Effects of Ischemic Leg Symptom-Inducing Exercise on Simultaneous Improvement in Patient Reported Outcomes and Six-Minute Walk Distance in Peripheral Artery Disease: The LITE Randomized Clinical Trial

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Background

Optimal exercise programs for peripheral artery disease (PAD) should improve both objective walking performance and participant reported outcomes (PROs).

Purpose

To assess whether walking exercise conducted at a pace inducing ischemic leg symptoms was more likely to improve both objective walking distance and PROs, compared to walking exercise at a pace without ischemic leg symptoms and a non-exercise control.

Methods

Design
- Post-hoc analysis of Low-Intensity Exercise Intervention in PAD (LITE) Trial

Sample
- N=305 participants with PAD randomized to one of three parallel groups for 12 months: 1) low intensity home-based exercise, 2) high intensity home-based exercise, and 3) non-exercise control group

Measures
- Composite outcome including improvement in both 6-minute walk test (6MW) total distance and PRO
- PROs:
  - Walking Impairment Questionnaire (WIQ) distance, speed, stair-climbing
  - Short Form-36 (SF-36) physical function

Data Analysis
- Participants categorized by improvement (change >0 or minimal clinically important difference [MCID]) in 6MW and PRO at 12-month follow-up:
  1. Improved both 6MW and PRO
  2. Improved 6MW but not PRO
  3. Improved PRO but not 6MW
  4. Neither 6MW or PRO improved
- Chi-square tests used to compare frequencies in each category by group

Results

Baseline Characteristics	Overall (N=242)	Group Low intensity (N=92)	Group High intensity (N=102)	Group Control (N=48)	p value
Age (years), mean (SD)	69.3 (9.3)	69.5 (9.8)	68.8 (8.7)	69.9 (9.6)	0.77
Women, n (%)	117 (48.4)	43 (46.7)	50 (49.0)	24 (50.0)	0.92
White, n (%)	86 (35.5)	35 (38.0)	32 (31.4)	19 (39.6)	0.50
Black, n (%)	148 (61.2)	51 (55.4)	69 (67.7)	28 (58.3)	0.20
ABI, mean (SD)	0.71 (0.19)	0.67 (0.19)	0.71 (0.19)	0.75 (0.20)	0.0490
BMI (kg/m²), mean (SD)	30.5 (6.8)	29.3 (5.6)	31.2 (7.2)	31.3 (8.0)	0.0959
Diabetes, n (%)	105 (43.4)	36 (39.1)	43 (42.2)	26 (54.2)	0.22
Current smoker, n (%)	68 (28.1)	33 (35.9)	24 (23.5)	11 (22.9)	0.11
Intermittent claudication, n (%)	34 (14.1)	13 (14.1)	14 (13.7)	7 (14.6)	0.99
Leg pain-not intermittent claudication, n (%)	192 (79.3)	73 (79.4)	82 (80.4)	37 (77.1)	0.90
Asymptomatic, n (%)	16 (6.6)	6 (6.5)	6 (5.9)	4 (8.3)	0.85
WIQ distance score, mean (SD)	36.4 (26.0)	36.9 (25.3)	36.6 (26.9)	35.3 (25.8)	0.94
6MW total distance (meters), mean (SD)	334.5 (97.9)	332.3 (96.3)	339.4 (103.0)	328.1 (91.0)	0.78

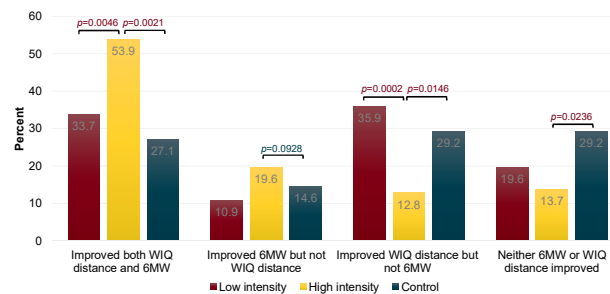Figure 1. Improvement in 6MW and WIQ Distance by Group

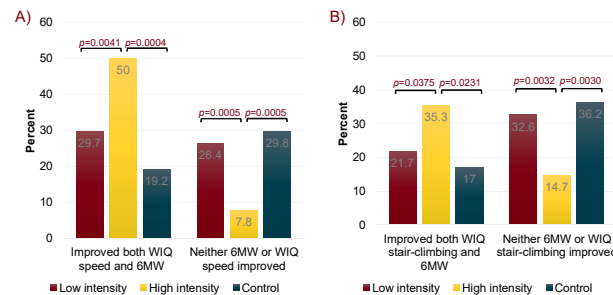Figure 2. Improvement in 6MW and WIQ Speed (A) and WIQ Stair-Climbing (B) by Group

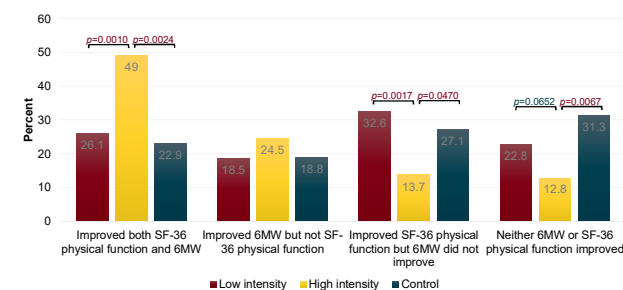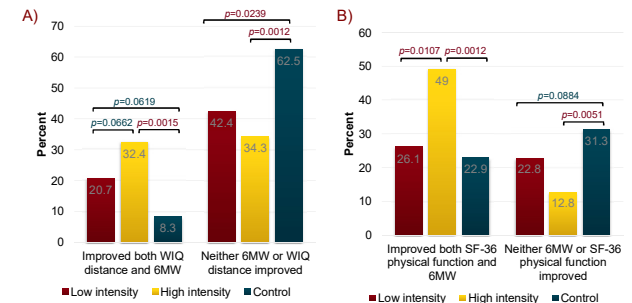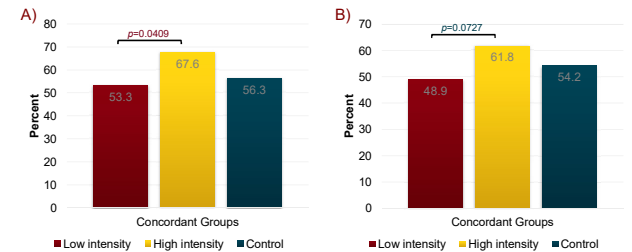Figure 3. Improvement in 6MW and SF-36 Physical Function by Group

Figure 4. MCID Improvement in 6MW and WIQ Distance (A) and SF-36 Physical Function (B) by Group

Note: MCIDs defined as 6MW ≥20 meters; WIQ distance ≥15 points; SF-36 ≥5 points

Figure 5. Concordance of 6MW and WIQ Distance (A) and SF-36 Physical Function (B) by Group

Discussion

- High intensity improves both 6MW and PROs more consistently
- Similar patterns when response defined as change >0 vs. MCIDs
- 6MW and PROs are complementary
- Need to identify participant characteristics that predict objective improvement as well as perception of improvement
- Limitations:
  - Post-hoc analyses, confirmation required
  - Data to explain these findings not collected

Acknowledgements