

Patient-Centered Care for PAD: Individualizing Treatment Strategies for Claudication

An overview of the aims of an NHLBI grant to evaluate shared decision-making in routine PAD care.

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Peripheral artery disease (PAD) affects up to 12 million Americans and accounts for a significant burden of health care expenditures in the United States.^{1,2} The most common symptom of PAD is claudication, which is pain upon exertion that is relieved with rest. The presence of PAD portends a poor prognosis, as patients with PAD have substantially higher rates of myocardial infarction, stroke, and cardiovascular death.³ Despite this increase in overall mortality, only a minority of patients with symptomatic PAD progress to critical limb ischemia (CLI) and require amputation.

Although the risk of limb loss is low, claudication has a major impact on a patient's quality of life (QOL) and well-being.^{4,5} Patients with claudication rate their physical functioning significantly lower than patients with congestive heart failure.⁵ More than 2 million individuals with claudication have a reduced QOL.⁶ Patients with claudication often avoid walking, which may exacerbate the decline in physical function and further impair their ability to perform activities of daily living. Moreover, depressive symptoms are present in a substantial proportion of patients with PAD and are associated with reduced functional capacity.⁷

Early revascularization of symptomatic PAD has not been shown to prevent progression to CLI; thus, the primary reason to recommend an intervention for patients with claudication is to improve QOL.³ However, the ability to identify patients most likely to benefit from an intervention and monitor their response to the intervention is dependent on a physician's ability to accurately assess a patient's preferences, QOL, risk tolerance, and subjective sense of physical limitations.

NHLBI GRANT OVERVIEW: INCORPORATING SHARED DECISION-MAKING INTO PAD CARE

When evaluating a patient with PAD, clinical indices such as the ankle-brachial index (ABI) and the Rutherford score are commonly used metrics for assessing severity of disease and clinical decision-making. The ABI correlates

well with a patient's risk of cardiovascular events but not with the patient's self-reported assessment of QOL.⁸ This is similar for the Rutherford score.⁹ Validated tools for assessing health-related QOL are not commonly used in clinical settings. In one study, surgeons asked patients a median of five questions prior to recommending a treatment strategy, and only 9% of questions elicited patient preferences.¹⁰ Another study found that surgeons are only moderately good at evaluating patients' QOL.¹¹ The result is that recommendations for treatments for PAD are heterogeneous among physicians and are based on clinical scoring systems and hemodynamic parameters that are poor proxies for the outcomes that matter most to patients.

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Aim 1: Develop and Validate Prediction Tools

To counsel patients in an individualized way, prediction tools will be developed to model changes in PROMs using existing data from the large PORTRAIT study.¹² PORTRAIT is a prospective, multicenter, international study that enrolled > 1,000 patients with PAD prior to receiving PAD therapies. The study collected information about patients' QOL before and after they received optimal medical therapy, supervised exercise therapy, or peripheral vascular intervention. QOL and health status were measured using a disease-specific evaluation, the Peripheral Artery Questionnaire (PAQ), which assesses the following domains

of patient function: physical function, symptom stability, social limitation, treatment satisfaction, and QOL.

The prediction tools will be able to project patients' changes in health status (ie, symptomatic, functional, and QOL benefits) after starting a comprehensive PAD treatment program and will help better understand who may have the greatest improvement in PAQ score with an invasive strategy compared with an initial conservative therapy (medical and/or supervised exercise). Once these prediction models have been developed, they will be validated using additional clinical trial data to ensure generalizability. After validation, these prediction models will be incorporated into an established PAD decision aid, SHOW ME PAD,¹³ to provide both qualitative and quantitative counseling material for patients seeking management of their claudication.

Aim 2: Improve Shared Decision-Making in Routine Care

Critically, despite substantial work in the field of decision sciences in PAD, there has been poor uptake of shared decision-making into clinical practice. The second aim of the grant will focus on improving the implementation of shared decision-making into routine vascular care. As part of this aim, a mixed-methods approach will be employed to assess beliefs, goals, and concerns regarding use of decision aids and shared decision-making among a diverse population of vascular nurses, office managers, physicians, and patients from clinics throughout Massachusetts. The information gathered will be used to propose strategies to facilitate implementation of shared decision-making and create a resource for external vascular clinics interested in implementing shared decision-making.

Aim 3: Assess the Impact of SHOW ME PAD on Treatment Decision Quality

Finally, a prospective pilot study will be conducted using the SHOW ME PAD decision aid to assess its impact on treatment decision quality. Fifty patients referred for the management of new claudication will be enrolled. Baseline PAQ measures will be collected, as well as baseline decision quality and knowledge assessments. Half of the patients will then undergo usual care and counseling, while the other half will be presented with the decision aid prior to their physician visit. After the visit, patients will undergo a decision quality and knowledge assessment, which will evaluate how much knowledge patients have about PAD and their sense of preparedness to make treatment decisions regarding their PAD.

SUMMARY

The primary goal of the treatment for claudication is to improve QOL. Therefore, validated methods for assessing

QOL and understanding how to incorporate patient preferences into routine clinical care is essential for improving outcomes. Through this work and other ongoing studies, the ultimate goal is to restructure PAD care so that it aligns treatment with the goals of each individual patient. ■

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