

PROM PAD WORKING GROUP



PATIENT-REPORTED OUTCOME MEASURES IN PAD (2018-2021)

Advancing patient-centered outcome measures in Peripheral Artery Disease

Peripheral artery disease (PAD) affects hundreds of millions of people around the world, causing disability, functional decline, limb loss, and death. Yet we understand relatively little about how the disease or the treatments we offer affect patients in their everyday lives. It has become critical that standardized approaches are developed to capture direct patient-reported outcome measures (PROMs) in PAD so that we can better measure clinical effectiveness and value in vascular care, and design treatments that are truly impactful. Incorporation of these PROMs into clinical trials, registries, and everyday practice provides a way forward to patient-centered care for the vascular patient.

To help improve the use of PROMS in PAD and CLTI, Vascular Cures created the PROM-PAD Working Group. The 2019 kickoff meeting of this group in the nation's capital brought together a multi-disciplinary group of clinical experts, scientists, governmental and industry stakeholders—as well as several patients with PAD who provided direct and powerful input. We are proud to have catalyzed this important work.

In 2022 the PROM-PAD working group published two papers that will advance this field. The goal of the effort was not simply to provide recommendations to the PAD community, but to catalyze implementation of PROMs in a feasible, meaningful, and scientifically sound fashion to improve the lives of patients with PAD.

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Patient-Reported Outcome Measures in Symptomatic, Non-Limb-Threatening Peripheral Artery Disease: A State-of-the-Art Review

Circulation: Cardiovascular Interventions, January 2022

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Patient-reported outcome measures (PROMs) have proven to be incredibly useful in evaluating disease progression and treatment efficacy. Several PROMs exist within the disease space for Peripheral Artery Disease (PAD), a problem with circulation that can occur in the blood vessels that supply the legs. However, PROMs related to PAD have varied levels of validation and there is an existing gap in knowledge surrounding which PROMs are best validated and therefore of most use to researchers. To address this issue, a literature review looked at studies using PROMs that included twenty-five or more patients with symptomatic PAD that had not progressed to chronic limb-threatening ischemia. The authors reviewed twenty-four PROMs of varying disease specificity, and with varying levels of patient and clinician-sourced content validation. Several PROMs demonstrated significant merit, including reliability, sensitivity to change, and overall evidence of validation. Disease-specific PROMs include the Peripheral Artery Questionnaire (PAQ), the Vascular Quality of Life Questionnaire (VasculQoL), and the Walking Impairment Questionnaire (WIQ); generic PROMs include the EQ-5D and SF-36. Moving forward, those who administer PROMs can use this review to better select which measures are most suited to their clinical or scientific goals.

A systematic review of patient-reported outcome measures patients with chronic limb-threatening ischemia

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Patient-reported outcome measures (PROMs) are valuable tools which help capture important aspects of patients' experience with disease, including treatment efficacy. Chronic limb-threatening ischemia (CLTI), the advanced form of Peripheral Artery Disease (PAD), is quickly becoming a major public health concern due to the high levels of amputations and mortality that result. Yet, there is no single PROM which directly and wholly relates to the experience of CLTI patients. This is due to the clinical heterogeneity with which CLTI presents, a challenge related to the fact that CLTI is often comorbid with other health challenges and can therefore manifest in different ways. Currently, clinicians and researchers are using a variety of PROMs to measure the outcomes of CLTI patients with limited effectiveness.

This paper systematically reviewed existing PROMs in the CLTI disease space in order to provide evidence-based conclusions on what gaps exist and must be overcome to establish a singular, rigorous PROM for CLTI patients. The researchers first identified each PROM, and then classified the measurements. PROMs had to be related to the quality of life of CLTI patients, although patients with claudication were also considered; over 20 PROMs resulted. They then performed an overall, chronological review of how each PROM was used for CLTI research or care and how those functions might contribute toward one, overarching CLTI patient-reported outcome measure. Ultimately, the development of such a PROM will take significant time and effort from a variety of disciplines and specialties, but will enhance CLTI research and care immeasurably.