

ORIGINAL RESEARCH

Non-Hispanic Black and Hispanic Patients Have Worse Outcomes Than White Patients Within Similar Stages of Peripheral Artery Disease

Corey A. Kalbaugh, PhD, MS; Brian Witrick, MPH; Laksika Banu Sivaraj ^{id}, BSc; Katharine L. McGinagle, MD, MPH; Catherine R. Lesko ^{id}, PhD; Samuel Cykert ^{id}, MD; William P. Robinson ^{id}, MD

BACKGROUND: Racial and ethnic disparities in outcomes following lower limb revascularization for peripheral artery disease have been ascribed to disease severity at presentation for surgery.

METHODS AND RESULTS: We calculated 1-year risk of major adverse limb events (MALEs), major amputation, and death for patients undergoing elective revascularization for claudication or chronic limb-threatening ischemia in the Vascular Quality Initiative data (2011–2018). We report hazard ratios according to race and ethnicity using Cox (death) or Fine and Gray subdistribution hazards models (MALE and major amputation, treating death as a competing event), adjusted for patient, treatment, and anatomic factors associated with disease severity. Among 88 599 patients (age, 69 years; 37% women), 1-year risk of MALE (major amputation and death) was 12.8% (95% CI, 12.5–13.0) in 67 651 White patients, 16.5% (95% CI, 5.8–7.8) in 15 442 Black patients, and 17.2% (95% CI, 5.6–6.9) in 5506 Hispanic patients. Compared with White patients, we observed an increased hazard of poor limb outcomes among Black (MALE: 1.17; 95% CI, 1.12–1.22; amputation: 1.52; 95% CI, 1.39–1.65) and Hispanic (MALE: 1.22; 95% CI, 1.14–1.31; amputation: 1.45; 95% CI, 1.28–1.64) patients. However, Black and Hispanic patients had a hazard of death of 0.85 (95% CI, 0.79–0.91) and 0.71 (95% CI, 0.63–0.79) times the hazard among White patients, respectively. Worse limb outcomes were observed among Black and Hispanic patients across subcohorts of claudication and chronic limb-threatening ischemia.

CONCLUSIONS: Black and Hispanic patients undergoing infrainguinal revascularization for chronic limb-threatening ischemia and claudication had worse limb outcomes compared with White patients, even with similar disease severity at presentation. Additional investigation aimed at eliminating disparate limb outcomes is needed.

Key Words: amputation ■ Black patients ■ ethnic groups ■ female sex ■ humans ■ intermittent claudication ■ peripheral artery disease

Peripheral artery disease (PAD) is a common circulatory disease associated with atherosclerosis that affects ≈7% of people aged ≥40 years in the United States.¹ PAD reduces blood flow to the limbs and can lead to pain, numbness, wounds that do not heal, and tissue death. People with PAD experience significant consequences, including functional limitations,^{2,3} reduced quality of life,^{4,5} a higher rate of

adverse limb events (eg, amputation),⁶ and mortality.⁷ PAD disproportionately affects patients from racial and ethnic minority groups compared with White individuals in the United States.^{1,8–10} Patients from racial and ethnic minority groups experience higher incidence of PAD, and among patients from racial and ethnic minority groups with PAD, outcomes are worse: these patients experience 2 to 5 times higher amputation

Correspondence to: Corey A. Kalbaugh, PhD, MS, 525 Edwards Hall, Clemson, SC 29631. E-mail: coreyk@clemson.edu

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CLINICAL PERSPECTIVE

What Is New?

- Black and Hispanic patients are at increased risk of poor limb outcomes when presenting at a similar stage of clinical severity.
- Use of Vascular Quality Initiative data source provides “real-world” evidence in a large population of patients receiving care for an important vascular disease.
- Increased generalizability was attributable to a variety of clinical providers contributing to Vascular Quality Initiative, representation across entire United States and parts of Canada, and inclusion of tertiary and community hospitals.

What Are the Clinical Implications?

- Providers should give careful consideration for all patients undergoing revascularization for claudication as our estimates exceeded natural history estimates of 1-year limb loss.
- More aggressive surveillance may be needed for Black and Hispanic patients with peripheral artery disease.
- Differences in comorbid conditions at presentation by race and ethnicity are not sole drivers of disparate outcomes; consider impact of system-level policies that differentially, and negatively, impact Black and Hispanic patients.

Nonstandard Abbreviations and Acronyms

CLTI	chronic limb-threatening ischemia
MALE	major adverse limb event
PVI	peripheral vascular intervention
sdHR	subdistribution hazard ratio
VQI	Vascular Quality Initiative

rates compared with White patients¹¹ and are 30% less likely to receive any limb salvage revascularization attempt before a major limb amputation.¹²

Some have argued that disease severity is *the* primary driver of observed PAD-related health disparities.¹³ Patients from racial and ethnic minority groups may present to vascular specialists who treat PAD with advanced disease because of poor access to primary care and higher prevalence of comorbidities.^{14,15} However, for patients who undergo lower extremity revascularization for a similar severity of PAD, the longitudinal, risk-adjusted outcomes for patients from racial and ethnic minority groups compared with White patients remain poorly characterized. Much of the current evidence of disparities is derived from administrative

databases, which can bias results and lack granularity, or single-institution studies that have limited generalizability.^{16–18} Existing data are often perioperative or reported for a short postoperative period of 30 days.¹⁹ There are also limited outcome-related data for patients who identify as Hispanic, representing an important knowledge gap attributable to the growing population of Hispanic people in the United States.

Some of these limitations are mitigated through the use of the VQI (Vascular Quality Initiative) registry,²⁰ a “real-world” database that contains longitudinal data for multiple racial and ethnic minority groups and has sufficient granularity to control for patient and procedural factors that may influence outcomes. The objectives of this study, therefore, were (1) to use the VQI registry to assess long-term limb outcomes and survival in Black and Hispanic patients compared with White patients after lower extremity revascularization and (2) to determine if disparities in outcome vary according to the severity of PAD before revascularization (claudication and chronic limb-threatening ischemia [CLTI]). We leverage and adapt a conceptual model commonly used to consider patient, physician, and health care variables and the impact of these variables on racial differences in the provision of care and resulting outcomes.²¹

METHODS

The data set and analytic methods for this project are available to other qualified researchers on request, pending approval by the Research Advisory Committee at the VQI.

Database

The Society for Vascular Surgery Patient Safety Organization established the VQI, a vascular procedure-based registry to document and improve the quality of care delivered to patients with vascular diseases. Provisioners of vascular care in the United States or Canada are eligible to participate in the VQI. A map of participating sites is included in the supplemental files (Figure S1). As of our study period, 536 centers and 5215 physicians were participating in a VQI registry.

A detailed description of the VQI registry has been previously published.²⁰ Briefly, trained data abstractors or clinicians input all data from each center into 1 of 14 major vascular procedure registries. Each registry contains information on patient demographic traits, comorbid conditions, imaging studies, medication use, and periprocedural details, in addition to in-hospital, 30-day, and long-term outcomes. Patients complete a 1-year follow-up visit for any procedure with outcome data at this point included in the registry.

Study Sample

This study used data from patients in the VQI registry who underwent a revascularization procedure from 2011 to 2018. We restricted our analysis to revascularization procedures indicated because of claudication (pain while walking) or CLTI (inadequate blood and oxygen supply). The Institutional Review Board of Clemson University determined the study met criteria for exemption because only deidentified data were used.

The unit of analysis for this study was an affected leg; individual patients could contribute 2 legs to this analysis. We identified the incident (first) procedure for the right and left legs of each patient. For example, a patient with 2 peripheral vascular intervention (PVI) procedures for a right leg and 2 bypasses for a left leg would only contribute the first PVI procedure on the right and the first bypass on the left to our analyses. Also, only the first procedure, regardless of limb, was used for time to death analyses. Patients were excluded if they were aged <18 years, did not have an indication of claudication, rest pain, or tissue loss for the intervened upon limb, or had a suprainguinal PVI. Patients of race and ethnicity other than non-Hispanic Black, non-Hispanic White, and Hispanic were also excluded from analyses.

Outcomes

Primary outcomes were (1) major adverse limb events (MALEs; defined as major amputation or reintervention of the limb in which the initial revascularization intervention occurred), (2) major amputation (defined as below or above knee), and (3) death. Limb outcomes were ascertained through follow-up visits and included in the registry by the trained abstractors with verification by the clinician before submitting to the VQI. The Social Security Death Index is linked to the VQI registry to ascertain deaths.

Demographics and Comorbidities

Demographics include race, sex, and age at procedure. These variables are abstracted from the medical record and may be self-reported by the patient or assigned by medical staff based on patients' presentation. All comorbid conditions are abstracted from the medical record. Although there are many additional comorbidity variables available, we only included those commonly used in PAD research. More information on how the variables were coded is described in the statistical analysis section below. Disease presentation was categorized as claudication or CLTI, which included ischemic rest pain, tissue loss, and gangrene. Comorbidities included diabetes, obesity (body mass index ≥ 30 kg/m²), hypertension, coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease (COPD), and dialysis-dependent kidney disease. The location of the intervention was

categorized as above or below knee, and the type of graft conduit was defined as vein or prosthetic. Type of intervention was defined as PVI or bypass.

Statistical Analysis

We compared the distribution of demographic characteristics and comorbidities across our 3 racial and ethnic groups. Confounder variables included in the overall model included race and ethnicity, age (quadratic), sex (male/female), CLTI (yes/no), diabetes (yes/no), smoking (current or former/never), COPD (no history/medications/home oxygen), dialysis dependence (yes/no), preoperative aspirin and statin use (yes/no), insurance status (insured/uninsured), congestive heart failure (yes/no), coronary artery disease (yes/no), and type of intervention (PVI/bypass).

We followed patients/limbs undergoing intervention until the first occurrence of MALE or major amputation (for each of those analyses, respectively) or death (a competing event, which precludes the occurrence of MALEs or major amputation). Data were administratively censored at 1 year.

To describe disparities in long-term outcomes after revascularization by race and ethnicity, we present crude cumulative incidence curves, stratified by race and ethnicity, for each outcome and 1-year risks with 95% CIs. To account for possibly correlated outcomes (in patients who contributed to the data with >1 limb revascularization), we estimated 95% CIs using the robust variance estimator.

To determine whether disparities are explained by disease severity at the time of revascularization, we present hazard ratios (HRs) for the association between race and ethnicity and each of our 3 outcomes, adjusted for the independent variables listed above, including comorbid illnesses. We present these associations overall and stratified by the primary measure of disease severity (claudication versus CLTI). We used Cox proportional hazards to calculate HRs and 95% CIs for the association between race and ethnicity and death. We used Fine and Gray subdistribution proportional hazards models to calculate subdistribution HRs (sdHRs) for the association between race and ethnicity and MALEs or major amputation, accounting for death as a competing event.²² To account for possibly correlated outcomes (in patients who contributed to the data with >1 limb revascularization), we estimated 95% CIs again using the robust variance estimator. All analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC).

RESULTS

Study Population

We identified 100 579 revascularizations (limbs) in 88 599 patients with a median follow-up of 298 days

(range, 0–365 days). The cohort was composed of 76% White (n=67 651), 17% Black (n=15 442), and 7% Hispanic (n=5506) patients. Most patients were men (63%) with high prevalence of traditional vascular risk factors (Table). Black and Hispanic patients were more likely to present with CLTI, diabetes, and dialysis dependence compared with White patients. White patients were more likely to have COPD compared with Black and Hispanic patients. Overall, CLTI was more common (57%; n=50 250) than claudication (43%; n=38 349) as the indication for revascularization, and nearly three fourths of patients had a PVI procedure as their incident (index) revascularization (Table S1 and Table S2).

Overall Population

Major Adverse Limb Event

One-year cumulative incidence of MALEs was 13.7% (95% CI, 13.5%–13.9%) among all patients. One-year cumulative incidence of MALEs was 12.8% (95% CI, 12.5%–13.0%) in White patients, 16.5% (95% CI, 16.0%–17.1%) in Black patients, and 17.2% (95% CI, 16.2%–18.2%) in Hispanic patients. Black and Hispanic patients had an adjusted hazard of MALEs that was 1.17 (95% CI, 1.12–1.22) and 1.22 (95% CI, 1.14–1.31) times the hazard among White patients, respectively (Figure 1A and Table S3).

Limb Amputation

One-year cumulative incidence of limb amputation was 3.4% (95% CI, 3.3%–3.5%) among all patients. One-year cumulative incidence of limb amputation was

2.7% (95% CI, 2.6%–2.8%) in White patients, 5.8% (95% CI, 5.4%–6.2%) in Black patients, and 5.6% (95% CI, 5.0%–6.2%) in Hispanic patients. Black and Hispanic patients had an adjusted hazard of amputation of 1.52 (95% CI, 1.39–1.65) and 1.45 (95% CI, 1.28–1.64) times the hazard among White patients, respectively (Figure 1B and Table S4).

Death

One-year risk of death was 7.9% (95% CI, 7.7%–8.1%) among all patients. One-year risk of death was similar in White patients (8.0%; 95% CI, 7.8%–8.2%), Black patients (7.8%; 95% CI, 7.4%–8.2%), and Hispanic patients (6.9%; 95% CI, 6.2%–7.5%). However, after adjusting for confounding factors, Black and Hispanic patients had a hazard of death of 0.85 (95% CI, 0.79–0.91) and 0.71 (95% CI, 0.63–0.79) times the hazard among White patients, respectively (Figure 1C and Table S5).

A table for number at risk for each outcome and race and ethnicity is included as Table S6 for Figure 1.

Disease Severity Presentation: Claudication Subcohort

During our study, 45 128 limbs in 38 349 patients were treated with revascularization for claudication. This subpopulation included 31 256 White (81%), 5297 Black (14%), and 1796 Hispanic (5%) patients. White patients were proportionately more represented in the claudication versus CLTI cohorts (81% versus 72%). Black patients with claudication were more likely to be women, to have diabetes, and to be on dialysis than White patients. Hispanic patients with claudication had

Table. Characteristics of Patients Undergoing Vascular Intervention by Race and Ethnic Group (N=88 599)

	Overall (N=88 599)	Non-Hispanic White patients (N=67 651)	Non-Hispanic Black patients (N=15 442)	Hispanic patients (N=5506)	P value
Characteristics					
Age at procedure, mean (SD), y	68.6 (11.2)	69.3 (11.0)	65.8 (11.2)	67.8 (11.6)	<0.0001
Female sex	32 878 (37.1)	23 675 (35.0)	7048 (45.6)	2155 (39.2)	<0.0001
Bypass intervention	23 556 (26.6)	18 204 (26.9)	3887 (25.2)	1465 (26.6)	<0.0001
CLTI	50 250 (56.7)	36 395 (53.8)	10 145 (65.7)	3710 (67.4)	<0.0001
Current smoker	29 759 (33.6)	22 877 (33.8)	5613 (36.4)	1269 (23.1)	<0.0001
Diabetes	47 628 (53.8)	33 930 (50.2)	9624 (62.3)	4074 (74.0)	<0.0001
Obese	29 550 (33.5)	22 592 (33.6)	5305 (34.5)	1653 (30.2)	<0.0001
Hypertension	78 704 (88.9)	59 387 (87.8)	14 327 (92.8)	4990 (90.7)	<0.0001
Coronary artery disease	28 316 (32.0)	22 492 (33.3)	4121 (26.7)	1703 (30.9)	<0.0001
Congestive heart failure	16 688 (18.8)	12 335 (18.2)	3307 (21.4)	1046 (19.0)	<0.0001
COPD	21 944 (24.8)	18 066 (26.7)	3021 (19.6)	857 (15.6)	<0.0001
Dialysis	7533 (8.5)	3941 (5.8)	2690 (17.4)	902 (16.4)	<0.0001

Data are given as number (percentage), unless otherwise indicated. CLTI indicates chronic limb-threatening ischemia; and COPD, chronic obstructive pulmonary disease.

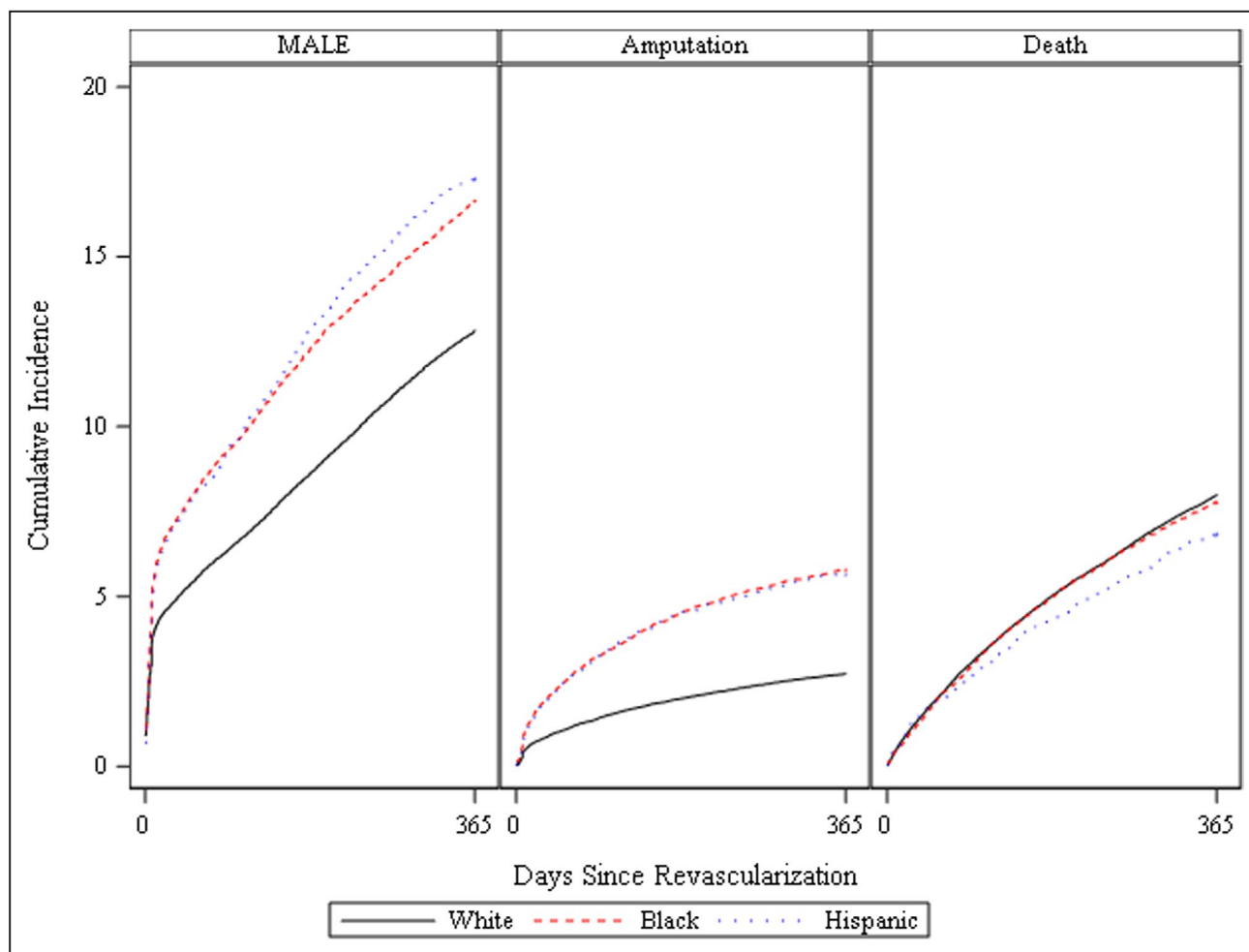


Figure 1. Overall cumulative incidence of major adverse limb events (MALEs) (A), major amputation (B), and death (C). Significance levels: MALEs: White vs Black race: <0.0001; White race vs Hispanic ethnicity: <0.0001; Black race vs Hispanic ethnicity: 0.3286. Amputation: White vs Black race: <0.0001; White race vs Hispanic ethnicity: <0.0001; Black race vs Hispanic ethnicity: 0.8388. Death: White vs Black race: 0.7734; White race vs Hispanic ethnicity: <0.0001; Black race vs Hispanic ethnicity: <0.0001.

a higher prevalence of diabetes and were more likely to be on dialysis than White patients. White patients with claudication had a higher prevalence of COPD than Black and Hispanic patients (Table S1).

Major Adverse Limb Events

Overall cumulative 1-year incidence of MALEs among patients being treated for claudication was 9.6% (95% CI, 9.3%–9.9%) and did not differ by race and ethnicity. After adjusting for confounders, the sdHRs comparing Black and Hispanic patients with claudication to White patients with claudication were 1.01 (95% CI, 0.92–1.10) and 1.08 (95% CI, 0.93–1.23), respectively (Figure 2A and Table S3).

Limb Amputation

We observed a 1-year cumulative incidence of amputation of 0.7% (95% CI, 0.6%–0.8%) among patients

treated for claudication. One-year cumulative incidence of amputation was nearly double in Black compared with White patients (1.2% versus 0.6%). In adjusted analyses, the sdHRs comparing Black and Hispanic patients with claudication to White patients with claudication were 1.59 (95% CI, 1.17–2.15) and 1.34 (95% CI, 0.81–2.21), respectively (Figure 2A and Table S4).

Death

One-year risk of death was 3.0% (95% CI, 2.8%–3.1%) among patients with claudication. One-year risk of death was similar among Black and White patients (3.1% versus 2.8%), but lower among Hispanic patients (2.3%). After adjusting for confounding factors, Black and Hispanic patients with claudication had a hazard of death of 0.92 (95% CI, 0.76–1.11) and 0.74 (95% CI, 0.54–1.03) times the hazard among White patients with claudication, respectively (Figure 2A and Table S5).

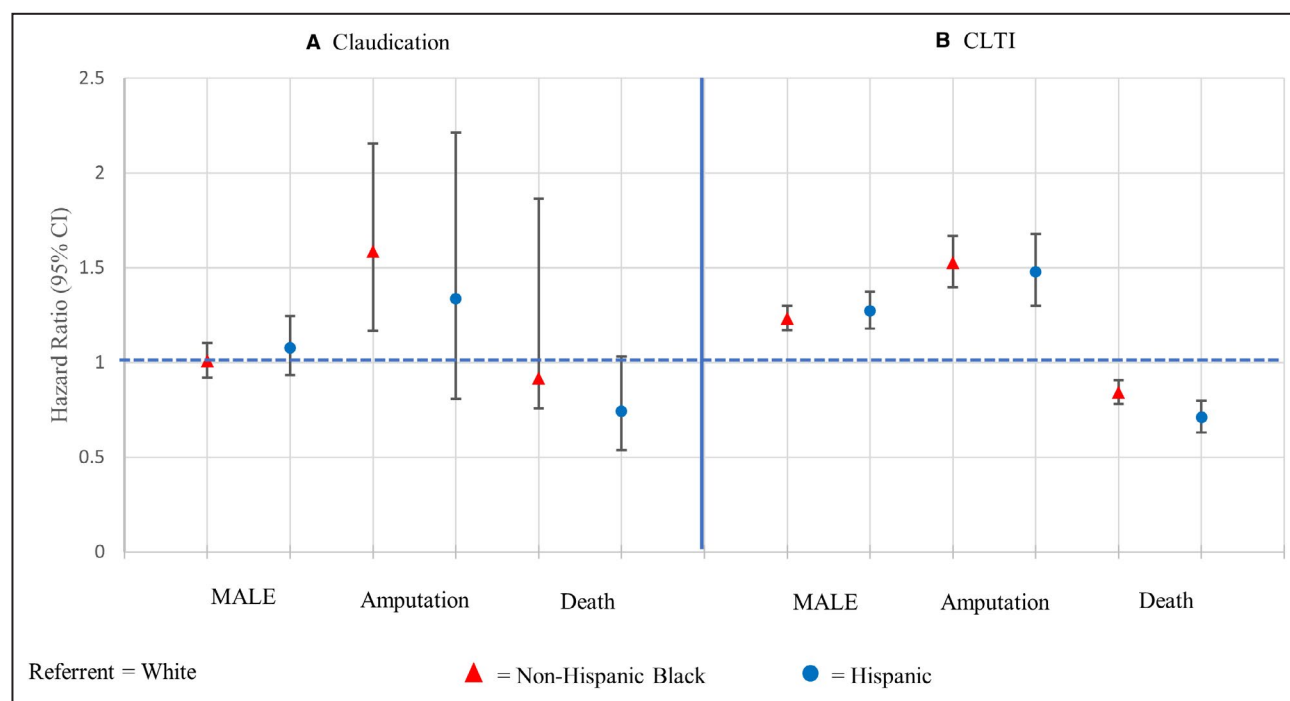


Figure 2. Adjusted hazard ratios of primary outcomes by claudication (A) and chronic limb-threatening ischemia (CLTI) (B). Hazard ratios were adjusted for patient race and ethnicity, sex, age, insurance status, treatment type, disease presentation, smoking status, diabetes, chronic obstructive pulmonary disease, dialysis-dependent kidney disease, preoperative aspirin and statin use, congestive heart failure, and coronary artery disease. MALE indicates major adverse limb event.

Presentation: CLTI Subcohort

During our study, 55 451 limbs in 50 250 patients were treated with revascularization for CLTI. This subpopulation included 36 395 White (72%), 10 145 Black (20%), and 3710 Hispanic (8%) patients. Black patients were proportionately more represented in the CLTI group than the claudication group (20% versus 14%). Like the claudication subcohort, Black patients with CLTI were more likely to be women, to have diabetes, and to be on dialysis than White patients. Hispanic patients with CLTI had a higher prevalence of diabetes and were more likely to be on dialysis than White patients. White patients with CLTI had a higher prevalence of COPD than Black and Hispanic patients (Table S2).

Major Adverse Limb Events

MALEs among patients being treated for CLTI were 17.1% (95% CI, 16.8%–17.4%) at 1 year. One-year incidence was significantly higher in Black (20.1%) and Hispanic (20.5%) patients than White patients (15.9%). After adjusting for confounders, the sdHRs comparing Black and Hispanic patients with CLTI to White patients with CLTI were 1.23 (95% CI, 1.17–1.30) and 1.27 (95% CI, 1.18–1.37), respectively (Figure 2B and Table S3).

Limb Amputation

An amputation event among patients treated for CLTI was 5.8% (95% CI, 5.5%–6.0%) at 1 year. Rates were nearly double in Black (8.4%) and Hispanic (8.1%) patients compared with White patients (4.8%). In adjusted analyses, the sdHRs comparing Black and Hispanic patients with CLTI to White patients with CLTI were 1.53 (95% CI, 1.40–1.67) and 1.48 (95% CI, 1.30–1.68), respectively (Figure 2B and Table S4).

Death

Death among patients treated for CLTI was 11.6% (95% CI, 11.4%–11.9%) at 1 year. White patients had higher death at 1 year (12.2%) compared with Black (10.4%) and Hispanic patients (9.1%). After adjusting for confounders, Black and Hispanic patients with CLTI had a hazard of death of 0.84 (95% CI, 0.78–0.91) and 0.71 (95% CI, 0.63–0.80) times the hazard among White patients with CLTI, respectively (Figure 2B and Table S5).

DISCUSSION

This analysis of >88 000 patients undergoing infrainguinal revascularization in the VQI demonstrates that non-Hispanic Black and Hispanic patients have significantly increased risk of MALEs and amputation on

long-term follow-up in comparison to White patients. With few exceptions, these risks are present for Black and Hispanic patients undergoing revascularization for both claudication and CLTI and are thus present irrespective of the severity of disease at presentation. Non-Hispanic Black and Hispanic race and ethnicity were independently predictive of poor limb outcomes, even after controlling for a multitude of patient and anatomic factors captured in the VQI.

We found that Black and Hispanic patients presenting for intervention with claudication had much higher amputation risk than (1) White patients in the VQI and (2) estimates based on estimates from natural history studies of claudication ($\approx 1\%/year$).²³ Vascular surgeons debate the merits of revascularization versus risk factor management in patients with claudication. Although smoking cessation counseling, exercise therapy, and prescription of important medications remain hallmarks of PAD treatment, few patients are optimally managed.²⁴ However, there is a growing body of evidence suggesting that intervention for claudication may negatively alter the natural history of disease, resulting in more amputations.²⁵ One-year amputation rates in this study exceeded natural history estimates for all race and ethnicity groups, which suggests that determining which patients with claudication benefit from surgical intervention remains a clinical challenge. In particular, the significantly higher 1-year amputation rates among Black and Hispanic patients with claudication indicate a population that warrants further examination. It is possible that surgeons are selecting patients for revascularization that they believe are at a particularly high risk for amputation. However, a disproportionate number of patients who required an amputation by 1-year postoperatively were from racial minority groups, and these patient populations should be informed of potential added risks of revascularization and surgeons may need to exercise caution in selecting patients with claudication to offer revascularization.

Non-Hispanic Black and Hispanic patients tend to present with more advanced stages of PAD compared with White patients.^{13,15,26} Late-stage PAD presentation is often thought to explain the disparate outcomes, particularly for limb amputation, that Black and Hispanic patients experience after revascularization. To assess the importance of disease stage, our article presents an important analysis of disparities within similar disease stages. Our analysis demonstrates that non-Hispanic Black and Hispanic patients have inferior limb outcomes compared with White patients among those presenting with claudication as well as those with CLTI. Consequently, there are likely other measured and unmeasured factors that drive the increased rate of MALEs and amputations in non-Hispanic Black and Hispanic patients.

To improve limb-based outcomes in Black and Hispanic patients, several factors should be considered. Clinically, it would be helpful to better understand the specific mechanisms of failure. Black and Hispanic patients who present with either claudication or CLTI are more likely to have developed PAD related to diabetes and renal disease. Black and Hispanic patients may particularly benefit from a more fastidious approach to risk factor management and a more uniform approach to the broader treatment of PAD. Still, although comorbidities, and associated complex small-vessel disease, may be partially driving the higher rate of MALEs and amputation in patients who present with late-stage PAD, these factors do not necessarily explain the differences observed in patients presenting with less advanced disease. Furthermore, it is improbable that differences in comorbidities at presentation by race and ethnicity are solely responsible for driving such a dramatic difference in outcomes. The vascular community should move toward more holistic, patient-centered approaches toward preoperative and operative planning.

Although appropriately planning to deliver the correct intervention at the correct time is critical, postoperative care may be equally important. Thus, more aggressive surveillance protocols for Black and Hispanic patients undergoing revascularization may be warranted. These protocols could identify prefailure stenoses or occlusions at the intervention site. Furthermore, these protocols should also ensure that all patients, including their Black and Hispanic patients, are on appropriate guideline-recommended medications. Incremental differences in each of these care markers may contribute to the disparate outcomes observed.

For decades, vascular surgeons have thought that populations at highest risk of limb loss would also be at highest risk of death. We would be remiss to not discuss how our study adds to a small literature finding slightly improved survival in Black and Hispanic patients in comparison to White patients despite worse limb outcomes following infrainguinal revascularization.^{19,27} These findings are complicated and require contextualization as we are concerned about selection bias in the VQI registries. One possible explanation is that the sickest Black and Hispanic patients with major comorbid illnesses decline or are influenced away from revascularization through their own beliefs or through the discomfort of their providers. Black patients are more likely than White patients to have a primary limb amputation without being offered revascularization.¹² In this context, Black and Hispanic patients experience poorer survival following amputation,²⁷ supporting the theory that the healthiest Black and Hispanic patients are channeled to receive revascularization, whereas sicker White patients, including those with highly morbid conditions, such as COPD, are offered revascularization

over amputation and are, thus, more likely to die with revascularization. For now, this is a hypothesis only on vascular surgery, but there is precedent to support this explanation in a report on racial differences in lung cancer surgery literature.²⁸ As a vascular community, we need better evidence about whether there are biases in what types of treatment are offered to Black and Hispanic patients with PAD and to what degree system-level factors hinder the delivery of appropriate care. If, however, the modest survival advantage we observed is true, then it appears that decades of vascular surgical dogma are erroneous, and patients predisposed to poor limb outcomes are not the same patients who experience the highest risk of death.

Last, we want to draw attention to the race and ethnicity disparities identified in crude analyses as these are the actual toll of human suffering experienced by patients with PAD. Adjusted analyses run the risk of downplaying the reality faced by patients, particularly those from racial and ethnic minority groups.^{29,30} For example, although adjusting for stage at presentation in our overall analyses answers the research question we posed (“is this disparity after vascular intervention explainable by differences in disease stage at presentation?”), it also runs the risk of “adjusting away” some of the effects of racist policies upstream from vascular intervention. Specifically, Black and Hispanic patients are more likely to develop PAD because of an inequitable distribution of social determinants of health (eg, access to care, access to specialists, and access to a Mediterranean-like diet), and less likely to receive timely diagnosis and treatment of PAD because of insufficient investment in health care coverage and infrastructure in predominantly Black and Hispanic communities.

Our study results are purely descriptive, and we are not attributing any causal interpretation to the association between race and ethnicity and outcomes. We have investigated one specific hypothesis about a mediator of the crude association: that Black and Hispanic patients experience poorer outcomes after revascularization attributable to differences in disease stage at the time of intervention. Furthermore, we do not have information on cause of death in the VQI registries, making it difficult to know exactly how differences in patient profiles (eg, increased COPD in White patients) contributed to patient death in this study. Although we can hypothesize about other mediators of these disparities, we have not provided information in support of or contradicting these alternative hypotheses.

The VQI registry was not designed specifically for research purposes, and follow-up past 1 year is limited. Registry information is updated manually and is subject to human error. However, we report longer-term outcomes (1 year) than many previous publications. In addition, the VQI is a “real-world” data source that provides a view of current outcomes in a large

population of patients undergoing lower extremity revascularization procedures for symptomatic PAD in both tertiary and community hospitals. Thus, our results are likely more generalizable to patients with PAD undergoing revascularization in the United States than prior studies.

CONCLUSIONS

Non-Hispanic Black and Hispanic patients undergoing infrainguinal revascularization for either claudication or CLTI had increased risk of long-term amputation and MALEs compared with White patients. This increased risk remained after adjustment for many risk factors for poor outcomes at time of revascularization, failing to support the theory that poor outcomes are solely a function of disease severity at the time of revascularization. Additional investigation aimed at eliminating disparate limb outcomes is needed and should focus on markers of optimal care delivery.

ARTICLE INFORMATION

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Affiliations

Department of Public Health Sciences (C.A.K., B.W., L.B.S.); and Department of Bioengineering (C.A.K.), Clemson University, Clemson, SC; Department of Surgery, School of Medicine, The University of North Carolina at Chapel Hill, Chapel Hill, NC (K.L.M.); Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD (C.R.L.); Department of Internal Medicine, School of Medicine, The University of North Carolina at Chapel Hill, Chapel Hill, NC (S.C.); and Division of Vascular Surgery, Southern Illinois University School of Medicine, Springfield, IL (W.P.R.).

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Disclosures

None.

Supplementary Material

Tables S1–S6

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SUPPLEMENTAL MATERIAL

Table S1. Characteristics of patients undergoing vascular intervention for claudication by race/ethnicity group (N=38,349).

	Overall (N=38,349)	Non- Hispanic White (N=31,256)	Non- Hispanic Black (N=5,297)	Hispanic (N=1,796)	P-value
Mean Age at Procedure, years (SD)	67.3 (10.2)	67.9 (10.2)	64.4 (10.0)	66.9 (10.9)	<.0001
Sex, % Female	13,279 (34.6)	10,251 (32.8)	2,359 (44.5)	669 (37.3)	<.0001
Intervention, % bypass	7,851 (20.5)	6,569 (21.0)	937 (17.7)	345 (19.2)	<.0001
Current smoker	14,668 (38.3)	11,787 (37.7)	2,320 (43.8)	561 (31.2)	<.0001
Diabetes	16,189 (42.2)	12,433 (39.8)	2,691 (50.8)	1,065 (59.3)	<.0001
Obese	13,320 (34.9)	10,779 (34.6)	1,977 (37.4)	564 (31.6)	<.0001
Hypertension	33,584 (87.6)	27,109 (86.8)	4,861 (91.8)	1,614 (90.0)	<.0001
Coronary artery disease	12,305 (32.1)	10,231 (32.7)	1,504 (28.4)	570 (31.7)	<.0001
Congestive heart failure	4,693 (12.2)	3,674 (11.8)	792 (15.0)	227 (12.6)	<.0001
COPD	9,760 (25.5)	8,397 (26.9)	1,043 (19.7)	320 (17.8)	<.0001
Dialysis	992 (2.6)	553 (1.8)	347 (6.6)	92 (5.1)	<.0001

SD=standard deviation; COPD=chronic obstructive pulmonary disease

Table S2. Characteristics of patients undergoing vascular intervention for CLTI by race/ethnicity group (N=50,250).

	Overall (N=50,250)	Non- Hispanic White (N=36,395)	Non- Hispanic Black (N=10,145)	Hispanic (N=3,710)	P-value
Mean Age at Procedure, years (SD)	69.5 (11.7)	70.5 (11.6)	66.6 (11.8)	68.2 (12.0)	<.0001
Sex, % Female	19,599 (39.0)	13,424 (36.9)	4,689 (46.2)	1,486 (40.1)	<.0001
Intervention, % bypass	15,705 (31.3)	11,635 (32.0)	2,950 (29.1)	1,120 (30.2)	<.0001
Tissue loss	41,521 (82.6)	30,133 (82.8)	8,243 (81.3)	3,145 (84.8)	<.0001
Current smoker	15,091 (30.0)	11,090 (30.5)	3,293 (32.5)	708 (19.1)	<.0001
Diabetes	31,439 (62.6)	21,497 (59.1)	6,933 (68.3)	3,009 (81.1)	<.0001
Obese	16,230 (32.5)	11,813 (32.6)	3,328 (33.0)	1,089 (29.5)	<.0001
Hypertension	45,120 (89.8)	32,278 (88.7)	9,466 (93.3)	3,376 (91.0)	<.0001
Coronary artery disease	16,011 (31.9)	12,261 (33.7)	2,617 (25.8)	1,133 (30.5)	<.0001
Congestive heart failure	11,995 (23.9)	8,661 (23.8)	2,515 (24.8)	819 (22.1)	<.0001
COPD	12,184 (24.3)	9,669 (26.6)	1,978 (19.5)	537 (14.5)	<.0001
Dialysis	6,541 (13.0)	3,388 (9.3)	2,343 (23.1)	810 (21.8)	<.0001

CLTI=chronic limb threatening ischemia; SD=standard deviation; COPD=chronic obstructive pulmonary disease

Table S3. Incidence and adjusted hazard ratio of Major Adverse Limb (MALE) Events stratified by disease severity and revascularization type and presented by race/ethnicity group (n=100,579 limbs).

	Population	Overall	White	sdHR (95% CI)	Black	sdHR (95% CI)	Hispanic	sdHR (95% CI)
		1 Yr Incidence (95% CI)	1 Yr Incidence (95% CI)		1 Yr Incidence (95% CI)		1 Yr Incidence (95% CI)	
Overall*	100,579	13.7 (13.5 – 13.9)	12.8 (12.5 – 13.0)	Ref	16.5 (16.0 – 17.1)	1.2 (1.1 - 1.2)	17.2 (16.2 – 18.2)	1.2 (1.1 - 1.3)
Claudication	45,128	9.6 (9.3 – 9.9)	9.4 (9.1 – 9.8)	ref	10.3 (9.5 – 11.0)	1.0 (0.9 - 1.1)	10.7 (9.4 – 12.1)	1.1 (0.9 - 1.2)
CLTI	55,451	17.1 (16.8 – 17.4)	15.9 (15.5 – 16.3)	ref	20.1 (19.3 – 20.8)	1.2 (1.2 - 1.3)	20.5 (19.2 – 21.8)	1.3 (1.2 - 1.4)

MALE, major adverse limb events; sdHR, Subdistribution Hazard Ratio; CLTI=chronic limb threatening ischemia; Adjusted for race/ethnicity, age, sex, CLTI (or tissue loss), diabetes, smoking, COPD, dialysis dependence, preoperative aspirin and statin, insurance status, congestive heart failure, coronary artery disease, and type of intervention

Table S4. Incidence and adjusted hazard ratio of Amputation Events stratified by disease severity and revascularization type and presented by race/ethnicity group (n=100,579 limbs).

		Overall	White		Black		Hispanic	
	Population	1 Yr Incidence (95% CI)	1 Yr Incidence (95% CI)	sdHR (95% CI)	1 Yr Incidence (95% CI)	sdHR (95% CI)	1 Yr Incidence (95% CI)	sdHR (95% CI)
Overall	100,579	3.4 (3.3 – 3.5)	2.7 (2.6 – 2.8)	ref	5.8 (5.4 – 6.2)	1.5 (1.4 - 1.7)	5.6 (5.0 – 6.2)	1.5 (1.3 - 1.6)
Claudication	45,128	0.7 (0.6 – 0.8)	0.6 (0.5 – 0.7)	ref	1.2 (0.9 – 1.5)	1.6 (1.2 - 2.2)	0.9 (0.5 – 1.3)	1.3 (0.8 - 2.2)
CLTI	55,451	5.8 (5.5 – 6.0)	4.8 (4.5 – 5.0)	ref	8.4 (7.9 – 9.0)	1.5 (1.4 - 1.7)	8.1 (7.2 – 9.0)	1.5 (1.3 - 1.7)

sdHR, Subdistribution Hazard Ratio; CLTI=chronic limb threatening ischemia;

Adjusted for race/ethnicity, age, sex, CLTI (or tissue loss), diabetes, smoking, COPD, dialysis dependence, preoperative aspirin and statin, insurance status, congestive heart failure, coronary artery disease, and type of intervention

Table S5. Incidence and adjusted hazard ratio of Survival (Death) Events stratified by disease severity and revascularization type and presented by race/ethnicity group (n=88,599).

		Overall	White		Black		Hispanic	
	Population	1 Yr Incidence (95% CI)	1 Yr Incidence (95% CI)	HR (95% CI)	1 Yr Incidence (95% CI)	HR (95% CI)	1 Yr Incidence (95% CI)	HR (95% CI)
Overall	88,599	7.9 (7.7 – 8.1)	8.0 (7.8 – 8.2)	Ref	7.8 (7.4 – 8.2)	0.9 (0.8 - 0.9)	6.9 (6.2 – 7.5)	0.7 (0.6 - 0.8)
Claudication	38, 349	3.0 (2.8 – 3.0)	3.1 (2.9 – 3.2)	Ref	2.8 (2.4 – 3.3)	0.9 (0.8 - 1.1)	2.3 (1.6 – 3.0)	0.7 (0.5 – 1.0)
CLTI	50,250	11.6 (11.4 – 11.9)	12.2 (11.9 – 12.6)	ref	10.4 (9.8 – 11.0)	0.8 (0.8 - 0.9)	9.1 (8.1 – 10.0)	0.7 (0.6 - 0.8)

MALE, major adverse limb events; HR, Hazard Ratio; CLTI=chronic limb threatening ischemia;

Adjusted for race/ethnicity, age, sex, CLTI (or tissue loss), diabetes, smoking, COPD, dialysis dependence, preoperative aspirin and statin, insurance status, congestive heart failure, coronary artery disease, and type of intervention

Table S6. Number at Risk by outcome and race/ethnicity group.

	30 Days	60 Days	90 Days	180 Days	365 Days
MALE					
White	72390	71152	70026	66978	23467
Black	16040	15678	15397	14597	4941
Hispanic	5672	5566	5476	5162	1713
Amputation					
White	75386	74477	73646	71729	26716
Black	16932	16645	16420	15876	5745
Hispanic	5981	5893	5830	5647	1999
Death					
White	66808	66209	65635	64289	51224
Black	15269	15114	14997	14679	11495
Hispanic	5433	5397	5363	5271	4204

MALE, major adverse limb events;