

Supervised Exercise Therapy for Peripheral Artery Disease (PAD)

American Heart Association



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Learning Objectives

- Learn the basics of **developing an exercise training program** for patients with symptomatic PAD.
- Learn how to **implement an exercise training program** for patients with symptomatic PAD.



Exercise Training in Patients With PAD

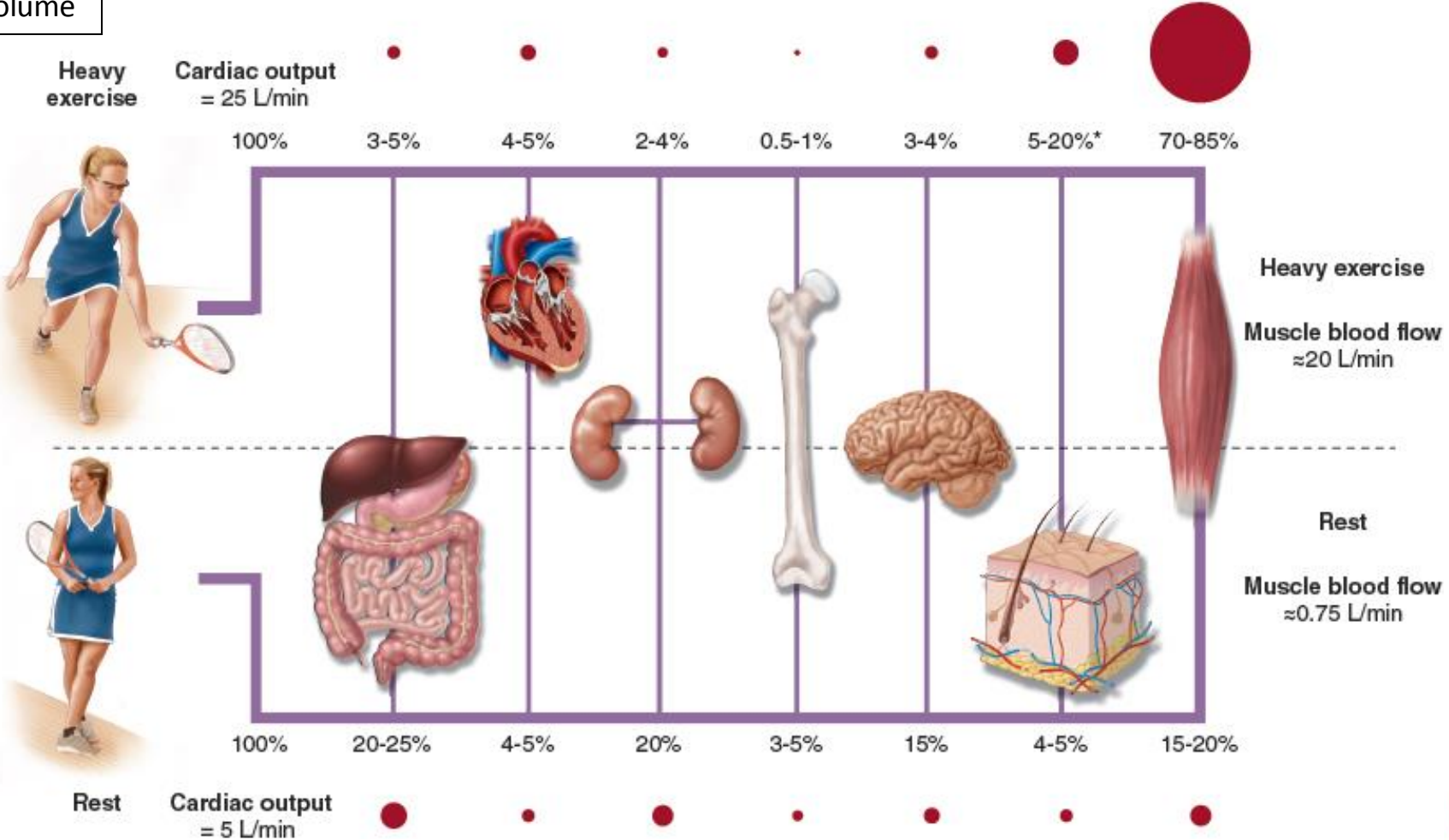
Exercise Training in Patients with PAD



- Efficacy of ***supervised treadmill training*** to improve walking distance in patients with claudication is well established
- Mechanisms by which exercise training improves walking include both local and systemic changes

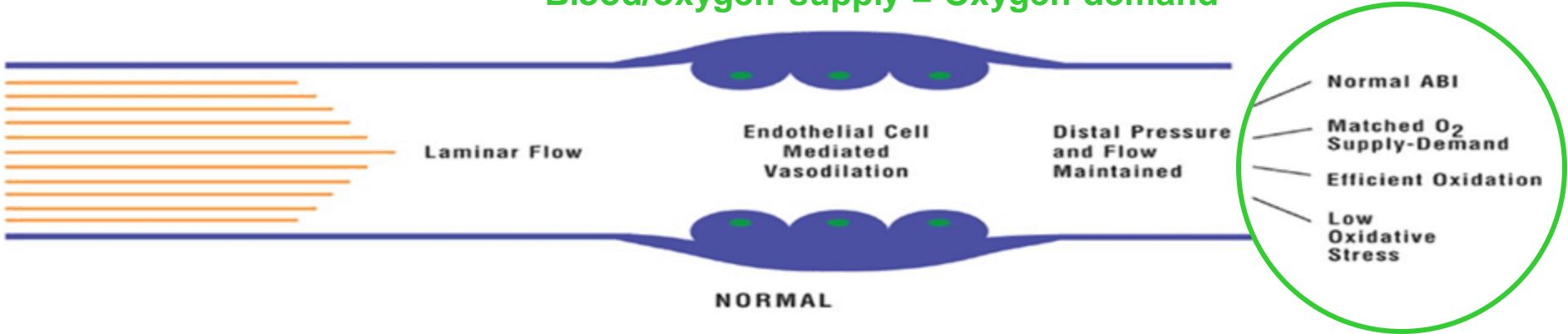
Understanding the Physiology of Exercise

Cardiac Output =
HR x stroke volume

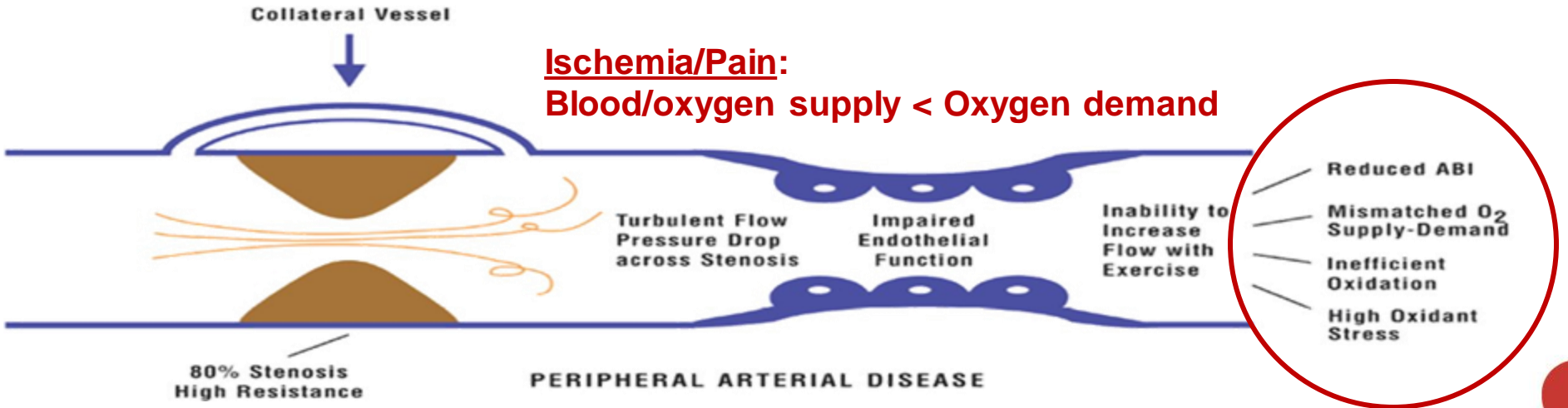


Understanding the Physiology of Exercise

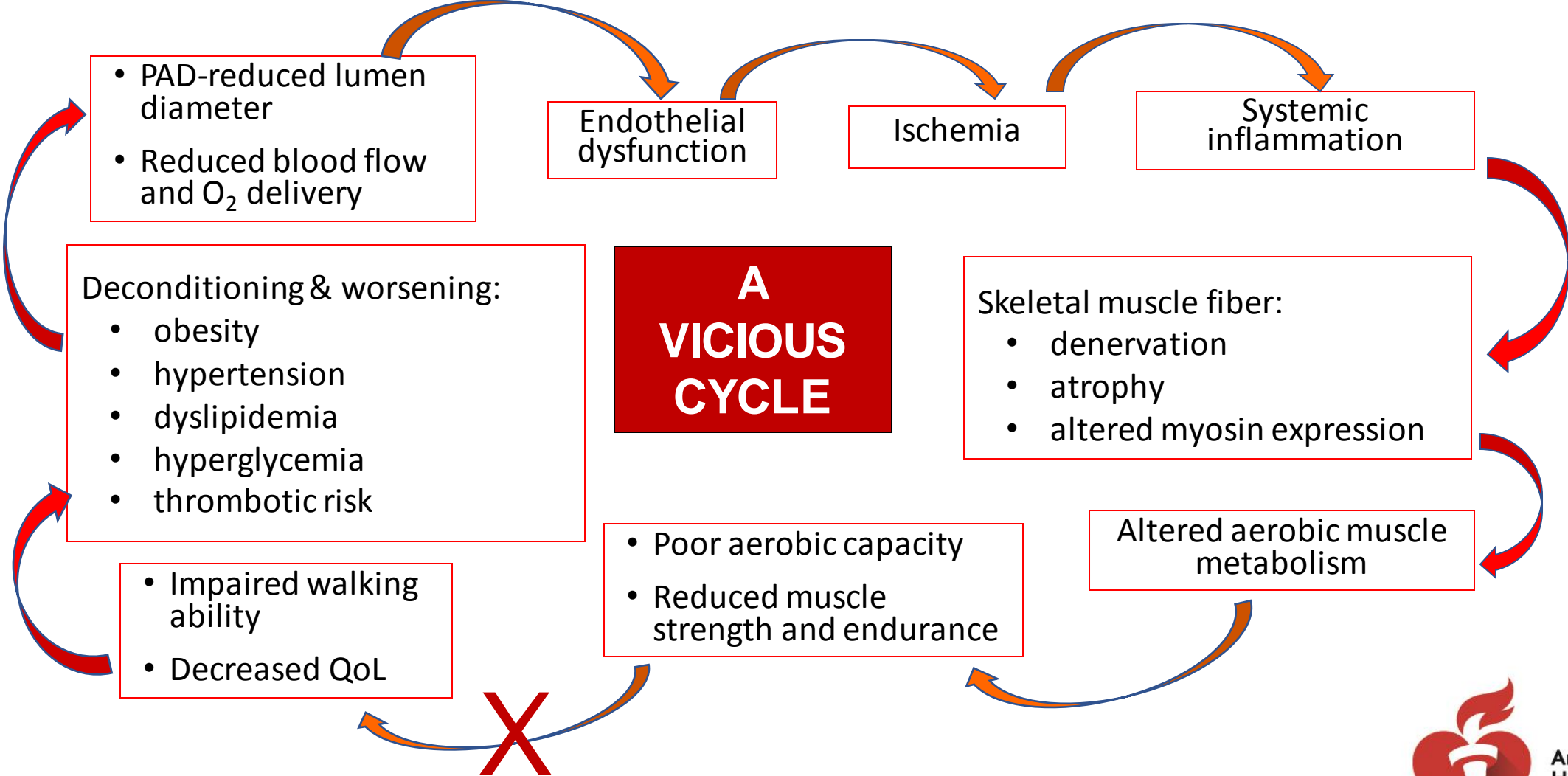
No ischemia/Pain:
Blood/oxygen supply = Oxygen demand



Ischemia/Pain:
Blood/oxygen supply < Oxygen demand

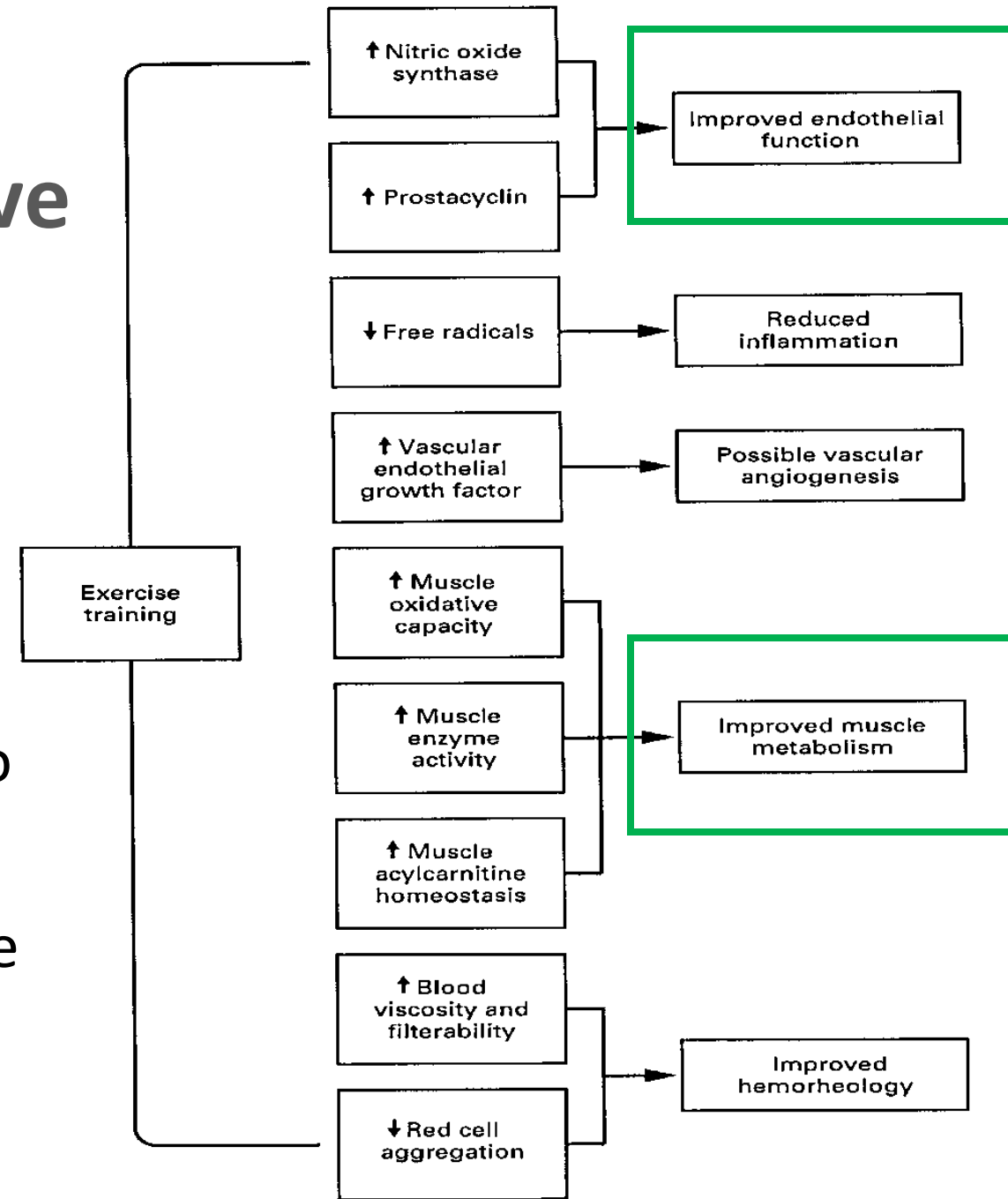


Pathophysiology of PAD



Proposed Mechanisms by Which Exercise May Improve Function and Symptoms

- Enhanced ATP production (mitochondrial function)
- Increased muscle strength
- Improved walking economy due to improved walking biomechanics
- Improved pain threshold/tolerance



Treadmill Exercise Training for Claudication

There is a wide range of response reported, depending on training methods and duration, as well as patient population.

Duration of Supervised Program	Change in Claudication Onset Distance (Meters)	% Change in Claudication Onset Distance	Change in Peak Walking Distance (Meters)	% Change in Peak Walking Distance
12 weeks (n=8)	156.60 (92–243 m)	103% (54–165%)	283.10 (191–402 m)	79% (42–137%)
24–52 weeks (n=7)	251.23 (155–310 m)	167% (109–230%)	334.06 (212–456 m)	92% (50–131%)
Overall (n=15)	203.93 m	128%	307.45	82%



Pain-Free Walking Exercise Therapy



- 12-week intervention of treadmill training to onset of pain—4 studies ([Mika, et al. 2005](#); [2006](#); [2011](#); [2013](#))
- **Studies 1–3:** (total n=196) resulted in:
 - Increase in pain-free walking distance of 110% (217 meters)
 - Increase in peak walking distance of 52% (247 meters)
 - No increases in inflammatory markers after exercise training (2005)
 - Erythrocyte deformability was significantly improved only in the exercise group (2011)
 - No improvement in control group

Pain-Free Walking Exercise Therapy

- **Study 4 (2013)** compared two treadmill walking protocols (12 weeks):
 1. *Traditional treadmill walking into moderate to severe discomfort*
 2. *Vs. treadmill walking only to the onset of claudication*
 - Both groups had statistically significant improvement in walking distance
 - No statistical differences between groups:

Moderate Intensity Group

- Improved pain-free walking distance 120% (*121 meters*)
- Improved peak walking distance 100% (*393 meters*)

Pain-Free Walking Group

- Improved pain-free walking distance 93% (*141 meters*)
- Improved peak walking distance 98% (*465 meters*)



Lower Extremity Cycling

Investigator	Sample Size	Duration	Change with Leg Cycling	Change with Treadmill Training	Change in Control
Sanderson, Askew et al. 2006	n=42	6 weeks	PWD +43m COD +16m	PWD +215m COD +174m	PWD -16m COD +49m
Walker, Nawaz et al. 2000	n=67	6 weeks	PWD +137m COD +114m		PWD none COD none
Zwierska, Walker et al. 2005	n=104	24 weeks	PWD +31% COD +57%		PWD none COD none

Aerobic Upper Body Exercise Therapy for PAD



Investigators From Sheffield, UK

- Series of studies comparing arm ergometry (arm cranking) versus leg cycling and control ([Walker, Nawaz et al. 2000](#), n=57; [Zwierska, Walker et al. 2005](#), n=104) or control ([Tew, Nawaz et al. 2009](#), n=51)
- Exercise training 2x/week; 40-minute sessions; 12–24 weeks
- Outcomes: 50% improvement in PFWD and 30% in MWD
- One study ([Tew, Nawaz et al. 2009](#)) found increased time to minimal ST_{O2} of calf muscle following 12 weeks of arm exercise

Exercise Training for Claudication (ETC) Study



Randomized, controlled pilot study to determine the relative efficacy of 12 weeks of 3x/week supervised treadmill training or arm ergometry alone, or in combination, versus ‘usual care’ in patients with claudication

- Claudication onset distance after 12 weeks exercise training: AE=+133m (82%); TM= +91.6m (54%); Combo= +62m (60%)
- Peak walking distance after 12 weeks of exercise training: AE=+182m (53%); TM= +295m (69%); Combo= +217m (68%)
- No improvement in control subjects

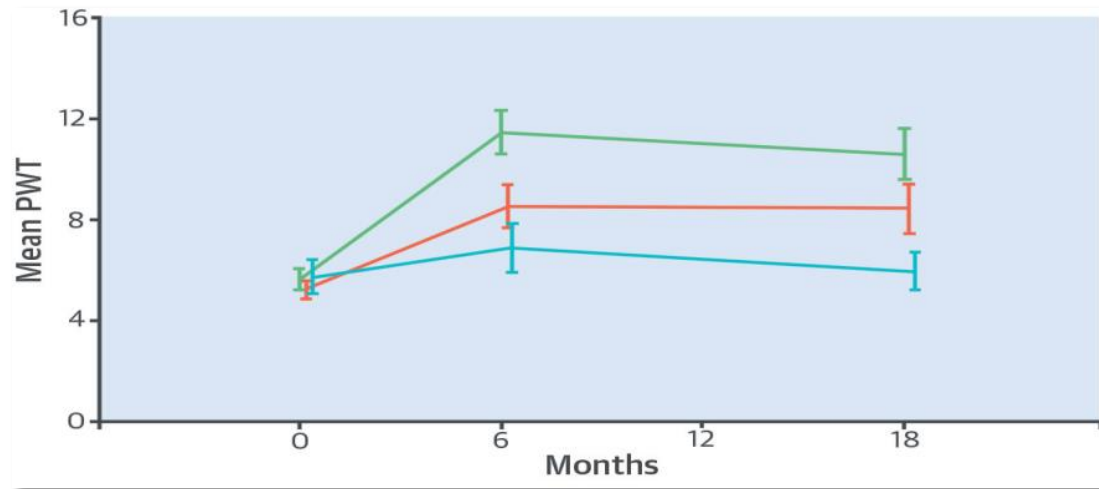


CLEVER:

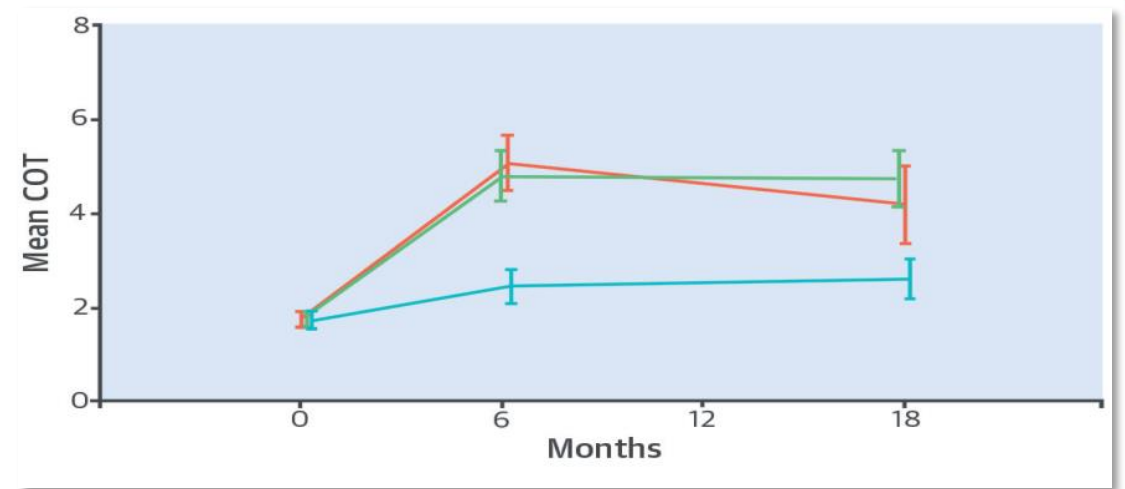
Supervised Exercise Versus Iliac Artery Stenting

Change from Baseline to Six (6) Months and 18 months

Peak Walking Time



Claudication Onset Time



— Optimal Medical Care — Stent — Supervised Exercise



CLEVER: Cost Effectiveness



Pre-planned analysis of cost effectiveness of supervised exercise (SE) stenting, and optimal medical care (OMC) for claudication

- Incremental cost effectiveness ratios (ICERS)
 - \$24,070 per quality adjusted life year gained for SE vs OMC
 - \$41,376 per quality adjusted life year gained for Stent vs OMC
 - \$122,600 per quality adjusted life year gained for Stent vs SE



CLEVER: Cost Effectiveness



“Given the increased expense and marginal benefits of ST relative to SE, there would appear to be no rational justification for covering ST but not SE for the treatment of claudication.”
(Reynolds, et al. p. 8)



Supervised Exercise Rehabilitation

COR-Class
(strength) of
recommendation

LOE-Level
(quality) of
evidence

COR	LOE	Recommendations
I	A	In patients with claudication, a supervised exercise program is recommended to improve functional status and QoL and to reduce leg symptoms.
I	B-R	A supervised exercise program should be discussed as a treatment option for claudication before possible revascularization.
IIa	A	In patients with PAD, a structured community- or home-based exercise program with behavioral change techniques can be beneficial to improve walking ability and functional status.
IIa	A	In patients with claudication, alternative strategies of exercise therapy, including upper-body ergometry, cycling, and pain-free or low-intensity walking that avoids moderate-to-maximum claudication while walking, can be beneficial to improve walking ability and functional status.



2016 PAD Guideline Definitions

Structured exercise program

- Planned program that provides individualized recommendations for type, frequency, intensity, and duration of exercise.
- Program provides recommendations for exercise progression to assure that the body is consistently challenged to increase exercise intensity and levels as functional status improves over time.

Supervised exercise program

- Program takes place in a hospital or outpatient facility.
- Program uses intermittent walking exercise as the treatment modality.
- **Program can be standalone or within a cardiac rehabilitation program.**
- Program is directly supervised by qualified healthcare provider(s).
- Training is performed for a minimum of 30–45 minutes/session; sessions are performed at least 3 times/week for a minimum of 12 weeks.
- Training involves intermittent bouts of walking to moderate-to-maximum claudication, alternating with periods of rest.
- Warm-up and cool-down periods precede and follow each session of walking.



2016 PAD Guideline Definitions

Structured community- or home-based exercise program

- Program takes place in the personal setting of the patient rather than in a clinical setting.
- Program is self-directed with guidance of healthcare providers.
- Healthcare providers prescribe an exercise regimen similar to that of a supervised program.
- Patient counseling ensures understanding of how to begin and maintain the program and how to progress the difficulty of the walking (by increasing distance or speed).
- Program may incorporate behavioral change techniques, such as health coaching or use of activity monitors.



CMS Coverage Language for SET for Treatment of Symptomatic PAD

- **3-1-2017:** “The Centers for Medicare & Medicaid Services (CMS) proposes 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).”
- **A SET program must include:**
 - Sessions lasting 30–60 minutes comprised of a therapeutic exercise-training program for PAD in patients with claudication
 - Three sessions per week
 - Up to 12 weeks of sessions
 - (CPT code: 93668)
- CMS proposes that 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 with a new referral if patients continue to be symptomatic.



Reimbursement

CPT code: 93668

Payment: for 2018 for on-campus hospital outpatient setting ~\$55 per session; recall patient pays for 20% or approximately \$11 per session

ICD10 Codes:

I73.9 Peripheral vascular disease, unspecified

I70.20 Unspecified atherosclerosis of native arteries of extremities

I70.21 Atherosclerosis of native arteries of extremities w/intermittent claudication

I70.22 Atherosclerosis of native arteries of extremities w/rest pain

(-) Add 6th character

1 – right leg 2 – left leg 3 – bilateral legs

NOTE: Always check with your Medicare Administrative Contractor (MAC) for specifics.



Our Experience

- Two projects that have informed implementation of SET for PAD
- PAD PRAIRIE Initiative
 - Implementing SET for PAD in communities in rural Minnesota
- Clinical implementation of SET for PAD throughout the Fairview cardiac rehabilitation centers in the Twin Cities Metropolitan area
- This has allowed us to see the “real world” implications of an implementation of a clinical PAD exercise program.



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Elements Needed

Develop Programmatic Infrastructure

- Identify medical director.
- Establish referral process. Make providers aware of availability SET for PAD.
 - May need changes to electronic health record
- Train cardiac rehabilitation staff about how to implement SET for PAD.
- Develop implementation process.



Baseline Assessment

- **Functional evaluation**
 - Graded Exercise Test (Gardner; Hiatt; Bronas/Treat-Jacobson)
 - Peak walking time or distance (PWT/D); claudication onset time or distance (COT/D)
 - 6-minute walk test
 - Short Physical Performance Battery
 - Timed Up and Go (TUG) Test
- **Subjective assessment**
 - Walking Impairment Questionnaire
 - Quality of life (PADQOL, VASCUQOL, PAQ)
 - Functional status (SF-36, PROMIS)
- **Orient patient to exercise equipment**



Peripheral Artery Disease Supervised Exercise Therapy Evaluation

Client Name: _____ MR#: _____ CSN#: _____

Date: _____ DOB/Age: _____ Diagnosis: _____

Medical History (check all that apply and explain)	
<input type="checkbox"/> Heart	<input type="checkbox"/> Other
<input type="checkbox"/> Lung	
<input type="checkbox"/> Stroke	
<input type="checkbox"/> Depression	
<input type="checkbox"/> Orthopedic	

Risk Factors for CAD (check all that apply)	
<input type="checkbox"/> Weight	<input type="checkbox"/> Exercise
<input type="checkbox"/> Stress	<input type="checkbox"/> HTN
<input type="checkbox"/> Cholesterol	<input type="checkbox"/> DM
<input type="checkbox"/> Family Hx	<input type="checkbox"/> Depression

Pain Screen:
 Intensity Rating: _____
 Location: _____ Onset: _____
 Duration of ea. Episode: _____
 Precipitating Factors: _____
 Alleviating Factors: _____

Stress test results (if available):
 Max HR: _____
 85% of max HR: _____
 Onset of Claudication: _____ minutes
 Peak MET Level: _____

Wounds Present:
 Do you have any wounds on your feet? Yes No
 Location of wounds: _____
 Do you know how to do a foot inspection? Yes No
 Handout provided? Yes No

ABIs:
 Right Pre Ex: _____ Post Ex: _____
 Left Pre Ex: _____ Post Ex: _____
 Symptoms of Claudication: _____
 Location of Claudication: _____



Peripheral Artery Disease Supervised Exercise Therapy Evaluation

6-Minute Walk Test:	Initial Date:	Discharge Date:
Total Time Walked		
Resting Heart Rate (bpm)		
Exercise Heart Rate		
Recovery Heart Rate		
Resting Blood Pressure (mm Hg)		
Exercise Blood Pressure		
Recovery Blood Pressure		
Claudication Onset Time (COT)		
Claudication Onset Distance (COD)		
Total Distance Walked (PWD)		
Effort Rating (OMNI Scale)		
O ₂ Saturation		

Peripheral Artery Disease Supervised Exercise Therapy Evaluation

Client Name: _____

MR#: _____

CSN#: _____

FALLS SCREEN (Circle one)

Have you fallen two or more times in the past year? Yes No

Have you fallen and had an injury in the past year? Yes No

Referral to Physical Therapy? Yes No

Outcomes: Initial

MET level (6 MWT): _____

MET level (treadmill): _____

TUG Test: 1st: _____ 2nd: _____

Discharge

MET level (6 MWT): _____

MET level (treadmill): _____

TUG Test: 1st: _____ 2nd: _____

Initial MET level (treadmill) is based on third visit. Discharge MET level (treadmill) is based on peak METs achieved at end of program.

Goals:

1. _____

2. _____

Initial Session: Comments: _____

Discharge Summary: Goals MET: Yes _____ No _____ Comments: _____

Evaluation Therapist Signature: _____ Date: _____ Time: _____

Discharging Therapist Signature: _____ Date: _____ Time: _____

Treadmill Walking Exercise



- Considered the gold standard for exercise therapy for PAD
 - Initial prescription (speed and grade of treadmill) is determined by baseline functional testing
 - Perform a treadmill familiarization to allow the patient to determine preferred walking speed
 - Training sessions consist of intermittent bouts of walking/resting based on claudication level
 - Use claudication scale to determine exercise/rest cycles

Claudication Pain Scale

- 0 = no pain** ← Resting or early exercise effort
- 1 = mild pain** ← 1st feeling of any pain in legs
- 2 = moderate pain** ← Pain level at which exercise training should cease
- 3 = intense pain** ← Nearly maximal pain
- 4 = unbearable pain** ← Most severe pain experienced



Claudication Pain Scale

0 = no pain ← Resting or early exercise effort

1 = onset of pain ← 1st feeling of any pain in legs

2 = mild pain

3 = moderate pain

4 = moderate pain

Where patient needs to stop during exercise training

5 = severe pain

Stop *before* you have severe pain.



Treadmill Walking Exercise



Intensity and Time

- Begin at initial speed/grade that brings on claudication within 2–5 minutes.
- Walk to bring on claudication.
 - Make progressive increases in walking time.
 - Stop and sit when you reach moderate intensity pain.
 - Resume when pain has completely subsided.
 - Continually repeat process for total time (walking + resting) of 30–60 minutes.
- Make progressive increases in grade and speed over time as walking duration improves.



Peripheral Artery Disease Supervised Exercise Therapy Daily Progress Note

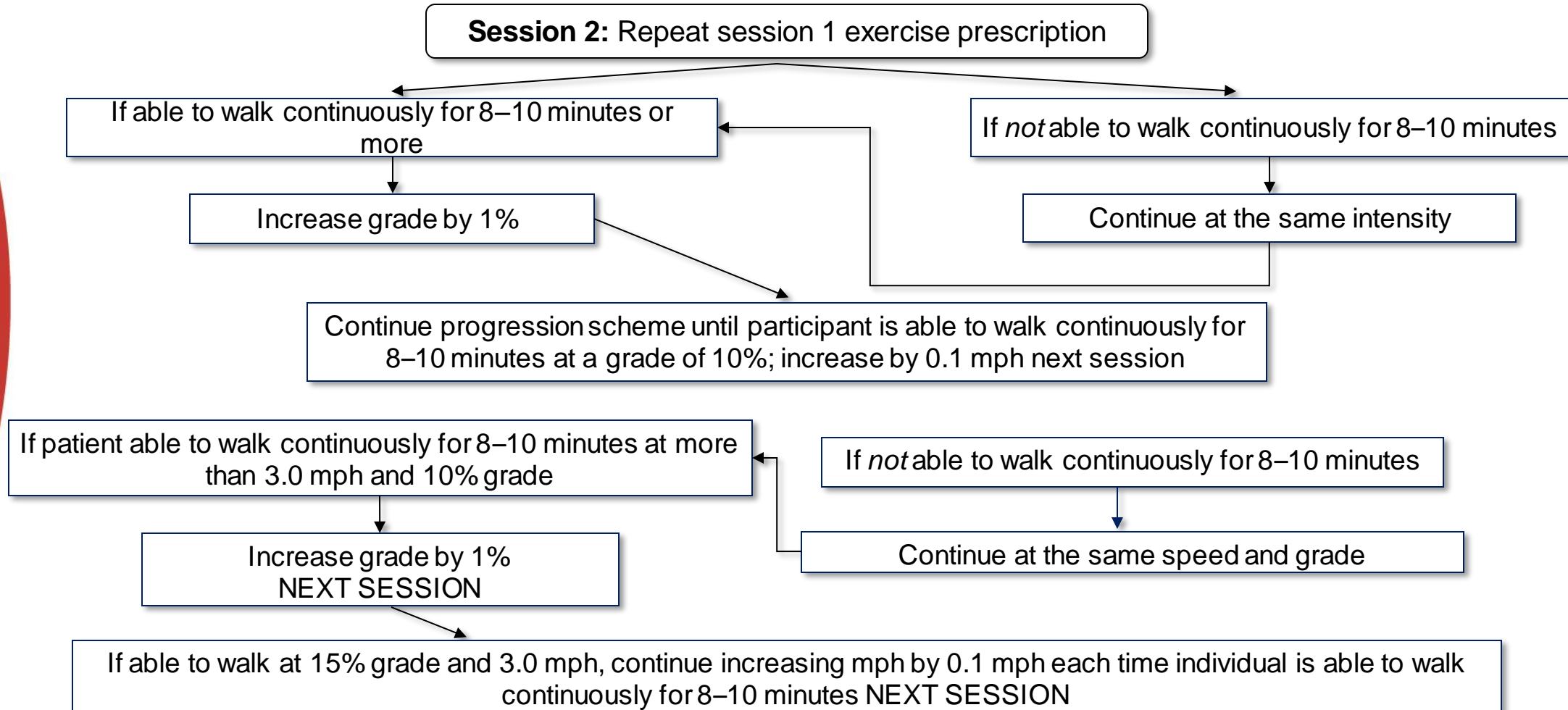
Diagnosis: _____

Date: /		Session #:			Blood Sugar: Pre:		Post:		
MODALITY	SPEED	GRADE	TIME	ONSET OF PAIN	PAIN (0-5 SCALE)	OMNI EFFORT	REST TIME	OTHER WORKLOAD	

Resting Heart Rate: _____ Exercise Heart Rate: _____ Resting Blood Pressure: _____
 Exercise Blood Pressure: _____ Total Exercise Time: _____ Total Rest Time: _____ Total Session Time: _____
 Symptoms Beyond Claudication Pain: _____ Home Exercise: _____
 Assessment/Progress: _____ Plan: _____
 Signature: _____ Date: _____ Time: _____

Treadmill Protocol

Session 1: Choose a comfortable walking speed and adjust grade as needed to induce a 3–4/5 claudication within 5–10 minutes. Have participant rest until pain dissipates. Repeat intervals 60 minutes as tolerated.



SET for PAD in the “Real World”



- Most PAD exercise trials have compared treadmill exercise to another condition (procedure, alternative exercise, control).
- Patients needed to be able to walk on a treadmill at 2 mph, otherwise they were excluded.
- We have found that many PAD patients are not willing or able to walk on a treadmill (balance, discomfort).
- Number of treadmills may be limited.
- Alternative forms of exercise should be considered.

SET for PAD in the “Real World”



- Try treadmill or other walking exercise first.
- If unable to perform treadmill exercise or if walking duration is so short that benefit is unlikely, consider alternative mode:
 - Seated aerobic arm exercise
 - Recumbent total body stepping (NuStep)
 - Lower extremity cycling
- Encourage the exercise therapists to apply their art and science as they do with cardiac rehabilitation.

PAD PRAIRIE Initiative

Arm Ergometry Protocol

Session 1–6: Initiate UBE-EX at 50–60 rpm; adjust ergometer resistance to promote moderate exertion (RPE 12–13). UBE-EX performed at intervals of 2:2 for entirety of 60-minute session

Session 7–12: Progress UBE-EX by increasing work/rest ratio to 3:2; adjust resistance to promote moderate intensity (RPE 12–13)

Session 13–30: Progress UBE-EX by gradually increasing work/rest ratios from 3:2 to 5:1 over several weeks. Adjust resistance to promote moderate to vigorous intensity (RPE 13–14)

Session 31: Progress UBE-EX by increasing work/rest ratio to 5:1 adjust resistance to promote vigorous intensity (RPE 14–15)

PAD PRAIRIE Initiative

Total Body Recumbent Stepping Protocol

Session 1: Determine comfortable step rate (50–80 steps per minute), adjust resistance (level) that induces 3–4/5 claudication within 5–10 minutes. Have participant rest until pain dissipates. Repeat intervals for entirety of 60-minute session.

Session 2: Repeat session 1 exercise prescription

If patient is able to exercise continuously for 8–10 minutes

Progress workload by 1 level

If patient is *not* able to exercise continuously for 8–10 minutes

Continue at same intensity

If patient is able to exercise at workload (level) 10 continuously for 8–10 minutes, increase pace (steps per minute) by 10

If patient is able to exercise continuously for 8–10 minutes

Progress workload by 1 level

If patient is *not* able to exercise continuously for 8–10 minutes

Continue at same intensity

If patient is able to exercise at workload (level) 20 continuously for 8–10 minutes, maintain intensity for remainder of program



Where to put a chair?

*Someone took
my treadmill!!*



Safety Considerations



- Potential to unmask new angina due to increased exercise capability
 - *Follow up on new signs and symptoms of coronary disease*
- Abrupt increase in claudication symptoms could signal worsening of lower extremity arterial disease
 - *Evaluate for deterioration in limb blood flow*

Safety Considerations



Assess legs and feet for indications of critical limb ischemia.

- Ask patient about sores or pain.
- If known open sore or pain, assess more often.
- Evaluate skin: color, hair, shiny, thin, fragile.

Critical Limb Ischemia

Dependent rubor



Elevation pallor



Collecting Outcome Data



- Not a CMS requirement, but part of “Best Practices” for Cardiac Rehabilitation
- Collect same measurements as at baseline
- **Functional**
 - Change in walking speed and grade
 - 6 MWT
 - Graded treadmill test to assess for pain-free and peak walking time
 - PROMIS or SF-36 questionnaire
 - WIQ (Walking Impairment Questionnaire)
- **Quality of Life**
 - PADQOL
 - VASCUQOL



Resources

- Intake and progress forms being finalized and can be adapted
- PAD PRAIRIE website <https://www.nursing.umn.edu/research/research-projects/pad-prairie/resources-providers> and videos available
 - Functional Assessment testing
 - 6-minute walk test
 - Timed Up and Go Test (TUG)
 - Short Physical Performance Battery
 - How to initiate progress a patient in supervised treadmill exercise and aerobic arm exercise
- Updated PAD Rehabilitation Toolkit available at no charge on AACVPR website
- AHA commissioned a Science Advisory “How to Implement Supervised Exercise Therapy for Patients With Symptomatic Peripheral Artery Disease,” which should be completed in the next six months.

