Experience with a Clinic-Based Supervised Exercise Program for Peripheral Artery Disease

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Disclosures

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Background

- 8.5 million Americans
- SET improves walking*
  - COD = 128m
  - PWD = 180m; 50-100% improvements
- CMS
- How well does PAD rehab work?

Purpose

• Objective
  • Implement and evaluate quality outcomes of a minimally supervised PAD-specific SET within a pre-existing Phase Cardiac Rehabilitation Program

• Aims
  1. Evaluate the referral, enrollment, and completion rates over a 9 month period
  2. Evaluate the effectiveness of the SET program
     • Walking outcomes
     • Physical function
### Recruitment Strategy

9/18/2015 to 5/19/2016

**Inclusionary criteria**
- Lifestyle limiting claudication
- Referral

**Exclusionary criteria**
- ACSM contraindications
- Foot ulcers/gangrene
- Ischemic rest pain

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**Steps:***

- **Screened**
  - Direct referral from providers
  - Letters to patients with history of PAD/previous study participants

- **Enrolled**
  - Not eligible/declined
  - Lost to follow-up

- **Completed 12 week follow-up**
Setting: WEL Program

- **Overview**
  - Peripheral Artery Disease Program is part of the “Wellness and Exercise for Life Program”
  - Self pay program (Scholarships are available)
  - CPT code for PAD Rehabilitation: 93668
**SET Program**

- **Rehabilitation team**
  - ACSM (RCEP, CES), CCRP
  - RN
- **Responsibilities of Rehab Team**
- **Evaluation**
  - 1 hour initial evaluation includes: 6 min walk, brief medical history, and exercise.
  - Monitor: Rhythm strip, HR, BP
  - Stress tests frequently not available
- **Session 1**
  - Go over protocols
  - Determine initial intensity
- **Sessions 2-36**
  - 1x week visit
  - Exercise log review

**Core Components**
- Baseline clinical evaluation & patient assessment
- Risk factor management and goal setting
- Psychosocial and vocational management
- Nutritional counseling
- Physical activity counseling & SET
Session 1: Determine speed & grade that induces 3-4/5 claudication within 8 min

Session 2: participant walks at Session 1 determined intensity to 3-4/5 claudication, sits down & rests until pain subsides. Continue Intervals for 60 minutes.

If participant is able to walk continuously for 8 minutes
- Increase grade by 1%

If participant is NOT able to walk continuously for 8 minutes
- Continue at same speed & grade

If participant is able to walk continuously for 8 minutes at 10% grade
- Increase speed by 0.1 mph; continue progression by speed until 3.0mph is reached based on ability to walk continuously for 8 minutes
Screened (n=75)

Enrolled (n=46)
- Completed 12 week follow-up (n=37)
  - Completed 36 sessions (n=6)
  - Completed fewer than 36 sessions (n=31)
- Lost to follow-up (n=9)
  - Unknown (n=4)
  - Deterioration in health (n=2)
  - Distance/transportation (n=2)
  - Lack of results (n=1)

Not eligible/declined (n=29)
- Declined (n=29)
  - Not interested (n=15)
  - Cost (n=7)
  - Time commitment (n=3)
- Ineligible (n=4)
  - Unstable medical condition/comorbidities (n=4)
## Demographics (n=46)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD)</th>
<th>Range</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>70.5 (7.7)</td>
<td>46-84</td>
<td></td>
</tr>
<tr>
<td>Gender (male)</td>
<td></td>
<td></td>
<td>28 (60.9)</td>
</tr>
<tr>
<td>Ethnicity (Caucasian)</td>
<td></td>
<td></td>
<td>45 (97.8)</td>
</tr>
<tr>
<td>BMI</td>
<td>33.2 (5.6)</td>
<td>22.0-49.4</td>
<td></td>
</tr>
<tr>
<td>Educational Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employment Status (retired)</td>
<td></td>
<td></td>
<td>40 (87.0)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD)</th>
<th>Range</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABI (worse leg)</td>
<td>0.61 (0.26)</td>
<td>(0.29-1.19)</td>
<td></td>
</tr>
<tr>
<td>PTA / Bypass</td>
<td></td>
<td></td>
<td>23 (50.0)</td>
</tr>
<tr>
<td>Amputation</td>
<td></td>
<td></td>
<td>3 (6.5)</td>
</tr>
<tr>
<td>Smoker: Cur. Past</td>
<td></td>
<td></td>
<td>4 (8.7) 36 (78.3)</td>
</tr>
<tr>
<td>HTN</td>
<td></td>
<td></td>
<td>44 (95.7)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td></td>
<td></td>
<td>43 (93.5)</td>
</tr>
<tr>
<td>DM</td>
<td></td>
<td></td>
<td>18 (83.7)</td>
</tr>
<tr>
<td>CAD / MI</td>
<td></td>
<td></td>
<td>24 (52.2)</td>
</tr>
</tbody>
</table>
# Feasibility

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Mean (SD)</th>
<th>Range</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrolled</td>
<td></td>
<td></td>
<td>46</td>
</tr>
<tr>
<td>Completed Follow-up</td>
<td></td>
<td></td>
<td>37 (80%)</td>
</tr>
<tr>
<td>Sessions Attended</td>
<td>23.1 (12.9)</td>
<td>4-58</td>
<td></td>
</tr>
<tr>
<td>Days between BL and Follow-up</td>
<td>90.9 (36.4)</td>
<td>23-199</td>
<td></td>
</tr>
<tr>
<td>Average Session per Week</td>
<td>2.0 (0.9)</td>
<td>0.2-4.2</td>
<td></td>
</tr>
<tr>
<td>Mode of exercise (treadmill)</td>
<td></td>
<td></td>
<td>36/37</td>
</tr>
</tbody>
</table>
Results: n=37

<table>
<thead>
<tr>
<th>Variable</th>
<th>BL</th>
<th>Follow-up</th>
<th>Change (%)</th>
<th>T-Test</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>6MWT (ft)</td>
<td>431.9 (217.1)</td>
<td>465.3 (180.1)</td>
<td>23.4 (5.4%)</td>
<td>-0.70</td>
<td>.49</td>
</tr>
<tr>
<td>- COD</td>
<td>1016.3 (396.4)</td>
<td>1131.4 (422.2)</td>
<td><strong>115.1ft / 35m</strong> (11%)</td>
<td>-2.71</td>
<td>.011*</td>
</tr>
<tr>
<td>- PWD</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Treadmill METS</td>
<td>2.88 (1.11)</td>
<td>3.79 (1.49)</td>
<td><strong>0.92 (34%)</strong></td>
<td>-6.36</td>
<td>0.001*</td>
</tr>
<tr>
<td>SPPB</td>
<td>3.54 (0.78)</td>
<td>3.5190.78)</td>
<td>-0.03 (-0.3%)</td>
<td>0.30</td>
<td>.77</td>
</tr>
<tr>
<td>- Balance</td>
<td>14.4 (5.0)</td>
<td>12.6 (5.6)</td>
<td>-1.8 (12.5%)</td>
<td>1.49</td>
<td>.15</td>
</tr>
<tr>
<td>- Chair rise</td>
<td>4.11 (1.22)</td>
<td>4.07 (1.13)</td>
<td>-0.04 (-0.4%)</td>
<td>0.26</td>
<td>.80</td>
</tr>
<tr>
<td>- 4m shuttle walk</td>
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</table>

BL and Follow-up data presented as mean (SD); significance denoted as *0.05
Relevance of Findings

6MWT
- Meaningful clinically important difference (MCID) in PAD RCT\(^{A}\)
  - 20m
  - 50m
- MCID post cardiac rehabilitation\(^{B}\)
  - 25m
- Change reported following traditional cardiac rehabilitation\(^{C}\)
  - 36m

Treadmill METS
- Treadmill MET change following traditional cardiac rehabilitation\(^{D}\)
  - 45%
- 1 MET increase during cardiac rehabilitation\(^{E}\)
  - 28% reduction in mortality
- MET level under 3.5 at exit\(^{F}\)
  - associated with higher adjusted 1 & 3 year mortality.

\(^{A}\) McDermott M, Guralnik J, Criqui M, RT et al. Six-minute walk is a better outcome measure than treadmill walking tests in therapeutic trials of patients with peripheral artery disease. Circulation. 2014 Jul 1;130(1):61-8


Conclusions

- A minimally supervised SET program in a phase III CR setting is feasible and effective
  - Physical function
  - Treadmill walking performance
- Challenges
  - Logs
  - Alternate mode of aerobic exercise training
- Foundation for CMS reimbursed PAD rehab