



HARVARD MEDICAL SCHOOL  
TEACHING HOSPITAL



# Before ~~Think Big Beyond Intervention:~~ Supervised Exercise

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Presenter Name/Date*



MASSACHUSETTS  
GENERAL HOSPITAL

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INSTITUTE FOR HEART,  
VASCULAR AND STROKE CARE

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## Conflicts of Interest

- **Consultant**

- Abbott Vascular (non-compensated)
- American Genomics, Inc
- Astra Zeneca Pharmaceuticals, Inc
- Biomet Biologics
- Boston Scientific (non-compensated)
- Cordis Corporation (non-compensated)
- Covidien (non-compensated)
- Ekos Corporation (DSMB)
- Medtronic (non-compensated)
- Micell, Inc
- Primacea

- **Board Member**

- VIVA Physicians (Not For Profit 501(c) 3 Organization)
  - [www.vivapvd.com](http://www.vivapvd.com)
- CBSET

- **Equity**

- Access Closure, Inc
- Embolitech, Inc
- Hotspur, Inc
- Icon Interventional, Inc
- I.C.Sciences, Inc
- Janacare, Inc
- MC10
- Northwind Medical, Inc.
- PQ Bypass, Inc
- Primacea
- Sadra Medical
- Sano V, Inc.
- Vascular Therapies, Inc

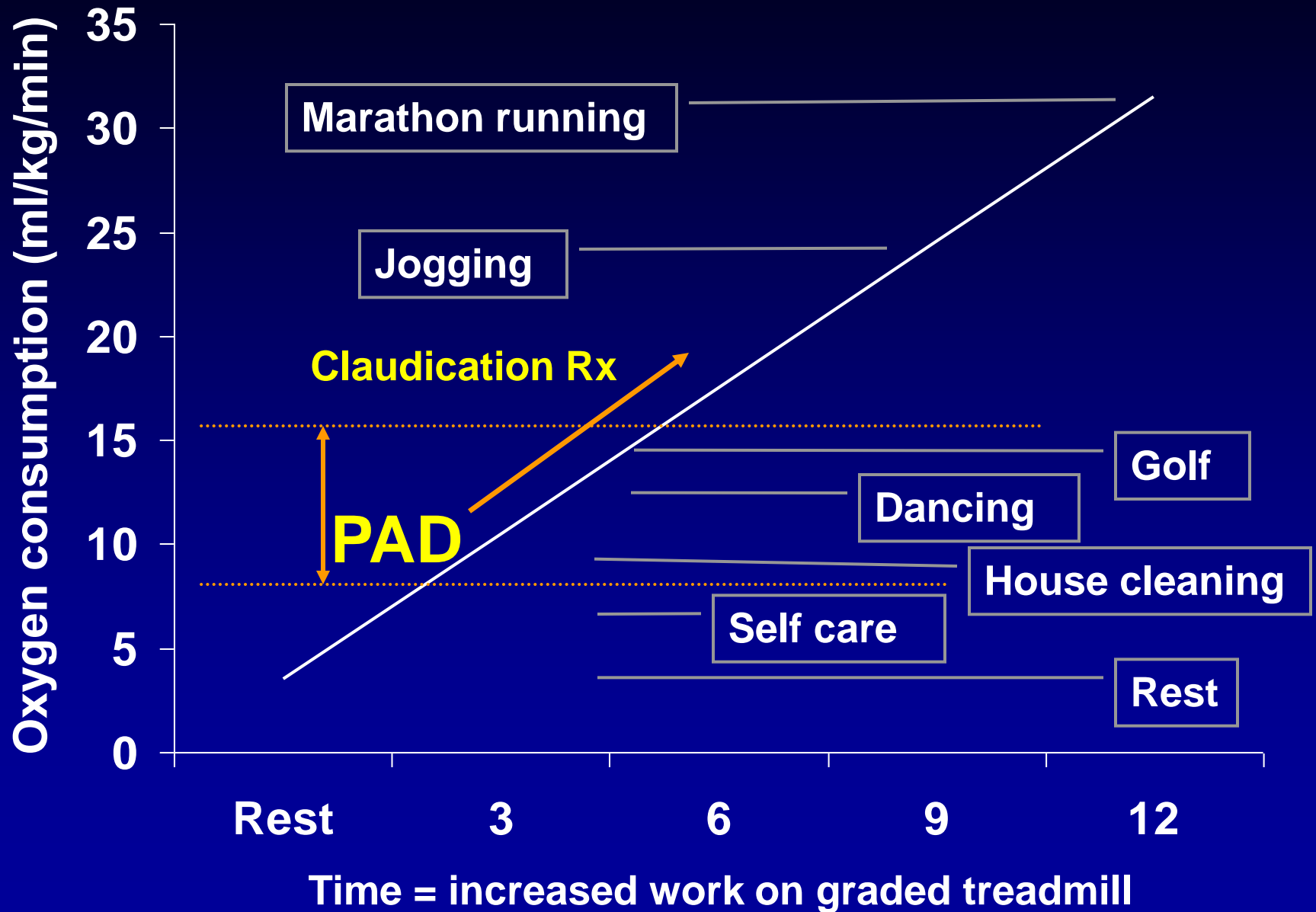
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# What is the Functional Impact of PAD?



# What are the Characteristics of an Ideal Claudication Intervention?

- Effective in increasing pain-free and maximal walking distance
- Effective in improving subjective symptoms
- Minimal morbidity
- No or minimal mortality
- Cost-effective
- Available to the millions of people with claudication

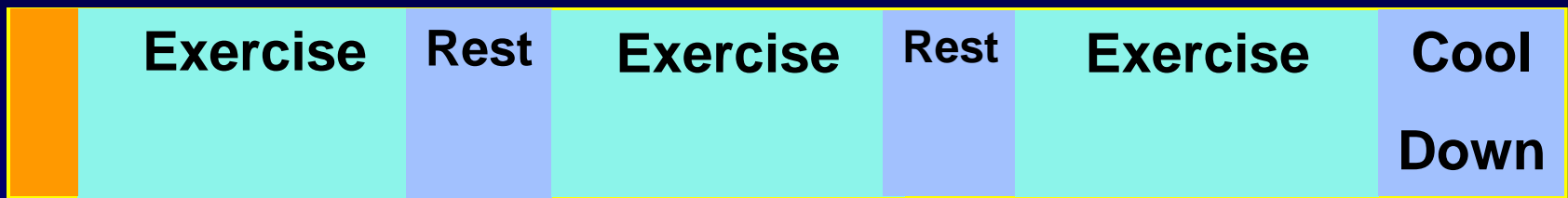
*Exercise training for IC serves as a model intervention*

# Claudication Exercise Programs

- Effective at improving exercise performance, walking ability and physical functioning
- Safe, with no recorded morbidity or mortality
- Potential to improve other atherosclerosis risk factors
- Patient must be motivated and compliant
- Supervised and performed 3 times/week
- Duration: usually 3 months (rarely longer)
- Cost-effective compared to invasive treatments
- Availability of supervised programs is limited

# The PAD Exercise Training Program

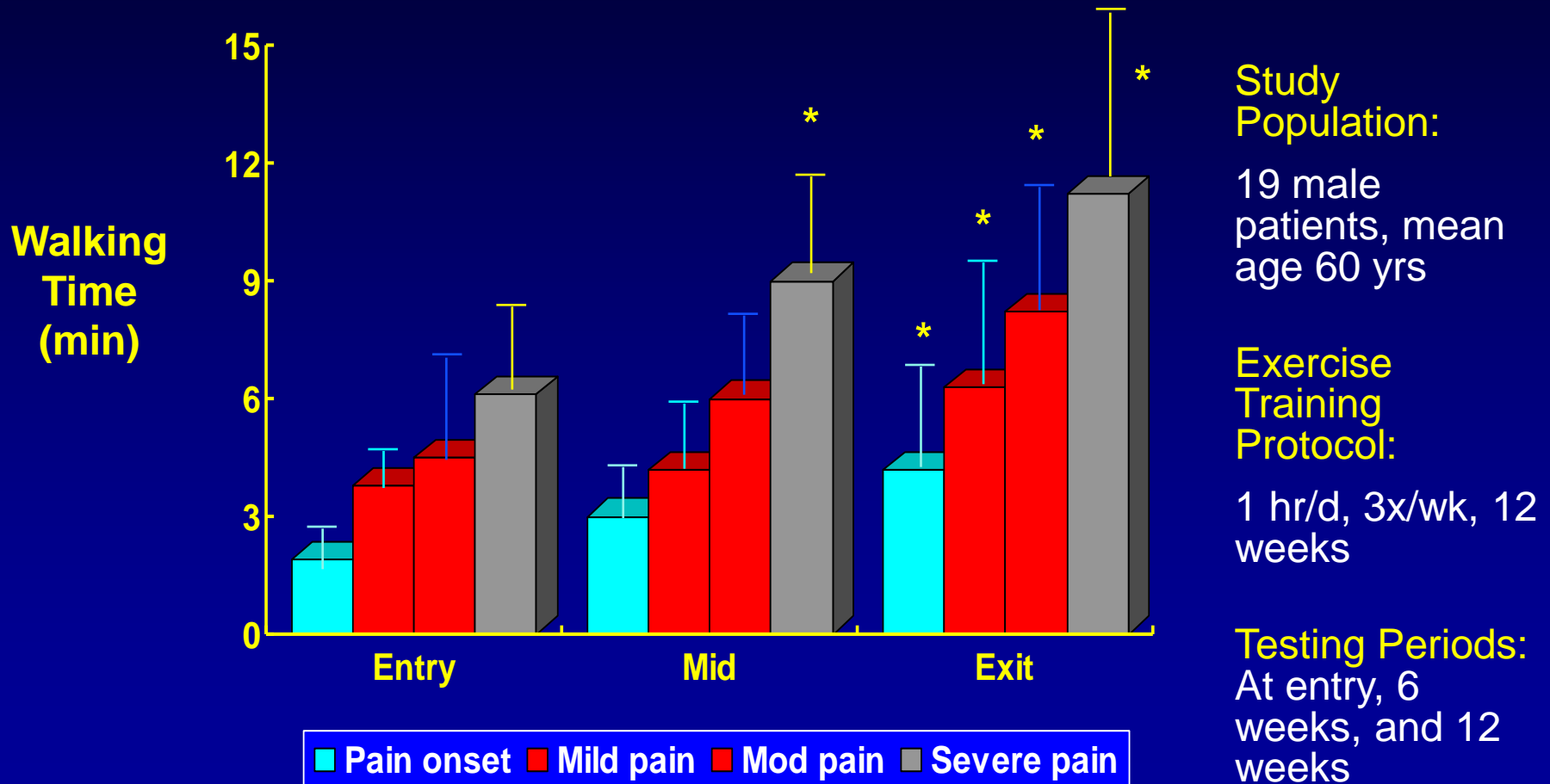
## Warm-up



- **Warm-up:** Approximately 5 minutes
- **Repeated exercise periods:** End at moderate claudication level
- **Rest Periods:** Until claudication abates

*This program has not been shown to be efficacious in a “home” setting. It requires a specific procedure and environment, much like invasive procedures...*

# Effects of Exercise Training *Claudication Pain Severity*



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

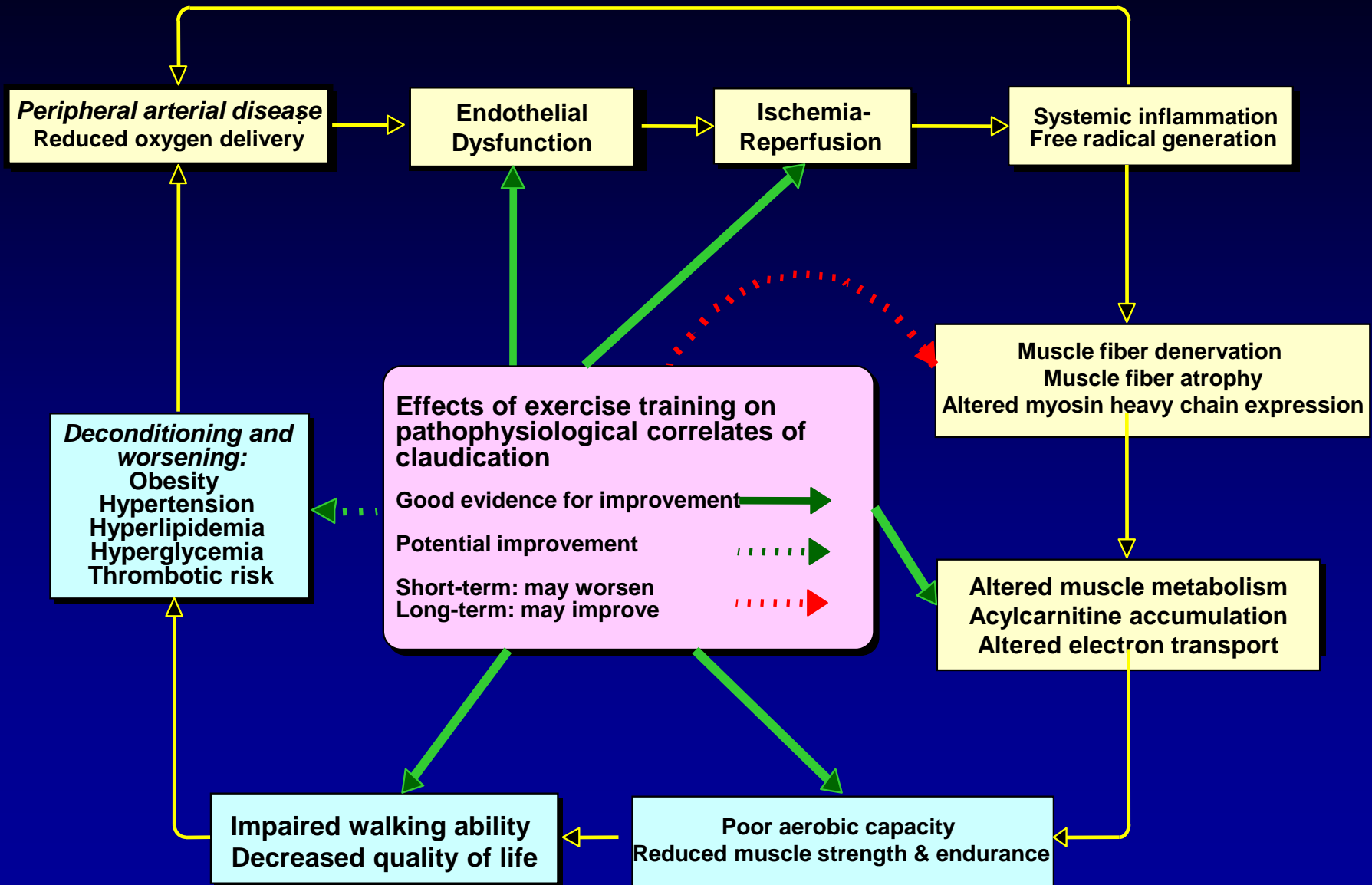
	Exercise	Control	Change
Pain-Free Walking Distance	<b>180% *</b>	40%	2 blocks
Maximal Walking Distance	<b>130% *</b>	30%	3 blocks

1 block = 80 m

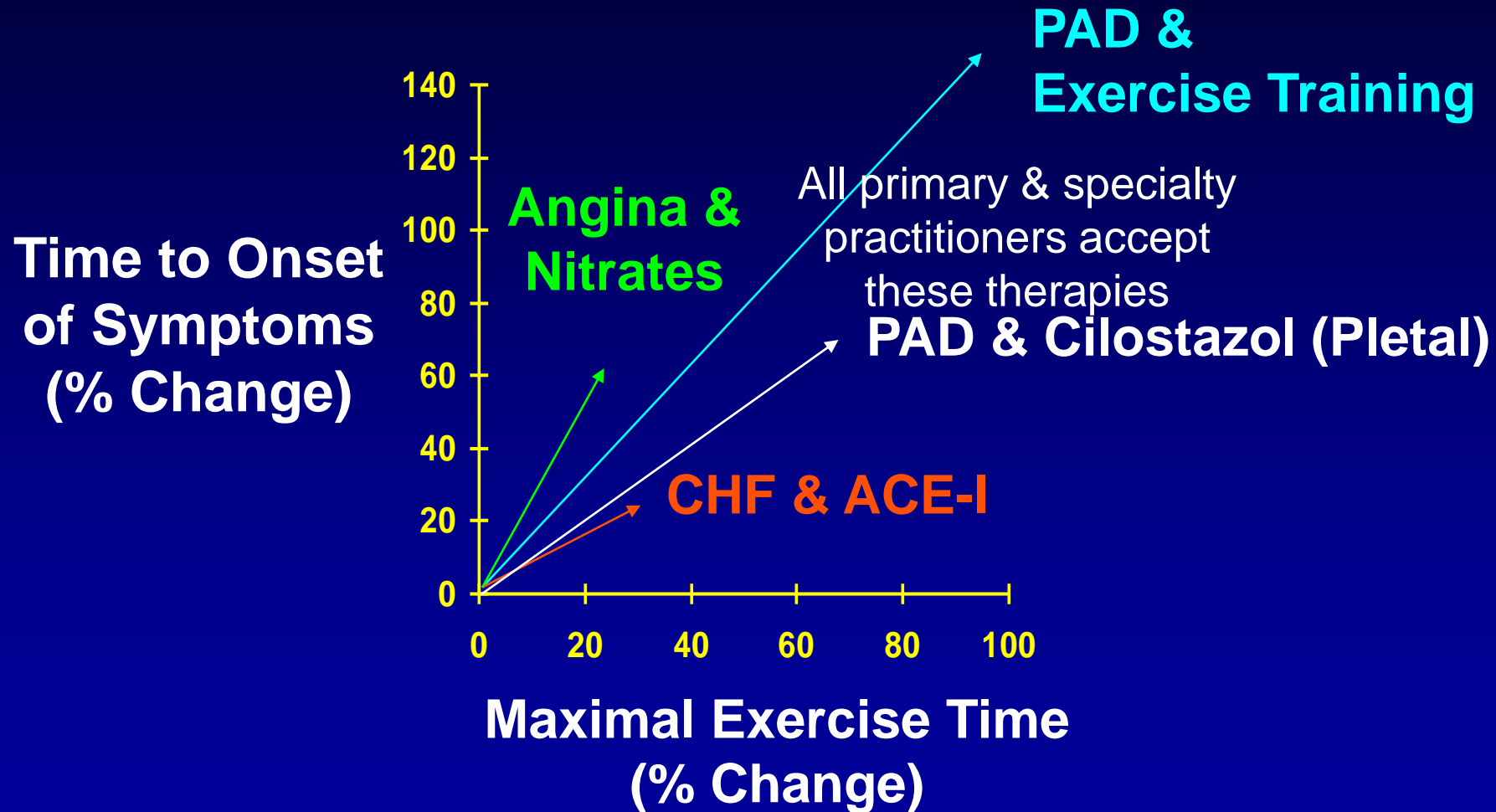
- Predictors of improvement
  - Moderate claudication pain
  - Walking exercise
  - > 3 (or 6) months exercise training
  - Supervised exercise



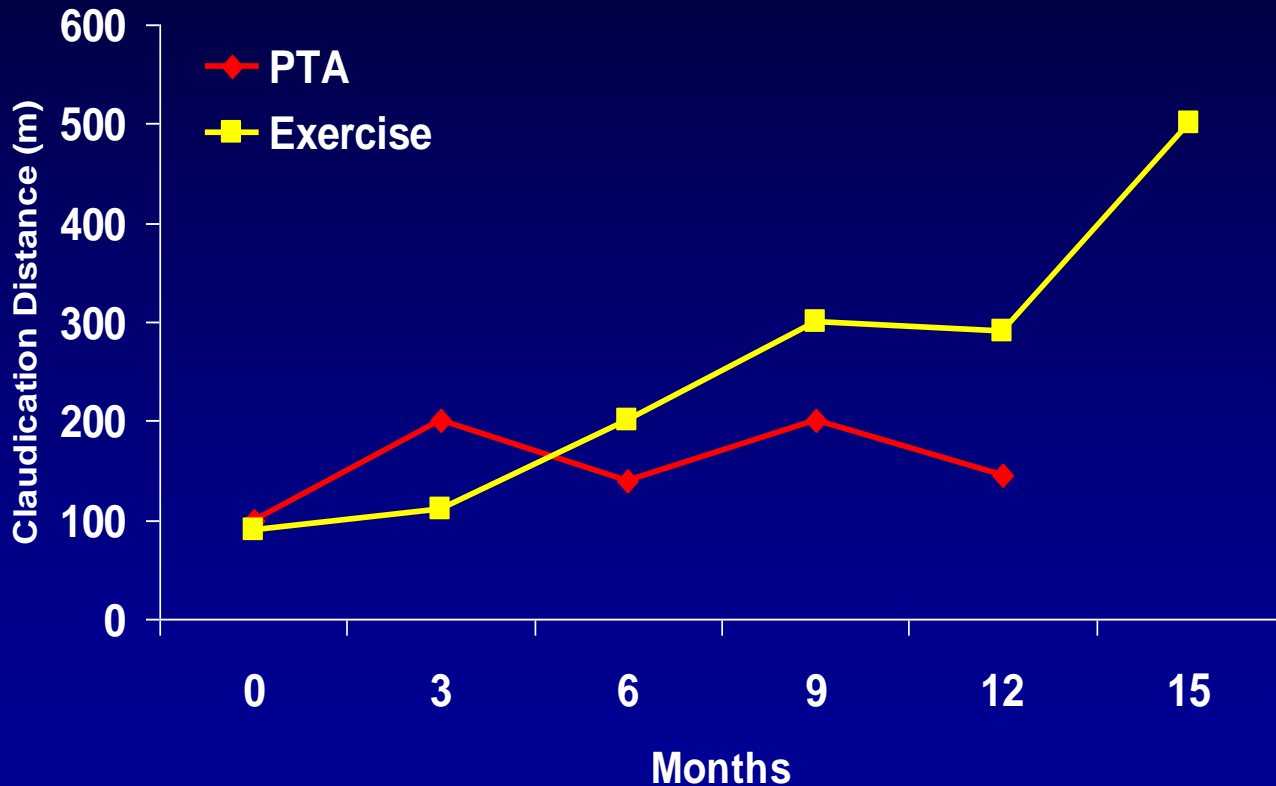
# Potential Mechanisms by Which Exercise Improves Claudication



# Relative Benefit of Exercise Training (vs. other care) in Cardiovascular Diseases

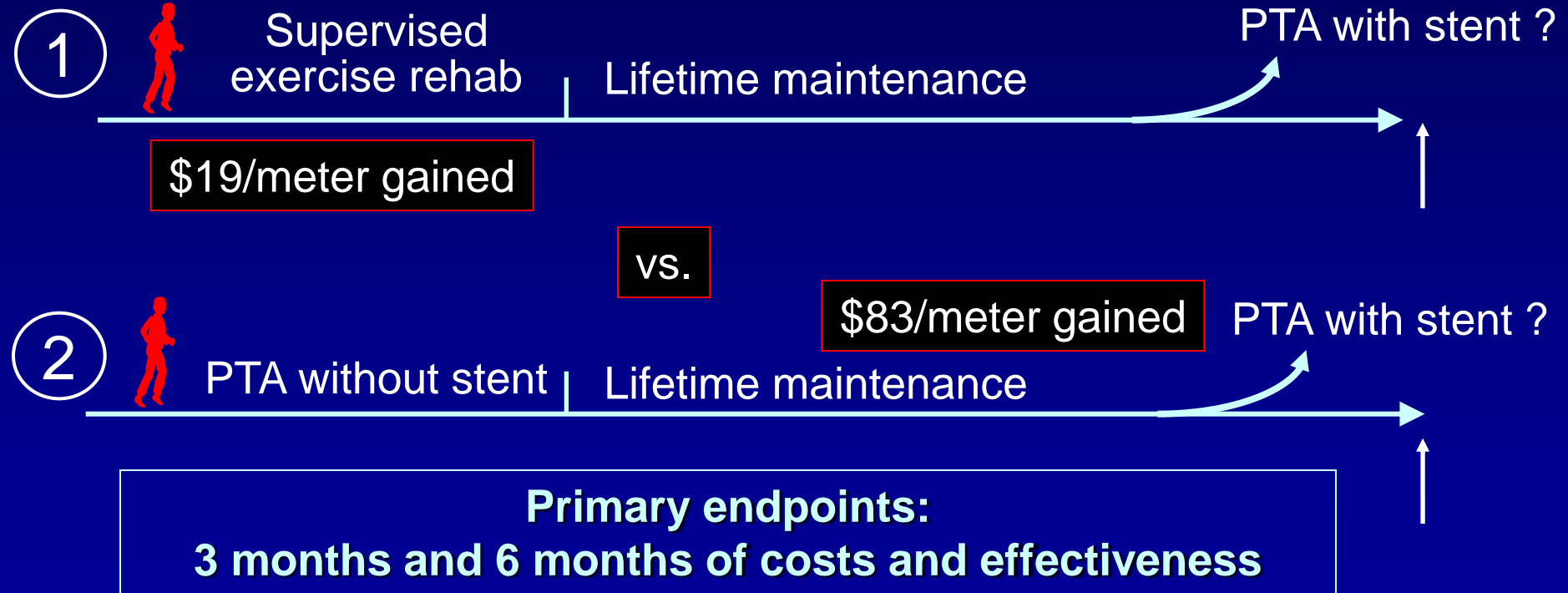


# Exercise Training vs PTA: Relative Long-term Effects on Claudication



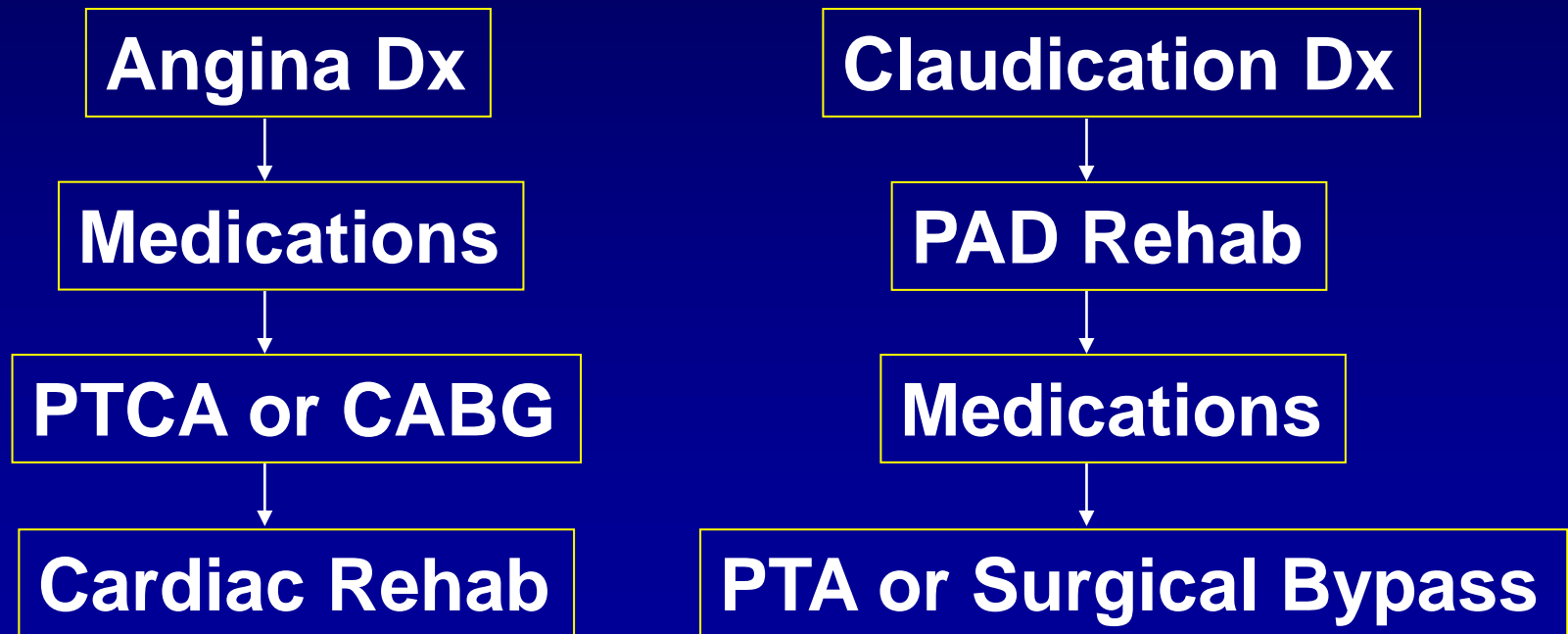
# A Model: Claudication Treatments Compared

Claudication treatment by (1) exercise rehabilitation or (2) PTA were compared in cost-effectiveness analysis at 3 months and 6 months

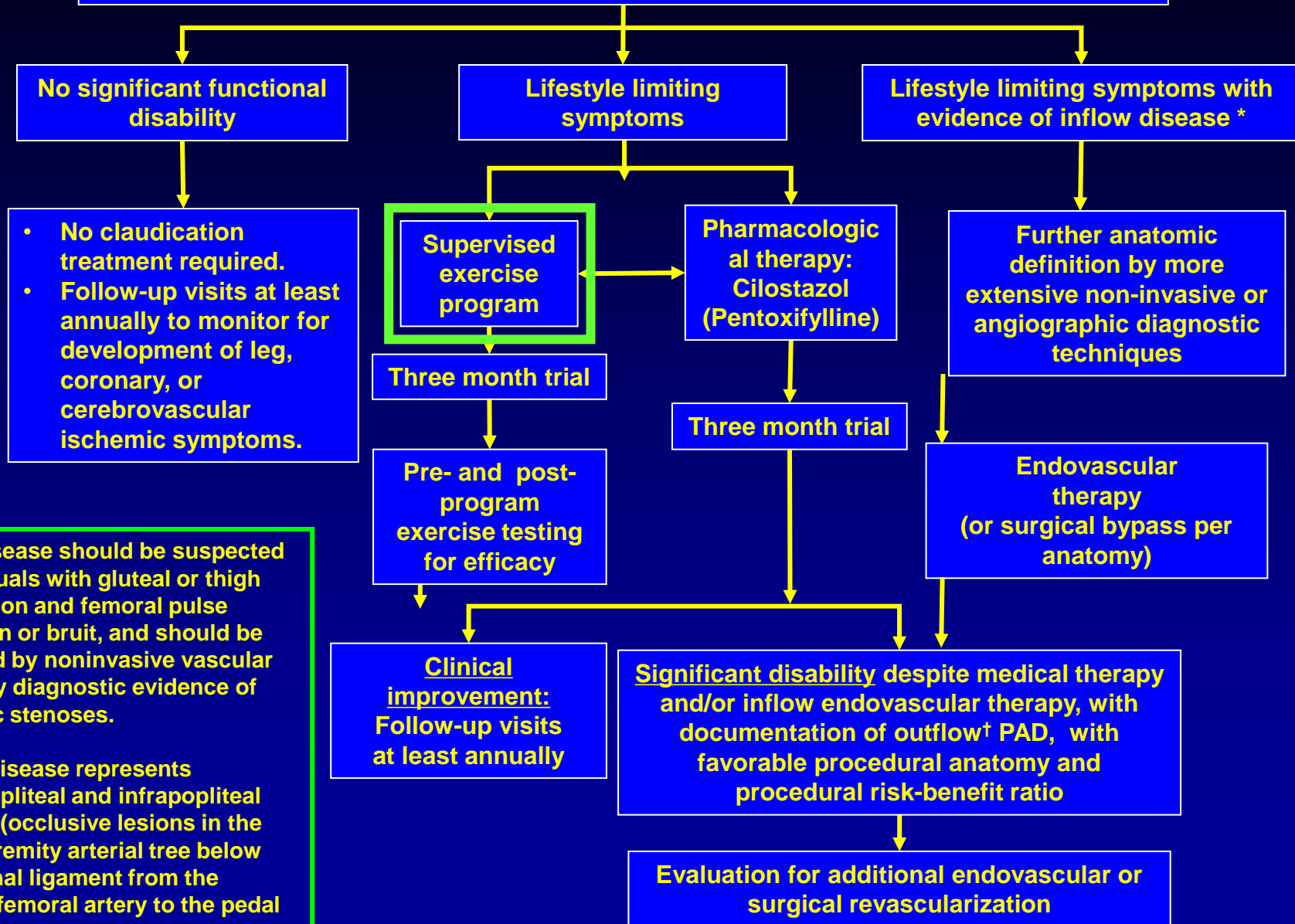


# When Should You Prescribe Exercise?

**PAD Rehabilitation is a “First Line” CVD intervention, and is therefore different from cardiac rehabilitation ...**



# Individual with Classic Claudication

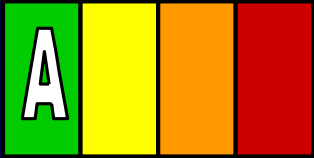


\* Inflow disease should be suspected in individuals with gluteal or thigh claudication and femoral pulse diminution or bruit, and should be confirmed by noninvasive vascular laboratory diagnostic evidence of aorto-iliac stenoses.

† Outflow disease represents femoropopliteal and infrapopliteal stenoses (occlusive lesions in the lower extremity arterial tree below the inguinal ligament from the common femoral artery to the pedal vessels).

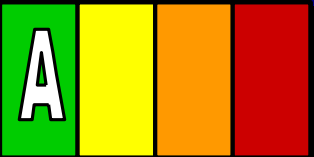
# Supervised Exercise Rehabilitation

I IIa IIb III



A program of supervised exercise training is recommended as an initial treatment modality for patients with intermittent claudication.

I IIa IIb III



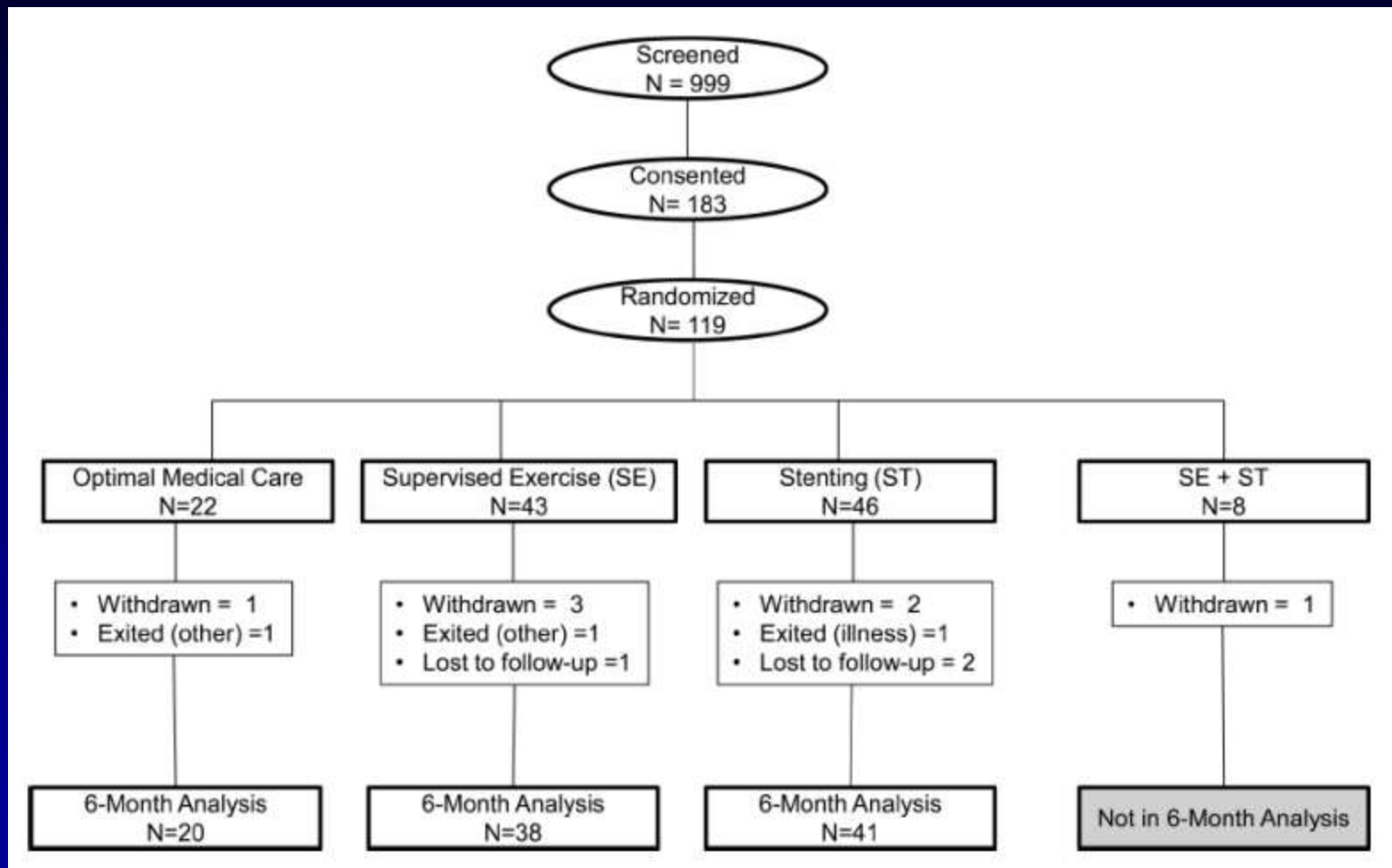
Supervised exercise training should be performed for a minimum of 30 to 45 minutes, in sessions performed at least three times per week for a minimum of 12 weeks.

# **Supervised Exercise Versus Primary Stenting for Claudication Resulting From Aortoiliac Peripheral Artery Disease Six-Month Outcomes From the Claudication: Exercise Versus Endoluminal Revascularization (CLEVER) Study**

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Beth A. Lewis, PhD; Joselyn Cerezo, MD; Niki C. Oldenburg, Dr. PH.; Claudia C. Thum, MA;  
Suzanne Goldberg, MSN; Michael R. Jaff, DO; Michael W. Steffes, MD; Anthony J. Comerota, MD;  
Jonathan Ehrman, PhD; Diane Treat-Jacobson, RN, PhD; M. Eileen Walsh, RN, PhD;  
Tracie Collins, MD; Dalynn T. Badenhop, PhD; Ulf Bronas, PhD;  
Alan T. Hirsch, MD; for the CLEVER Study Investigators



# CLEVER

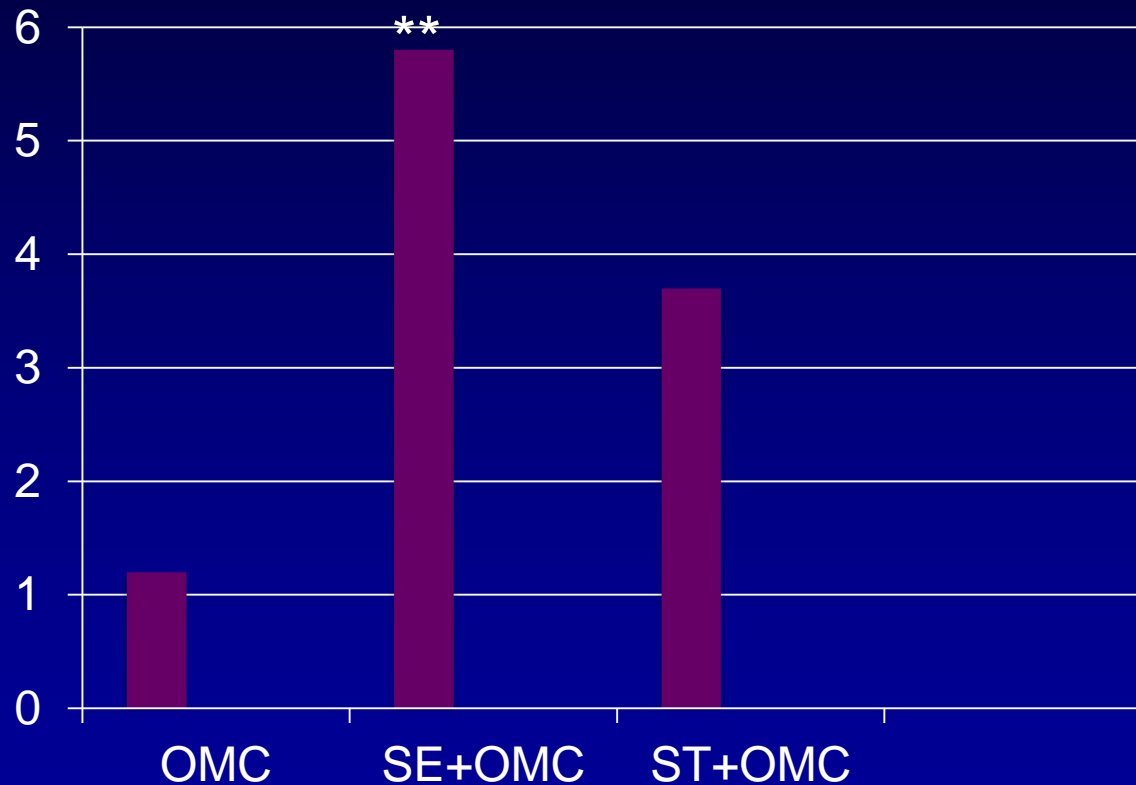


# CLEVER

	OMC (n=22)	SE+OMC (n=43) Mean±SD	ST+OMC (n=46) Mean±SD	<i>P</i>
<b>Risk factors</b>				
Blood pressure, mm Hg				
SBP	136.2±13.7	134.9±22.0	135.9±18.5	0.953
DBP	77.2±10.1	73.9±12.0	73.5±11.5	0.453
<b>Lipid profile</b>				
LDL, mg/dL	105.1±38.6	101.2±41.8	104.1±30.1	0.903
HDL, mg/dL	48.3±12.3	49.3±15.5	48.2±14.5	0.935
Triglycerides, mg/dL	135.3±69.7	146.8±81.9	147.4±141.7	0.902
HbA <sub>1c</sub> , %	6.3±1.3	6.1±1.1	6.4±1.2	0.499
C-reactive protein, mg/dL	1.0±0.2	1.0±0.3	1.0±0.3	0.866
Fibrinogen, mg/dL	408.4±66.1	416.4±105.1	400.3±96.3	0.737
<b>Anthropomorphic characteristics</b>				
BMI, kg/m <sup>2</sup>	28.1±5.9	27.7±5.2	29.3±6.0	0.412
Waist circumference, cm	100.2±14.2	97.3±13.6	102.3±14.9	0.269
<b>ABI and baseline performance</b>				
ABI (lowest limb)	0.73±0.18	0.66±0.20	0.66±0.20	0.381
PWT, min	5.5±2.5	5.3±2.3	5.2±2.0	0.854
COT, min	1.7±0.7	1.6±0.9	1.7±0.83	0.891
7-d free-living steps, n	21 971±16 499	16 803±10 610	20 480±12 765	0.330
Hourly free-living steps, n	343±411	264±216	291±196	0.582

# CLEVER—Primary Endpoint

Change in PWT from Baseline to 6-Months



# CLEVER—Quality of Life

Measure	OMC (n=20)	SE+OMC (n=38)	ST+OMC (n=41)	P, SE vs OMC	P, ST vs. OMC	P, SE vs ST
Change from baseline to 6 mo						
SF-12 physical	1.2±11.0	5.9±10.1	6.6±8.5	0.047	0.023	0.958
SF-12 mental	-2.4±8.0	-2.2±11.5	-1.7±9.9	0.810	0.713	0.862
WIQ pain severity	16.3±34.7	26.3±36.3	40.4±43.9	0.251	<0.001	0.014
WIQ walking distance	-0.5±26.0	25.1±27.6	43.8±42.2	0.007	<0.001	0.029
WIQ walking speed	1.47±15.69	16.5±19.7	30.8±31.0	0.007	<0.001	0.007
WIQ stair climbing	10.2±29.3	24.0±20.9	29.3±39.1	0.071	0.051	0.539
PAQ physical limitation	0.6±22.5	16.2±19.2	28.1±30.9	0.012	<0.001	0.043
PAQ symptoms	1.0±17.2	16.3±21.4	29.2±27.4	0.008	<0.001	0.002
PAQ social limitation	-10.6±29.6	8.8±30.0	17.6±30.2	0.016	<0.001	0.156
PAQ treatment satisfaction	-8.1±19.1	4.6±20.7	4.0±25.9	0.013	0.010	0.323
PAQ quality of life	0.8±26.7	17.3±20.8	30.4±28.3	0.011	<0.001	0.006
PAQ summary	-3.1±18.6	13.8±17.0	28.0±26.4	0.001	<0.001	0.002

# Exercise Therapy for PAD

- It works
- Low risk
- High efficacy
- Low Cost
- Does not burn a bridge to future revascularization