### PANEL DISCUSSION

# CLTI Preamputation Care Pathways

Reflections on an analysis of CLTI care trends highlight areas where pre- and postamputation care need to evolve, efforts to make CLTI care more uniform and equitable, and more.

With Eric A. Secemsky, MD, MSc, RPVI, FACC, FAHA, FSCAI, FSVM; Lee Kirksey, MD, MBA; and Elina Quiroga, MD, MPH

### LOWER-INTENSITY CARE CORRELATES WITH ADVERSE OUTCOMES POSTAMPUTATION; DISPARITIES PERSIST

The presence of disparities related to gender, race/ethnicity, and socioeconomic factors and their relation to amputation risk are well-documented and discussed in the literature. However, little is known about how disparities in intensity of care received for chronic limb-threatening ischemia (CLTI) are impacted by individual and socioeconomic factors.

In a paper published in *Circulation: Cardiovascular Intervention*, Secemsky et al sought to uncover (1) the association of patient, hospital, and geographic characteristics with the intensity of vascular care a patient with CLTI received in the year before a major lower limb amputation, and (2) how that intensity of care relates to postamputation outcomes.<sup>1</sup>

Understanding these patterns is crucial for equitable delivery of care, as it allows for clinical, health system, and public health strategies to be devised to support uniform disease management and vascular health promotion. The study's authors further expand on their findings and explain how care pathways can be optimized for patients with CLTI.

In your analysis published in Circulation: Cardiovascular Intervention,¹ it was found that in the year prior to CLTI-related amputation, certain patient or hospital characteristics (eg, gender, income level, treatment at a safety-net hospital) were associated with low-intensity care for CLTI, and 63.3% of patients did not receive angiography or revascularization by any method. What are some ways in which CLTI preamputation pathways can evolve to provide better care for these patients before they undergo amputation—or, to prevent the amputation?

**Dr. Kirksey:** Increased use of the WIfl (Wound, Ischemia, foot Infection) score to characterize patients on the continuum of neuroischemia and infection will give us a better idea of the global presentation of

similar patient cohorts. For patients in whom elective amputation is proposed, one approach I find valuable is multidisciplinary review of the patient with the lens of soft tissue management and unidentified revascularization options from providers who may not be primarily involved and, to that extent, have a fresh set of eyes. Almost like a "tumor board" concept.

The persistent challenge is that there are "judgment" and "experiential" components to advanced creative revascularization and soft tissue reconstruction options. This approach may mitigate confirmation bias heuristics that influence our decision-making. Patients and families seem to like this concept. For practitioners working geographically remotely, technology can bridge the gap. Additionally, we should encourage the development of CLTI networks to escalate intensity of care in a timely fashion when clinically necessary. When

these prearranged relationships are in place, patients can be "handed off" more efficiently.

For example, we all manage different patient populations within our respective practices. In my Cleveland Clinic practice, we see a lot of postendovascular/primary revascularization failure patients with CLTI. Our clinical outcomes are much better when we can see these patients sooner and have time to evaluate all our options. To that end, it is our responsibility to do the work up front to let patient and provider communities know that we embrace that type of complex peripheral artery disease (PAD) care.

### And, how does provider knowledge/education come into play here?

**Dr. Quiroga:** The study's finding that nearly two-thirds of patients did not receive adequate care before amputation highlights the critical need for enhanced provider education in PAD. We need to reach out to those patients before they develop CLTI. We have made significant advancements in our knowledge of PAD management and treatment; however, a huge gap in care delivery persists, reflecting the uneven distribution of these improvements across different populations. This emphasizes the need for more outreach and thorough education of primary care doctors and health care workers about early PAD detection and timely specialist referral.

## Why is lower-intensity care associated with more severe adverse events postamputation, and what changes can be made to postamputation care/follow-up to improve outcomes for these patients?

**Dr. Secemsky:** Our findings likely suggest that preamputation intensity of care is a marker of the vascular care provided at the health care institution where the patient is being treated. As such, if this premise is correct, it seems likely that postamputation care may also be suboptimal. Thus, the target for intervention really becomes improving the resources and care coordination at these centers for patients who have undergone an amputation. This is not an easy intervention, as many of these centers may have a challenging payer mix and, as we found, are often safety-net hospitals. State- and federal government—level involvement may be needed to support these sites, thus complicating the pathway to improved vascular care.

**Dr. Kirksey:** These findings are a function of a "systems" failure to manage this complex patient population. We must get buy-in from each of the health care

### **KEY FINDINGS**

- Among Medicare beneficiaries who underwent major amputation due to CLTI, two-thirds of patients only received low-intensity vascular care, defined as no angiogram or revascularization attempt, before undergoing amputation.<sup>1</sup>
- Key socioeconomic and hospital characteristics associated with lower-intensity care include low income, male gender, and treatment at a safety-net hospital.<sup>1</sup>
- Low-intensity care leading up to an amputation was associated with more long-term adverse outcomes.<sup>1</sup>

providers that share in the care of our PAD patients to more consistently appreciate their overall cardiovascular risk profile (ie, a population health model). Our evidence-based best practices for PAD management must be integrated into the patient's overall chronic disease care by their primary care, cardiology, podiatry, and endocrinology teams. Just as importantly in this valuebased care population health model, is that health care systems and practices managing patients reliably with best practices and thus achieving better long-term outcomes are reimbursed at a higher rate for their creation of "value." Payers need to incentivize providers for the behavior that improves patient care. Finally, we have to acknowledge that amputations at all levels are fraught with high rates of postoperative complications in the face of diabetes, smoking, ischemia, infection, malnutrition, and end-stage renal disease. This is the reason that we should do all that we can to avoid this fate.

Low-income adults and safety-net hospitals were both linked in the study to low-intensity care and higher mortality rates postamputation. What kind of support is needed here, and what steps can physicians working at safety-net hospitals and in low-income areas take to combat these trends?

**Dr. Kirksey:** The overall issue is a complex societal challenge of disparate resources for some communities and the hospitals that serve those communities. I do have some thoughts on what we, as individual providers, can think about at our local level. I conduct a lot of work in the area of health care career pipeline development, both at the research level and in my network of influence. I share with young people and adults that I am relatively agnostic in terms of medical specialty or health care career choice. I say this because

no matter the area of health science (nurse, pharmacist, bioengineer, therapist, hospital administrator, vascular surgeon, cardiologist), if that person is part of a group that is underrepresented in medicine, they are more likely to care deeply about the critical issues that speak to health disparities—of which PAD is just one of many. We can insert any disease state into the sentence (cancer, heart disease, etc), and the causes are multifactorial and can be traced to social determinants of health. If you are a Black American, Hispanic American, Indigenous American, or rural/low-income White American provider, then you are more likely to conduct research to identify the root cause of disparities, return to a representative community to deliver clinical care, and bridge the key education, awareness, and trust gaps in that community to enhance both health and health care. You are also more likely to speak up and advocate for key governmental policy issues that impact health disparities. Therefore, with professional societies and within our respective institutions, we should support the individuals who conduct this critical work.

Dr. Secemsky: I think most of the united vascular community is committed to high-level care for our CLTI patients. More limb salvage programs have emerged over the years, and there has been improved coordination among involved specialties. However, the majority of hospitals across the United States lack dedicated vascular specialists, including vascular surgeons. These centers are likely more vulnerable to poor outcomes due the lack of specialized treatments and dedicated care pathways. Raising awareness has been key, and there are several parallel efforts from our societies that are trying to achieve better outreach and education. But, there also remains a need to train more vascular specialists and reinforce that training so vascular care is received throughout the entire country.

We now understand that there are patterns when it comes to not only the care a patient with CLTI receives but also how the level of care is tied to outcomes. How might knowledge of these patterns inform treatment, protocols, and the overall care pathway for CLTI patients? What are some clinical, health system, and policy efforts that may address this?

**Dr. Kirksey:** Perhaps the best description to date of the comprehensive opportunities is a paper from Creager et al entitled, "Reducing Nontraumatic Lower Extremity Amputation by 20% by 2030." The paper provides comprehensive guidance at the multiple levels. Health care systems and providers are no different

than other parts of our market-driven society, and we typically behave in a fashion that creates the greatest economic upside. One significant opportunity given escalating health care costs is to design and implement a chronic disease management pathway for PAD that is aligned with quality care rather than volume.

To that extent, the term intensity used in our manuscript should not be conflated with volume of care, in my opinion. I suggest thinking of intensity as highvalue, purposeful, timely care. Think of the patient with PAD who has effective smoking cessation, highintensity statin, and good offloading shoe wear for a known biomechanical foot deformity. If this patient were to require revascularization, then it would be evidence-based and influenced by their clinical limb threat presentation, anatomic disease pattern, and comorbidity risk profile. Furthermore, for the patient who just needs optimal medical management for intermittent claudication, there is some incentive for the team to be rewarded for successfully providing good medical care. Better medical management of the 80% of PAD patients that have no limb threat/ CLTI will have a dramatic downstream effect on rates of limb loss and cardiovascular disease outcomes. The Amputation Reduction and Compassion Act led by the late Representative Donald M. Payne Jr. is a tremendous step in the right direction to address some of these issues, and I applaud the efforts of multiple societies to engage with this bill to reach key common points of agreement, including definition of key quality metrics for care goals.

Although management options for CLTI have made significant advancements and are well established, the delivery of this care is still not uniform or equitable, despite community and societal efforts promoting amputation reduction. Is there a need to redirect current awareness campaigns, research, etc? What might that look like?

**Dr. Kirksey:** It is very important to take a comprehensive look at the population at greatest risk for undergoing amputation. Understanding the heterogeneous nature of the limb amputation patient is essential to inform and focus our collaborative efforts on the correct areas of opportunity.

First, depending on the local or regional population demographics, 50% (on average) of patients in whom a minor or major amputation was performed underwent that procedure because of a diabetic foot complication (most commonly infection) and absent of any PAD. To that extent, it is important that our overarching

efforts to reduce "all" amputations are comprehensive across multiple specialties, including first-line providers like primary care, podiatric medicine, endocrinology, advanced practice nursing, and emergency medicine. Health care provision continues to operate in a tribal sort of way, with proceduralists promoting procedures in direct alignment with the economic support of the medical device industry. We should continue to explore and develop opportunities to identify the patients who benefit from evidence-based revascularization; however. contemporary evidence is clear that the vast majority of patients need optimal medical management with appropriate preventive foot care. Importantly, these efforts must extend to federally qualified health centers in rural and underserved urban communities, as well as other underresourced communities where significant distance and financial barriers impact access to care. For many years, the American Podiatric Medical Association has been working to create uniform coverage of podiatric services among state Medicaid health insurance, which of course covers the most vulnerable of Americans across all communities.

Second, we must understand that the burden of cardiovascular and cerebrovascular complications is considerable in the CLTI cohort, as demonstrated by the BEST-CLI and BASIL-2 trials. Polyvascular disease has a considerable emotional and financial toll on both the patient and family. For that reason, we should consider the high-yield, dramatic opportunities for improving the high reliability initiation and maintenance of guideline-directed medical therapy (GDMT) for this group of patients. Specifically, statins continue to be underused, and smoking cessation efforts are sporadically applied and widely ineffective even in clinical trial patients for whom we would expect to see some degree of positive medical treatment bias.

At the heart of the PAD epidemic is a broad continuum that begins with the social determinants of health that impact disease burden and patient access to health care, which is best managed by timely diagnosis and continuous, uninterrupted management of chronic disease. We need much more financial support for research of implementation science for population interventions on PAD. We continue to be fixated on procedures in exclusion of prevention. Thus, it is critical that educational resources for awareness be directed at educating first-line providers who are tasked with caring for the PAD patient population. I commend efforts like the PAD National Action Plan from the American Heart Association; Closing the Gap from Boston Scientific Corporation; and Save Legs, Change Lives from Johnson & Johnson to name a few outstanding efforts to help educate on this vulnerable patient group. The available resources and care team in each community will look different; however, it is important that we accept the heterogeneity of these multidisciplinary PAD teams.

We should also maintain a sharp focus on describing the metrics that define high-quality PAD care: (1) high use of GDMT, (2) selective use of revascularization for intermittent claudication based on presentation and anatomic distribution of disease, (3) prevention of wound recurrence through established best practices for wound surveillance for patients in "remission" from neuroischemic wound etiology, and (4) creation of value-based reimbursement models that align with key metrics to encourage and financially incentivize high-quality PAD care. This will require specialty society/government payer dialogue.

# What other aspects of the care pathway for CLTI patients are deserving of further research? Are there any other patterns you've recognized when it comes to levels of care and who undergoes amputation?

Dr. Kirksey: As this paper proves, the intensity of vascular care preceding major amputation is a primary determinant of favorable outcomes. Presumably, the health care system that has an established PAD care team that provides rapid patient access to care, triages patients based upon acuity, applies evidence-based approaches for both medical and procedural management, and conducts lifelong PAD patient surveillance represents the ideal delivery model. One overarching challenge that continues to prevent this goal is the presence of health care deserts, specifically relating to the specialty providers essential to care teams involved in PAD patient management. The rural South, Midwest, Pacific Coast, and Southwest all struggle with this challenge. Workforce surveys are consistent in showing that provider density is greatest in high-population, metropolitan communities. New graduates of training programs generally desire to live in larger communities and practice in larger groups. It is essential that we carefully investigate how we can assist our colleagues and hospitals within these health care deserts to recruit and retain providers. Of course, the existential threat of the rural community hospital is closely tied to the overall challenge. Even within the health care-dense areas of our community, some of our most vulnerable communities rely upon under resourced, federally qualified health centers. Implementation research should focus on how we use technology to more equitably distribute resources, including electronic medical records and digital health platforms, to support these frontline providers. As a continuation of this point, how do we ensure that "high-intensity" PAD care is of value to the system? It has been described in the literature that the CLTI patient with advanced tissue loss can be a loss leader for the cardiovascular service line. However, if we are thoughtful and innovative in charting the path forward with our new PAD care paradigm, we will turn the loss leader into the financial "value" driver.

### How has this study impacted how you look at care trends for CLTI at your own institution and/or community?

**Dr. Quiroga:** The findings of this study are particularly impactful for my perspective as I practice at a safety-net hospital. In response to these results, we are now compelled to examine our care trends for CLTI at a more granular level and evaluate where the gap is. A critical question arises concerning the timing of patient presentation. Are patients arriving to a specialist at a point where amputation is the only life-saving treatment left? This leads to a broader inquiry about the effectiveness of our outreach and education efforts, particularly toward at-risk populations at risk and in training frontline providers about PAD.

Furthermore, the study prompts a reflection on potential biases in our own practice. Are there inherent biases influencing the intensity of care provided to different patient groups? How do we evaluate and mitigate those biases? It is my hope that this study not only illuminates these issues for me but also serves as a catalyst for self-reflection among all of us working in preventing amputations.

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<sup>1.</sup> Secensky EA, Kirksey L, Quiroga E, et al. Impact of intensity of vascular care preceding major amputation among patients with chronic limb-threatening ischemia. Circ Cardiovasc Interv. 2024;17:e012798. doi: 10.1161/CIRCINTERVENTIONS.122.012798

<sup>2.</sup> Creager MA, Matsushita K, Arya S, et al. Reducing nontraumatic lower-extremity amputations by 20% by 2030: time to get to our feet: a policy statement from the American Heart Association. Circulation. 2021;143:e875-e891. doi: 10.1161/CIR.00000000000000967.