Pragmatic Implementation Science to Assess Lipid Optimization in Peripheral Artery Disease: Design and Conduct of the Randomized OPTIMIZE PAD-1 Trial

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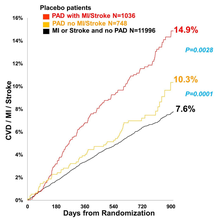
BACKGROUND

- Patients with peripheral artery disease (PAD) are at heightened risk for ischemic events
- Reducing low-density lipoprotein cholesterol (LDL-C) can lower this risk



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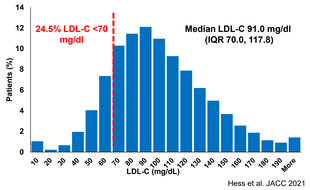
LDL-C is Poorly Controlled Among Patients with PAD (n=18,747)



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- Lipid-lowering therapies are underused in PAD
- Implementation science aims to improve this gap, but few randomized trials exist
- The design and conduct of the OPTIMIZE PAD-1 trial are presented here

STUDY DESIGN

- 1º objective: to evaluate the efficacy of a multidisciplinary vascular care team including a clinical pharmacist and an intensive algorithm-based approach for lipid management versus usual care supplemented with provider education
- 2º objective: to assess the impact of a structured quality assurance program (EQuIP) on variability in 6-minute walk test (6MWT) distance
- Key eligibility criteria: Patients with non-coronary arterial disease cared for at University of Colorado with goal LDL-C<70 mg/dl per ACC/AHA guidelines and screening LDL-C ≥70 mg/dl

Figure 1. OPTIMIZE PAD-1 Study Design

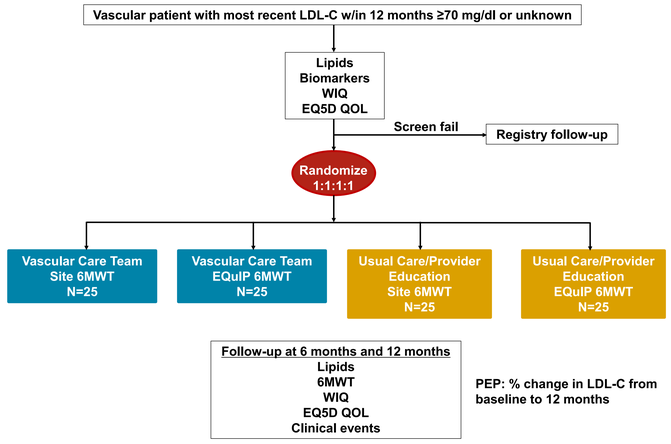


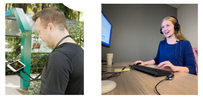
Figure 2. Pragmatic Features of OPTIMIZE PAD-1

Identification of potential participants and events via EMR

Remote recruitment and electronic consent process

Home-based lipid measurement

Telehealth visits with vascular medicine and pharmacy



Virtually monitored home-based 6MWT

RESULTS

Figure 3. CONSORT Diagram

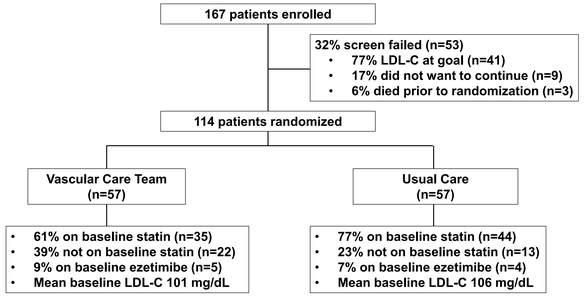


Table 1. Baseline Characteristics

	Vascular Care Team (N=57)	Usual Care (N=57)
Demographics, n (%)		
Age, mean (SD), years	67 (9.9)	66 (10.4)
Female sex	19 (33.3)	22 (38.6)
Hispanic/Latino	2 (3.5)	2 (3.5)
Race		
Black/African American	11 (19.3)	7 (12.3)
White	46 (80.7)	50 (87.7)
Comorbidities (n, %)		
Hypertension	43 (75.4)	42 (73.7)
Diabetes	15 (26.3)	20 (35.1)
Heart failure	10 (17.5)	5 (8.8)
Atrial fibrillation/flutter	11 (19.3)	6 (10.5)
Chronic kidney disease	12 (21.1)	12 (21.1)
Current smoker	16 (28.1)	19 (33.3)
Coronary artery disease*	26 (45.6)	14 (24.6)
Cerebrovascular disease	13 (22.8)	9 (15.8)
Peripheral artery disease	43 (75.4)	45 (78.9)
PAD with critical limb ischemia	9 (15.8)	18 (31.6)
Prior lower extremity revascularization	29 (67.4)	25 (55.6)
Prior major amputation	2 (3.5)	3 (5.3)
Baseline ABI (median, IQR)[1]	0.67 (0.54-0.82)	0.80 (0.55-0.95)
Polyvascular disease[2]*	24 (42.1)	12 (21.1)
Other arterial vascular disease[3]	15 (34.9)	11 (24.4)

IQR, interquartile range; PCSK9, proprotein convertase subtilisin/kexin type 9; TIA, transient ischemic attack
[1]Calculated among patients with PAD
[2]Defined as any two of the following: coronary artery disease, cerebrovascular disease, or peripheral artery disease
[3]Defined as non-coronary, non-cerebrovascular, and non-lower extremity arterial disease
*p-value <0.05

LIMITATIONS

- OPTIMIZE PAD-1 is being conducted at a single site

CONCLUSIONS

- ~2/3 LDL-C levels were not at goal in patients with vascular disease, and ~30% were not on baseline statin
- OPTIMIZE PAD-1 will provide insight into the effectiveness of interprofessional, algorithm-based care in improving lipid management in vascular disease
- OPTIMIZE PAD-1 will also assess the benefit of EQuIP in reducing variability in 6MWT distance
- Pragmatic randomized trials in PAD patients are feasible to strengthen implementation science

IMPLICATIONS

- If successful, this pilot implementation study could be expanded to test its efficacy in different healthcare systems
- This model could also be adapted to improve management of other chronic diseases, such as diabetes and hypertension

DISCLOSURES

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