Supervised Exercise Therapy for Peripheral Artery Disease (PAD)

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Financial Disclosure

National Heart Lung and Blood Institute
Margaret A. Cargill Foundation
Learning Objectives

1. The audience will learn the risk factors associated with PAD, and the clinical presentation of patients with symptomatic PAD.

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

3. The audience will learn how to implement an exercise training program for patients with symptomatic PAD.
Peripheral Artery Disease (PAD)

- PAD is a disorder caused by atherosclerosis that limits blood flow to the limbs

- PAD is under-diagnosed and under-treated compared to other cardiovascular diseases

- PAD is associated with a marked increase in global cardiovascular health risks:
  - Heart attack, stroke, and death
  - Claudication and functional impairment
  - Gangrene and amputation
Pathophysiology of Peripheral Artery Disease

- Systemic atherosclerotic disorder caused by build-up of plaque in the walls of the arteries that supply the legs

- Commonly co-exists with coronary and carotid disease, placing patients at risk of cardiovascular ischemic events
Clinical Presentation of Peripheral Artery Disease
Claudication

- The term ‘claudication’ derived from the Latin word *claudicato* meaning ‘to limp’ after the Emperor Claudius who walked with a limp.
- Claudication arises when there is insufficient blood flow to meet the metabolic demands in leg muscles during ambulation.
- Claudication is characterized by pain, aching, or fatigue in working muscles of the lower extremity.
### Clinical Presentation

**Asymptomatic:** Without obvious symptomatic complaint (but often with a functional impairment).

**Classic/Typical Claudication:**
- Lower extremity cramping or aching during exertion
- Involves the calf muscles
- Consistent (reproducible) onset with exercise
- Steadily increases during walking
- Relief within 10 minutes of rest
- Not present at rest

**“Atypical” leg pain:** Lower extremity discomfort that does not meet all the classic claudication criteria
- Is exertional, but does not consistently resolve with rest.
- Does not consistently limit exercise at a reproducible distance.
- Is located in muscles other than the calf (i.e. buttock or thigh)
Location of Obstruction Influences Symptoms

- Aorta or iliac artery: Buttock, hip, thigh
- Femoral artery or branches: Thigh, calf
- Popliteal artery: Calf, ankle, foot
Questions for Patients

- Do you normally walk? If no, why not?
- Do you develop discomfort in your legs when you walk?
  - *Cramping, aching, fatigue* (Yes)
- Do you get the same pain when you are sitting, standing, stooping or lying down? (No)
- Do symptoms only start when you walk? (Yes)
- Do symptoms ever go away while walking? (No)
- Does the discomfort always occur at about the same distance? (Yes)
- Do symptoms resolve once you stop walking? (How long?) (5 min)
- Tell me what happens when you go for a walk
The Ankle Brachial Index
The Ankle Brachial Index (ABI)

Noninvasive, objective, measurement of the ratio of ankle systolic pressure to arm systolic pressure using a handheld Doppler, to quantify the degree of arterial insufficiency
The Ankle-Brachial Index (ABI)

- Cost-effective tool that confirms the diagnosis of PAD. It can be a routine test in primary care practice for:
  - Individuals at risk for lower extremity PAD
  - Individuals with classic claudication symptoms or chronic symptoms such as ischemic rest pain, gangrene, non-healing ulcers

- An abnormal ABI is a powerful predictor of increased risk of future atherosclerotic cardiovascular events:
  - The lower the ABI, the worse the prognosis
Individuals at Risk for Lower Extremity PAD

- Age less than 50 years, with diabetes and one other atherosclerosis risk factor
- Age 50 to 64 years of age and history of smoking or diabetes
- Age 65 years and older regardless of risk factor profile
- Individuals with known atherosclerotic disease in another vascular bed (e.g., coronary, carotid, subclavian, renal, mesenteric artery stenosis, or AAA).
Concept of the ABI

The systolic blood pressure in the leg should be approximately the same as the systolic blood pressure in the arm.

Therefore, the ratio of systolic blood pressure in the leg vs the arm should be approximately 1 or slightly higher.

ABI has been found to be 69-79% sensitive and 83-99% specific for PAD diagnosed with other imaging.

## Interpreting the Ankle–Brachial Index

<table>
<thead>
<tr>
<th>ABI</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.00–1.40</td>
<td>Normal</td>
</tr>
<tr>
<td>0.91–0.99</td>
<td>Borderline</td>
</tr>
<tr>
<td>0.70–0.90</td>
<td>Mild</td>
</tr>
<tr>
<td>0.40–0.69</td>
<td>Moderate</td>
</tr>
<tr>
<td>&lt;0.40</td>
<td>Severe</td>
</tr>
<tr>
<td>&gt;1.40</td>
<td>Noncompressible vessels</td>
</tr>
</tbody>
</table>

Adapted from Rooke, et al., Circulation, 2011
## Resting ABI > 1.00 – 1.40

| Typical claudication symptoms or a clinical presentation suggestive of PAD | • Consider exercise ABI  
  • If the post-exercise ABI is normal:  
    • Consider other non-arterial causes of leg pain |
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Atypical symptoms</td>
<td>• Consider other non-arterial causes of leg pain (e.g., neuropathy, DJD, compartment syndrome, etc.)</td>
</tr>
</tbody>
</table>
Treadmill Test: Functional Testing to Aid with Diagnosis

Clinical Evaluation: History & Physical

↓

Suspect PAD

↓

Perform Ankle-Brachial Index (ABI)

↓

Normal ABI with typical symptoms of claudication

↓

Treadmill Functional Testing

Patients with claudication will normally display a ≥20-mm Hg drop in ankle pressure following exercise

↓

PAD Diagnosis

Medical Management of PAD
## Two major goals in treating patients with PAD

<table>
<thead>
<tr>
<th>Limb Outcomes</th>
<th>Cardiovascular morbidity and mortality outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Improved ability to walk</td>
<td>- Decrease in morbidity from non-fatal MI and stroke</td>
</tr>
<tr>
<td>- Increase in peak walking distance</td>
<td>- Decrease in cardiovascular mortality from fatal MI and stroke</td>
</tr>
<tr>
<td>- Improvement in quality-of-life (QoL)</td>
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<tr>
<td>- Prevention of progression to CLI and amputation</td>
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</tbody>
</table>
Exercise Training in 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

Heavy exercise: Cardiac output = 25 L/min

Rest: Cardiac output = 5 L/min

Muscle blood flow:
- Heavy exercise: ≈20 L/min
- Rest: ≈0.75 L/min
Understanding the Physiology of Exercise

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

Ischemia/Pain:
Blood/oxygen supply < Oxygen demand
Pathophysiology of PAD

- PAD-reduced lumen diameter
- Reduced blood flow and O₂ delivery

Endothelial dysfunction

Ischemia

Systemic inflammation

Deconditioning & worsening:
- obesity
- hypertension
- dyslipidemia
- hyperglycemia
- thrombotic risk

A VICIOUS CYCLE

Skeletal muscle fiber:
- denervation
- atrophy
- altered myosin expression

- Impaired walking ability
- Decreased QOL

- Poor aerobic capacity
- Reduced muscle strength and endurance

- Altered aerobic muscle metabolism

X
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.

<table>
<thead>
<tr>
<th>Duration of supervised program</th>
<th>Change in Claudication Onset Distance (Meters)</th>
<th>% Change in Claudication Onset Distance</th>
<th>Change in Peak Walking Distance (Meters)</th>
<th>% Change in Peak Walking Distance</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 Weeks (n=8)</td>
<td>156.60 (92-243 m)</td>
<td>103% (54-165%)</td>
<td>283.10 (191-402 m)</td>
<td>79% (42-137%)</td>
</tr>
<tr>
<td>24-52 weeks (n=7)</td>
<td>251.23 (155-310 m)</td>
<td>167% (109-230%)</td>
<td>334.06 (212-456 m)</td>
<td>92% (50-131%)</td>
</tr>
<tr>
<td>Overall (n= 15)</td>
<td>203.93 m</td>
<td>128%</td>
<td>307.45</td>
<td>82%</td>
</tr>
</tbody>
</table>

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
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)
<table>
<thead>
<tr>
<th>Investigator</th>
<th>Sample Size</th>
<th>Duration</th>
<th>Change with Leg Cycling</th>
<th>Change with Treadmill Training</th>
<th>Change in Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sanderson (2006)</td>
<td>n=42</td>
<td>6 weeks</td>
<td>PWD +43m COD +16m</td>
<td>PWD +215m COD +174m</td>
<td>PWD -16m COD +49m</td>
</tr>
<tr>
<td>Walker (2000)</td>
<td>n=67</td>
<td>6 weeks</td>
<td>PWD +137m COD +114m</td>
<td></td>
<td>PWD none COD none</td>
</tr>
<tr>
<td>Zwierska (2005)</td>
<td>n=104</td>
<td>24 weeks</td>
<td>PWD +31% COD +57%</td>
<td></td>
<td>PWD none COD none</td>
</tr>
</tbody>
</table>
Investigators from Sheffield, UK

- Series of studies comparing arm ergometry (arm cranking) versus leg cycling and control (Walker, 2000, n=57; Zwierska 2005, n=104) or control (Tew, 2010 n=51)
- Exercise training 2x/week; 40 minute sessions; 12-24 weeks
- Outcomes: 50% improvement in PFWD and 30% in MWD
- One study (Tew, 2010) 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

Treat-Jacobson, et al, VMJ, 2009
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

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

<table>
<thead>
<tr>
<th><strong>COR</strong></th>
<th><strong>LOE</strong></th>
<th><strong>Recommendations</strong></th>
</tr>
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<tbody>
<tr>
<td>I</td>
<td>A</td>
<td>In patients with claudication, a supervised exercise program is recommended to improve functional status and QoL and to reduce leg symptoms.</td>
</tr>
<tr>
<td>I</td>
<td>B-R</td>
<td>A supervised exercise program should be discussed as a treatment option for claudication before possible revascularization.</td>
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<tr>
<td>IIa</td>
<td>A</td>
<td>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.</td>
</tr>
<tr>
<td>IIa</td>
<td>A</td>
<td>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.</td>
</tr>
</tbody>
</table>

**COR-Class (strength) of recommendation**

**LOE-Level (quality) of evidence**

| 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. There are 2 types of structured exercise program for patients with PAD:  
1. Supervised exercise program  
2. Structured community- or home-based exercise program |
| Supervised exercise program | Structured exercise program that takes place in a hospital or outpatient facility in which intermittent walking exercise is used as the treatment modality. Program can be standalone or can be made available within a cardiac rehabilitation program. Program is directly supervised by qualified healthcare provider(s). Training is performed for a minimum of 30 to 45 min per session, in sessions performed at least 3 times/wk for a minimum of 12 wk. Patients may not initially achieve these targets, and a treatment goal is to progress to these levels over time. 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. |
| Structured community- or home-based exercise program | Structured exercise program that takes place in the personal setting of the patient rather than in a clinical setting. Program is self-directed with the guidance of healthcare providers who prescribe an exercise regimen similar to that of a supervised program. Patient counseling ensures that patients understand how to begin the program, how to 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 and/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

- 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
Elements Needed

Develop programmatic infrastructure

• Identify medical director
• Establish referral process – Make providers aware of availability SET for PAD
  • May need changes to EHR
• 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

Date: ___________________________  DOB/Age: _______ Diagnosis: _______

<table>
<thead>
<tr>
<th>Medical History</th>
<th>(Check all that apply and explain)</th>
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<tbody>
<tr>
<td>☑ Heart</td>
<td>☑ Other</td>
</tr>
<tr>
<td>☑ Lung</td>
<td></td>
</tr>
<tr>
<td>☑ Stroke</td>
<td></td>
</tr>
<tr>
<td>☑ Depression</td>
<td></td>
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<tr>
<td>☑ Orthopedic</td>
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<table>
<thead>
<tr>
<th>Risk Factors for CAD</th>
<th>(check all that apply)</th>
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<tbody>
<tr>
<td>☑ Weight</td>
<td>☑ Exercise</td>
</tr>
<tr>
<td>☑ Stress</td>
<td>☑ HTN</td>
</tr>
<tr>
<td>☑ cholesterol</td>
<td>☑ DM</td>
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<tr>
<td>☑ Family Hx</td>
<td>☑ Depression</td>
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<thead>
<tr>
<th>Pain Screen:</th>
</tr>
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<tbody>
<tr>
<td>Intensity Rating __</td>
</tr>
<tr>
<td>Location _____ Onset ______ Duration of ea. Episode ______ Precipitating Factors ______ Alleviating Factors ______</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stress test results (if available):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max HR: ______ 85% of max HR ____ Onset of Claudication: _______ minutes.</td>
</tr>
<tr>
<td>Peak MET Level: __________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Wounds Present:</th>
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</thead>
<tbody>
<tr>
<td>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</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Right Pre Ex</th>
<th>Post Ex</th>
<th>Left Pre Ex</th>
<th>Post Ex</th>
<th>Symptoms of Claudication:</th>
<th>Location of Claudication:</th>
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<table>
<thead>
<tr>
<th>ABIs</th>
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<tbody>
<tr>
<td>Right Pre Ex</td>
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</table>
**PERIPHERAL ARTERY DISEASE SUPERVISED EXERCISE THERAPY EVALUATION**

<table>
<thead>
<tr>
<th>6 Minute Walk Test:</th>
<th>Initial Date:</th>
<th>Discharge Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Time Walked</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resting Heart Rate (bpm)</td>
<td></td>
<td></td>
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<tr>
<td>Exercise Heart Rate</td>
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<tr>
<td>Recovery Heart Rate</td>
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<td></td>
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<tr>
<td>Resting Blood Pressure (mm Hg)</td>
<td></td>
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</tr>
<tr>
<td>Exercise Blood Pressure</td>
<td></td>
<td></td>
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<tr>
<td>Recovery Blood Pressure</td>
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<td></td>
</tr>
<tr>
<td>Claudication Onset Time (COT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Claudication Onset Distance (COD)</td>
<td></td>
<td></td>
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<tr>
<td>Total Distance Walked (PWD)</td>
<td></td>
<td></td>
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<tr>
<td>Effort Rating (OMNI Scale)</td>
<td></td>
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<tr>
<td>O2 Saturation</td>
<td></td>
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</tr>
</tbody>
</table>
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 (6 MWT): __________
MET level (treadmill): __________ MET level (treadmill): __________
TUG Test: 1st: __________ 2nd: __________ 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

1 = mild pain

2 = moderate pain

3 = intense pain

4 = unbearable pain

Resting or early exercise effort

1st feeling of any pain in legs

Pain level at which exercise training should cease

Nearly maximal pain

Most severe pain experienced

ACSM Guidelines for Exercise Testing and Prescription, 2017
Claudication Pain Scale

0 = no pain
1 = onset of pain
2 = mild pain
3 = moderate pain
4 = moderate pain
5 = severe pain

Resting or early exercise effort

1\textsuperscript{st} feeling of any pain in legs

Where patient needs to stop during exercise training

Stop \textit{before} you have severe pain
Treadmill Walking Exercise

- **Intensity and Time**
  - *Begin at initial speed/grade that brings on claudication during walking test*
  - Graded treadmill test; 6-minute walk test
  - *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*
Diagnosis: ____________________________________________________________

<table>
<thead>
<tr>
<th>Date: /</th>
<th>Session #</th>
<th>Blood Sugar: Pre:</th>
<th>Post:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>MODALITY</th>
<th>SPEED</th>
<th>GRADE</th>
<th>TIME</th>
<th>ONSET OF PAIN</th>
<th>PAIN (0-5 SCALE)</th>
<th>OMNI EFFORT</th>
<th>REST TIME</th>
<th>OTHER WORKLOAD</th>
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Signature: __________________________ Date: _____ Time: ________________
Treadmill Protocol

Initiate exercise training intensity appropriate for individual physical fitness requirements. This should be a comfortable walking speed that could be maintained for 8-10 minutes.

Walk to moderate pain (3-4 of 5 on the claudication pain scale) after which the participant stops, sits down and rests until all pain subsides. Continue this process for 30-60 minutes.

If able to walk continuously for 8-10 minutes or more

Increase grade by 1%
NEXT SESSION

If not able to walk continuously for 8-10 minutes

Continue at the same speed and grade

If able to walk at 10% grade and 2.0 mph continuously for 8 minutes

Increase speed by 0.1 mph and maintain 10% grade
NEXT SESSION

If able to walk continuously for 8-10 minutes at more than 3.0 mph and 10% grade

Increase grade by 1%
NEXT SESSION

If not able to walk continuously for 8-10 minutes

Continue at the same speed and grade

If able to walk at 15% grade and 3.0 mph, continue increasing mph by 0.1 mph each time individual is able to walk continuously for 8-10 minutes NEXT SESSION
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 step (NuStep)*
  - *Lower extremity cycling*
- Encourage the exercise therapists to apply their art and science as they do with cardiac rehabilitation
Exercise performed at intervals of 2 minutes of exercise and 2 minutes of rest. Continue this process for 60 minutes. Initiate exercise training at 50 RPM. Set watt level at an intensity that will elicit a perceived exertion of “somewhat hard” (4–6 on Omni Scale or 12–14 on RPE Scale).

Session 7, after 2 weeks increase to intervals of 3 minutes (intervals of 3 minutes of exercise, 2 minute of rest)

Session 13, decrease rest to 1 minute (intervals of 3 minutes of exercise, 1 minute of rest)

Session 19, increase to intervals of 4 minutes of exercise and 1 minute of rest

Session 25, increase to intervals of 5 minutes of exercise and 1 minute of rest

Continue with 5 minutes of exercise and 1 minute of rest until 12 weeks (36 sessions) of exercise training has been completed
Cycling or Recumbent Stepping Protocol

**Participant exercises to moderate pain (3–4/5 on claudication pain scale) after which participant sits down and rests until all pain subsides (0/5 on claudication leg pain scale). Start next exercise bout. Continue this process for the entire 60 minute session.**

**Initial pace:** 50–60 SPM  
**Resistance:** 1

**Patient exercises to RPE of 15 (Borg 6–20 scale) or 7 (10 point scale) after which participant sits down and recovers for 2 minutes. Start next exercise bout. Continue this process for entire 60 minute session.**

- If participant is able to exercise continuously for 8 minutes or more:
  - Increase resistance by 1  
  - NEXT SESSION

- If participant is unable to exercise continuously for 8 minutes:
  - Continue at same resistance

- If participant is able to cycle at resistance of 10 at 50–60 RPM continuously for 8 minutes:
  - Increase speed to 60–70 RPM and maintain resistance of 10  
  - NEXT SESSION

- If participant is unable to cycle continuously for 8 minutes or more:
  - Continue at same resistance

- If participant is able to cycle continuously for 8 minutes or more:
  - Increase resistance by 1  
  - NEXT SESSION

- If participant is able to cycle at resistance of 20 at 60–70 RPM continuously for 8 minutes increase RPM to 70–80 RPM.
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 assess more often
• 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 web site [https://www.nursing.umn.edu/research/research-projects/pad-prairie/resources-providers](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