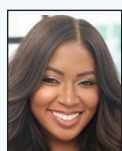


Addressing Amputation Disparities

Exploring disparities in United States amputation rates and ways to effect change.

With Olamide Alabi, MD, FACS; Foluso Fakorede, MD; Lee Kirksey, MD, MBA; and Katharine L. McGinigle, MD, MPH



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PATIENT, POPULATION, AND CLINICAL FACTORS

How would you summarize what is known about the current disparities in peripheral artery disease (PAD)-related amputations and barriers to equitable access, both nationally and in your community?

Dr. Kirksey: This is a very complex issue. We could dedicate a book to discussing the problem and not even touch on solutions. It involves the confluence of social determinants of health (SDH), access to quality health care, and an implicit bias that is known to exist within the health care delivery system. Poor Black, Latinx, and Native American populations, as well as poor White populations, have higher rates of major limb amputation. Attempting to discuss these groups as a monolith is fraught with inaccuracy because while they all share socioeconomic disadvantages, they also have distinct differences. Simply categorizing the problem by demographics is not enough. For example, when the groups are adjusted for social and economic fac-

tors and PAD severity at presentation, Black patients are more likely to undergo major limb amputation and not be offered attempts at functional limb preservation. This suggests that our health care delivery to Black, Indigenous, and Latinx Americans may suffer the same bias that we see in everyday social interaction.

Dr. Fakorede: Nationally, lack of awareness of the clinical, economic, and human impact of this epidemic at the patient, provider, payor, hospital, and community levels has significantly contributed to this attitude of indifference toward limb loss, particularly in racial/ethnic minorities. We have normalized the inhumane act of removing a limb despite its disabling and deadly impact, which parallels most well-known cancers.^{1,2} Yet many PAD-related amputations are preventable if these at-risk individuals are aggressively screened for risk factors and optimally treated with guideline-recommended therapies and/or limb-preserving interventions. However, our health care system continues

to pay a significant downstream cost for such a preventable epidemic by failing to prudently act upstream. The amputation lottery, which includes race, income, insurance status, geographic location, intensity of hospital vascular care, and modifiable risk factors, determines a patient's outcome.³

For patients with PAD, these factors determine whether the outcome is a limb amputation or ultimately an adverse cardiovascular event such as heart attack, stroke, or death. The practice of unnecessary amputations disproportionately affects patients located in medically underserved rural communities like the Mississippi Delta.⁴⁻⁶ Mississippi is the poorest state, has the lowest number of physicians per capita, and has a 38% Black population.⁷ A recent *Journal of the American College of Cardiology* article on rural versus urban outcomes showed significant racial health disparities in PAD-related risk factors; diabetes mellitus- and hypertension-related mortality rates were two to three times higher among Black adults compared with White adults in rural regions of America.⁸ The stark racial disparities exhibited in treatment and outcomes stem from structural inequities. In my community, these are rooted in generational barriers to comprehensive quality care, underinvestment in SDH, and a severe trust deficit due to discriminatory practices. Furthermore, access to quality primary, preventive, and specialist care for these at-risk patients is further hindered by a fragmented vascular community guided by flawed policies that are influenced by underrepresentation in clinical trials and the United States Preventative Services Task Force (USPSTF) statements on PAD screening that lead to underdiagnosis.

Dr. Alabi: Although emerging literature continues to primarily identify these disparities, there has been very little work published toward disparity elimination.

One barrier I often see relates to perception. Perceptions, how we as interventionalists and advanced practice providers view the patients we are presented, can often inform how aggressively we provide care to patients. For example, before moving to the South, I heard many tales about how patients “show up too late” and even heard some relay, “Why should I expend so much effort for someone who doesn’t care enough about their own health (or limbs)?” This is heard and wholeheartedly believed in the conversations we have amongst ourselves and the literature we publish (“delayed presentation” as a covariate of interest). I have found that this is not the entire story. For example, many of our patients with chronic limb-threatening ischemia (CLTI) are under the care of a physician or even cared for by a home health nurse or wound center before they get referred to us. These folks may not recognize the arterial component that is contributing to nonhealing wounds or future limb loss. The delay in referral in these situations is not of the

patient's doing and is just one example of an atypical access concern that is very real and quite pervasive. Another example of barriers is how we define success. Question: What do you do with a nonfunctional/will-never-be-functional limb with severe PAD? Interestingly, this is a controversial topic among specialties; however, what we have categorically failed to ask is, “What does the patient want?” We need to listen to the stories of our patients, understand what quality of life means to them⁹ and their families, and develop true shared decision-making models that are patient-centric.

How effectively do current guidelines address screening and handling of patients potentially at risk for amputation?

Dr. McGinigle: As we have seen with the herculean public health efforts related to COVID-19 prevention and vaccination, the messaging and guidelines often fail to reach the populations most in need. The current guidelines for PAD screening are reasonable, but they need to be more broadly applied in all populations, specifically in vulnerable populations. Guidelines related to the care of patients with CLTI highlight the need for comprehensive multidisciplinary vascular care but would benefit from more prescriptive language. The implementation of these guidelines is variable, and there is evidence of overutilization of highly reimbursed interventions without the other necessary social and medical interventions. I support the creation of limb salvage as a recognized subspecialty and the creation of limb salvage centers of excellence to elevate and standardize best evidence-based practices with a focus on long-term, value-based care.

Dr. Kirksey: Improving access to high-quality health maintenance is paramount to preventing progression to PAD and diabetes. It would be most ideal to have broad awareness among frontline providers of the prevalence of and risk factors for PAD and limb loss. The USPSTF position on the use of the ankle-brachial index has been a limiting factor in the broadscale application of this simple yet powerful test to identify PAD. We need to continue having constructive, informative dialogue with the agency and develop a repository of evidence that supports the effectiveness of early identification of PAD in the prevention of heart attack, stroke, and limb loss. I'm currently working with a team that includes Aruna Pradhan, MD, MSc, and Ayanna Buckner, MD, on the ARISE-MP trial, a prospective study on precisely this area for high-risk patients.

Dr. Alabi: This is a very fine line. We do not have firm evidence that early screening improves limb outcomes. We do have anecdotal evidence that early screening may potentiate increases in unnecessary peripheral interventions.

In general, we want to do the right thing for patients. We just don't know what the right thing is just yet, but we are avidly working on it! We can do screening; it's the handling that I worry most about.

Dr. Fakorede: We have failed to appropriately screen the populations at highest risk for PAD/CLTI and subsequently amputation. These include minorities with the highest prevalence of cardiovascular disease (CVD) or risk factors (namely, diabetes, hypertension, coronary artery disease [CAD], stroke, chronic kidney disease [CKD], and obesity). As African Americans tend to present with greater comorbidities, such as chronic renal disease, obesity, and diabetes, they typically face an increased risk of amputation, repeat intervention, and mortality.¹⁰⁻¹² The populations most at risk (including the aging population) correlate with those with the highest atherosclerotic burden. The root of unnecessary amputation lies in the failure to perform early screening or medical treatments of at-risk patients, the lack of procedural interventions using a multidisciplinary approach due to lack of awareness of options for patients, and the lack of broad implementation of policies to incentivize screening at-risk patients, which would mitigate amputation-first strategies.

The USPSTF should switch from screening the general population for PAD to screening those who are considered at risk based on American College of Cardiology (ACC)/American Heart Association (AHA) guidelines. The USPSTF has acknowledged that “the prevalence of PAD is disproportionately higher among racial/ethnic minorities and low-socioeconomic populations” and recognized “these well-established disparities in care.” However, the USPSTF notes the evidence for screening and treatment in these populations is currently lacking and that “Future research should include diverse populations and report on their outcomes.”¹³ The reality is that to date, the representation of African Americans in PAD device and cardiometabolic clinical trials is usually < 5%, and it is < 1% for Latinx patients.^{14,15} Generation-spanning underrepresentation contributes to these policies, and “indeterminate” statements regarding PAD screening perpetuate disparities in treatment and outcomes. Policies to screen for those who are at highest risk of adverse cardiovascular outcomes must be aggressive and target the appropriate population to effect change.

A recent article published in *Surgery*,¹⁶ coauthored by Dr. McGinigle and Samantha D. Minc, MD, MPH, described PAD-related amputation as a marker for health disparities and mentioned the necessity to act more aggressively earlier in the disease process. How can this concept be embraced successfully in a way that also prevents overapplication?

Dr. Alabi: The need to act more aggressively, to me, suggests a strong multidisciplinary approach to medical therapy and risk factor modification (RFM) in vulnerable patients. It does not necessarily mean more procedures. That “over-application” can lead to worse outcomes. We know that revascularization in mild manifestations of arterial occlusive disease can lead to CLTI, presumably in patients whose natural history would not have been to progress to this in the absence of “early revascularization.” We need to find that balance. I believe that balance can be better determined through healthy multidisciplinary collaboration.

Dr. Kirksey: We cannot operate or proceduralize our way out of this amputation epidemic, especially because at least half of patients that lose their limb do so in the absence of PAD. Their limb loss is due to a diabetic foot complication, usually infection related. Although yes, we need to act aggressively, in my reading there is limited to no evidence suggesting that patients with mild, moderate PAD and intermittent claudication have a lower lifetime risk of amputation after undergoing preemptive angiography and intervention. But, I fully endorse identifying these patients early in the process with the goal of implementing lifestyle change and RFM with guideline-directed medical therapy, potentially adding in a chronic disease health education worker similar to what is done for heart failure patients.

Dr. McGinigle: Amputation is a preventable complication of PAD and diabetes, and I do not believe that there should be any fear of overapplication of health care because we are currently so poor at amputation prevention. Although surgeons and other vascular specialists tend to treat patients once they have already developed limb-threatening complications of diabetes and CVD, there is no reason why we cannot help identify and treat these patients earlier in the process. With earlier disease identification and better access to medical care, there are multiple lifestyle and medication optimizations that can be made such that revascularization is never needed and amputation never becomes a real threat.

Dr. Fakorede: The Amputation Reduction and Compassion (ARC) Act addresses this in a thoughtful and comprehensive manner. Educating all stakeholders and their support teams about PAD and how it progresses to CLTI is a vital first step. The primary care community must understand the pathogenesis of PAD and why coverage for screening is a win for their patients.

We must also ensure this concept is included in our curricula for the next generation of multidisciplinary PAD/CLTI teams. We then have to screen for it just as we do for cancers based on clinical history, symptom review, and

physical examination (socks off). The ACC/AHA guidelines provide payors and clinicians with a framework of which populations are considered at risk and must be screened.¹⁷ A majority of these patients also have atypical or not commonly recognized symptoms. Screening for diabetes with the new USPSTF guidelines¹⁸ would hopefully lead to additional awareness and screening for those at risk for major complications of the diabetes-obesity (diabesity) epidemic: CKD, high blood pressure, stroke, CAD, and PAD. These risk factors, as well as age and race, unfortunately contribute to high amputation rates if left unchecked. Reimbursement guidelines would determine if we would see an under- or overallocation, but the ARC Act will fund for screening without cost-sharing requirements.

NEXT STEPS

What new research would be most helpful in further understanding and addressing amputation disparities?

Dr. McGinigle: We have known about amputation disparities for decades, and they persist without improvement. To me, the most helpful research is not strictly medical research but rather in the social sciences about how to better deliver care before it is too late. Unfortunately, even with the National Institutes of Health's commitment to diversity, equity, and inclusion, there has been little change in the diversity of clinical trial participants. Existing clinical trials provide rich information on medications, devices, and interventional/surgical outcomes but fail to include sufficient numbers of women and non-White patients, so the results are difficult to generalize to the populations who need the most attention in our efforts to improve equity in limb salvage rates.

Dr. Fakorede: A unified PAD awareness campaign is atop any wish list. We need standardized data representing a local snapshot of racial- and ethnic-based disparities in the PAD-related amputation rates (both inpatient and outpatient). We need a registry that only includes women, racial minorities, and indigent care patients and is supported by major stakeholders using all existing devices; cardiometabolic trials have had significant underrepresentation of these groups to date. The relationship between patient demographics, risk factors, lifestyle, medications, and patient education in terms of disparities in PAD/CLTI treatment and outcomes has to be further elucidated on a local/community level using real-world data.

Dr. Kirksey, can you tell us about the SCOPE CLI registry that you're involved in as a site Principal Investigator for Cleveland Clinic?

Dr. Kirksey: Patient-reported outcomes are critical to understanding a patient's perception of their disease process and the factors that improve their adherence to recommended therapies. Kim Smolderen, PhD, and Carlos Mena-Hurtado, MD, at Yale have designed a fantastic study to analyze exactly those variables. This comes on the heels of the PORTRAIT registry. Understanding the patient side in granular detail is a long-neglected important component of patient-centered decision-making. For example, a 60-year-old man presenting with complex anatomy, multiple failed endovascular or open procedures, and a hypercoagulable state may actually have a procedure fatigue and a different perception of his "limb-preservation journey" vis-à-vis the provider.

Dr. Alabi, along with your role as a site Principal Investigator for the SCOPE CLI registry, you recently received funding to study disparities in access and treatment for PAD among veterans. What can you tell us about the goals and design of your study?

Dr. Alabi: I want to better understand variations in care among all patients with PAD. I recently received intramural and extramural funding to examine this in both a veteran as well as a nonveteran population, and we are avidly working on these projects. Regarding the veteran-specific award, this represents a next step to some of the work completed by my mentors and colleagues. Dr. Phil Goodney has done extensive work studying variations in care among the Medicare population, and based on this work, we know that certain populations and regions of the country have a higher chance of being offered primary amputation without assessment for or completion of revascularization.¹⁹⁻²¹ Due to the body of work that is emerging from Dr. Shipra Arya, we also know that "Black race" is an independent predictor for major amputation among veterans.²² Furthermore, she has reported that Black veterans with relatively mild arterial disease manifestations (such as claudication) and standard comorbidities are at nearly the same risk of major amputation as White veterans with end-stage PAD who live in more affluent neighborhoods. That should shock us all. So even in the Veterans Health Administration (VHA), which is the largest integrated health care system in America, we see this profound level of disparate outcomes. There is a lot of potential strength to what the VHA can do for the health and wellness of veterans given the way they, as a system, provide care. I seek to eventually determine if we are leveraging that strength well among all populations and what opportunities exist for targeted improvement.

Dr. Fakorede, one of the crucial needs you identified in the *ProPublica* article "The Black

American Amputation Epidemic” is the need for more specialists in rural areas. What are some possible solutions to ensure coverage in these underserved areas?

Dr. Fakorede: This is a major problem facing trends in the cardiovascular workforce and particularly rural markets: significant shortages in both primary care and multidisciplinary specialist teams that are needed to address this PAD epidemic. We must incentivize the recruitment and retention of specialists to rural areas with evidence of quality improvement interventions and programs (traditional inpatient and hybrid outpatient delivery models) using evidence-based medicine to effect outcomes, increase access to quality care, and defray cost to rural beneficiaries who constantly face economic inequities. We need federal, state, local, and industry policies to incentivize the recruitment of physicians and nonphysicians (diabetic educators, nurses, wound care, pharmacists, community navigators) to adequately capture and address the gaps in care and address the elusive SDH. To build a multidisciplinary team with support for a CLTI limb salvage program, these stakeholders have to incentivize providers (via loan forgiveness programs) to be recruited and retained in these rural and underserved health areas. Educate patients and providers on the basics of PAD, available treatment options in the continuum of care, and how/when to seek a second opinion. Explain the progression from PAD to CLTI if preventive steps are not initiated. Establish partnerships with industry to target vulnerable patients with CLTI by meeting them where they are and by community-driven initiatives that use proxies such as nurses and community navigators. I believe that with thoughtful collaboration, this can be accomplished in a cost-effective manner, and we can thwart the enormous financial and emotional costs to our health care system.

Increased awareness and trust between the community and the health care system are seen as critical steps to proper PAD care. What kinds of outreach campaigns might work best?

Dr. Kirksey: Before one can make inroads to the communities most impacted by this epidemic of health and health care inequity, trust must be established. In many communities, centuries of perceived and real discordant treatment have left individuals feeling hopeless. Building trust requires hard work and does not occur overnight. Soliciting the assistance of community leaders, including faith-based and existing community-facing organizations, is a great place to start. Meeting the people “where they live” and are most comfortable is my approach. There is sound evidence that using trusted physicians who are members of the community to lead such efforts is an effective strategy, especially

if there is racial concordance. This works in the Native American, Black, Latinx, and differing rural communities and facilitates effective communication.

Dr. Fakorede: Recognizing the strengths of the community you serve is the first step. The faith-based community is the pillar of strength in every Black community. It is a unique venue to effectively communicate with all the community stakeholders in hopes of reducing disease burden, building trust in the medical community, improving access to quality care, and dealing with some of the challenges (lack of transportation, food deserts, etc) for improving regional care. This is a direct-to-consumer approach: Participate in community educational outreach to raise awareness and cultivate literacy on the risk factors that contribute to PAD disparities.

Dr. Alabi: The community-based participatory research model represents a large gap in care that needs to be filled in our field. The thought that health care can best be optimized in the clinic or even in a clinic setting is archaic and does not reach people where they are. The idea that we should not use marketing tools such as social media to educate communities is antiquated. Our messaging matters, and our community engagement is vital.

There are groups pilot testing the development of PAD screening sites in community locations such as barbershops and hair salons (similar to what was done for hypertension management). Locations such as these can stand as safe pillars in the community that are frequented by members of various vulnerable populations with individuals present in whom they have trust, whether that is the hair care specialist or adjacent clients.

How would you summarize what needs to happen to effect lasting change in amputation prevention and with bridging disparities in particular?

Dr. Alabi: Move the discussion from disparity identification to health and PAD equity. Drs. McGinle and Minc summarized the topic well in their recent publication, but I believe we need more community engagement to create sustainable change. Listening to the stories of members of vulnerable communities who are afflicted by PAD, identifying community leaders and stakeholders and engaging them in collaborative ways, designing community-level interventions that can be measured and improved upon, and lobbying for change at the policy-maker level all benefit those with various manifestations of PAD. I think the Society for Vascular Surgery’s Population Health Task Force is one entity that will help move us in the right direction. This task force seeks to bridge gaps and interface with multidisciplinary

plinary collaborative efforts, provide education for referring centers and patients alike, leverage the power of informatics, engage and learn from community stakeholders, effect impactful changes from policy to practice, and more.

Dr. Kirksey: As a society, we have to acknowledge that inequity exists and look for systematic opportunities to address the inequity. "Systematic" suggests that it is not just at the individual level but also at the structural level. At the health care system level, we need to work on improving the pipeline of racial diversity among providers for the respective communities that they serve. Racial concordance facilitates communication and effective delivery of clinical care. Even in discordant circumstances, efforts to reduce implicit bias have been shown to be effective. For clinical care, we should begin to leverage the power of artificial intelligence and the electronic medical record to identify high-risk patients and implement early RFM and guideline-directed medical therapy in the reduction of progression of PAD and diabetes. At the policy level, there must be economic consequences for excessively high hospital amputation rates along with disease severity-adjusted and socioeconomic status-adjusted parameters.

Dr. McGinagle: Suggestions that Dr. Minc and I provided in our *Surgery* commentary include: (1) determine the patterns of disease and disparity in your community, (2) get involved in PAD screening and diabetic foot care, (3) build a culturally diverse limb salvage team, (4) start an outreach clinic to position care closer to those in need, (5) actively work to improve rates of women and under-represented groups in your research and clinical trials, and (6) advocate for the needs of your patients at the hospital, local, state, and federal policy levels—with the understanding that underserved communities need greater resource allocation to achieve equity.

Dr. Fakorede: First, we can galvanize all stakeholders and societies to raise national awareness. Prime time slots at all society meetings should focus on this topic. No single specialty provides comprehensive PAD/CLTI care, nor can any single specialty effectively eliminate these disparities. Covering PAD screening is vital to reducing the global costs of PAD care and addressing this trend of performing amputations on patients prior to offering limb- and life-preserving strategies such as optimal medical therapy, supervised exercise therapy, and an angiogram. We need to build support for the ARC Act to help prevent vulnerable individuals from developing serious complications from PAD. Policies are also needed that encourage adoption of quality improvement/assurance measures for PAD care in both inpatient and outpatient settings.

We must improve access to quality care in geographic regions lacking specialties or resource-poor areas by incentivizing providers who go unrecruited to work in rural and underserved areas; focus on recruitment and retention of minorities into leadership positions and principal investigators of clinical trials and on community outreach-led efforts to gather data and regain trust; address SDH via sustainable algorithm- and community-based strategies that demonstrate effectiveness and engender trust with shared decision-making; develop partnerships and educational workshops with local community or faith-based leaders in your community to raise PAD/CLTI awareness, especially among leaders of vulnerable populations.

Individually, we can help to raise awareness in our own respective societies and daily practices about disparities in care, and better understand local amputation rates, economic impact, and how it varies by race and sex. We can volunteer our time for health care screenings and community PAD education, specifically for vulnerable populations, and participate in advocacy highlighting a personal commitment to making a difference in eliminating these disparities, one interaction at a time. ■

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