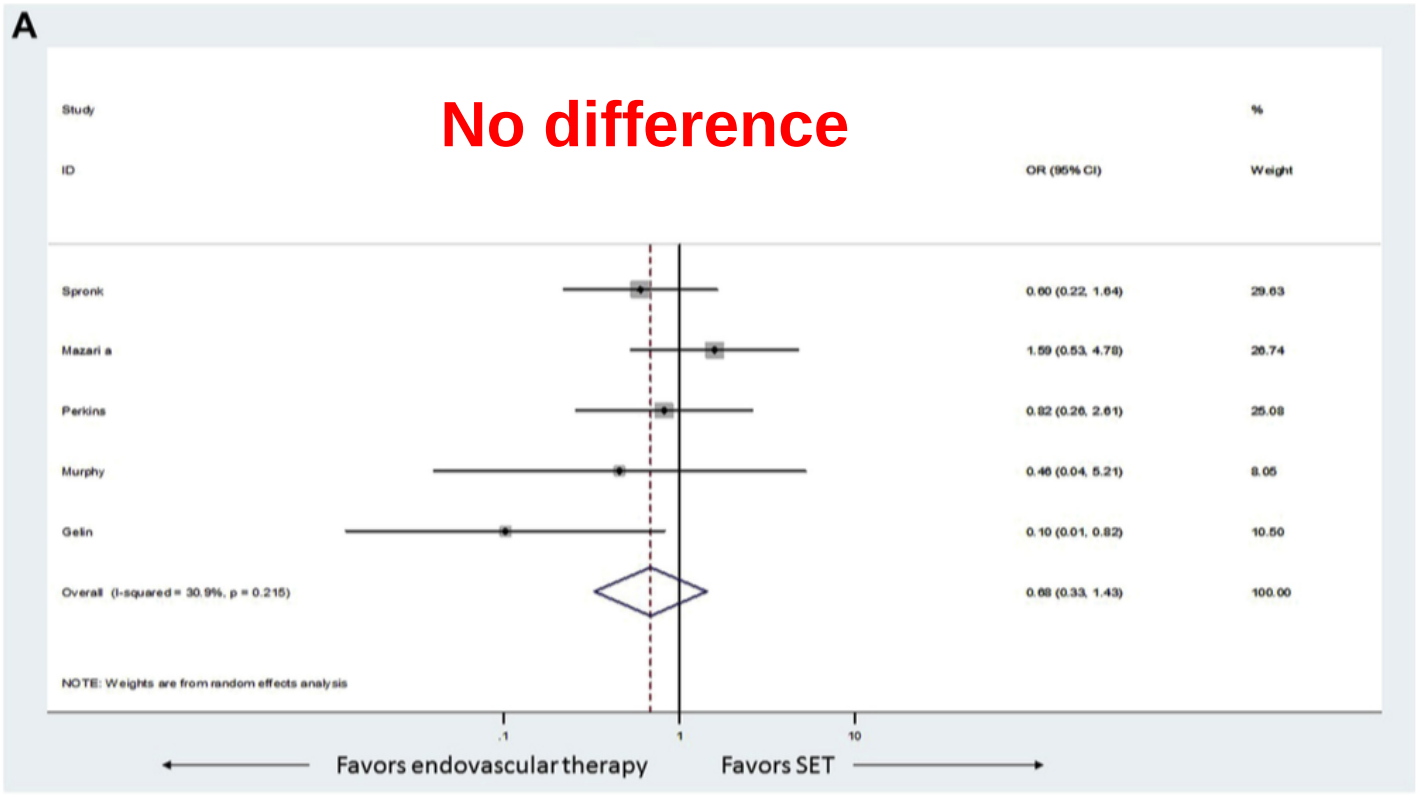


- Results:
  - Maximal walking distance SET vs. SET + endo

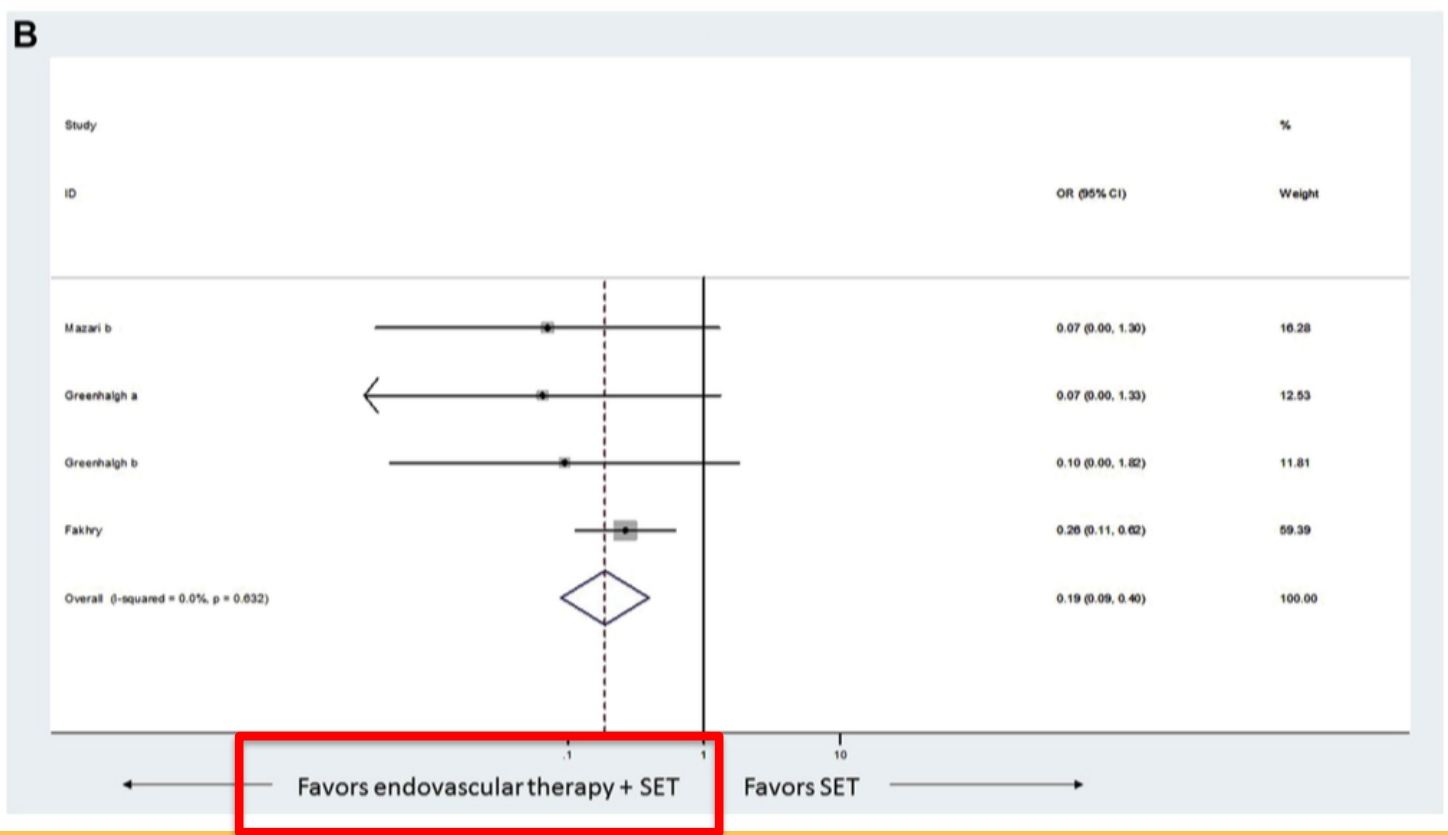


- Results:
  - Need for revascularization or amputation at f/u SET vs. endo only

FIGURE 4 Forest Plot for Need for Revascularization or Amputation on Follow-Up



- Results:
  - Need for revascularization or amputation at f/u SET vs. SET + endo



Summary

- No benefit to endovascular intervention alone compared to SET
  - maximal walking distance
  - Need for repeat intervention/amputation
- There IS a potentiating effect of combined endovascular intervention AND exercise
  - Improvement in all outcome measures

In Conclusion: Vascular Rehab is indeed for Real!

- SET has been known to provide benefits to claudicants for 3 decades
  - Increased maximal and pain free walking distance
  - Improved quality of life assessment
  - Recommended first line therapy for claudication
- Now covered by Medicare – 2018!
  - 3rd party payers pending
- Ability to use endovascular treatment in conjunction with SET may further improve patient outcome
  - Further studies needed
  - Aortoiliac vs. femoropopliteal interventions
  - Longer term outcomes

Thank you for your attention