JAMA Surgery | Original Investigation | ASSOCIATION OF VA SURGEONS

Progression to Chronic Limb-Threatening Ischemia After Index Revascularization for Claudication

Olamide Alabi, MD, MS; Rae Rokosh, MD; Xinyan Zheng, MS; Caitlin W. Hicks, MD, MS; Emily L. Spangler, MD, MS; Gabriela Velazquez, MD; Kakra Hughes, MD, PhD; Philip Goodney, MD, MS; Elizabeth L. George, MD; Jialin Mao, MD, PhD; Shipra Arya, MD, SM; Matthew A. Corriere, MD, MS

IMPORTANCE Claudication is associated with walking impairment, but amputation risk is generally low unless symptoms progress to chronic limb-threatening ischemia (CLTI). Disparities in amputation risk have been described previously, but population-specific rates of revascularization for claudication, postrevascularization progression from claudication to CLTI, and rates of guideline-based risk-reduction pharmacotherapy are unknown.

OBJECTIVE To explore the impact of intersectional identity among a cohort of patients with claudication on progression to CLTI, amputation, and mortality following revascularization.

DESIGN, SETTING, AND PARTICIPANTS This national cohort study was conducted using the Vascular Quality Initiative (VQI) procedural registry, which was linked to the Medicare dataset of patients who underwent index revascularization for claudication from January 1, 2016, to December 31, 2019. Patients with claudication undergoing an index lower-extremity revascularization procedure (aortoiliac and infrainguinal arterial occlusive disease) at VQI-participating centers were eligible for inclusion. Data analysis was conducted from December 2024 to February 2025.

EXPOSURE The primary exposure was an intersectional variable combining race, ethnicity, and sex.

MAIN OUTCOMES AND MEASURES The primary outcome was development of CLTI within 180 days after index revascularization (defined by a validated CLTI-specific *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision [ICD-10]* code). Secondary outcomes included major amputation and mortality. Survival analyses were used to examine outcomes.

RESULTS Among 10 012 patients undergoing revascularization for claudication (median [IQR] age, 71 [66-76] years; 3850 female patients [38.5%]), self-identified intersectional identity distribution was 151 (1.5%) Hispanic men, 92 (0.9%) Hispanic women, 502 (5.0%) non-Hispanic Black men, 422 (4.2%) non-Hispanic Black women, 5509 (55.0%) non-Hispanic White men, and 3336 (33.3%) non-Hispanic White women. Black and Hispanic patients with claudication were more likely to have diabetes and be undergoing dialysis. Black men had the highest prevalence of active smokers (38.6%) while Hispanic women were more often never smokers (30.4%). A higher proportion of White men (80.9%) were receiving preoperative statin therapy compared to all other groups. The highest rates of postrevascularization progression to CLTI within 180 days were observed among Black women (11.8%; Hispanic: 3.8%; White: 5.9%), followed by Hispanic men (8.8%; Black: 7.2%; White: 5.2%). Major amputation rates were also highest among Black patients (180 days: Black women, 0.8%; Black men, 0.7%).

CONCLUSIONS AND RELEVANCE According to the results of this cohort study, Black women had the highest rate of postrevascularization progression from claudication to CLTI. Development of practice- and policy-level standards incentivizing evidence-based claudication management may support equitable outcomes and reduce disparities.

Invited Commentary

Supplemental content

Author Affiliations: Author affiliations are listed at the end of this article.

Corresponding Author: Olamide Alabi, MD, MS, Department of Surgery, Emory University School of Medicine, 1365 Clifton Rd, Bldg A, Ste A2207, Atlanta, GA 30322 (olamide.alabi@emory.edu).

JAMA Surg. doi:10.1001/jamasurg.2025.5556
Published online December 17, 2025.

Claudication is prevalent among 7% of adults over age 50 years and is the mildest form of symptomatic peripheral artery disease (PAD).[1,2] Most patients with claudication do not experience disease progression to chronic limb-threatening ischemia (CLTI), which increases the risk for reintervention, major amputation, and mortality.[3] Reported rates of progression to CLTI are low over 5 years.[4,5] Lower-extremity revascularization (LER) for claudication, however, has also been reported as a risk factor for progression to CLTI.[6-8] Diabetes, chronic kidney disease, and smoking are established risk factors for progression to CLTI in patients with claudication.[9-11] Increasing age, male sex, and early LER for claudication were also implicated as risk factors for disease progression.[7,8]

Race- and sex-based disparities in CLTI outcomes have been widely reported; however, outcomes among structurally vulnerable populations with claudication remain understudied.[12] While sociodemographic factors, such as ethnoracial identity and self-reported gender, have been previously reported as strong risk factors for inferior clinical outcomes in patients with CLTI, it is unclear how these social constructs influence outcomes in patients with claudication. Health care disparities approaches based on intersectionality, a framework in which one's experiences and outcomes are shaped by the complex interplay of multiple social identities, allow for more nuanced understanding of how health care access and delivery differentially affect treatment outcomes for various populations.

The objectives of this study are 2-fold—first, to examine disease progression to CLTI among patients undergoing an index LER for claudication, and second, to determine if disease progression varies between groups based on their self-reported ethnoracial and sex identities.

Key Points

Question What is the risk of disease progression after an index lower-extremity revascularization for claudication, and does this risk differ based on one's ethnoracial and sex identification?

Findings In this cohort study within a large procedural registry linked to Medicare claims data that included 10 012 adults with claudication, the rate of symptom progression from claudication to chronic limb-threatening ischemia was 5.85% at 180 days after index revascularization. White men and women had progression rates below the mean; Black women had a much higher rate of progression at 180 days.

Meaning Revascularization for claudication, the mildest symptomatic manifestation of peripheral artery disease, is associated with increased risk for symptomatic disease progression, particularly among Black women.

Methods

Data Sources

The Vascular Quality Initiative (VQI) is a procedural registry that collects sociodemographic, procedural, and outcomes data from more than 980 participating centers.[13] The Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION) database links the VQI to patient-level Medicare claims data, providing a more complete longitudinal record of health care utilization for patients after vascular surgery.[14] We implemented the 2019 VQI-VISION Medicare claims linkage data, which encompasses all VQI procedures among Medicare beneficiaries between 2003 and 2019. Due to known crosswalk challenges between *International Classification of Diseases, Ninth Revision (ICD-9)* and *Tenth Revision* (*ICD-10*) coding systems, the analysis dataset was restricted to years 2016 to 2019. This study was approved by the institutional review boards of Emory University and Weill Cornell Medicine with a waiver of consent, as data were deidentified, and adheres to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines for cohort studies.[15]

Study Population

Using VQI-VISION, we identified the index peripheral vascular intervention (PVI), supra-inguinal bypass (SUPRA), and/or infra-inguinal bypass (INFRA) performed on adults at VQI-participating centers for claudication between January 1, 2016, and December 31, 2019. These procedures are coded under each module (PVI, SUPRA, and INFRA) as structured variables within VQI. We excluded individuals with a prior diagnosis of CLTI, including index LER for CLTI; those with a procedural indication of aneurysm, acute limb ischemia, or emergent LER; any patient not enrolled in fee-for-service Medicare at the time of their index VQI procedure; and patients with a new CLTI diagnosis code within 30 days of the index LER (**Figure 1**).

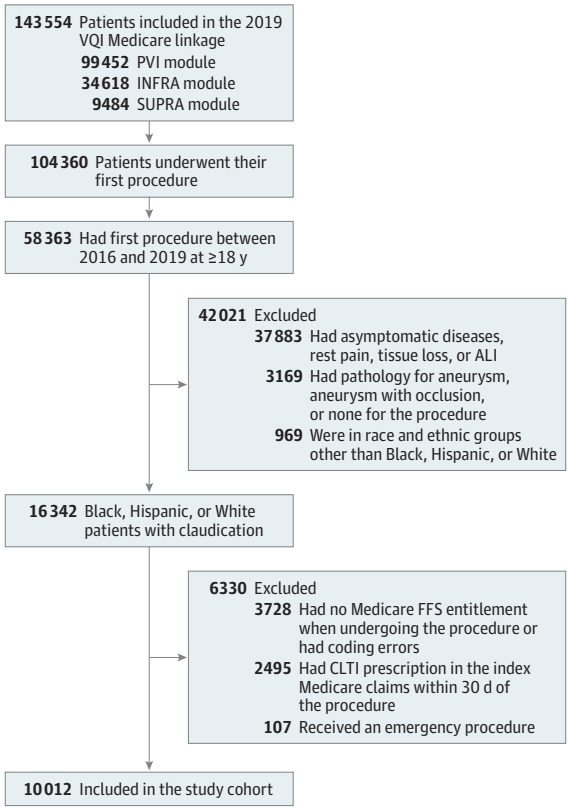
Outcome Measures

The primary outcome was the development of CLTI, defined by a new *ICD-10* code for CLTI within 180 days after the index LER.[16] The secondary outcome was reintervention, major amputation, and the development of CLTI within 1 year after the index LER. Reintervention was defined using *Current Procedural Terminology* (*CPT*) codes for any subsequent endovascular, open surgical, or hybrid vascular procedure after the index LER (eTable 1 in Supplement 1). Reinterventions, minor (below the ankle) amputations, and major (above the ankle) amputations were identified using Medicare claims. Vital status was obtained from the Medicare Master Beneficiary Summary File.

Exposure Variable

The primary exposure variable of interest was a combined descriptive demographic variable of self-identified gender and ethnoracial identity. Gender was drawn from Medicare data, and race was drawn from Medicare and VQI data. This includes Hispanic men, Hispanic women, non-Hispanic Black men, non-Hispanic Black women (hereafter referred to as Black men and women), non-Hispanic White men, and non-Hispanic White women (hereafter referred to as White men and women). Race and ethnicity are distinct and separate social constructs that are not mutually exclusive (eg, Hispanic patients can identify as Black, White, or another race). While we

Figure 1. Flowchart Depicting Inclusion and Exclusion Criteria



ALI indicates acute limb ischemia; CLTI, chronic limb-threatening ischemia; FFS, fee-for-service Medicare; INFRA, infra-inguinal bypass; PVI, peripheral vascular intervention; SUPRA, supra-inguinal bypass; VQI, Vascular Quality Initiative.

created nonoverlapping categories for self-identified ethnoracial identity for the purposes of this analysis, we are aware that individuals identify themselves both within and outside of these categorizations. Of note, Asian and Native American individuals made up less than 0.2% of the cohort and were excluded from analysis.

Risk Factors

Covariates at the time of the index LER were identified from the VQI registry. These included smoking status (never, prior, current), geographic residence (rural, urban), median national percentile rank of the area deprivation index (ADI), baseline comorbidities (coronary artery disease, congestive heart failure, chronic obstructive pulmonary disease, diabetes, chronic kidney disease, end-stage kidney disease undergoing dialysis, hypertension, obesity [body mass index (BMI), calculated as weight in kilograms divided by height in meters squared, of ≥30 or <30]), anatomic segment treated (aortoiliac only, femoropopliteal only, tibial only, femoropopliteal and tibial, aortoiliac, and any other segment), and preoperative as well as postoperative guideline-directed medical therapy (GDMT) use. Age (<65, 65-79, or ≥80 years) was determined using Medicare data.

Statistical Analysis

Baseline characteristics stratified by the combined demographic variable were compared using χ^2 and Kruskal-Wallis tests, as appropriate. Risks of progression to CLTI, reintervention, and amputation were evaluated with survival analysis. Estimated 180-day and 1-year risk of adverse events were compared using Kaplan-Meier curves and log-rank tests. In the time-to-event analysis, individuals were censored at death, when transitioning out of fee-for-service Medicare or into Medicare Advantage, or at the end of follow-up, whichever occurred first.

To identify factors associated with progression to CLTI for Black and White patients, we created univariable and multivariable Cox proportional hazards models. Hispanic patients were excluded from the multivariable analyses given the small sample size. The multivariable model adjusted for age, diabetes, congestive heart failure, chronic kidney disease and end-stage kidney disease undergoing dialysis, smoking history, and anatomic segment treated. Hazard ratios were reported with 95% confidence intervals. Multivariable models were performed with the aforementioned adjustments for patients with aortoiliac and infrainguinal revascularizations, separately. The rate of reintervention, defined as the number of reinterventions per 100 person-years, was calculated based on 3-year follow-up. The rate of reintervention was compared using unadjusted quasi-Poisson regression. Analyses were conducted using SAS version 9.4 (SAS Institute). $P < .05$ was considered significant via 2-tailed tests.

Results

Among the 10 012 patients in our cohort who underwent LER for claudication at VQI-participating centers between 2016 and 2019, median (IQR) age was 71 (66-76) years, and 3850 patients (38.5%) were female. The intersectional identity composition included 502 (5.0%) Black men, 422 (4.2%) Black women, 151 (1.5%) Hispanic men, 92 (0.9%) Hispanic women, 5509 (55.0%) White men, and 3336 (33.3%) White women (**Table 1**). Black men (median [IQR] age, 68 [63-74] years) and Black women (median [IQR] age, 68 [64-74] years) were younger at the time of index LER for claudication compared to their counterparts ($P < .001$). Over one-quarter of all Black men (145 [28.9%]) and women (114 [27.0%]) were younger than 65 years compared to 24 (15.9%) Hispanic men, 17 (18.5%) Hispanic women, 731 (13.3%) White men, and 473 (14.2%) White women ($P < .001$). The median (IQR) length of follow-up was 1.59 (0.75-2.53) years for men and 1.59 (0.76-2.57) years for women.

Baseline differences among groups are summarized in Table 1. More than half of the cohort (5493 patients [54.9%]) described themselves as former smokers. Black and Hispanic women had the highest prevalence of never smoking (19.0% and 30.4%, respectively). Individuals from racial and ethnic minoritized groups had significantly higher rates of diabetes (Black men: 47.6%; Black women: 50.5%; Hispanic men: 49%; Hispanic women: 60.9%; White men: 39.4%; White women; $P < .001$). Black men (7.8%) and Black women (8.4%) were more

Table 1. Baseline Characteristics Among Medicare Patients Undergoing Index Lower-Extremity Revascularization for Claudication at Vascular Quality Initiative–Participating Centers 2016-2019[a]

Characteristic	No. (%)							*P* value
		Non-Hispanic White		Non-Hispanic Black		Hispanic		
	Total (N = 10 012)	Male (n = 5509)	Female (n = 3336)	Male (n = 502)	Female (n = 422)	Male (n = 151)	Female (n = 92)	
Age, median (IQR), y	71 (66-76)	71 (67-76)	72 (67-78)	68 (63-74)	68 (64-74)	71 (66-77)	72 (66.5-78)	<.001[b]
Smoking habit								
Never	1112 (11.1)	418 (7.6)	514 (15.4)	47 (9.4)	80 (19.0)	25 (16.6)	28 (30.4)	<.001[c]
Prior	5493 (54.9)	3252 (59.1)	1667 (50.0)	261 (52.0)	197 (46.7)	77 (51.0)	39 (42.4)	
Current	3403 (34.0)	1837 (33.4)	1153 (34.6)	194 (38.6)	145 (34.4)	49 (32.5)	25 (27.2)	
Diabetes	3890 (38.8)	2172 (39.4)	1136 (34.0)	239 (47.6)	213 (50.5)	74 (49.0)	56 (60.9	<.001[c]
HTN	8942 (89.6)	4919 (89.6)	2933 (88.2)	471 (93.8)	396 (94.1)	137 (90.7)	86 (94.5)	<.001[c]
CAD	3736 (37.3)	2327 (42.3)	1011 (30.3)	163 (32.5)	136 (32.2)	66 (43.7)	33 (35.9)	<.001[c]
COPD	3211 (32.1)	1727 (31.4)	1218 (36.5)	88 (17.5)	121 (28.7)	37 (24.5)	20 (21.7)	<.001[c]
CHF	1357 (13.6)	773 (14.0)	386 (11.6)	83 (16.6)	78 (18.5)	24 (15.9)	13 (14.1)	<.001[b]
CKD and ESKD								
eGFR ≥60 mL/min/1.73 m^2	6281 (63.1)	3614 (65.9)	1917 (57.9)	363 (72.6)	252 (60.3)	84 (56.4)	51 (55.4)	<.001[c]
eGFR 30-60 mL/min/1.73 m^2	3232 (32.5)	1695 (30.9)	1237 (37.4)	≥11	119 (28.5)	≥11	≥11	
eGFR 15-30 mL/min/1.73 m^2	202 (2.0)	≥11	≥11	<11	12 (2.9)	<11	<11	
eGFR <15 mL/min/1.73 m^2	20 (0.2)	≥11	<11	<11	0	0	0	
Dialysis	213 (2.1)	87 (1.6)	41 (1.2)	39 (7.8)	35 (8.4)	<11	<11	
Obesity	3210 (32.1)	1820 (33.1)	1027 (30.9)	149 (29.7)	147 (35.0)	45 (29.8)	22 (23.9)	.05[c]
Preop aspirin	7702 (76.9)	4321 (78.4)	2481 (74.4)	400 (79.7)	323 (76.5)	115 (76.2)	62 (67.4)	<.001[c]
Preop P2Y12 inhibitor	4013 (40.1)	2264 (41.1)	1246 (37.4)	210 (41.8)	188 (44.5)	60 (39.7)	45 (48.9)	.001[c]
Preop statin	7841 (78.3)	4456 (80.9)	2484 (74.5)	393 (78.3)	315 (74.6)	116 (76.8)	77 (83.7)	<.001[c]
Preop anticoagulation	1284 (12.8)	762 (13.8)	387 (11.6)	53 (10.6)	40 (9.5)	27 (17.9)	15 (16.3)	.001[c]
Postop aspirin	8414 (84.2)	4689 (85.3)	2753 (82.7)	433 (86.6)	351 (83.2)	120 (79.5)	68 (73.9)	<.001[c]
Postop P2Y12 inhibitor	7356 (73.6)	4001 (72.8)	2465 (74.0)	371 (74.1)	340 (80.6)	107 (70.9)	72 (78.3)	.01[c]
Postop statin	8237 (82.5)	4657 (84.7)	2629 (79.0)	421 (84.0)	331 (78.4)	121 (80.1)	78 (84.8)	.001[c]
Postop anticoagulation	1500 (15.0)	900 (16.4)	451 (13.5)	60 (12.0)	45 (10.7)	27 (17.9)	17 (18.5)	<.001[c]
Revascularization method								
Endovascular	7689 (76.8)	4101 (74.4)	2630 (78.8)	397 (79.1)	360 (85.3)	≥11	≥11	<.001[c]
Open surgical	1603 (16.0)	934 (17.0)	514 (15.4)	85 (16.9)	37 (8.8)	20 (13.2)	13 (14.1)	
Hybrid	720 (7.2)	474 (8.6)	192 (5.8)	20 (4.0)	25 (5.9)	<11	<11	
Anatomic zone treated								
Aortoiliac only	3547 (35.5)	1879 (34.2)	1389 (41.6)	100 (20.0)	106 (25.1)	47 (31.1)	26 (28.3)	<.001[c]
Femoropopliteal only	4777 (47.8)	2645 (48.1)	1496 (44.9)	280 (56.0)	236 (55.9)	74 (49.0)	46 (50.0)	
Tibial only	316 (3.2)	200 (3.6)	51 (1.5)	34 (6.8)	18 (4.3)	<11	<11	
Femoropopliteal + tibial	520 (5.2)	258 (4.7)	161 (4.8)	54 (10.8)	26 (6.2)	≥11	<11	
Aortoiliac + other	839 (8.4)	517 (9.4)	238 (7.1)	32 (6.4)	36 (8.5)	≥11	<11	
Geographic residence								
Rural	2328 (24.2)	1375 (26.1)	818 (25.5)	55 (11.5)	41 (9.9)	≥11	<11	<.001[c]
Urban	7282 (75.8)	3903 (73.9)	2393 (74.5)	425 (88.5)	372 (90.1)	≥11	≥11	
Median ADI								
1-35	2187 (22.8)	1181 (22.4)	719 (22.4)	106 (22.1)	101 (24.5)	50 (34.7)	30 (36.1)	<.001[c]
36-56	2436 (25.4)	1376 (26.1)	813 (25.3)	98 (20.4)	86 (20.8)	35 (24.3)	28 (33.7)	
57-75	2433 (25.3)	1380 (26.2)	817 (25.4)	109 (22.7)	86 (20.8)	≥11	<11	
76-100	2551 (26.6)	1339 (25.4)	862 (26.8)	167 (34.8)	140 (33.9)	≥11	≥11	

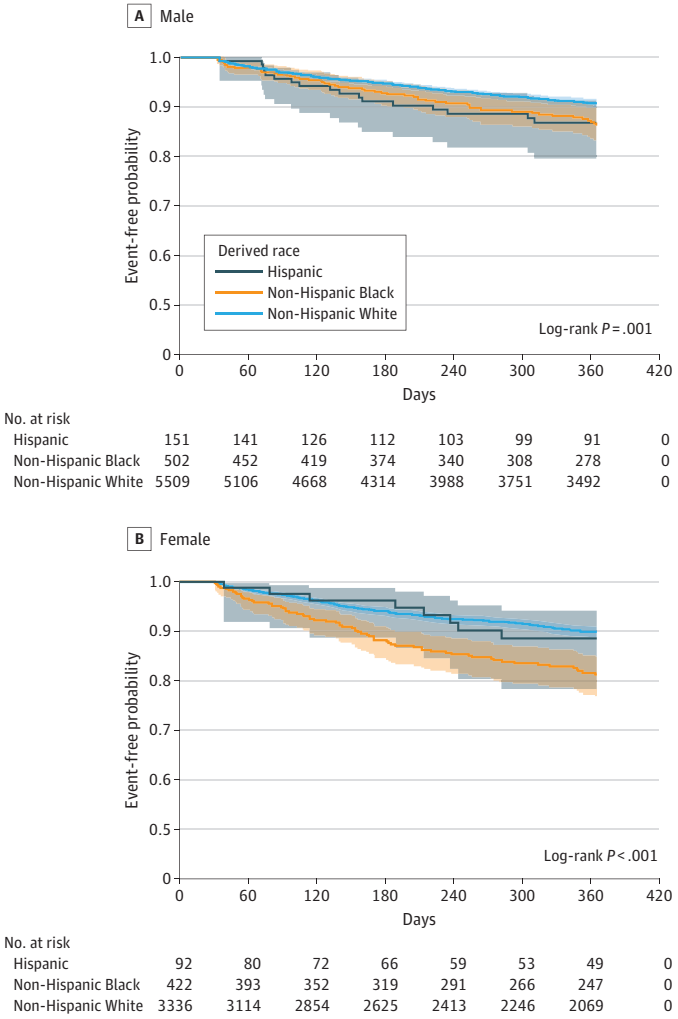
Abbreviations: ADI, area deprivation index; CAD, coronary artery disease; CHF, congestive heart failure; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate; ESKD, end-stage kidney disease; HTN, hypertension; preop, preoperative; postop, postoperative.

[a] To ensure patients as well as facilities participating within the Vascular Quality Initiative remain deidentified, reporting of small patient volumes is not allowed. Race data were drawn from Medicare and the Vascular Quality Initiative.

[b] Kruskal-Wallis *P* value.

[c] χ^2 *P* value.

Figure 2. Freedom From Progression to Chronic Limb-Threatening Ischemia (CLTI) Among Patients Undergoing Index Revascularization for Claudication



Shaded area corresponds to the relevant 95% confidence interval.

likely to be undergoing dialysis at the time of the index procedure. There were no significant differences noted in the rate of obesity. GDMT use prior to index LER was 76.9% for aspirin use, 40.1% for P2Y12 receptor inhibitors, and 78.3% for statin use. GDMT prescription improved postoperatively, with rates of 84.2% for aspirin, 73.6% for P2Y12 receptor inhibitor, and 82.5% for statin use.

Anatomic segments treated during LER varied significantly between groups. The femoropopliteal segment was the most frequently treated anatomic segment for Black men (280 [56.0%]) and Black women (236 [55.9%]), as well as for Hispanic men (74 [49.0%]) and women (46 [50.0%]). Black men had significantly higher rates of femoropopliteal + tibial disease (54 [10.8%]) as well as tibial-only disease (34 [6.8%]). Only 51 White women (1.5%) had isolated tibial disease treated. Revascularization method varied by groups; while most patients (7689 [76.8%]) underwent endovascular treatment for their index LER for claudication, 360 Black women (85.3%) underwent endovascular treatment.

White men (26.1%) and White women (25.5%) were more likely to live in rural areas, whereas approximately 1 in 10 Black individuals (94 [10.4%]) and Hispanic individuals lived in rural areas ($P < .001$). When examining patients who had ADI data available, a high proportion of Hispanic men (34.7%) and women (36.1%) lived in the least-deprived neighborhoods, whereas a high proportion of Black men (34.8%) and women (33.9%) lived in the most deprived areas ($P < .001$).

Progression to CLTI

There were significant differences noted throughout the duration of follow-up between the groups in terms of progression to CLTI after index LER for claudication (**Figure 2**). Median (IQR) progression to CLTI within 180 days after index LER for claudication was 5.4% (4.9%-6.0%) among men and 6.5% (5.8%-7.4%) among women (**Table 2**). There were ethnoracial differences in median (IQR) percentage disease progression among men, with 7.2% (5.1%-10.0%) of Black men, 8.8% (5.1%-15.0%) of Hispanic men, and 5.2% (4.6%-5.8%) of White men

Table 2. Event Rates for Outcomes After Lower-Extremity Revascularization for Claudication Within the Vascular Quality Initiative Vascular Implant Surveillance and Interventional Outcomes Network (VQI-VISION), 2016-2019

	Median (IQR), %				
			Non-Hispanic		
Outcome	Overall	Hispanic	Black	White	*P* value
Progression to CLTI, male					
180 d	5.4 (4.9-6.0)	8.8 (5.1-15.0)	7.2 (5.1-10.0)	5.2 (4.6-5.8)	.05
1 y	9.7 (8.9-10.5)	13.1 (8.3-20.3)	13.7 (10.6-17.5)	9.2 (8.4-10.1)	.01
Progression to CLTI, female					
180 d	6.5 (5.8-7.4)	3.8 (1.2-11.2)	11.8 (9.0-15.4)	5.9 (5.1-6.8)	<.001
1 y	11.1 (10.0-12.2)	11.4 (5.8-21.6)	18.7 (15.1-23.2)	10.1 (9.0-11.3)	<.001
Major amputation, male					
180 d	0.2 (0.1-0.3)	0 (0-0)	0.7 (0.2-2.2)	0.1 (0.1-0.3)	.03
1 y	0.3 (0.2-0.5)	0 (0-0)	1.0 (0.4-2.7)	0.3 (0.2-0.5)	.047
Major amputation, female					
180 d	0.2 (0.1-0.4)	0 (0-0)	0.8 (0.3-2.4)	0.1 (0.1-0.4)	.03
1 y	0.4 (0.3-0.8)	0 (0-0)	0.8 (0.3-2.4)	0.4 (0.2-0.7)	.42
Any amputation, male					
180 d	0.4 (0.2-0.6)	0 (0-0)	0.9 (0.3-2.4)	0.3 (0.2-0.5)	.11
1 y	1.1 (0.8-1.4)	0 (0-0)	2.1 (1.0-4.1)	1.0 (0.8-1.4)	.08
Any amputation, female					
180 d	0.4 (0.2-0.6)	0 (0-0)	0.8 (0.2-2.4)	0.3 (0.2-0.6)	.35
1 y	0.8 (0.5-1.2)	0 (0-0)	1.3 (0.6-3.2)	0.7 (0.5-1.1)	.30
Reintervention, male					
180 d	19.9 (18.9-20.9)	22.3 (16.2-30.2)	22.1 (18.6-26.2)	19.6 (18.6-20.7)	.45
1 y	27.6 (26.4-28.9)	33.7 (26.2-42.7)	33.4 (29.0-38.2)	27.0 (25.7-28.3)	.03
Reintervention, female					
180 d	19.3 (18.0-20.6)	13.6 (7.7-23.4)	24.0 (20.1-28.6)	18.8 (17.5-20.3)	.03
1 y	27.9 (26.4-29.4)	27.8 (18.8-40.1)	33.5 (28.9-38.6)	27.2 (25.6-28.8)	.03
Mortality, male					
180 d	2.6 (2.2-3.1)	0.7 (0.1-4.7)	2.4 (1.3-4.3)	2.7 (2.3-3.2)	.35
1 y	5.1 (4.5-5.7)	2.5 (0.8-7.5)	5.4 (3.6-8.1)	5.1 (4.6-5.8)	.38
Mortality, female					
180 d	2.4 (1.9-2.9)	1.2 (0.2-8.3)	1.8 (0.9-3.7)	2.5 (2.0-3.1)	.56
1 y	4.8 (4.2-5.6)	3.0 (0.7-11.5)	2.7 (1.5-5.0)	5.2 (4.4-6.1)	.10

Abbreviation: CLTI, chronic limb-threatening ischemia.

progressing to CLTI within 180 days after their index LER for claudication (P = .05). Median (IQR) progression to CLTI at 1 year after index LER was lowest among White men (9.2% [8.4%-10.1%]) and White women (10.1% [9.0%-11.3%]) and highest among Black men (13.7% [10.6%-17.5%]; P = .01) and Black women (18.7% [15.1%-23.2%]; P < .001).

On univariate Cox regression analysis, the risk of progression to CLTI within 180 days after index LER for claudication did not significantly differ when comparing Black men to White men (hazard ratio [HR], 1.40; 95% CI, 0.97-2.01; P = .07) or when comparing Hispanic men to White men (HR, 1.67; 95% CI, 0.93-2.97; P = .08). There were no significant differences between Hispanic women and White women in terms of progression to CLTI within 180 days after index LER. Black women, however, were twice as likely to progress to CLTI within 180 days after index LER for claudication (HR, 2.06; 95% CI, 1.49-2.84; P < .001) than White women. Patients with diabetes or congestive heart failure were less likely to progress to CLTI within 180 days after index LER for claudication, but those undergoing dialysis (compared to those with an estimated glomerular filtration rate >60 mL/min/1.73 m^2) were more likely to progress to CLTI within 180 days after index LER for claudication (eTable 2 in Supplement 1).

On multivariable Cox regression analysis, Black men, compared to White women, remained significantly more likely to progress to CLTI within 180 days after index LER for claudication after controlling for age, comorbidities, anatomic segment of disease treated, and GDMT use (adjusted HR [aHR], 1.56; 95% CI, 1.11-2.19; P = .01) (**Table 3**). This remained true for the outcome of progression to CLTI within 1 year as well (aHR, 1.51; 95% CI, 1.14-1.99; P = .004) (Table 3). The risk for progression to CLTI at 180 days and 1 year were both similar between Black men and White men.

Among those who underwent aortoiliac revascularization with or without more distal concomitant revascularization, progression to CLTI was similar among Black men and White men at 1 year, as well as among Black women and White women at 1 year. For those who underwent infrainguinal re-

Table 3. Multivariable Cox Regression Model Examining Intersectional Identity and Progression to Chronic Limb-Threatening Ischemia

	Non-Hispanic Black			
	Male		Female	
Model[a]	180 d	1 y	180 d	1 y
Model 1[b]				
aHR (95% CI)	1.29 (0.89-1.87)	1.38 (1.04-1.84)	1.97 (1.42-2.72)	1.90 (1.46-2.49)
P value	.18	.03	<.001	<.001
Model 2[c]				
aHR (95% CI)	1.25 (0.86-1.82)	1.31 (0.98-1.75)	1.76 (1.26-2.46)	1.68 (1.28-2.20)
P value	.24	.07	.001	<.001
Model 3[d]				
aHR (95% CI)	1.25 (0.86-1.80)	1.31 (0.99-1.75)	1.96 (1.42-2.71)	1.83 (1.40-2.39)
P value	.25	.06	<.001	<.001
Model 4[e]				
aHR (95% CI)	1.36 (0.94-1.97)	1.45 (1.09-1.93)	2.11 (1.53-2.91)	1.99 (1.53-2.59)
P value	.10	.01	<.001	<.001
Model 5[f]				
aHR (95% CI)	1.10 (0.75-1.60)	1.14 (0.85-1.53)	1.56 (1.11-2.19)	1.51 (1.14-1.99)
P value	.64	.37	.01	.004

Abbreviation: aHR, adjusted hazards ratio.

[a] Adjustments made within each model. Non-Hispanic White was referent for all models.

[b] Model 1: age (<65 years, 65-79 years, >80 years).

[c] Model 2: diabetes, congestive heart failure, chronic kidney disease and dialysis dependence, smoking status (prior/current vs never).

[d] Model 3: anatomic segment treated during index lower-extremity revascularization (aortoiliac only, aortoiliac with any other segment, femoropopliteal only, femoropopliteal and tibial, and/or tibial only).

[e] Model 4: guideline-directed medical therapy (preoperative antiplatelet/statin, postoperative antiplatelet/statin, other medications including antihypertensives, cilostazol, anticoagulation).

[f] Model 5: models 1-4 combined.

vascularization, Black women were significantly more likely to progress to CLTI compared to White women at 1 year (aHR, 1.49; 95% CI, 1.07-2.08, *P* = .02) (eTable 3 in Supplement 1).

Reintervention

During follow-up, reintervention rates among Black men, Hispanic men, and White men were 38.07, 38.34, and 29.98 reinterventions per 100 person-years, respectively (*P* = .007). The reintervention rates among Black women, Hispanic women, and White women were 42.72, 34.50, and 31.53 reinterventions per 100 person-years, respectively (*P* = .003). On Kaplan-Meier analysis, there were no significant differences noted in the risk of reintervention at 180 days after index LER among men (*P* = .45), but significant differences were noted among women (Black women: 24.0%; Hispanic women: 13.6%; White women: 18.8%; *P* = .03). Significant differences between the risk of reintervention at 1 year after index LER were noted in male (*P* = .02) and female (*P* = .03) groups (Table 2).

Amputation

We examined minor and major amputations after index LER for claudication, given that any amputation after an LER for claudication would be unexpected (Table 2). On Kaplan-Meier analysis, among men, the risk of 180-day major amputation ranged from 0.7% for Black men, 0% for Hispanic men, and 0.1% for White men (*P* = .03) and 1.0%, 0%, and 0.3% at 1 year (*P* = .047), respectively. White women had a major amputation event risk of 0.1% at 180 days after LER for claudication compared to Black women (0.8%) and Hispanic women (0%) (*P* = .03), but there were no significant differences noted for 1-year risk of major amputation. For any amputation, there were no significant differences noted among men or women at 180 days (*P* = .11 vs *P* = .35) or 1 year (*P* = .08 vs *P* = .29).

Discussion

We used VQI-VISION data to examine outcomes in patients with claudication and observed 3 important findings that may prompt further study to better characterize intersectional identity-based disparities in PAD. First, for all comers, progression to CLTI was not an uncommon event. Second, nearly 1 in 5 Black women progressed to CLTI within 180 days after an index LER for claudication. Finally, 1 in 4 Black patients with claudication was under the age of 65 years when they underwent an index LER for claudication in the VQI-VISION dataset.

Historical data suggest that progression from claudication to CLTI is rare.[17,18] Taylor and colleagues[19] reported a low rate of procedural complications and improved quality of life in a single-center cohort of 1000 consecutively treated patients with claudication and therefore recommended that proceduralists be more aggressive with offering LER for claudication. Notably, 70% of their patient population had aortoiliac disease treated, which, similar to our findings, has a relatively low associated risk for progression to CLTI after LER for claudication. In a more recent single-center study with 1051 patients, LER for claudication was associated with a higher rate of CLTI progression compared to those who had nonoperative claudication management.[10] In fact, a meta-analysis examining 35 studies comparing LER vs nonoperative management of claudication found that up to 21% progressed to CLTI over the subsequent 5 years.[8] Other established risk factors for progression to CLTI after a diagnosis of claudication include comorbidities (eg, diabetes, end-stage kidney disease receiving dialysis), patient behaviors (eg, tobacco abuse), and proceduralist practice patterns (eg, early intervention, tibial intervention, multiple reinterventions).[7,11,20]

It is well established that race- and sex-based disparities exist in PAD prevalence, treatment, and outcomes.[12,21] For example, PAD prevalence is highest among men and Black patients,[22] and Black and Hispanic patients with PAD have the highest rates of major amputation compared to White patients[23-25]; practice patterns vary for infrainguinal revascularization, with women being more likely to receive angioplasty without stenting.[26] In addition, women tend to have lower amputation rates than men.[27] In the current study, we observed that women with claudication had higher rates of progression to CLTI and reintervention at 180 days and 1 year compared to men with claudication. Our study took the examination of progression to CLTI among patients with claudication a step further to better understand intersectional ethnoracial and gender identity and its association with progression to CLTI. We found that Black women with claudication had the highest risk for CLTI progression at both 180 days and at 1 year. Vascular clinicians' awareness of intersectional disparities in claudication outcomes will augment their ability to appropriately counsel patients regarding their individualized risks for adverse outcomes.

Our work also encourages future investigators to delineate which populations are at highest risk for specific adverse outcomes, determine causative factors, and develop more precise interventions relevant for that population. For example, in our study of VQI-VISION data, 1 in 4 Black patients with claudication were under the age of 65 years. Patients with premature PAD have a more aggressive disease course, with worse limb outcomes and higher rates of cardiovascular events.[28] In our study, women under the age of 65 years had higher risk of disease progression compared to women over age 65 years, and, as mentioned, Black women had the highest risk. This may suggest that premature PAD is a major driver of disease progression, particularly in Black women, and future investigations should study potential interactions there, as well the population-level distribution of inflammatory and prothrombotic biomarkers that have been implicated in premature PAD.

While studies investigating genetic, biologic, and social causes for disease progression in claudication are warranted, there is also a need to further examine practice patterns and clinician behavior. Several studies documented wide variation in claudication care practices that can lead to poor outcomes including, but not limited to, early PVI (LER performed within 6 months of a new claudication diagnosis), tibial interventions, and overutilization of LER in particular sites of service or certain communities.[29-32] Other work demonstrates that early LER as well as multiple reinterventions for claudication are drivers of progression to CLTI.[7,11] While some sites of service may provide greater access to care, particularly to individuals from racial and ethnic minoritized communities, there is evidence that this care is more likely to be considered inappropriate (ie, risk outweighs benefit) per the key principles outlined in the Society for Vascular Surgery appropriate use criteria for management of intermittent claudication.[33-35]

Limitations

There are several limitations to consider when interpreting our results. A new diagnosis code for CLTI after LER for claudication is a surrogate method for defining patient progression to CLTI during the study period; however, this method may not capture every patient who develops ischemic rest pain, nonhealing wounds, or gangrene after LER for claudication, nor does it elucidate the mechanism driving CLTI development. This validated approach, however, has been widely implemented and is the best surrogate method available to conduct this analysis with a large administrative dataset. We examined patients who received LER at VQI-participating centers with linkage to Medicare claims data in order to reduce loss to follow-up and improve identification of adverse outcomes therein. It is very possible this study is not generalizable to non-VQI patients who do not receive Medicare coverage. However, there is currently no better available dataset that captures the granular details present in the VQI that would allow us to examine this question in patients with claudication receiving their care at non-VQI-participating centers. Neither VQI nor Medicare claims data indicate if reinterventions are planned or staged or unplanned secondary to restenosis or loss of patency.

Conclusions

Per the results of this national cohort study, Black women with claudication had the highest rate of progression to CLTI after LER. Lack of adherence to established appropriate use criteria, overutilization, and/or early LER among those with claudication may perpetuate disparate care. Given the preponderance of evidence and societal guidelines describing the value of exercise therapy as first-line treatment for claudication and established poor equitable application of GDMT, there is a critical need to develop evaluative metrics at the payor and policy level that ensure that all patients with claudication receive the equitable care they deserve.

ARTICLE INFORMATION

Accepted for Publication: October 21, 2025.

Published Online: December 17, 2025. doi:10.1001/jamasurg.2025.5556

Author Affiliations: Surgical and Perioperative Care, Atlanta VA Health Care System, Decatur, Georgia (Alabi); Division of Vascular Surgery and Endovascular Therapy, Department of Surgery, Emory University School of Medicine, Atlanta, Georgia (Alabi, Rokosh); Department of Population Health Sciences, Weill Cornell Medical College, New York, New York (Zheng, Mao); Johns Hopkins University School of Medicine, Baltimore, Maryland (Hicks); Birmingham VA Health Care System, Birmingham, Alabama (Spangler); University of Alabama at Birmingham (Spangler); Wake Forest University School of Medicine, Winston-Salem, North Carolina (Velazquez); Howard University College of Medicine, Washington, DC (Hughes); Geisel School of Medicine at Dartmouth, Hanover, New Hampshire (Goodney); Stanford University School of Medicine, Palo Alto, California (George, Arya); The Ohio State University College of Medicine, Columbus (Corriere).

Author Contributions: Ms Zheng and Dr Mao had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.
Concept and design: Alabi, Goodney, George, Arya, Corriere.
Acquisition, analysis, or interpretation of data: All authors.
Drafting of the manuscript: Alabi, Rokosh, Zheng,

Mao, Goodney, Corriere.
Critical review of the manuscript for important intellectual content: All authors.
Statistical analysis: Zheng, Goodney, Mao.
Administrative, technical, or material support: Alabi, Rokosh, Velazquez-Ramirez, Goodney, George, Corriere.
Supervision: Alabi, Corriere.

Conflict of Interest Disclosures: Dr Hicks reported speaker's bureau fees from Cook Medical and W. L. Gore; consultant fees from Boston Scientific; and career development awards from the American College of Surgeons and the US National Institute of Diabetes and Digestive and Kidney Diseases outside the submitted work. Dr Spangler reported grants from the VA Rehabilitation Research and Development (I01RX003965-01A2; telehealth-delivered home-based walking for vets with peripheral artery disease [TREK-PAD]; principal investigator: EA Jackson) outside the submitted work. Dr Arya reported grants from VA Health Systems Research and serving as a consultant for Gore Medical outside the submitted work. Dr Corriere reported personal fees from serving as a US Food and Drug Administration panelist outside the submitted work. No other disclosures were reported.

Funding/Support: This study was funded by grants from the US Veterans Affairs (Alabi: VA VISN7 Research Development Award), the National Heart, Lung, and Blood Institute (Mao: K01HL159315), the VA Health Systems Research (Arya: IIR Merit 20-077; I01HX003215-01A1), and American Heart Association Transformational Project Award (25TPA1479692).

Role of the Funder/Sponsor: The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

Meeting Presentation: This paper was presented at the plenary session of the Association of VA Surgeons; April 8, 2025; Atlanta, Georgia.

Disclaimer: The opinions expressed in this article are those of the authors and do not necessarily reflect the position or policy of the US Department of Veterans Affairs or the US government.

Data Sharing Statement: See Supplement 2.

REFERENCES

1. Criqui MH, Matsushita K, Aboyans V, et al; American Heart Association Council on Epidemiology and Prevention; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Radiology and Intervention; Council on Lifestyle and Cardiometabolic Health; Council on Peripheral Vascular Disease; and Stroke Council. Lower extremity peripheral artery disease: contemporary epidemiology, management gaps, and future directions: a scientific statement from the American Heart Association. *Circulation*. 2021;144(9):e171-e191. doi:10.1161/CIR.0000000000001005

2. Sigvant B, Wiberg-Hedman K, Bergqvist D, et al. A population-based study of peripheral arterial disease prevalence with special focus on critical limb ischemia and sex differences. *J Vasc Surg*. 2007;45(6):1185-1191. doi:10.1016/j.jvs.2007.02.004

3. Duff S, Mafilios MS, Bhounsule P, Hasegawa JT. The burden of critical limb ischemia: a review of recent literature. *Vasc Health Risk Manag*. 2019;15:187-208. doi:10.2147/VHRM.S209241

4. Fowkes FG, Rudan D, Rudan I, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet*. 2013;382(9901):1329-1340. doi:10.1016/S0140-6736(13)61249-0

5. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC guideline on the management of patients with lower extremity peripheral artery disease: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation*. 2017;135(12):e686-e725. doi:10.1161/CIR.0000000000000470

6. Jones WS, Patel MR, Dai D, et al. Temporal trends and geographic variation of lower-extremity amputation in patients with peripheral artery disease: results from U.S. Medicare 2000-2008. *J Am Coll Cardiol*. 2012;60(21):2230-2236. doi:10.1016/j.jacc.2012.08.983

7. Sorber R, Dun C, Kawaji Q, et al. Early peripheral vascular interventions for claudication are associated with higher rates of late interventions and progression to chronic limb threatening ischemia. *J Vasc Surg*. 2023;77(3):836-847.e3. doi:10.1016/j.jvs.2022.10.025

8. Sigvant B, Lundin F, Wahlberg E. The risk of disease progression in peripheral arterial disease is higher than expected: a meta-analysis of mortality and disease progression in peripheral arterial disease. *Eur J Vasc Endovasc Surg*. 2016;51(3):395-403. doi:10.1016/j.ejvs.2015.10.022

9. Rymer JA, Mulder H, Narcisse DI, et al. Association of disease progression with cardiovascular and limb outcomes in patients with peripheral artery disease: insights from the EUCLID trial. *Circ Cardiovasc Interv*. 2020;13(10):e009326. doi:10.1161/CIRCINTERVENTIONS.120.009326

10. Madabhushi V, Davenport D, Jones S, et al. Revascularization of intermittent claudicants leads to more chronic limb-threatening ischemia and higher amputation rates. *J Vasc Surg*. 2021;74(3):771-779. doi:10.1016/j.jvs.2021.02.045

11. Kim TI, Kiwan G, Mohamedali A, et al. Multiple reinterventions for claudication are associated with progression to chronic limb-threatening ischemia. *Ann Vasc Surg*. 2021;72:166-174. doi:10.1016/j.avsg.2020.10.004

12. McDermott MM, Ho KJ, Alabi O, et al. Disparities in diagnosis, treatment, and outcomes of peripheral artery disease: JACC scientific statement. *J Am Coll Cardiol*. 2023;82(24):2312-2328. doi:10.1016/j.jacc.2023.09.830

13. The Vascular Quality Initiative. Accessed January 12, 2022. https://www.vascularqualityinitiative.org/

14. Mao J, Moore KO, Columbo JA, Mehta KS, Goodney PP, Sedrakyan A. Validation of an indirect linkage algorithm to combine registry data with Medicare claims. *J Vasc Surg*. 2022;76(1):266-271.e2. doi:10.1016/j.jvs.2022.01.132

15. Ghaferi AA, Schwartz TA, Pawlik TM. STROBE Reporting Guidelines for Observational Studies. *JAMA Surg*. 2021;156(6):577-578. doi:10.1001/jamasurg.2021.0528

16. Bose S, Stonko DP, Kiang SC, et al. Validation of *ICD-10* codes to distinguish between claudication and chronic limb-threatening ischemia in patients undergoing peripheral vascular intervention using Medicare-matched registry data. *Circ Cardiovasc Qual Outcomes*. 2025;18(7):e011467. doi:10.1161/CIRCOUTCOMES.124.011467

17. Peabody CN, Kannel WB, McNamara PM. Intermittent claudication. surgical significance. *Arch Surg*. 1974;109(5):693-697. doi:10.1001/archsurg.1974.01360050087019

18. McAllister FF. The fate of patients with intermittent claudication managed nonoperatively. *Am J Surg*. 1976;132(5):593-595. doi:10.1016/0002-9610(76)90351-2

19. Taylor SM, Kalbaugh CA, Healy MG, et al. Do current outcomes justify more liberal use of revascularization for vasculogenic claudication? a single center experience of 1,000 consecutively treated limbs. *J Am Coll Surg*. 2008;206(5):1053-1062. doi:10.1016/j.jamcollsurg.2007.12.033

20. Froud JLJ, Landin M, Wafi A, et al. Rate and predictors of disease progression in patients with conservatively managed intermittent claudication: a systematic review. *Ann Vasc Surg*. 2025;112:183-192. doi:10.1016/j.avsg.2024.12.009

21. Kim ESH, Arya S, Bryce Y, et al; American Heart Association Council on Peripheral Vascular Disease; Council on Cardiovascular and Stroke Nursing; Council on Clinical Cardiology; Council on Genomic and Precision Medicine; Council on Quality of Care and Outcomes Research; and Stroke Council. Sex differences in peripheral vascular disease: a scientific statement from the American Heart Association. *Circulation*. 2025;151(14):e877-e904. doi:10.1161/CIR.0000000000001310

22. Allison MA, Ho E, Denenberg JO, et al. Ethnic-specific prevalence of peripheral arterial disease in the United States. *Am J Prev Med*. 2007;32(4):328-333. doi:10.1016/j.amepre.2006.12.010

23. Shaw PM, Chandra V, Escobar GA, Robbins N, Rowe V, Macsata R. Controversies and evidence for cardiovascular disease in the diverse Hispanic population. *J Vasc Surg*. 2018;67(3):960-969. doi:10.1016/j.jvs.2017.06.111

24. Chen L, Zhang D, Shi L, Kalbaugh CA. Disparities in peripheral artery disease hospitalizations identified among understudied race-ethnicity groups. *Front Cardiovasc Med*. 2021;8:692236. doi:10.3389/fcvm.2021.692236

25. Barshes NR, Sharath S, Zamani N, Smith K, Serag H, Rogers SO. Racial and geographic variation in leg amputations among Texans. *Tex Public Health J*. 2018;70(3):22-27.

26. Ramkumar N, Suckow BD, Brown JR, et al. Role of sex in determining treatment type for patients undergoing endovascular lower extremity revascularization. *J Am Heart Assoc*. 2019;8(17):e013088. doi:10.1161/JAHA.119.013088

27. Ramkumar N, Suckow BD, Behrendt CA, et al. Association between sex and long-term outcomes of endovascular treatment for peripheral artery disease. *Catheter Cardiovasc Interv*. 2023;101(5):877-887. doi:10.1002/ccd.30617

28. Mehta A, Dhindsa DS, Hooda A, et al. Premature atherosclerotic peripheral artery disease: An underrecognized and undertreated disorder with a rising global prevalence. *Trends*

Cardiovasc Med. 2021;31(6):351-358. doi:10.1016/j.tcm.2020.06.005

29. Hicks CW, Wang P, Bruhn WE, et al. Race and socioeconomic differences associated with endovascular peripheral vascular interventions for newly diagnosed claudication. *J Vasc Surg*. 2020;72(2):611-621.e5. doi:10.1016/j.jvs.2019.10.075

30. Bose S, Dun C, Sorber R, et al. Practice patterns surrounding the use of tibial interventions for claudication in the Medicare population. *J Vasc Surg*. 2023;77(2):454-462.e1. doi:10.1016/j.jvs.2022.08.033

31. Dun C, Stonko DP, Bose S, et al. Trends and factors associated with peripheral vascular interventions for the treatment of claudication from 2011 to 2022: a national Medicare cohort study. *J Am Heart Assoc*. 2024;13(14):e033463. doi:10.1161/JAHA.123.033463

32. Bose S, McDermott KM, Dun C, et al. Infrapopliteal endovascular interventions for claudication are associated with poor long-term outcomes in Medicare-matched registry patients. *Ann Surg*. Published online June 6, 2024. doi:10.1097/SLA.0000000000006368

33. Tsou TC, Dun C, Bose S, et al. Practice patterns of peripheral vascular interventions for peripheral artery disease in the office-based laboratory setting versus outpatient hospital. *J Vasc Surg*. 2024;80(5):1525-1536.e7. doi:10.1016/j.jvs.2024.06.006

34. Woo K, Siracuse JJ, Klingbeil K, et al; Society for Vascular Surgery Appropriateness Committee. Society for Vascular Surgery appropriate use criteria for management of intermittent claudication. *J Vasc Surg*. 2022;76(1):3-22.e1. doi:10.1016/j.jvs.2022.04.012

35. Bath J, Lawrence PF, Neal D, et al. Endovascular interventions for claudication do not meet minimum standards for the Society for Vascular Surgery efficacy guidelines. *J Vasc Surg*. 2021;73(5):1693-1700.e3. doi:10.1016/j.jvs.2020.10.067