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School of Nursing, University of Minnesota
Financial Disclosures

National Heart Lung and Blood Institute
Margaret A. Cargill Foundation
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

- 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

Altered aerobic muscle metabolism

- Poor aerobic capacity
- Reduced muscle strength and endurance

- Impaired walking ability
- Decreased QoL

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>

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:

<table>
<thead>
<tr>
<th></th>
<th>Moderate Intensity Group</th>
<th>Pain-Free Walking Group</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Improved pain-free walking distance 120% <em>(121 meters)</em></td>
<td>Improved pain-free walking distance 93% <em>(141 meters)</em></td>
</tr>
<tr>
<td></td>
<td>Improved peak walking distance 100% <em>(393 meters)</em></td>
<td>Improved peak walking distance 98% <em>(465 meters)</em></td>
</tr>
</tbody>
</table>
## Lower Extremity Cycling

<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, Askew et al. 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, Nawaz et al. 2000</td>
<td>n=67</td>
<td>6 weeks</td>
<td>PWD +137m COD +114m</td>
<td>PWD none</td>
<td>COD none</td>
</tr>
<tr>
<td>Zwierska, Walker et al. 2005</td>
<td>n=104</td>
<td>24 weeks</td>
<td>PWD +31% COD +57%</td>
<td>PWD none</td>
<td>COD none</td>
</tr>
</tbody>
</table>
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 STO2 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

Treat-Jacobson, Bronas et al. 2009
CLEVER: Supervised Exercise Versus Iliac Artery Stenting

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

**Peak Walking Time**

**Claudication Onset Time**

Murphy, T.P. et al. J Am Coll Cardiol. 2015; 65(10):999-1009
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>COR</th>
<th>LOE</th>
<th>Recommendations</th>
</tr>
</thead>
<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>
</tr>
<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>
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.
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:**
  - Three sessions per week
  - Up to 12 weeks of sessions
  - (CPT code: 93668)
  - Sessions lasting 30–60 minutes comprised of a therapeutic exercise-training program for PAD in patients with claudication

- 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.
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

<table>
<thead>
<tr>
<th>Client Name: __________________________</th>
<th>MR#: __________</th>
<th>CSN#: ________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: ________________________________</td>
<td>DOB/Age: ________</td>
<td>Diagnosis: ________</td>
</tr>
</tbody>
</table>

### Medical History
(check all that apply and explain)
- **Heart**
- **Lung**
- **Stroke**
- **Depression**
- **Orthopedic**

### Risk Factors for CAD
(check all that apply)
- **Weight**
- **Exercise**
- **Stress**
- **HTN**
- **Cholesterol**
- **DM**
- **Family Hx**
- **Depression**

### Pain Screen:
- Intensity Rating: ________________
- Location: ________________
- Onset: ________________
- Duration of ea. Episode: ________________
- Precipitating Factors: ________________
- Alleviating Factors: ________________

### 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

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

### ABIs:
- Right Pre Ex: ________________ Post Ex: ________________
- Left Pre Ex: ________________ Post Ex: ________________
- Symptoms of Claudication: ________________
- Location of Claudication: ________________
### 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>
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<tr>
<td>Resting Heart Rate (bpm)</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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<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>
</tr>
<tr>
<td>Recovery Blood Pressure</td>
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<tr>
<td>Claudication Onset Time (COT)</td>
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</tr>
<tr>
<td>Claudication Onset Distance (COD)</td>
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<tr>
<td>Total Distance Walked (PWD)</td>
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<tr>
<td>Effort Rating (OMNI Scale)</td>
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<td>O₂ Saturation</td>
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</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  →  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
1 = onset of pain
2 = mild pain
3 = moderate pain
4 = moderate pain
5 = severe pain

Stop before you have severe pain.

Resting or early exercise effort
1st feeling of any pain in legs
Where patient needs to stop during exercise training
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:**

<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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</table>

**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:**

---

546345  Rev 8/17  Progress Note/Clinic Note  

Original: Medical Record  

Page 1 of 2
**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.

**Session 2:** Repeat session 1 exercise prescription

- If able to walk continuously for 8–10 minutes or more:
  - Increase grade by 1%
  - Continue progression scheme until participant is able to walk continuously for 8–10 minutes at a grade of 10%; increase by 0.1 mph next session
- If not able to walk continuously for 8–10 minutes:
  - Continue at the same intensity

If patient 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

_Treat-Jacobson, Bronas, et al, 2009_
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

Session 2:
- Repeat session 1 exercise prescription

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.
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.