Combination Therapy Lipid Management in Peripheral Artery Disease: Insights from the OPTIMIZE PAD-1 Trial

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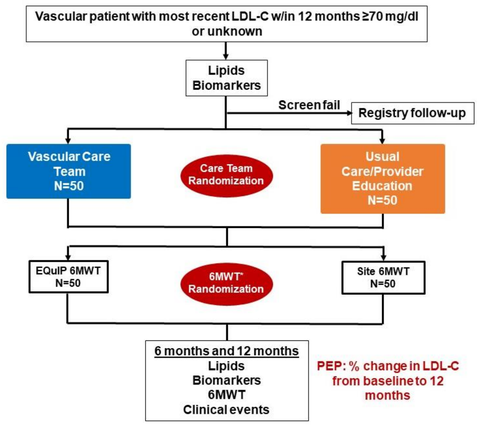
BACKGROUND

- 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]
- Recent data highlight the importance of combination therapy in achieving LDL-C goals[3]

[1]Bonaca MP, et al. *Circulation* 2018;137:338-350
[2]Hess CN, et al. *J Am Coll Cardiol* 2021;77:3016-3027
[3]Nissen S, et al. *N Engl J Med* 2023;388:1353-1364

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

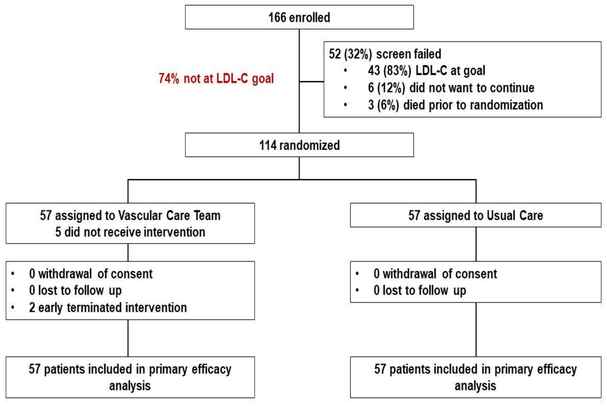
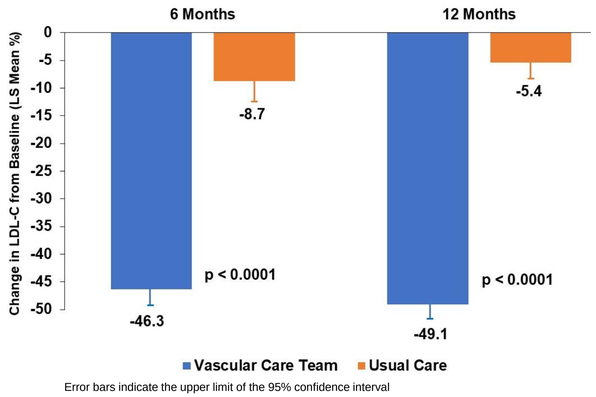


Table 1. Baseline Characteristics

	Vascular Care Team (N=57)	Usual Care (N=57)
Demographics, %		
Age, mean (SD), years	67 (9.9)	66 (10.4)
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

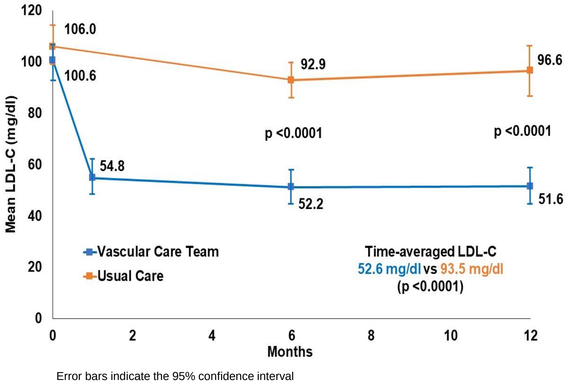
IQR, interquartile range; SD, standard deviation
[1]Calculated among patients with PAD
[2]Defined as any two of the following: coronary artery disease, cerebrovascular disease, or peripheral artery disease
[3]Defined as non-coronary, non-cerebrovascular, and non-lower extremity arterial disease
*p-value <0.05

Figure 3. Percent Change in LDL-C from Baseline



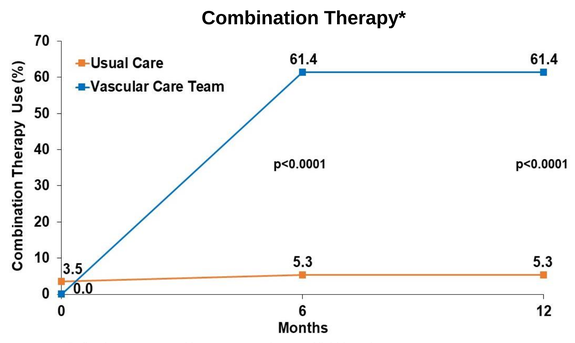
Error bars indicate the upper limit of the 95% confidence interval

Figure 4. Temporal Trend in LDL-C Level

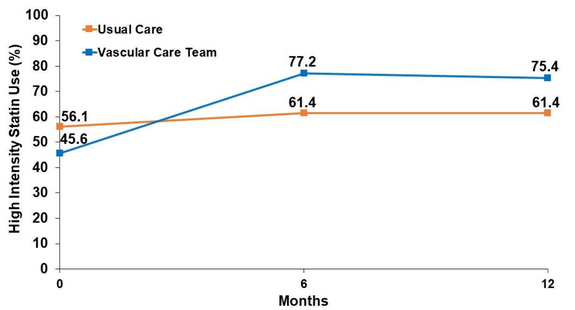


Error bars indicate the 95% confidence interval

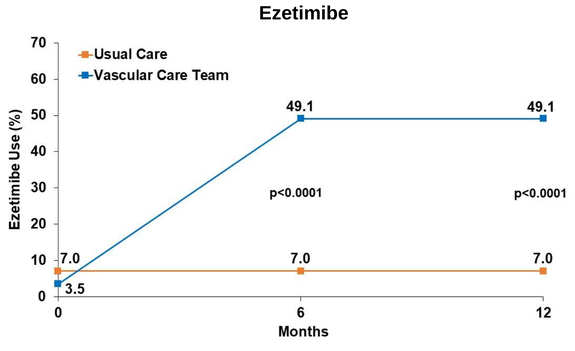
Figure 5. Lipid-Lowering Therapy Use Over Time



*Defined as treatment with two or more classes of lipid-lowering agents



*Defined as atorvastatin ≥40 mg daily, rosuvastatin ≥20 mg daily, or simvastatin 80 mg daily



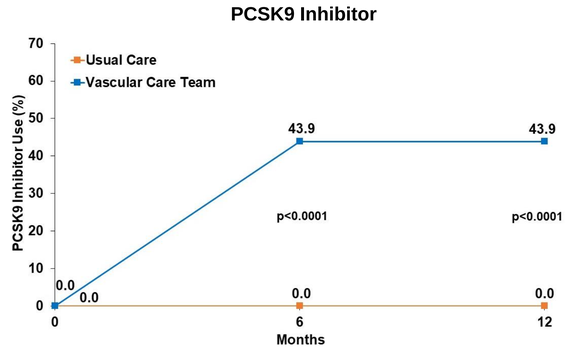
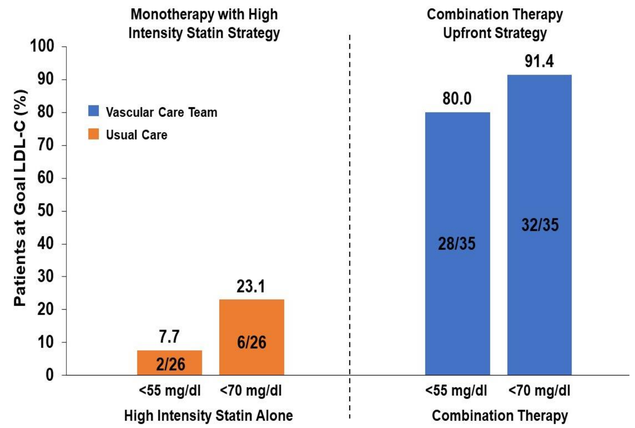


Figure 6. Achieved LDL-C by Lipid-Lowering Regimen



LIMITATIONS

- OPTIMIZE PAD-1 was conducted at a single site

CONCLUSIONS

- Among patients enrolled in OPTIMIZE PAD-1, LDL-C levels were not at goal for ~3/4 of patients with vascular disease
- In the Usual Care group provided guideline-based recommendations, there was a slight increase in use of high intensity statin but not in use of combination therapy, reflecting current practice
- Patients in the Usual Care arm treated with high intensity statin alone were at goal LDL-C <55 mg/dl and <70 mg/dl less than 25% and 10% of the time, respectively
- The Vascular Care Team approach significantly increased use of combination therapy, and more patients in this group achieved goal LDL-C using both thresholds

IMPLICATIONS

- These findings demonstrate that treatment of vascular patients with high intensity statin alone is often insufficient and highlight the importance of combination therapy in achieving goal LDL-C
- 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 patients
- Increasing provider awareness of the need for combination therapy may also be useful to help improve lipid management in this patient population

DISCLOSURES

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