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Mind the Gap:
The Case for Screening High-Risk Communities for PAD

Executive Summary

Peripheral artery disease (PAD) is defined as a common circulatory problem in which narrowed arteries reduce blood flow to your limbs. While common, it is a preventable chronic illness characterized by dangerously restricted blood flow to a patient's limbs.

Caused by a build-up of fatty deposits called plaque in a person's arteries over time, PAD causes debilitating leg pain and often leads to multiple complications including gangrene, diabetic foot ulcers, and amputation if left untreated. Estimates suggest that 85% of the amputations that are performed on diabetic Americans each year are a direct result of foot ulcers, a complication associated with PAD. In addition, PAD is associated with an increased risk of cardiovascular and cerebrovascular events, including stroke, myocardial infarction, and death. As a progressive, often asymptomatic disease that is often diagnosed late in the disease progression, PAD is as serious of a disease as cancer.

Across the country, approximately 20 million Americans have been diagnosed with PAD, including 1 in 20 Americans over the age of 50. When common risk factors such as diabetes and smoking are included in the analysis of prevalence, as many as one-third of patients are estimated to suffer from the disease. Similarly, more than 30 million Americans with diabetes and an additional 84.1 million Americans with prediabetes are at an elevated risk of developing PAD in their lifetimes.

A growing body of research shows that African Americans, Hispanics, and Native Americans have a substantially greater risk of developing PAD and requiring amputations than their white counterparts.

Despite the clear risks, the U.S. Preventative Services Task Force (USPSTF) released updated guidelines concluding "that the current evidence is insufficient to assess the balance of benefits and harms of screening for peripheral artery disease and cardiovascular disease risk with the ankle-brachial index (ABI) in asymptomatic adults."

In making recommendations for the general public – as opposed to individuals most at risk for developing PAD – the USPSTF's guidelines put the most at-risk communities at even greater risk. Recognizing the USPSTF's recommendation is flawed, many cardiovascular physicians believe that the USPSTF guidelines are doing a great disservice to those at-risk populations. Indeed, the USPSTF noted in its response to public comments to the "I statement" (i.e. recommendation of insufficient evidence of benefit of PAD screening for the general population) that commenters (1) "cited evidence that the prevalence of PAD is disproportionately higher among racial/ethnic minorities and low-socioeconomic populations," and (2) "noted that the I statement could discourage testing and perpetuate disparities in treatment and outcomes." In response to these comments, the USPSTF itself stated it "*recognizes these well-established disparities in care*," yet remarkably the USPSTF still has not reviewed the evidence for PAD screening for at-risk populations.

The USPSTF should immediately review the data as it relates to the appropriateness of screening at-risk populations including those with a history of smoking, diabetes, and other cardiovascular diseases.



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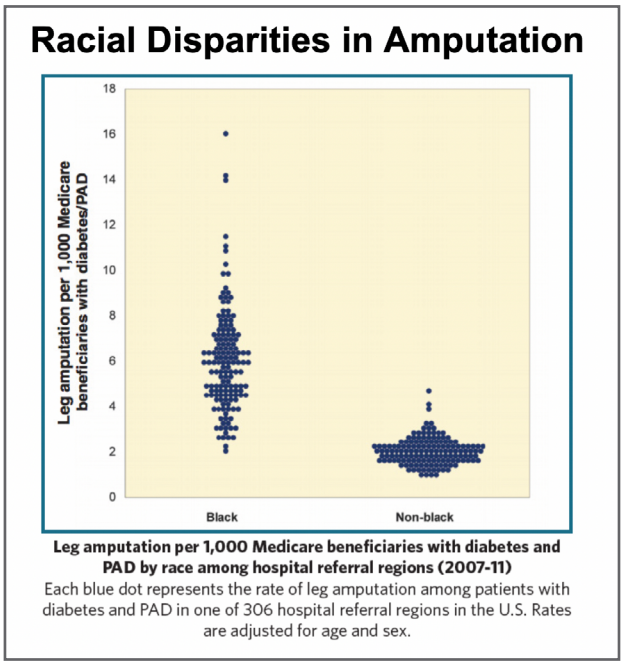
Minorities are most at-risk of PAD

Peripheral artery disease (PAD) is defined as a common circulatory problem in which narrowed arteries reduce blood flow to your limbs. While common, it is a preventable chronic illness characterized by dangerously restricted blood flow to a patient's limbs.

While PAD can affect Americans of any race, minorities and communities of color are most vulnerable to the disease. Estimates suggest that approximately 20 million Americans have been diagnosed with PAD, including 1 in 20 Americans over the age of 50. The prevalence increases for sub-populations that exhibit risk factors such as diabetes and smoking, which data show as factors in as many as one-third of patients living with PAD. Similarly, more than 30 million Americans with diabetes and an additional 84.1 million Americans with prediabetes are at an elevated risk of developing PAD in their lifetimes.

Moreover, while older Americans tend to be more susceptible to PAD than younger Americans, elderly patients of color suffer from a disproportionately high rate of PAD. According to one study, the highest prevalence of PAD occurs in Americans who identify as non-Hispanic Black women 70 years or older (25.3%), non-Hispanic Black women with chronic kidney disease (21.7%) and Mexican American men 70 years or older (20.85%). Consistent with previous research, the authors also found that non-Hispanic Blacks were especially sensitive to the aggregate effect of multiple risk factors when it comes to the prevalence of PAD.

The effects of PAD on minorities suggest similar disparities exist in patient outcomes. Of the 200,000 non-traumatic limb amputations that take place in the United States each year, 85% of which are caused by preventable complications related to foot ulcers, minorities are more likely to lose their legs than white Americans. Sadly, African American patients with diabetes are more than three times more likely to have their limbs surgically removed than their white counterparts. Similarly, Native Americans in the western U.S. are twice as likely to suffer from PAD than white Americans, while Hispanics are 75% more likely to develop the disease.



Leg amputation per 1,000 Medicare beneficiaries with diabetes and PAD by race among hospital referral regions (2007-11)
Each blue dot represents the rate of leg amputation among patients with diabetes and PAD in one of 306 hospital referral regions in the U.S. Rates are adjusted for age and sex.

Because PAD is diagnosed and treated in less than 13 percent of all affected patients, and a majority of the estimated 200,000 annual non-traumatic amputations can be avoided with the proper care, the importance of screening cannot be understated.

Early detection has played a key role to ending disparities in the prevalence and impact of cardiovascular disease. Research shows that the death rate for African Americans declined by 25% from 1999 to 2016, while the racial gap for deaths due to heart disease in people aged 65 or older completely closed. Driven by strong educational outreach, screening, and early detection, these approaches represent real progress.

Yet despite the clear benefits of early detection for PAD, some authoritative sources inexplicably fail to recommend screening among at-risk populations. This does a major disservice to minority and at-risk communities that are shown to benefit from screening.

USPSTF: A Missed Opportunity

In July 2018, the U.S. Preventative Services Task Force (USPSTF) released updated guidelines for screening for peripheral artery disease and cardiovascular disease. In regard to peripheral artery disease and cardiovascular disease, the USPSTF recommended against screening using the ankle-brachial index (ABI) methodology because it found "insufficient evidence to assess the balance of benefits and harms."

Unfortunately, this recommendation is flawed because the USPSTF focused its guidelines on PAD screening for the general population (i.e. Americans of all ages, ethnic and racial backgrounds, socioeconomic status, and health histories). This conclusion makes it significantly less likely that minorities and individuals in high-risk communities will be screened for PAD until it is too late to save their limbs.

What is an ABI test?

An ankle-brachial index (ABI) test is a simple way to check how well a person's blood is flowing. When a patient has PAD, blockages exist limiting oxygen to the limbs. The ABI test compares the blood pressure at the ankle with the blood pressure at the arm. If the blood flow at the ankle is low, the patient may have PAD.

This is because PAD often does not present symptoms in African American patients until it has progressed to more serious stages of the disease. Moreover, while the USPSTF said future research is needed, there is already significant research showing that PAD screenings can help minorities prevent, manage, and avoid the worst outcomes associated with PAD.

The USPSTF should review the data already collected by the American College of Cardiology and American Heart Association in the development of their joint practice guidelines, which recommend ABI screening among high-risk patients.

ACC/AHA Recommendations for Resting ABI for Diagnosing PAD

COR	LOE	Recommendations
I	B-NR	In patients with history or physical examination findings suggestive of PAD (Table 4), the resting ABI, with or without segmental pressures and waveforms, is recommended to establish the diagnosis.[60–65]
I	C-LD	Resting ABI results should be reported as abnormal (ABI ≤0.90), borderline (ABI 0.91–0.99), normal (1.00–1.40), or noncompressible (ABI >1.40).[46,63–66]
IIa	B-NR	In patients at increased risk of PAD (Table 3) but without history or physical examination findings suggestive of PAD (Table 4), measurement of the resting ABI is reasonable.[41,42,67–89]
III: No Benefit	B-NR	In patients not at increased risk of PAD (Table 3) and without history or physical examination findings suggestive of PAD (Table 4), the ABI is not recommended.[87,90]

Patients at Increased Risk of PAD

- Age ≥65 y
- Age 50–64 y, with risk factors for atherosclerosis (diabetes mellitus, history of smoking, hyperlipidemia, hypertension) or family history of PAD
- Age <50 y, with diabetes mellitus and 1 additional risk factor for atherosclerosis
- Atherosclerotic disease in another vascular bed (coronary, carotid, subclavian, renal, mesenteric artery stenosis, or AAA)

Screening: A Success Story in the Epicenter of the PAD Epidemic

When Dr. Foluso Fakorede, an interventional cardiologist, moved to the Mississippi Delta, he was shocked by the extent of the PAD epidemic across the state, especially amongst the Black and African American community. Mississippi is home to the highest percentage of African Americans of any state in the U.S.

In the year prior to his arrival, his local hospital performed 56 major amputations and zero diagnostic tests for PAD. Moreover, more than nine in 10 amputees he met had never had a diagnostic test for PAD or an appropriate vascular evaluation to salvage their limbs. Knowing that non-traumatic amputations can be avoided with the proper care, Dr. Fakorede set out to turn the tide by organizing a proactive campaign to screen individuals in high-risk communities for PAD.

Dr. Fakorede addresses a community center in MS on the importance of cardiovascular health.

Setting to work, Dr. Fakorede quickly created a care team to educate, screen, diagnose and treat the community's most at-risk patients. Since many at-risk people are asymptomatic until it's too late to save their limbs, Dr. Fakorede's team decided to meet people where they were in the community, including schools, churches and health fairs.

In addition to arming individuals with information about cardiovascular health, Dr. Fakorede's team distributed a health questionnaire, which was used to identify individuals most at risk for PAD. Only when an individual exhibited risk factors – including diabetes, nicotine use, heart disease, kidney disease and hypertension, among others – was that person screened. Seeing the benefits early screening brought to the community, many church leaders invited Dr. Fakorede to speak to their congregations and encourage them to ask their physicians about getting screened for PAD and cardiovascular disease. Interventional care was only provided when clinically appropriate, which resulted in far fewer amputations across the area.

In just one year, the results were remarkable. Through the efforts of Dr. Fakorede's team, the local hospital performed nearly 500 diagnostic tests and just seven amputations, equaling a dramatic 87.5 percent decrease. While the USPSTF may have found no evidence to support the benefits of PAD screening, Dr. Fakorede's experience shows how early detection can save the limbs—and lives—of people in high-risk communities.

Dr. Fakorede's experience suggests that high-risk communities benefit greatly from increased access to screening and early detection for PAD.

Conclusion

Healthcare professionals and policymakers should heed the guidance of the American College of Cardiology and American Heart Association, which recommends ABI screening among high-risk patients. Early screening has been shown to reduce the probability of an amputation due to PAD by 90 percent but is greatly underutilized as only 12.5 percent of patients with PAD are identified by physicians and treated. Overall, a majority of the estimated 200,000 annual non-traumatic amputations that occur in the United States every year can be avoided with the proper care.

The USPSTF should revisit their recommendation on PAD screening and review the data as it relates to PAD screening for at-risk populations. Moving forward, PAD screening should be encouraged in order to improve patient outcomes, reduce long-term healthcare costs, and eliminate racial disparities in the cardiovascular space.