Pragmatic Implementation Science to Assess Lipid Optimization in Peripheral Artery Disease: Primary Results of the OPTIMIZE PAD-1 Trial

Connie N. Hess, MD, MHS,[1,2] Mark R. Nehler, MD,[1,2] Ashley Daffron, PharmD,[1] Justin T. Morrison, MD,[1] Cullen E. Buchanan, MD,[3] Joseph J. Saseen, PharmD,[1] Victoria E. Anderson,[2] Christopher P. Cannon, MD,[2,4] Judith Hsia, MD,[1,2] Marc P. Bonaca, MD, MPH[1,2]

[1]University of Colorado School of Medicine; [2]CPC Clinical Research; [3]Medical College of Wisconsin; [4]Harvard Medical School

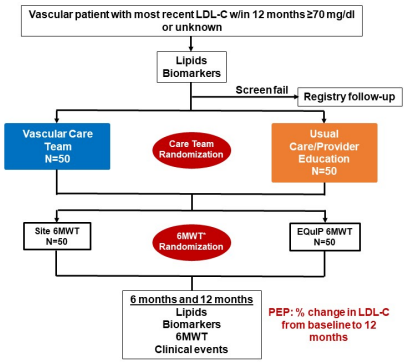
BACKGROUND

- Reducing low-density lipoprotein cholesterol (LDL-C) in peripheral artery disease (PAD) lowers risk of ischemic events[1]
- Lipid-lowering therapies are underused in PAD[2]
- Implementation science aims to improve this gap, but few randomized trials exist

[1]Bonaca MP, et al. *Circulation* 2018;137:338-350
[2]Hess CN, et al. *J Am Coll Cardiol* 2021;77:3016-3027

STUDY DESIGN

Figure 1. OPTIMIZE PAD-1 Study Design



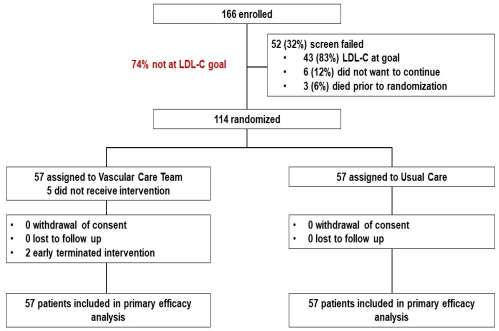
*6-minute walk test (6MWT) results to be reported separately

1º objective: To evaluate the efficacy of an interprofessional vascular care team including a clinical pharmacist and an intensive algorithm-based approach for lipid management versus usual care supplemented with provider education

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

RESULTS

Figure 2. CONSORT Diagram*



*trial ongoing

Table 1. Baseline Characteristics

	Vascular Care Team (N=57)	Usual Care (N=57)
Demographics, %		
Age, mean (SD), years	67 (9.9)	66 (10.2)
Female sex	33	39
Hispanic/Latino	4	4
Race		
Black/African American	19	12
White	81	88
Comorbidities, %		
Hypertension	75	74
Diabetes	26	35
Heart failure	18	9
Atrial fibrillation/flutter	19	11
Chronic kidney disease	21	21
Current smoker	28	33
Coronary artery disease*	46	25
Cerebrovascular disease	23	16
Peripheral artery disease (PAD)	75	79
PAD with critical limb ischemia	16	32
Prior lower extremity revascularization	67	56
Prior major amputation	4	5
Baseline ABI, median (IQR)[1]	0.67 (0.54-0.82)	0.80 (0.55-0.95)
Polyvascular disease[2]*	42	21
Other arterial vascular disease[3]	35	24

IQR, interquartile range
[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

Figure 3. Lipid-Lowering Therapy Use Over Time

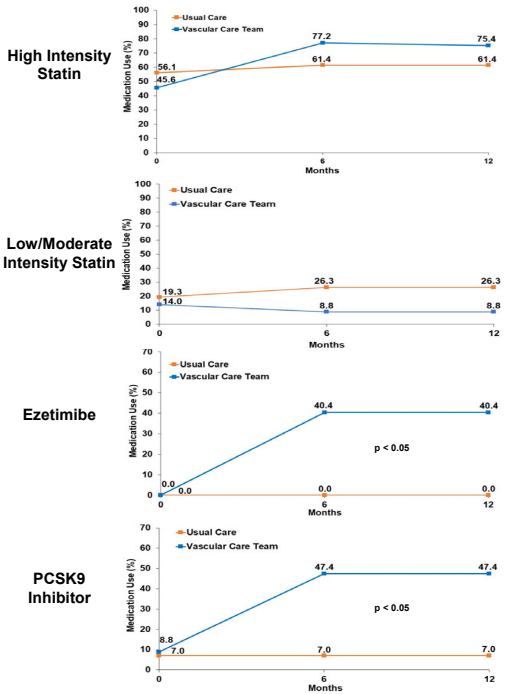
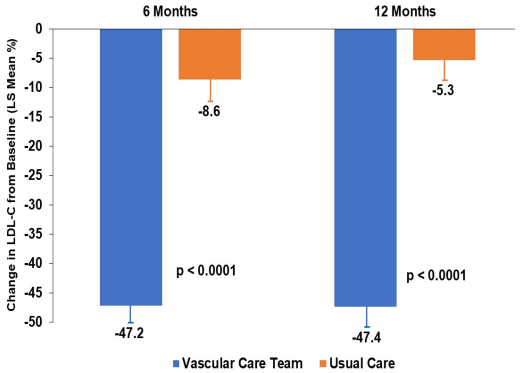
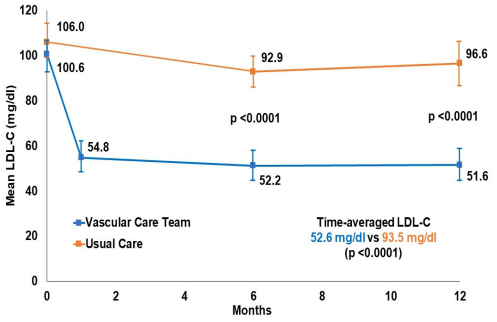


Figure 4. Change in LDL-C from Baseline



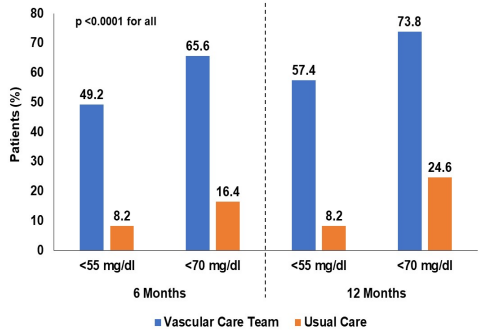
Error bars indicate the upper limit of the 95% confidence interval

Figure 5. Temporal Trend in LDL-C Level



Error bars indicate the 95% confidence interval

Figure 6. Proportion of Subjects at Goal LDL-C



LIMITATIONS

- OPTIMIZE PAD-1 was conducted at a single site

CONCLUSIONS

- LDL-C levels were not at goal for ~3/4 of patients with vascular disease, and statins and ezetimibe were used at baseline in 51% and 8%, respectively
- No increase in use of combination lipid lowering therapies was observed over 12 months in the Usual Care group
- Interprofessional care with an algorithm using multiple agents designed to achieve goal LDL-C in one step is effective for improving lipid management in vascular disease
- The interventional arm achieved LDL-C <55 mg/dl within 1 month with significantly more individuals at goal
- Results were achieved with drug obtained using standard insurance/payers rather than provided through the study

IMPLICATIONS

- OPTIMIZE PAD-1 demonstrates that healthcare systems can achieve better lipid management through use of a Vascular Care Team, leveraging an interprofessional model with pharmacy support and algorithm-based care

DISCLOSURES

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