A Structured Quality Assurance Program Reduces Six Minute Walk Test Variability: Insights from the OPTIMIZE PAD-1 Trial

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BACKGROUND

- Patients with peripheral artery disease (PAD) have impaired walking capacity and function
- The 6-minute walk test (6MWT) is an important functional assessment, but variability in results may limit its utility and interpretation

STUDY DESIGN

Figure 1. OPTIMIZE PAD-1 Study Design

Vascular patient with most recent LDL-C ≤12 months ≤70 mg/dl or unknown

Lipid Biomarkers
Screening
LKCI
Regulatory follow-up

Objectives:
1) To evaluate the efficacy of an interprofessional vascular care team and intensive algorithm-based approach for lipid management versus usual care
2) To evaluate the effect of a structured quality assurance program (EQuIP) on variability in 6MWT compared with site-conducted testing

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

METHODS

- Due to COVID-19, all 6MWT were performed virtually
- Patients assigned to site-conducted 6MWT were sent a tape measure and written instructions, which were reviewed over the phone
- The EQuIP program included real-time virtual monitoring and multiple features to try to control for variability, including careful assessments of course length, assessing course length: clear of obstacles; impact of carrying objects (add course length)
- Variability in 6MWT was assessed using Levene’s test

RESULTS

Figure 2. Baseline and Follow-Up 6MWT

Figure 3. Variability in 6MWT

Table. Baseline Characteristics

Baseline EQuIP Site

<table>
<thead>
<tr>
<th>Site</th>
<th>n (N=32)</th>
<th>6MWT</th>
<th>EQuIP</th>
<th>Site</th>
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</thead>
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| Median distance walked (meters) | 240.8 | 295.3 | 299.53 | 428.7 |
| Variance ratio | 0.21 | 0.37 | 0.0014 | 0.0142 |

Figure 4. CONSORT Diagram

- Site 6MWT
- 6MWT
- Site EQuIP
- 6MWT EQuIP

LIMITATIONS

- OPTIMIZE PAD-1 was conducted at a single site

CONCLUSIONS

- This randomized trial of EQuIP demonstrated a highly significant 80% reduction in 6MWT variability at baseline that was maintained through follow-up compared with site-reported results
- EQuIP also resulted in better follow-up than site-conducted 6MWT

IMPLICATIONS

- Use of EQuIP for trials assessing 6MWT as an outcome in patients with vascular disease could improve data quality and reduce the study sample size
- For example, assuming a difference in mean 6MWT of 25 meters (SD of 100) with 2-sided alpha of 0.05, 563 patients would need to be randomized 1:1 to achieve 80% power. An 80% reduction in variability would translate to 101 patients needing to be randomized (i.e., 80% fewer patients).

DISCLOSURES