



Association of Race with Long-Term Outcomes in Patients Undergoing Popliteal and Infra-Popliteal Percutaneous Peripheral Arterial Interventions

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ABSTRACT

Background: Race-related differences in clinical features, presentation, treatment and outcomes of patients with various cardiovascular diseases have been reported in previous studies. However, the long-term outcomes in black versus white patients with popliteal and/or infra-popliteal peripheral arterial disease (PAD) undergoing percutaneous peripheral vascular interventions (PVI) are not well known.

Methods and results: We retrospectively evaluated long-term outcomes in 696 patients (263 blacks and 433 whites) who underwent PVI for popliteal and/or infra-popliteal PAD at our institution between 2007 and 2012. When compared to white patients, black patients were younger (70 ± 11 vs. 72 ± 11 ; $P = 0.002$) and had more comorbidities: higher creatinine (2.04 ± 2.08 vs. 1.33 ± 1.16 ; $P < 0.0001$) with more ESRD (19% vs. 6%; $P < 0.0001$) and more diabetes (64% vs. 55%; $P = 0.004$). At mean follow-up of 36 ± 20 months, there was no statistically significant difference between black and white patients either in all-cause mortality (29% vs. 32%; $P = 0.38$) or in major amputation (4.4% vs. 4.2%; $P = 0.88$), respectively. In a multi-variate Cox proportional hazard model, repeat ipsilateral percutaneous revascularization or bypass were lower in black patients (HR = 0.64 [95% CI 0.46–0.89]; $P = 0.007$) and major adverse vascular events (MAVE) were lower in black patients as well (HR = 0.7 [95% CI 0.56–0.89]; $P = 0.003$).

Conclusion: Black patients undergoing popliteal or infra-popliteal PVI had similar mortality and major amputation, but lower repeat revascularization and MAVE compared to white patients. These data support the use of PVI in minorities despite higher baseline comorbidities and call for more research to understand the mechanisms underlying the high mortality irrespective of race.

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1. Introduction

Atherosclerosis involving popliteal and infra-popliteal vessels alone or in addition to the more proximal ileo-femoral bed is more likely to result in limb-threatening ischemia, subsequently increasing the risk of amputation and tissue loss. In the United States, between 150,000 and 300,000 cases of critical limb ischemia (CLI) are diagnosed every year [1]. These patients have restricted mobility [2], and higher morbidity leading to higher utilization of economic resources [3,4]. At one-year post-diagnosis, 30% of CLI patients will

have a major amputation and 25% will die; at three years, the mortality rate reaches 60% [5].

Race-related differences in PAD have been described in relation to underlying comorbidities [6], risk of amputation [7,8], pre-operative testing before amputation [9], graft patency [10,11], and short as well as long-term outcomes [12,13] in surgically re-vascularized patients.

Despite technological advances to treat small vessel PAD and salvage limbs with endovascular techniques [14–16], racial differences in outcomes remain. In the National Inpatient Sample (NIS) database, black subjects made up a higher proportion of patients admitted for CLI and undergoing amputation, with a lower proportion undergoing revascularization [8]. The same pattern was also seen across US Medicare beneficiaries [17]. In addition, infra-popliteal interventions were reported to be more frequent in blacks compared to whites (62.6% vs 44.3% respectively) [18]. The clinical efficacy of such interventions was proven in multiple studies [19–21]. However, these studies were done in

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homogenous ethnic groups in Japan and Finland [22]. The goal of this study was to investigate the association of race with long-term outcomes in patients undergoing popliteal and infra-popliteal peripheral arterial interventions.

2. Methods

2.1. Study population

We evaluated all patients enrolled in the Laser in infra-popliteal and popliteal stenosis (LIPS) study who were treated at a single tertiary hospital. Details of this study have been previously published [23,24]. In summary, we retrospectively reviewed clinical information in 731 who underwent endovascular revascularization with laser-assisted balloon angioplasty or balloon angioplasty in the popliteal and/or infra-popliteal vessels between 2007 and 2012 in the Saint John Hospital and Medical Center cardiac catheterization laboratory. The primary indication for the PVI was claudication or CLI. Patients younger than 18 years old and those of other or unknown race ($n = 35$) were excluded. Of the remaining 696 patients that were analyzed, 263 (37.8%) were black and 433 (62.2%) white. The use of laser or balloon angioplasty was left to the discretion of the operator. Commonly used laser devices included the Turbo Elite 0.9 to 2.3 mm and the Turbo Tandem 2.0 (Spectranetics Corporation). Balloon angioplasty was performed using a variety of catheters. Use of secondary prevention medications (statins and antihypertensive medications for hypertensive patients) and life style changes (exercise and smoking cessation) was expected to be in compliance with guidelines [25]. Mean follow-up was 36 ± 20 months. This study was approved by the Institutional Review Board at the Saint John Hospital and Medical Center (IRB number is 347173).

2.2. Data collection

Data on demographic characteristics and medical histories were abstracted by reviewing the electronic medical records. Baseline lesion characteristics and procedural outcomes (angiographic endpoints) were obtained by reviewing patients' angiograms and procedural operative reports. Disease severity was classified according to the guideline from the Inter-Society Consensus for the management of peripheral artery diseases (TASC II) [5]. Long-term outcomes were collected by review of electronic medical records and follow-up phone calls to patients or their secondary contact listed on their demographic information. In a few patients, mortality data were also obtained from online public database using patients' names and social security numbers (<http://www.genealogybank.com/gbnk/ssdi>).

2.3. Definitions and outcomes

Major amputation was defined as any amputation at or above the ankle. Minor amputation is defined as any amputation of mid foot or toes. The primary outcome was survival free of ipsilateral major limb amputation. Secondary outcomes included all ipsilateral limb major or minor amputations, need for repeat revascularization (by PVI) or bypass surgery of the ipsilateral limb, and all-cause mortality. Major Adverse Vascular Events (MAVE) defined as a composite of death, major amputation and repeat revascularization or bypass.

2.4. Statistical analysis

Univariate analysis was done using Student's *t*-test, analysis of variance and chi-squared analysis as appropriate. Multivariable analysis was done using Cox proportional hazards models. Factors on univariate analysis that were found to be statistically significantly associated with each outcome were included in the multivariable analysis. All data were

analyzed using SPSS v. 24.0 and a *P*-value of 0.05 or less was considered to indicate statistical significance.

3. Results

3.1. Baseline characteristics

Table 1 shows the differences in demographic and clinical characteristics by race of the 696 patients in the study. Women accounted for more than half the patients among blacks and only 40% among whites. Despite being younger black patients had more comorbidities including higher body mass index, higher creatinine, higher HgA1C, more hypertension and more end-stage renal disease.

3.2. PAD description, treatment and burden

Laser-assisted balloon angioplasty was utilized more in black compared with white patients (63.9% vs. 48.75, $p < 0.001$). Table 2 shows anatomical description and severity of the disease in both groups. Black patients underwent less prior bypass and had more distal branches involved with no difference in frequency of TASC D lesions between the two groups.

3.3. Long-term outcomes

Table 3 shows long-term outcomes in both groups. At mean follow up of 36 ± 20 months, the primary outcome of ipsilateral major amputation was similar between blacks and whites (4.2% vs. 4.4%; $P = 0.88$). All-cause mortality rate also was similar in the 2 cohorts (28.9% vs. 32.1%; $P = 0.38$). The need for subsequent surgical bypass after the index intervention was similarly low in both groups. Composite of repeat revascularization or bypass was lower in black patients (20.5% vs. 27.3%; $P = 0.046$). The composite outcome of MAVE was also lower in blacks (43.1% vs. 52.4%; $P = 0.02$).

3.4. The influence of race on repeat revascularization or bypass

Table 4 shows an adjusted multi-variable analysis for repeat revascularization or bypass using Cox proportional hazards model.

Table 1
Baseline characteristics.

Variable	Black ($n = 263$)	White ($n = 433$)	<i>P</i> Value ^a
Sex, n % (male)	113(43%)	263 (60.7%)	< 0.0001
Age, Y	70 \pm 11	72 \pm 11	0.002
Body Mass Index, kg/m ²	29 \pm 7	28 \pm 6	0.003
Creatinine, mg/dl	2.04 \pm 2.08	1.33 \pm 1.16	< 0.0001
Glomerular filtration rate ^a , ml/min/1.73 m ²	59 \pm 36	64 \pm 29	0.119
Hemoglobin, mg/dl	12.0 \pm 1.7	12.4 \pm 1.9	0.004
HgA1c, mg/dl	7.2 \pm 1.9	6.8 \pm 1.3	0.022
DM, n %	168 (64%)	235 (55%)	0.016
Insulin use, n %	100 (60%)	137 (58%)	0.805
CVA, n %	69 (27%)	105 (25%)	0.581
CAD, n %	174 (67%)	301 (71%)	0.304
Hypertension, n %	257 (99%)	407 (96%)	0.017
CHF, n %	68 (26%)	115 (27%)	0.809
Atrial fibrillation, n %	34 (13%)	102 (24%)	0.001
CABG, n %	49(19%)	140 (33%)	< 0.0001
Hyperlipidemia, n %	250 (96%)	406 (95%)	0.598
ESRD, n %	49 (19%)	26 (6%)	< 0.0001
Smoking, n %	169 (65%)	293 (69%)	0.306

DM diabetes mellitus; HgA1c, glycosylated hemoglobin; CVA, cerebrovascular disease; CAD, coronary artery disease; CHF, congestive heart failure; CABG, coronary artery bypass grafting; ESRD, end-stage renal disease.

Statistically significant *P* values are in bold.

^a *P* value for global difference.

^a The Modification of Diet in Renal Disease (MDRD) study equation.

Table 2
Disease description.

Variable	Black (n = 263)	White (n = 433)	P value*
Prior peripheral bypass, n%	10 (3.8%)	33 (7.7%)	0.041
Prior contralateral limb amputation, n %	22 (8.5%)	43 (10.1%)	0.479
Anatomical Distribution			0.023
Popliteal lesions, n %	57 (21.7%)	110 (25.4%)	
Anterior tibial lesions, n %	88 (33.5%)	144 (33.3%)	
Peroneal, n %	32 (12.2%)	46 (10.6%)	
Posterior tibial, n %	45 (17.1%)	97 (22.4%)	
Tibioperoneal trunk, n %	41 (15.6%)	36 (8.3%)	
TASC D lesions ^a , n%	215 (81.7%)	349 (80.6%)	0.708

Statistically significant P values are in bold.

* P value for global difference.

^a Arterial lesions classified by Trans-Atlantic Inter-Society Consensus (TASC II).

Blacks had less repeat revascularization or bypass after adjustment (HR = 0.64 [95% CI 0.46 to 0.89]; P = 0.007) (Fig. 1).

3.5. The influence of race on MAVE

Table 5 presents an adjusted multi-variate cox proportional hazard model for MAVE. Blacks had lower MAVE (HR = 0.7 [95% CI 0.56 to 0.89]; P = 0.003) (Fig. 2).

4. Discussion

Our study results show that in a cohort of patients who underwent percutaneous PVI for popliteal and/or infra-popliteal disease, black patients were younger yet had more baseline comorbidities, less prior bypass and more distal branches involved compared with white patients. Despite that, blacks had similar rates of major and minor amputation as well as all-cause mortality but had lower incidence of repeat revascularization or bypass which was the primary cause for lower incidence of the composite endpoint of MAVE compared to whites.

While no prior study has evaluated race-related differences in long-term outcomes and comorbidities among blacks and whites with infra-popliteal PAD, some earlier studies have examined this in patients undergoing surgical, endovascular and PVI above the knee. Most of these studies have shown worse PAD and worse outcomes in blacks. Rivero et al. [18] in a study evaluating black and white men undergoing surgical and/or endovascular intervention reported a lower limb salvage rate at 5 years in blacks compared to whites. It was attributed to advanced ischemia and complicated anatomy at presentation. They demonstrated that black patients were more likely to undergo infra-popliteal intervention in addition to popliteal or supra-popliteal revascularization. Infra-popliteal intervention was an independent predictor of worse outcomes regardless of race. Loja et al. [26] used administrative data set from

Table 3
Long-term outcomes.

Outcomes	Black (n = 263)	White (n = 433)	P value*
Major amputation	11 (4.2%)	19 (4.4%)	0.880
Any amputation (including minor)	31 (11.8%)	52 (12%)	0.930
Major amputation or death	81 (30.8%)	150 (34.6%)	0.300
Repeat revascularization	52 (19.8%)	111 (25.6%)	0.070
Repeat surgical bypass			0.990
Fem-pop	3 (1.1%)	5 (1.2%)	
Other	1 (0.4%)	2 (0.5%)	
Repeat revascularization or bypass	54 (20.5%)	118 (27.3%)	0.046
Death	76 (28.9%)	139 (32.1%)	0.375
Critical limb ischemia-related hospitalization	57 (21.7%)	98 (22.4%)	0.520
MAVE	114 (43.1%)	227 (52.4%)	0.02

MAVE major adverse vascular events.

Statistically significant P values are in bold.

* P value for global difference.

Table 4
Multivariate cox regression analysis of repeat revascularization or bypass.

Variables	HR	95% CI		P value
		Lower	Upper	
Black race	0.64	0.46	0.89	0.007
CVA	1.46	1.06	2.02	0.02
Prior peripheral bypass	1.76	1.07	2.86	0.027
DM	1.40	1.02	1.93	0.037
Total pre ^a	1.14	1.08	1.21	<0.001

Statistically significant P values are in bold.

^a Pre-procedure total lesion severity (Yamasaki) score(23).

California (2005–2009) and showed that blacks even after adjustment for disease severity had worse amputation-free survival following endovascular therapy compared with white patients at 1 year (HR = 1.68 [95% CI 1.44–1.96]; P < 0.001). Additionally, the need for reintervention was higher in black patients (HR = 1.17 [95% CI 1.06–1.30]; P = 0.002). Selvarajah et al. [11] examined graft failure in infra-inguinal disease from (2005–2011) National Surgical Quality Improvement Program database and found that compared to whites, blacks presented with advanced disease, required more distal revascularization and had higher 30-day graft failure even after adjustment for disease severity (adjusted OR = 1.26 [95% CI 1.05–1.5]; P = 0.011). In contrast, Brothers et al. [27] looked at Society of Vascular Surgery Quality Initiative database (2003–2015) and reported that at a median follow up of 18 months, black patients undergoing infra-inguinal revascularization had better overall survival compared to white patients.

The similarities and differences between prior studies and ours need to be highlighted. While increase prevalence of comorbidities and extent of PAD in prior reports were similar to our study, prior reports evaluated race-related PVI outcomes focused on administrative data [11,26,27], studied mostly supra-popliteal PVI and included both surgical and endovascular treatment [11,18,26,27], were limited to male patients [18] and some reported a shorter follow-up [11].

In general, racial disparities in outcomes of PAD may be related to poorly studied and/or understood differences in genetic, biological, clinical, environmental, population-related and socio-economic factors including access to health care.

The clinical characteristics of our patients might offer some insights to explain these differences. At baseline, black patients were younger than white patients, which may have favorably influenced the need for repeat revascularization in black patients. Also, white patients had more prior leg bypass surgery, which could have affected the operator's decision-making threshold for ipsilateral bypass or revascularization procedure. Black patients had more distal vessel lesions, which may have made them less attractive targets for repeat revascularization.

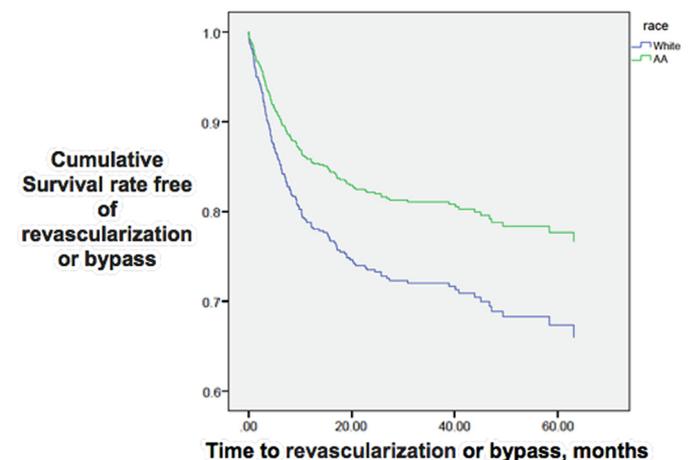


Fig. 1. Cumulative survival rate free of repeat revascularization or bypass curve.

Table 5
Multivariate cox regression analysis of major adverse vascular events (MAVE).

Variables	HR	95% CI		P value
		Lower	Upper	
Black race	0.70	0.56	0.89	0.003
CVA	1.41	1.11	1.80	0.005
CHF	1.41	1.12	1.79	0.004
Atrial fibrillation	1.31	1.02	1.68	0.04
DM	1.49	1.18	1.88	0.001
Prior contralateral limb amputation	1.67	1.19	2.34	0.003
Dissection during procedure	1.60	1.18	2.15	0.002

Statistically significant P values are in bold.

The differences in patient populations specifically as it relates to supra- versus infra-popliteal revascularization, with our study being the one that included the highest number of patients who underwent popliteal and infra-popliteal PVI, could be a reason to have these differences.

Nguyen et al. [28,29] suggested differences in biological factors and chronic inflammation are likely to play a role in this disparity and Kalinowski et al. [30] found more endothelial dysfunction during ongoing vascular disturbances in blacks. However, our dataset did not include data about inflammatory and/or endothelial dysfunction markers, so we can't adjust for that.

Socio-economic factors that include less access to healthcare and lower follow up rates rather than the true lower frequency of recurrent CLI is thought to be an important factor in these disparities [31,32]. This could be a reason why our black patients had less repeat revascularization or bypass. However, it is less likely to be a major factor with significant impact on outcomes since amputations and death rates were similar in our groups.

Revascularization has been previously shown to be associated with worse PAD outcomes and was less utilized in blacks compared to whites. However, our study showed similar major outcomes between blacks and whites who underwent popliteal and/or infra-popliteal PVI which calls for being more aggressive in treating this population and more research is essential to understand the complex and multi-factorial race-PAD interaction.

Finally, the data from the international haplotype map of the human genome [33] may provide information of race-related genetic differences which may further enhance our understanding of the racial differences in outcomes. Nevertheless, all these remain hypotheses to be proven by further studies.

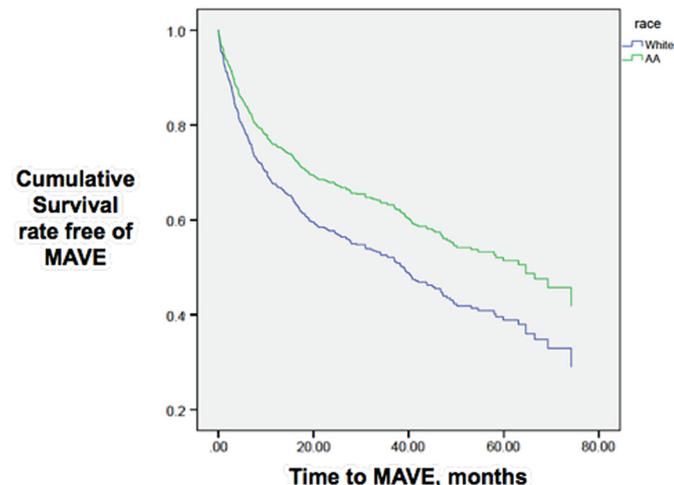


Fig. 2. Cumulative survival rate free of MAVE curve.

5. Limitations

This is a retrospective, observational, single-center study thus inference regarding causation is uncertain. We are unable to account for the influence of missing and unmeasured confounders. Our study findings are applicable to black patients compared with white patients undergoing PVI and should not be extrapolated to other racial and ethnic groups. We had only intermediate term data and longer follow up data is needed. We only evaluated popliteal and infra-popliteal disease and extrapolating to other arterial segments should be made with caution.

6. Conclusion

Black patients undergoing popliteal or infra-popliteal PVI had similar mortality and major amputation, but lower repeat revascularization or bypass compared to white patients. These data support the use of PVI in all patients including blacks and call for more research to understand the mechanisms underlying the high mortality irrespective of race so as to target strategies to improve this in patients with infra-popliteal PAD that otherwise have worse outcomes compared with supra-popliteal PVI.

Disclosures

The authors report no financial relationships or conflicts of interest regarding the content herein.

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