



Cost-Effectiveness of Critical Limb Ischemia Treatments—Critical Gaps Remain

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Chronic limb-threatening ischemia (CLTI) is the most severe form of peripheral artery disease (PAD). It is estimated that CLTI affects 220 to 3500 per 1,000,000 people annually in the United States.¹ Patients with CLTI are extremely limited in their ability to function, similar to patients with other severe chronic illnesses. Furthermore, patients with CLTI suffer significantly reduced life expectancy. A 2-year mortality as high as 40% has been reported.² As such, while revascularization procedures are the cornerstone of treatment and address the acute presenting symptoms, the care of CLTI patients is complex and goes well beyond interventions. In modern practice, it is of paramount importance to optimize medical therapy, address comorbid physical and psychosocial disabilities, and respond to common yet unanticipated conditions that may span from infection to systemic acute ischemic events.¹ Sadly, patients with CLTI suffer from serious disparities in care delivery and quality. Populations living in areas with fewer resources suffer negative outcomes.³ Thus, unfortunately, we must account for total costs of care when addressing this disease condition. Indeed, it has been estimated that the cost of care for CLTI patients was \$4 billion annually in the United States in 2007.⁴ Since then, the prevalence of the disease has risen, the complexity of care has increased, and the cost of health care has skyrocketed. As such, understanding the cost-effectiveness of various approaches to treatment is of great importance.

Against this backdrop, Perlander and colleagues set out to compare the cost-effectiveness of 2 revascularization strategies for CLTI, surgical and endovascular, in a Swedish health care system.⁵ The authors utilized a prospective cohort for their analysis. Patients underwent procedures according to a predetermined protocol, and there was no overlap between the indication for surgical and endovascular interventions. Patients were followed for reintervention and mortality. Other measures were collected,

including quality-of-life metrics. The authors concluded that at 2 years the cost of treatment with surgical revascularization was significantly higher than that of endovascular interventions, without tangible benefit to patient well-being, despite lower amputation-free survival. These data are thought provoking, and point to the potential impacts that treatment decisions can have on a system-of-care level. However, the study of CLTI must account for a series of other factors,⁶ many of which were missing from the current report. Thus, the study by Perlander and colleagues offers an opportunity to focus on the existing gaps in our understanding of cost-effectiveness in the care for CLTI patients.

First, the cost of care for CLTI patients goes well beyond the revascularization procedures, or even other hospital-associated costs. Many CLTI patients require prolonged rehabilitation (often inpatient) well after discharge or remain permanently disabled, either in the community or in long-term care facilities. Thus, understanding cost must account for utilization of resources including prosthetics, non-hospital-based facilities, visiting nurses, wound-care specialists, physical and occupational therapy, etc. Furthermore, the cost of engaging a team of specialists and optimizing medical and wound care must not be ignored. In addition, patients with CLTI often rely on their families and communities for assistance with everyday activities. By including these costs, there is an opportunity to emphasize the complete resources required for CLTI patients. Finally, many patients who struggle with recovery following revascularization for CLTI do not return to their gainful employment for weeks to months (sometimes never). This has a quantifiable cost to society that is difficult to monetize.

Technically, the current study reported on patients with femoral-popliteal lesions. Most patients with CLTI have infrapopliteal artery disease as 1 component of multilevel atherosclerosis.

Procedural data were not reported and there was no overlap between initial inclusion to the surgical and the endovascular group. Indications for reintervention were not clinical, but rather derived from an ultrasound metric termed “peak systolic velocity ratio.” These characteristics deviate from the modern care of patients with CLTI. First, many patients with CLTI require revascularization of below-the-knee lesions. Next, an endovascular-first approach has become ubiquitous in many centers globally, often despite a complex anatomical distribution of disease. Within the “endovascular” category, there is much variability in medical device choice. This variability considerably influences outcomes and cost. Finally, while reintervention for patients with CLTI may rely on imaging-only criteria at times, it is most commonly a decision that accounts for patient characteristics and symptoms as well as imaging criteria. This is specifically important in the context of the current study, as much of the cost was driven by reintervention.

For readers who live in regions other than Sweden, the data presented in the current paper may not be fully applicable. Sweden offers universal health care in parallel to private insurance. In contrast, the health care system in the United States is a combination of private insurance and government-subsidized programs. These differences surely lead to great variability in the availability of strategies to treat CLTI and to differences in the cost of implementing these tools.

We applaud the authors on shedding light on a topic that does not receive adequate attention. We agree that as CLTI is prevalent, and caring for these patients is resource intensive, data on the most effective acute and long-term strategies that integrate total costs of care are extremely valuable and lacking. While the current analysis leaves us with many unanswered questions, it is fortunate that there is an ongoing randomized controlled trial, BEST-CLI.⁷ This study, which is an international (United States and Canada), prospective, multicenter trial, will hopefully answer many salient questions pertaining to the care of CLTI patients, including the issue of cost. By utilizing randomized data and reporting detailed information concerning procedural and postprocedural resource utilization, we hope that BEST-CLI will offer guidance as to the cost-effectiveness of various treatment strategies in the care of these challenging and unfortunate patients.

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