Exploring Patient-Centered Outcomes in CLI: The SCOPE-CLI Registry

Rationale and status of the SCOPE-CLI registry, study endpoints, and key questions both the physician and patient should ask.

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Patients with a diagnosis of critical limb ischemia (CLI) face a high risk of mortality and amputation, but with the majority surviving the year after their diagnosis, little is known about patients' quality of life and functioning. Patients may deal with rest pain, nonhealing wounds, or gangrene and have care trajectories that are resource intense. The patients' perspectives of the disease experience and what matters most to them as they navigate the care process have not been well described.

RATIONALE, GOALS, AND STATUS OF SCOPE-CLI

The SCOPE-CLI study is a prospective observational registry that was uniquely codesigned with patients who have CLI to capture the disease and care experiences, treatment preferences, and health status outcomes of this vulnerable population.[1]

SCOPE-CLI aims to further characterize the clinical characteristics, treatment patterns, and outcomes of patients diagnosed with CLI, examine treatment patterns and variability across practices to identify gaps in quality care delivery, and map out patient trajectories in terms of patient-centered outcomes in order to identify which care profiles are associated with better outcomes, pinpoint current gaps, and start targeting modifiable intervention targets to improve the health status of patients with CLI.

Because much of the current body of evidence focuses on clinical outcomes such as mortality or amputation, there is a scarcity of data that sheds light on the patient-centered experience. Studying the patient experience is long overdue and will allow us to develop chronic disease management programs and shared-decision frameworks tailored to patients' needs. Unique to the SCOPE-CLI registry is that it adopts a broad conceptual framework of risk, including patients' stress experiences and mental health, as well as the nature of the care interactions with their providers and the referrals they are receiving to address their care needs from a holistic perspective.

Another important contribution of SCOPE-CLI is that it will help clarify how patients understand their disease and how they refer to their own condition. Patient perceptions about CLI and the terminology they use to describe their condition have not been well described, and there remains a disconnect with how clinicians define CLI prevention and treatment. If we want to improve CLI outcomes, a shared understanding and commonality of the disease experience, knowledge, and nomenclature needs to be established between patient and providers so that they can work together to manage this chronic disease.

There are 10 multidisciplinary centers currently enrolling patients in SCOPE-CLI in the United States and one center in Australia, including interventional cardiology and vascular surgery practices. Enrollment began in August 2021, and there are 162 patients enrolled as of April 2022. The enrollment target is 816 patients.

STUDY ENDPOINTS

Although information on traditional endpoints such as mortality and amputation will be collected, the main emphasis is on CLI-specific health status. Within the registry, we have built in the ability to validate a purposely designed health status questionnaire, the Peripheral Artery Questionnaire-CLI, that asks patients about their unique health status experiences as a function of their disease stage, which has never been done before. For example, a patient who just underwent an amputation has different concerns than a patient who is awakened by pain during the night, and so it is important to ask the right questions.

KEY QUESTIONS CLINICIANS SHOULD ASK THEIR PATIENTS

Other than focusing on leg symptoms, wound healing, and avoiding amputations, increasing data have shown the major impact of CLI on patients' mental health and the complexity of comorbidities, including addiction and mental health disorders. Asking about the broader context of functioning and care needs is key, and connecting patients with the care they need to navigate those challenges is important. Conversations related to a patient's mental state, their families, and how CLI affects them are important in order to determine their individualized treatment goals and preferences.

KEY QUESTIONS PATIENTS SHOULD ASK THEIR CLINICIANS

There are many questions to ask the multidisciplinary CLI care team, including available resources for lifestyle (eg, smoking cessation, diabetes care, physical activity, dietary changes) and mental health support (eg, depression, other mental health needs), specific treatment goals, and support groups for both patients and their caregivers. In addition, patients might ask about how they can be active in their disease management process, their available treatment options and the pros and cons of each, and how treatment success will be defined.

SUMMARY

The SCOPE-CLI study will provide context as to what it means to live with CLI as seen from the patients' perspective, highlight barriers in accessing care, and describe the impacts on patients' quality of life. The study will provide information to identify areas of action that can be targeted in sustainable quality improvement programs and patient-centered decision-making and outcomes assessment platforms for this population. ■

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1. Scierka LE, Mena-Hurtado C, Shishehbor MH, et al. The shifting care and outcomes for patients with endangered limbs - critical limb ischemia (SCOPE-CLI) registry overview of study design and rationale. Int J Cardiol Heart Vasc. 2022;39:100971. doi: 10.1016/j.ijcha.2022.100971

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