

Lower Extremity PAD: How to Get Your Patients Back on Their Feet

Diane Treat-Jacobson, PhD, RN, FSVM, FAHA, FAAN
Professor and Associate Dean for Research
University of Minnesota School of Nursing

Financial Disclosure

National Heart Lung and Blood Institute
Margaret A. Cargill Foundation

Learning Objectives

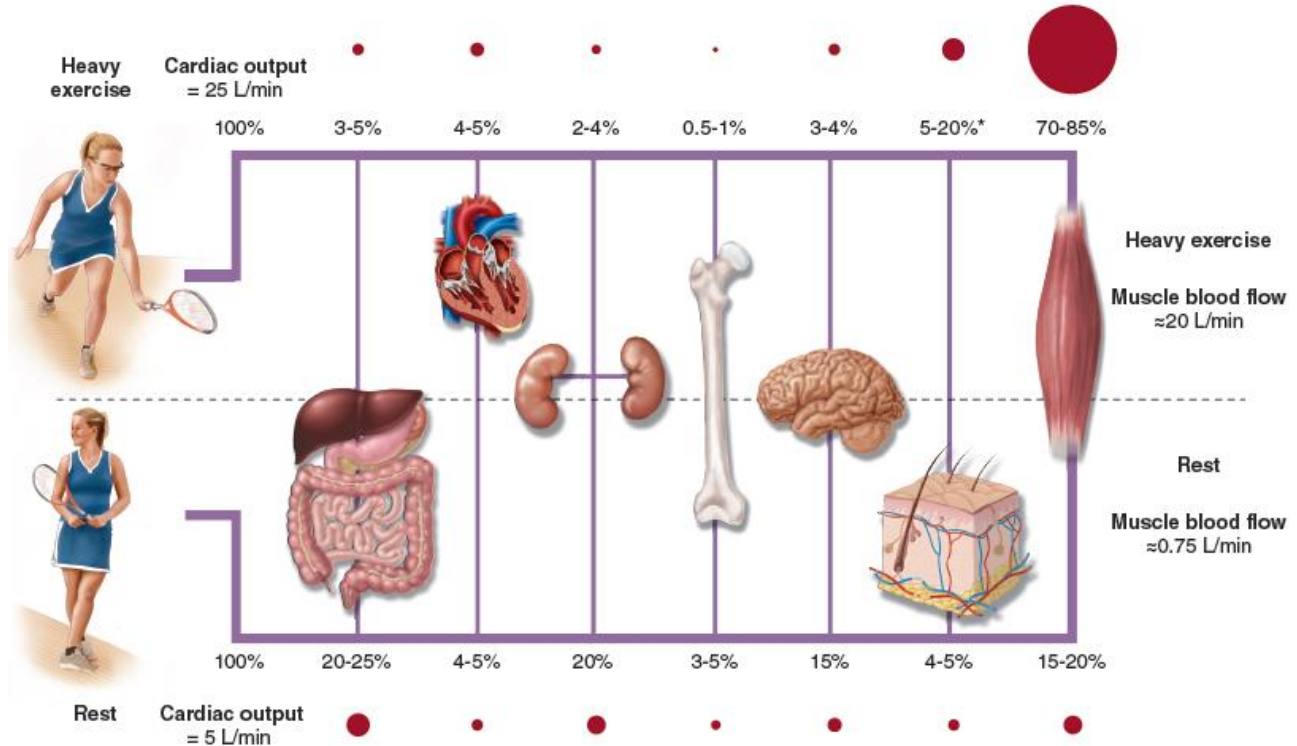
1. The audience will learn the basics of developing an exercise training program for patients with symptomatic PAD.
2. The audience will learn how to implement an exercise training program for patients with symptomatic PAD.

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

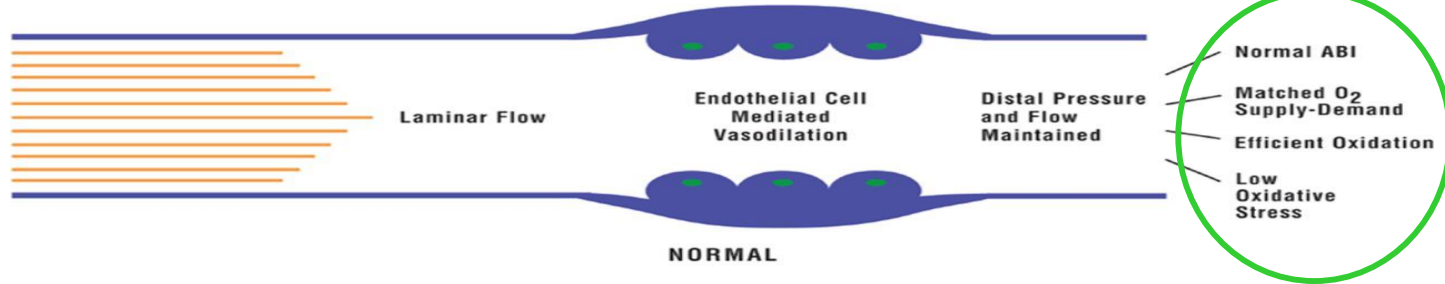
Cardiac Output =
HR x stroke volume



Understanding the Physiology of Exercise

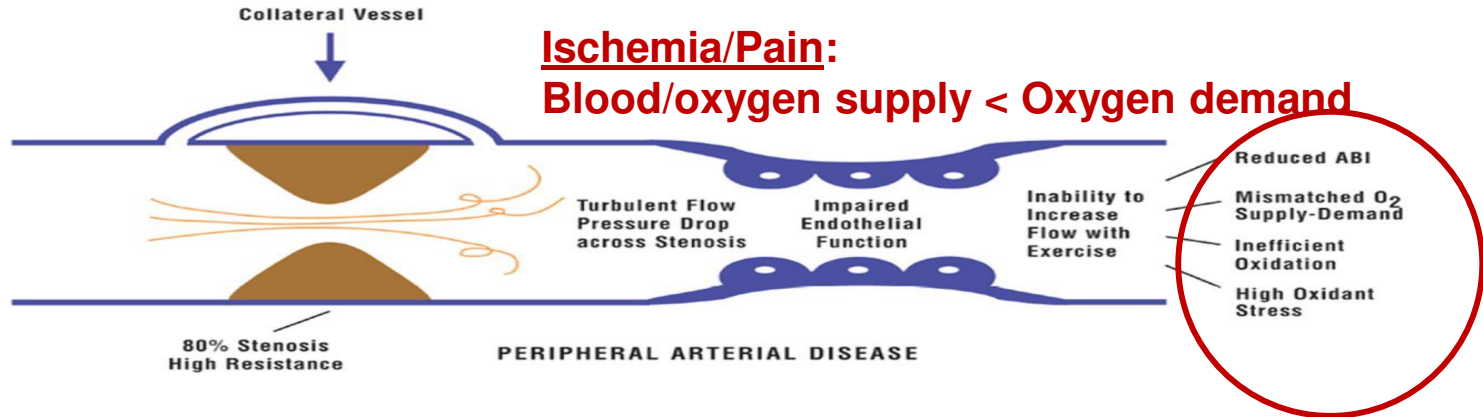
No ischemia/Pain:

Blood/oxygen supply = Oxygen demand

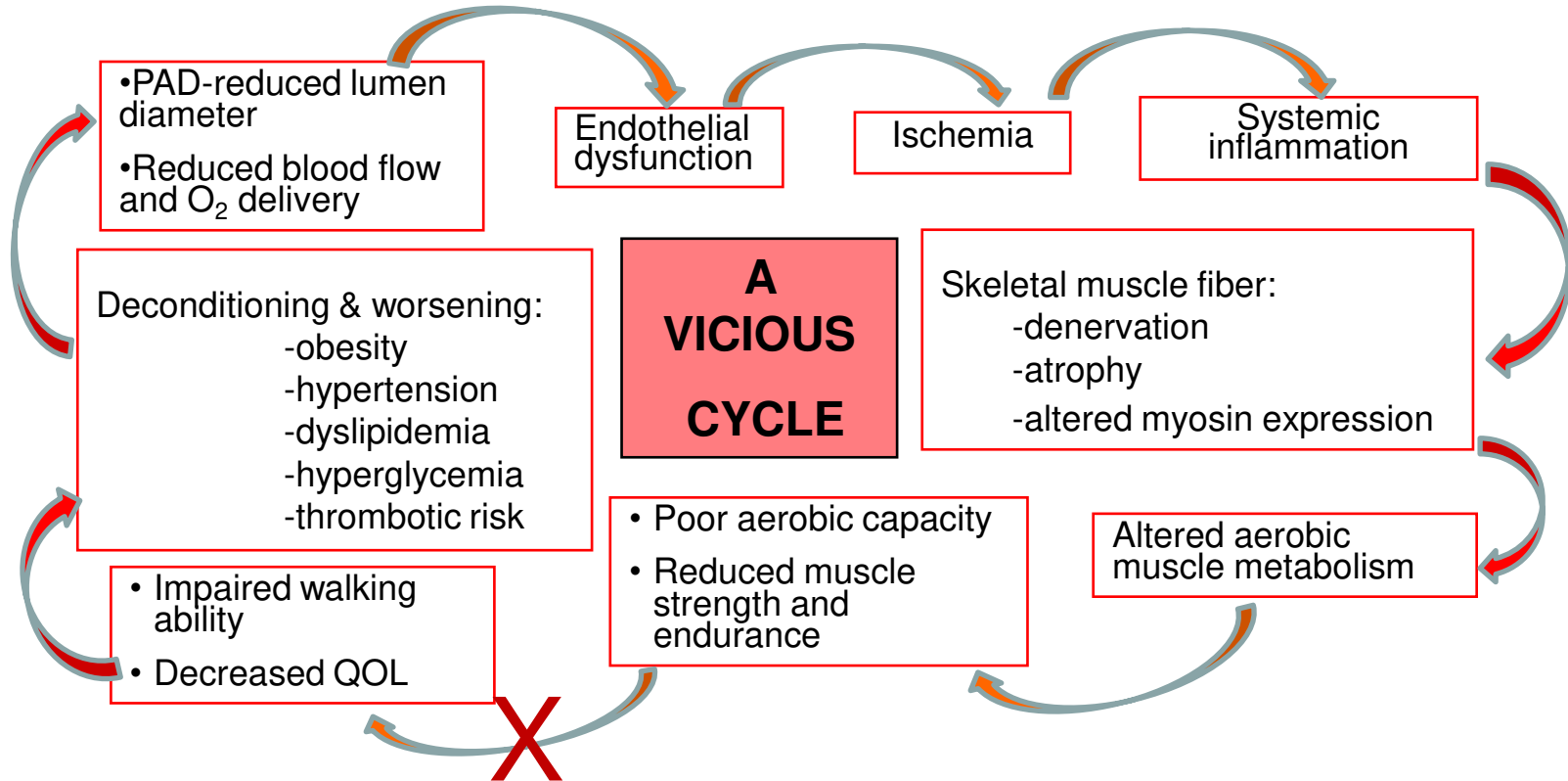


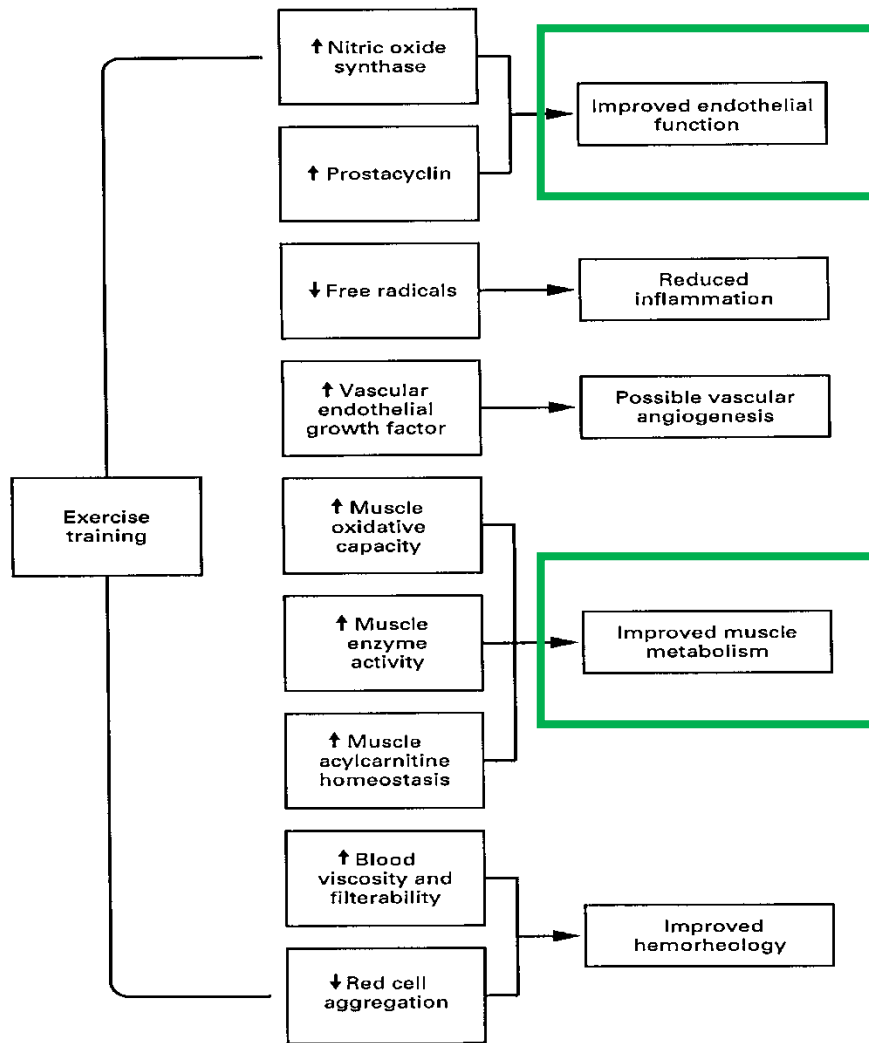
Ischemia/Pain:

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 2 treadmill walking protocols (12 weeks)
 - Traditional treadmill walking into moderate to severe discomfort
 - 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 STO_2 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= +295 m (69%); Combo= +217m (68%).*
 - No improvement in control subjects

Treadmill vs. Resistance Exercise Training

Author/Year	Sample Size	Program duration	Change with Resistance Training	Change with Treadmill Walking Group
Hiatt, Wolfel, et al (1994)	n=29	12 weeks	PWD: + 107 m (30%) PFWD: +1.6 m	PWD: + 273 m (74%) PFWD: +182 m
McDermott, Ades, et al (2009)	n=156	26 weeks	PWD: + 129 m (34%) PFWD: +102 m (60%)	PWD: +212 m (51%) PFWD: +156 m (110%)
Ritti-Dias, Wolosker et al (2010)	n= 30	12 weeks	PWD: +157 meters (25%) PFWD: +146 meters (42%)	PWD: +149 m (26%) PFWD: +127 m (37%)
			Change with High Intensity Resistance Training	Change with Low-Intensity Resistance Training
Parmenter, Raymond, et al (2013)	n=22	26 weeks	6mwt PWD: +60m (19%) 6mwt PFWD: +77m (77%)	6mwt PWD: -9m (-12%) 6mwt PFWD: -3m (-2%)

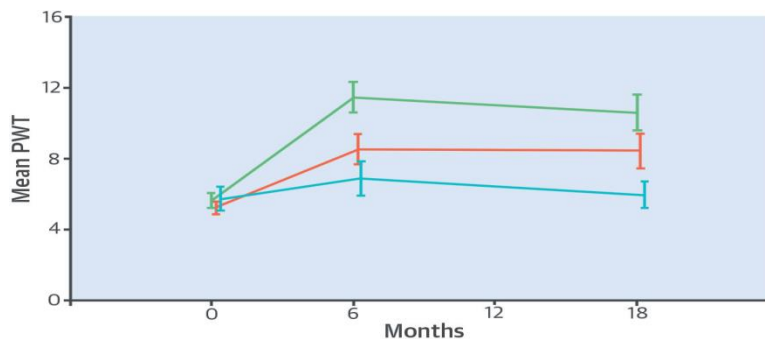
Structured Community-Based Exercise in PAD

Investigator	Sample Size	Duration	Change with Unsupervised Training	Change with Supervised Training	Change in Controls
<u>Gardner, Parker, et al (2011)</u> (Step Monitored)	n=119	3months	PWD + 111m PFWD +120m	PWD +192m PFWD+148m	PWD -10s PFWD -14m
<u>Gardner, Parker et al (2014)</u> (Step Monitored)	n=180	3months	6mwt +45m PWD +98m PFWD +93m	6mwt +15m PWD +152m PFWD +93m	6mwt +4m PWD +13m PFWD +16m
<u>McDermott, Liu, et al (2013)</u> (Group-mediated CBI)	n=194	6months	6mwt +42m PWD +82m PFWD +77m		6mwt -11m PWD +.53m PFWD +.42m

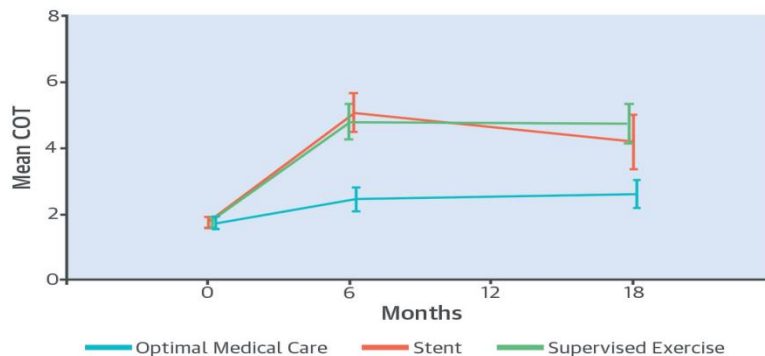
CLEVER: Supervised Exercise Versus Iliac Artery Stenting

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

Peak Walking Time



Claudication Onset Time



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)

Reynolds, et al., JAHA, 2014; 3:e001233

Supervised Exercise Rehabilitation

COR-Class
(strength) of
recommendati
on

LOE-Level
(quality) of
evidence

[Gerhard-Herman M. et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease.](#)
Circulation.
2016;69(11):1465-1508.

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.

CMS coverage determination for SET for treatment of symptomatic PAD

- Supervised exercise therapy (SET) is approved for reimbursement for patients with symptomatic PAD if referred by a qualifying provider (CPT code: 93668)
- Up to 36 sessions of 30-60 minutes of exercise within a 12-week period
- An additional 36 sessions will be covered with a new referral if patients continue to be symptomatic (must use the KX modifier for reimbursement)
- Covers lifetime limit of 72 sessions
- Reimbursement rate set at \$55.00/session with 20% co-pay
- Supplemental insurance should cover co-pay

Requirements

- Supervised exercise training must:
- be conducted in a hospital outpatient setting or physician office
- be delivered by qualified personnel
- be under direct supervision of physician, PA or APRN, trained in both BLS and ACLS
- Physician referral must include:
- Face-to-face visit with physician
- Patient information about PAD risk factor reduction (education, counseling, behavioral interventions)
- Confirmation that patient is diagnosed with symptomatic PAD
- ABI not required
- Pain level rating not required

Reimbursement

CPT code: 93668

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

Reimbursable ICD-10 Codes (Claudication must be present)

- I70.2 Atherosclerosis of native extremities (I70.211, I70.212, I70.213, and I70.218)
- I70.3 Atherosclerosis of unspecified type of bypass graft(s) of the extremities (I70.311, I70.312, I70.313, and I70.318)
- I70.41 Atherosclerosis of autologous vein bypass graft(s) of the extremities (I70.411, I70.412, I70.413, and I70.418)
- I70.51 Atherosclerosis of non-autologous vein bypass graft(s) of the extremities (I70.511, I70.512, I70.513, and I70.518)
- I70.6 Atherosclerosis of non-biological bypass graft(s) of the extremities (I70.611, I70.612, I70.613, and I70.618)
- I70.7 Atherosclerosis of other type of bypass graft(s) of the extremities (I70.711, I70.712, I70.713, and I70.718)

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

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
- Determine starting mode of exercise

Peripheral Artery Disease Supervised Exercise Therapy Evaluation

Client Name: _____

MR#: _____ CSN#: _____

Date: _____

DOB/Age: _____ Diagnosis: _____

Medical History (Check all that apply and explain)	
☐ Heart	☐ Other _____
☐ Lung	
☐ Stroke	
☐ Depression	
☐ Orthopedic	

Pain Screen:

Intensity Rating _____

Location _____ Onset _____

Duration of ea. Episode _____

Precipitating Factors _____

Alleviating Factors _____

Risk Factors for CAD (check all that apply)	
☐ Weight	☐ Exercise
☐ Stress	☐ HTN
☐ cholesterol	☐ DM
☐ Family Hx	☐ Depression

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: _____

PERIPHERIAL 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: _____

Establish primary exercise modality

Attempt treadmill unless inappropriate.

Goal 1: establish intensity where moderate claudication develops at approximately 5-10 minutes into bout.

Goal 2: evaluate session 1 regarding performance and safety, choose primary training modality

If relative contraindications to TM training are present, consider alternative training modality based on health history and needs analysis

Relative treadmill Contraindications

- 1. ABI less than 0.5
- 2. Foot wound
- 3. High fall risk
- 4. Poor treadmill performance (i.e. short 1-2 minute bouts at low intensity)

If treadmill training is chosen as primary training modality, continue with treadmill protocol; progress as indicated by treadmill algorithm.

Re-evaluate after 12 sessions

Total Body
Recumbent
Stepping
Lower Body
Cycle
Ergometer

Upper
Body
Ergometer

Indications to switch from treadmill training as primary training modality

1. Treadmill contraindications
2. Low intensity (less than 2.5 METS) and total walking time (under 20 minutes/session)
3. No progression in protocol has been made

Switch primary
training modality

OR

Continue with
protocol

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 = onset of pain

1st feeling of any
pain in legs

2 = mild pain

3 = moderate pain

4 = moderate pain

5 = severe pain

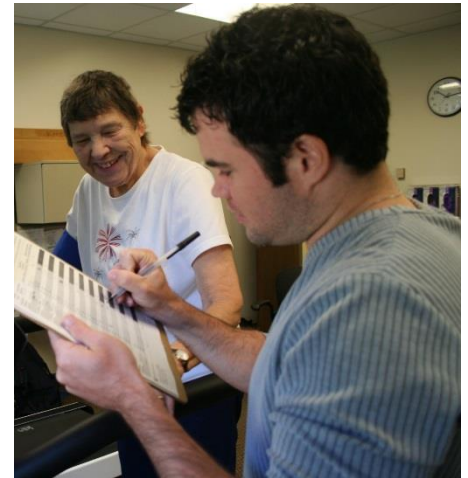
Where patient needs to stop
during exercise training

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*
 - Stop walking and sit when reach moderate intensity pain
 - Resume when pain has completely subsided
 - Continually repeat process for total time (walking + resting) of 30 to 60 minutes
- *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: Determine the comfortable walking speed and grade that induces moderate exertional leg symptoms within 5-10 minutes. Have patient rest (sitting or standing) until pain dissipates. Repeat intervals for entirety of 60-minute session as able.



Session 2-36: Continue with exercise prescription until patient is able to accumulate 30-45 minutes of walking during a 60-minute session.



Session 2-36: Progress treadmill intensity by speed or incline (e.g. 0.1 mph or 1%) if walking bouts are over 10 minutes. Ensure bouts still induce moderate exertional leg symptoms after between 5-10 minutes and patient is still able to accumulate 30-45 minutes of walking during a 60-minute session.

Our Experience

- 2 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 a implementation of a clinical PAD exercise program

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
 - *Recumbent total body stepping (NuStep)*
 - *Lower extremity cycling*
 - *Seated aerobic arm exercise*
- Encourage the exercise therapists to apply their art and science as they do with cardiac rehabilitation

Protocol for non-treadmill-based exercise

Do exertional leg symptoms limit exercise performance on non-treadmill exercise modality?

Yes

Session 1: Perform exercise at patient-determined rate (e.g. 50-80 RPM/SPM) and adjust workload to induce moderate exertional leg symptoms within 5-10 minutes. Have patient rest until symptoms dissipate. Repeat intervals for entire 60-minute session

Session 2-36: Continue with exercise prescription until patient is able to accumulate 30-45 minutes of exercise during a 60-minute session

Session 2-36: Progress workload if exercise bouts are over 10 minutes. Ensure bouts continue to induce moderate exertional leg symptoms within 5-10 minutes and patient is able to accumulate 30-45 minutes of exercise during a 60 minute session.

No

Session 1-36: Follow exercise prescription guidelines for continuous aerobic exercise in outpatient exercise programs. Exercise should start from 20 minutes and gradually progress to 60 minutes per session. Intensity should progress from moderate to vigorous intensity (rating or perceived exertion 11-15)

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)



Someone took my treadmill!!

Where to put a chair?



Courtesy of Jon Ehrman, PhD

Safety Considerations

- ECG guided exercise testing recommended for patients with prior history of symptomatic cardiac disease
- Unstable heart disease should be treated prior to initiation of SET
- 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 assess more often
 - Skin: color, hair, shiny, thin, fragile

- 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 Evaluation
 - *Graded Exercise Test*
 - *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)*



Resources

- Intake and progress forms being finalized and can be adapted
- PAD PRAIRIE web site <https://www.nursing.umn.edu/research/research-projects/pad-prairie/resources-providers> videos available
 - *Functional Assessment testing*
 - 6 minute walk test
 - Timed up and go test
 - 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 web site
- AHA commissioned a Science Advisory: “How to Implement Supervised Exercise Therapy for Patients with Symptomatic Peripheral Artery Disease” Should be completed within next 6 months

Thank you