Racial differences in long-term outcomes among black and white patients with drug-eluting stents

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Background Some studies suggest that black patients may have worse outcomes after drug-eluting stent (DES) placement. There are limited data characterizing long-term outcomes by race. The objective was to compare long-term outcomes between black and white patients after percutaneous coronary intervention (PCI) with DES implantation.

Methods We analyzed 915 black and 3,559 white (n = 4,474) consecutive patients who underwent DES placement at Duke University Medical Center from 2005 through 2013. Over 6-year follow up, we compared rates of myocardial infarction (MI), all-cause mortality, revascularization, and major bleeding between black and white patients. A multivariable Cox regression model was fit to adjust for potentially confounding variables. Dual-antiplatelet therapy use over time was determined by patient follow-up surveys and compared by race.

Results Black patients were younger; were more often female; had higher body mass indexes; had more diabetes mellitus, hypertension, and renal disease; and had lower median household incomes than white patients ($P < .001$). At 6 years after DES placement, black relative to white patients had higher unadjusted rates of MI (12.1% vs 10.1%, hazard ratio 1.25, 95% CI 1.00-1.57, $P = .05$) and major bleeding (17.8% vs 14.3%, hazard ratio 1.28, 95% CI 1.07-1.54, $P = .01$), but there were no significant differences in other outcomes. After multivariable adjustment, there were no statistically significant racial differences in any of these outcomes at 6 years. Similarly, dual-antiplatelet therapy use was comparable between racial groups.

Conclusions Unadjusted rates of MI and major bleeding over long-term follow up were higher among black patients compared to white patients, but these differences may be explained by racial differences in comorbid disease. (Am Heart J 2019;214:46-53.)

Patients with symptomatic coronary artery disease (CAD) often require percutaneous coronary intervention (PCI) with drug-eluting stent (DES) implantation. The superiority of DES over bare metal stents (BMSs) for preventing vessel restenosis is well established; however, prior studies report racial differences in the utilization of DES and outcomes following DES implantation. Patients who self-identify as black are less likely than their white counterparts to undergo PCI and other invasive cardiac procedures.[1-3] Black relative to white patients who undergo PCI for symptomatic CAD are less likely to receive a DES.[4-7] Several explanations for these disparities have been proposed including socioeconomic factors and patient refusal driven by minority mistrust of the medical system.[2,6,8] There is a growing body of data, however, that suggests race can influence outcomes following PCI when interventions are equivalent.

Some studies examining the association between race and outcomes after PCI with DES deployment found that black patients are more likely to develop stent thrombosis, experience myocardial infarction (MI), and have an increased mortality than white patients who undergo PCI[9-11], whereas other studies have found no differences by race after adjusting for confounders.[12,13] What is not well understood are how outcomes differ between black and white patients with DES over an extended follow-up period. The aim of this study is to determine if outcomes between black and white patients who underwent PCI with DES implantation at Duke University Medical Center differ over long-term follow up.

Methods

Data sources and definitions

The study population included individuals from the Duke Databank for Cardiovascular Disease (DDCD), a database of patients who have undergone cardiac catheterization at Duke University Medical Center. The DDCD methods have

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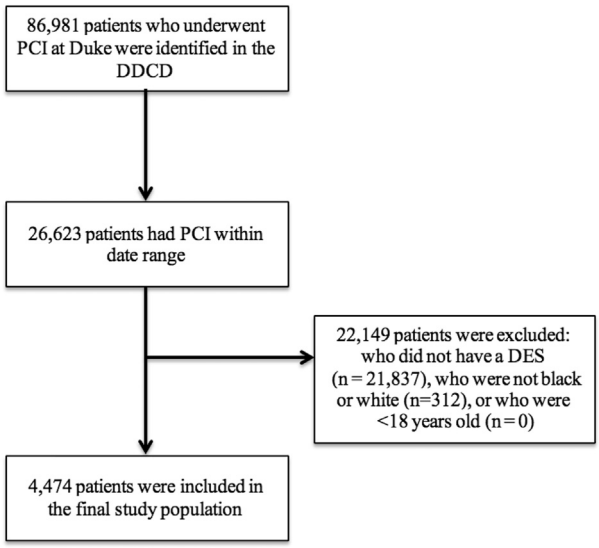
Figure 1



Flow diagram of patient identification and selection. This flow diagram details how patients were identified from the DDCD and were included in the final analysis.

been described previously.[14,15] Briefly, the databank includes baseline demographics, medical history, physical examination, and angiographic and procedural data. Follow-up information was obtained from Duke University Health System records and by routine DDCD follow-up questionnaires at 6 and 12 months postprocedure and annually thereafter. Nonresponders to self-administered questionnaires were contacted by phone.

Medication use was collected at the time of PCI and from follow-up surveys. Clinical outcomes of interest included all-cause death, MI, revascularization (PCI or coronary artery bypass graft), and *major bleeding* (defined as a bleeding diagnosis that led to hospital admission). A composite outcome of all-cause death, MI, or revascularization termed *major adverse cardiovascular events* (MACE) was also analyzed among the prespecified outcomes. Deaths were determined from Duke hospital system records and from follow-up surveys. Vital status for patients lost to follow-up was assessed via the National Death Index.[16] Follow-up MI and revascularization events were based on clinical diagnoses assigned by the patient's physician and electronic operative and angiographic results recorded in the DDCD. When these events occurred outside of Duke and were reported via follow-up surveys, records were requested from the patient's medical provider and adjudicated by 2 members of the DDCD team.

Bleeding events were determined from primary and secondary *International Classification of Diseases, Ninth Revision,* diagnosis codes used in prior studies[17-21] (supplemental materials). Median household income was determined by linking individual patient data at the census block group level using current patient addresses with data from the American Community Survey (2011). *Dual-antiplatelet therapy* (DAPT) was defined as reported use of aspirin and concomitant use of a $P2Y_{12}$ inhibitor (clopidogrel, ticagrelor, ticlopidine, or prasugrel). DAPT use at discharge was determined from health system medication records on the day of or within 7 days after PCI. Adherence to DAPT was determined using patient's self-reported follow up surveys supplemented with health system medication records. Because information from DDCD follow-up was last collected in January 2015, medication use and follow-up for clinical events were censored after January 2015.

Patient population

Patients for this analysis were identified from 86,981 unique patients who underwent cardiac catheterization at Duke University Medical Center from 1985 through 2015. Patients were excluded from this cohort if they did not undergo PCI between January 1, 2005, and June 30, 2013, (n = 60,358), did not receive a DES (n = 21,837), were <18 years old (n = 0), or did not self-identify as either black or white (n = 312). This left 4,474 patients meeting inclusion criteria for our study population (Figure 1).

Statistical methods

Characteristics of the patient population were stratified by race. Continuous variables were presented as median (25th-75th percentiles) and categorical variables as count (percent). Comparisons between races were performed using Wilcoxon rank sum and χ^2 tests for continuous and categorical variables, respectively.

χ^2 tests were used to compare DAPT use between races at each point during follow-up (discharge, 6

Table I. Patient characteristics

Characteristics	Black patients (n = 915)	White patients (n = 3559)	*P* values
Demographics			
Age	60 (52-68)	64 (55-72)	<.001
Female	418 (45.7%)	1054 (29.6%)	<.001
Median household income, $	36,800 (29,700-48,200)	44,900 (35,200-59,000)	<.001
Medical history			
BMI	29.9 (26.0-34.0)	29.0 (25.6-32.7)	<.001
Diabetes mellitus	413 (45.1%)	1011 (28.4%)	<.001
Hypertension	714 (78.0%)	2495 (70.1%)	<.001
Hyperlipidemia	545 (59.6%)	2378 (66.8%)	<.001
History of renal disease*	89 (9.7%)	107 (3.0%)	<.001
Previous or current smoker	357 (39.0%)	1572 (44.2%)	.005
History of atrial fibrillation	59 (6.4%)	354 (9.9%)	.001
History of cerebrovascular disease	77 (8.4%)	302 (8.5%)	.946
History of congestive heart failure	174 (19.2%)	598 (16.9%)	.107
NYHA class (CHF severity)			.027
None	788 (87.2%)	3136 (89.2%)	
I	16 (1.8%)	44 (1.3%)	
II	39 (4.3%)	123 (3.5%)	
III	37 (4.1%)	165 (4.7%)	
IV	24 (2.7%)	48 (1.4%)	
History of peripheral vascular disease	82 (9.0%)	305 (8.6%)	.707
Charlson Comorbidity Index†			<.001
0	422 (46.1%)	2091 (58.8%)	
1	310 (33.9%)	987 (27.7%)	
2	90 (9.8%)	326 (9.2%)	
3+	93 (10.2%)	155 (4.4%)	
Ejection fraction (n)	578	2305	
Median (Q1-Q3)	54.4 (43.4-60.4)	55.0 (45.8-63.0)	<.001
Previous PCI	216 (23.6%)	898 (25.2%)	.311
Previous CABG	178 (19.5%)	990 (27.8%)	<.001
Previous MI	449 (49.1%)	1628 (45.7%)	.072
Previous BMS Placement	165 (16.5%)	645 (16.7%)	.892
Discharge medications			
Aspirin	881 (96.3%)	3442 (96.7%)	.522
ACE inhibitors	680 (74.3%)	2567 (72.1%)	.185
β-Blockers	835 (91.3%)	3151 (88.5%)	.019
Statins	831 (90.8%)	3215 (90.3%)	.656
Oral anticoagulants‡	32 (3.5%)	136 (3.8%)	.646

BMI, body mass index; *NYHA*, New York Heart Association.
* Renal disease is defined as serum creatinine >3.0, use of dialysis, or renal transplant.
† Charlson Comorbidity Index is an index that predicts the risk of mortality for a given patient based on number of comorbidities
‡ Oral anticoagulants include warfarin, apixaban, rivaroxaban, and dabigatran.

months, 1 year, etc). Outcomes including MI, revascularization, all-cause death, and major bleeding were assessed from time of index PCI using cause-specific Cox proportional-hazards models, considering the competing risk of death for nonfatal events. Follow-up was censored at the earliest of death, end of follow-up, or median follow-up time of the cohort (approximately 6 years). Kaplan-Meier and cumulative incidence rates were presented for each outcome by race, and cause-specific hazard ratios (HRs) (with 95% CIS) comparing the risk of events between black and white race were estimated by Cox regression. Potentially confounding baseline comorbidities and demographic characteristics including median household income were prespecified adjustment covariates and fit in a multivariable Cox regression model to adjust for potential imbalances between race groups (Appendix A).

Model assumptions and the extent of missing data were evaluated. Linearity of the continuous variables was assessed and eventually fit with natural cubic splines. The proportional-hazards assumption was evaluated using weighted Schoenfeld residuals for the main comparison groups and determined to be a reasonable approximation. The extent of missing data was negligible for a majority of the variables used in the adjusted analyses (<1.10%), except for the number of diseased vessels (~6.8%). Descriptive summaries were reported excluding missing values. For regression models, patients missing information on

Table II. Angiographic and procedural characteristics

Characteristics	Black patients (n = 915)	White patients (n = 3559)	*P* values
Indication for PCI			.003
Stable angina	277 (30.3%)	1278 (35.9%)	
Unstable angina	294 (32.1%)	1137 (31.9%)	
STEMI	151 (16.5%)	556 (15.6%)	
NSTEMI	190 (20.8%)	581 (16.3%)	
MI unspecified*	3 (0.3%)	7 (0.2%)	
Year of PCI			.919
2005-2007	531 (58.0%)	2063 (58.0%)	
2008-2010	178 (19.5%)	711 (20.0%)	
2011-2013	206 (22.5%)	785 (22.1%)	
Vascular access			.842
Femoral	957 (95.7%)	3684 (95.3%)	
Radial	40 (4.0%)	171 (4.4%)	
Other	3 (0.3%)	12 (0.3%)	
Intraprocedural anticoagulation†			
Heparin	377 (37.7%)	1418 (36.7%)	.547
Direct thrombin inhibitor	419 (41.9%)	1618 (41.8%)	.973
Vessel treated with stent			
Left anterior descending artery	385 (42.1%)	1581 (44.4%)	.202
Left circumflex artery	327 (35.7%)	1137 (31.9%)	.029
Left main coronary artery	33 (3.6%)	169 (4.7%)	.138
Right coronary artery	334 (36.5%)	1367 (38.4%)	.289
Total stent length, mm	23.0 (16.0-39.0)	24.0 (16.0-40.0)	.122
Minimum stent diameter			.321
≤3 mm	772 (84.4%)	3049 (85.7%)	
>3 mm	143 (15.6%)	510 (14.3%)	
Number of diseased vessels			.358
0	8 (0.9%)	41 (1.2%)	
1	416 (48.8%)	1541 (46.4%)	
2	246 (28.9%)	947 (28.5%)	
3	182 (21.4%)	793 (23.9%)	
Multiple stents placed‡	365 (39.9%)	1538 (43.3%)	.065

* "MI unspecified" refers to patients who experienced an MI but STEMI or NSTEMI was undocumented.
† The heparin subgroup includes patients who received heparin or enoxaparin during PCI. The direct thrombin inhibitor group includes patients who received argatroban, bivalirudin, or lepirudin during PCI.
‡ Represents patients that had more than 1 stent placed during their index PCI.

number of diseased vessels were coded using a separate categorical level for this covariate; for other covariates, missing values were imputed using the cohort median and mode for continuous and categorical variables, respectively. All statistical analyses were performed using SAS v9.4 (SAS Institute, Cary, NC). A 2-tailed *P* value ≤ .05 was considered statistically significant.

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No extramural funding was used to support this work. The authors are solely responsible for the design and conduct of this study, all study analyses, the drafting and editing of the paper, and its final contents.

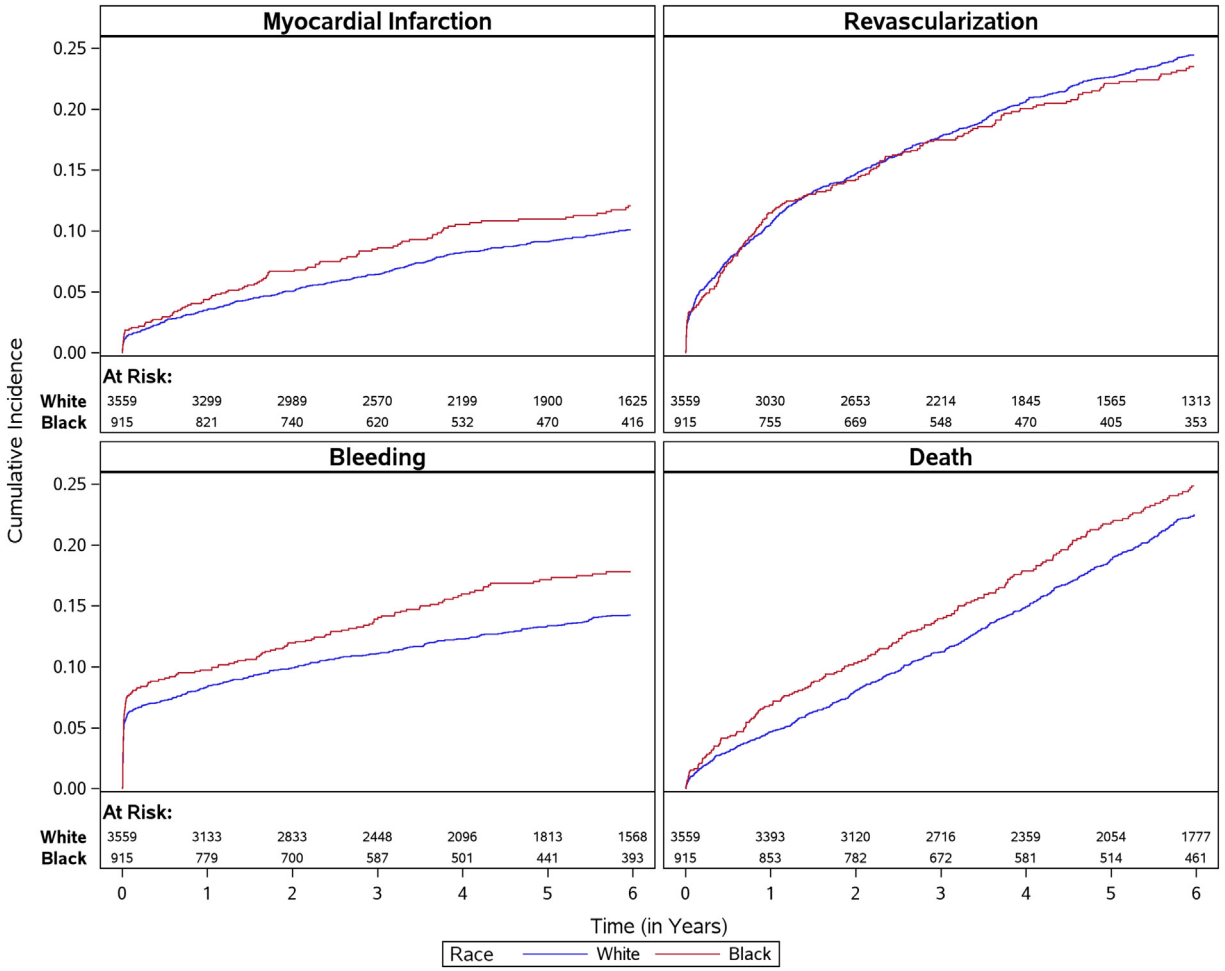
Results

Patient and procedural characteristics

Among 4,474 patients who underwent PCI with DES implantation between January 1, 2005, and June 30, 2013, 915 (20.5%) were black and 3,559 (79.5%) were white. Compared to white patients, black patients were younger and more likely to be female (*P* < .001). Black patients had a median household income of $36,800, whereas white patients had a median household income of $44,900. Comorbid conditions including diabetes mellitus, hypertension, and renal disease were more common among black patients as compared to white patients. Furthermore, black patients had more symptomatic heart failure (*P* = .027) with a slightly lower median ejection fraction and worse Charlson Comorbidity Index scores at baseline (*P* < .001). White patients had more hyperlipidemia (*P* < .001) and atrial fibrillation (*P* = .001), and were more likely to smoke (*P* = .005) and to have had a prior coronary artery bypass graft (*P* < .001) than black patients (Table I).

Indications for PCI differed as a function of race. Black patients were less likely to undergo PCI for stable angina than white patients but were more likely to have PCI for ST-elevation MI (STEMI), non–ST-elevation MI (NSTEMI), and unstable angina (*P* = .003). The left anterior descending artery was the most commonly treated vessel

Figure 2



Unadjusted 6-year outcomes among black and white patients with DES.These Kaplan-Meier curves demonstrate the unadjusted outcomes for black and white patients over 6-year follow-up. The cumulative incidences for events are represented on the y-axis, and time after DES placement is shown on the x-axis.

among all patients. Black patients were more likely than white patients to undergo PCI of the left circumflex artery ($P = .029$). Other angiographic and procedural data including year of PCI, vascular access, intraprocedural anticoagulation used, stent dimensions, the number of stents deployed, and discharge medications did not vary significantly by race (Table II).

Outcomes

Kaplan-Meier curves comparing 6-year outcomes between black and white patients are shown in Figure 2. Median (25th-75th) length of follow-up was 6.0 (2.9-6.0) years for black patients and 6.0 (3.1-6.0) years for white patients. At 6 years, both the unadjusted and adjusted rates of MACE did not differ significantly between black and white patients (45.5% vs 44.4%, aHR 1.00, 95% CI 0.89-1.13, $P = .99$). Black relative to white patients had significantly higher unadjusted rates of MI (12.1% vs 10.1%, HR 1.25, 95% CI 1.00-1.57, $P = .05$) and major bleeding (17.8% vs 14.3%, HR 1.28, 95% CI 1.07-1.54, $P = .01$), but there were no significant differences in mortality (24.9% vs 22.5%, $P = .07$) or revascularization (23.5% vs 24.4%, $P = .80$). After adjustments for relevant clinical factors, all racial differences in outcomes were no longer statistically significant, although the black-white difference in bleeding trended toward statistical significance (17.8% vs 14.3%, aHR 1.19, 95% CI 0.98-1.46, $P = .08$) (Table III). Even when excluding household income as an adjustment variable, outcomes did not differ by race (supplemental materials).

DAPT use

At discharge, 96.1% of black versus 96.6% of white patients were started on DAPT ($P = .41$). Use of DAPT

Table III. Outcomes at 6 years stratified by race

Outcomes	Black patients (n = 915)	White patients (n = 3559)	Unadjusted HR (95% CI)	Unadjusted *P* value	Adjusted HR* (95% CI)	Adjusted *P* value
MACE	381 (45.54%)	1425 (44.39%)	1.06 (0.95-1.19)	.32	1.00 (0.89-1.13)	.99
All-cause mortality	199 (24.85%)	688 (22.52%)	1.15 (0.99-1.35)	.07	1.10 (0.93-1.31)	.28
MI	101 (12.08%)	324 (10.11%)	1.25 (1.00-1.57)	.05	1.04 (0.82-1.32)	.76
Revascularization	199 (23.51%)	801 (24.44%)	0.98 (0.84-1.14)	.80	0.94 (0.80-1.11)	.48
Major bleeding	152 (17.80%)	475 (14.26%)	1.28 (1.07-1.54)	.01	1.19 (0.98-1.46)	.08

The number of patients with an event through 6 years after index PCI and the cumulative % of patients with an event through 6 years are reported by race. HRs are reported for black patients versus white patients.
Revascularization represents patients requiring PCI or coronary artery bypass grafting after index PCI.
* Adjustment variables include age, BMI, year of PCI, indication for PCI, Charlson Comorbidity Index, gender, previous CABG, history of MI, hypertension, hyperlipidemia, renal disease, smoking status, number of diseased vessels, congestive heart failure severity, diabetes, and median household income.

decreased over time: by 12 months, 75.9% of black versus 76.9% of white patients remained on DAPT ($P = .58$), and at the end of 36 months, 61.5% of black and 64.6% of white patients remained on DAPT ($P = .17$). There were no significant racial differences in DAPT utilization at any point over the follow-up period (Figure 3). Clopidogrel was the most commonly used $P2Y_{12}$ inhibitor (supplemental materials).

Discussion

This study of 4,474 black and white patients who underwent PCI with DES implantation found that long-term outcomes following PCI do not differ significantly by black versus white race. Among the growing body of data comparing racial variations in outcomes following PCI, this study has the longest follow-up to date with a sizeable number of black patients for comparison. An additional strength of this study was our ability to adjust for median household income and compare DAPT use over time by race. These data have been notable exclusions from some prior research.

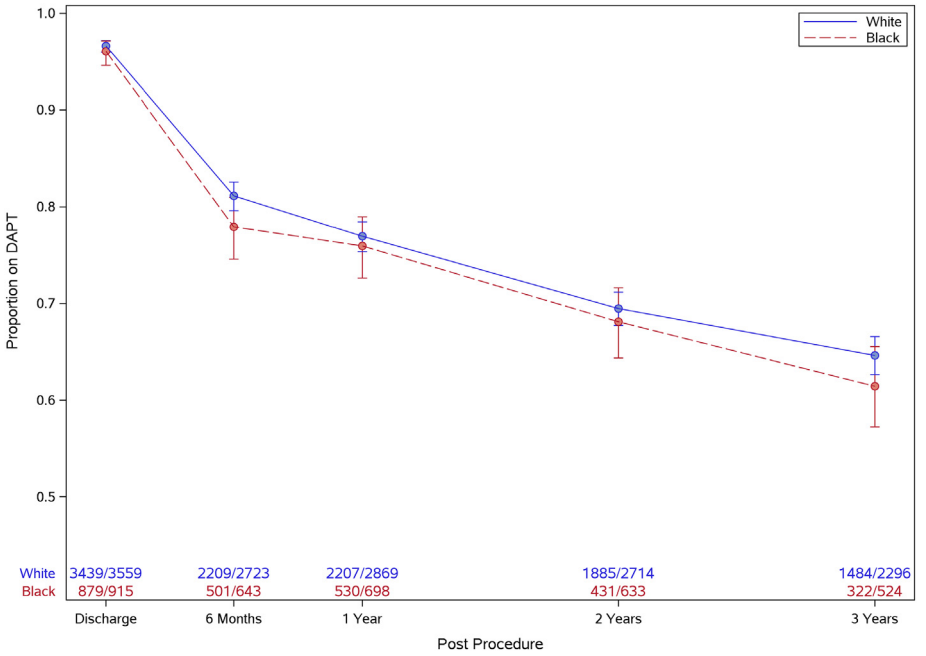
Through 6 years of follow-up, the rates of MACE, death, MI, revascularization, and major bleeding were similar between black and white patients after adjusting for medical history. Black patients did, however, have higher unadjusted rates of MI and major bleeding than white patients. Black relative to white patients in our study had a greater burden of comorbid diseases at baseline including diabetes mellitus, hypertension, and renal disease. Furthermore, black patients had a lower socioeconomic status as evidenced by their overall lower median household income. The higher unadjusted rate of MI observed among black patients may be largely explained by black patients having more cardiovascular disease risk factors at baseline.

Although nonsignificant, there remained a trend toward more bleeding in blacks relative to whites after adjustment. Oral anticoagulant and DAPT use were comparable between racial groups. Angiographic and procedural data did not differ significantly between patient groups, so this is unlikely to have contributed to these observed differences. One potential explanation for this difference in bleeding risk is the significantly higher rate of renal dysfunction among black patients as compared to white patients (9.7% vs 3.0%). It is estimated that 50% of patients with renal dysfunction will experience a bleeding complication related to uremic bleeding, thrombocytopenia, or complications of dialysis.[22] Given the retrospective nature of this analysis, it is impossible to delineate all factors that contributed to each adverse bleeding event for each patient. Renal dysfunction may have contributed to the increased risk of bleeding among black patients; however, there are likely other unmeasured factors that were not captured in our analysis that may contribute as well.

Our findings should be contextualized in the setting of other studies that have examined racial disparities in DES-related outcomes. Several prior studies had similar findings to our study. A large, 2017 analysis of black and white VA patients who underwent PCI with either DES or BMS placement found that the adjusted rates of mortality and readmissions for MI at 1 year were similar by race, although the unadjusted rate of 1-year mortality was higher among blacks.[13] Much like our study, black patients had more comorbidities at baseline, and this largely accounted for the higher unadjusted rate of mortality at 1 year. Black relative to white patients from the TAXUS IV, TAXUS V, and ATLAS trials had significantly higher adjusted rates of MI, yet there were no significant racial differences in MACE, cardiac death, all-cause mortality, or target-vessel revascularization at 5 years.[10] Our study provides additional data beyond the aforementioned study in that we had a larger sample size and accounted for median household income, which has been shown to impact adjusted outcomes in prior research.[12] These differences may explain the differential findings in these 2 analyses.

Not all prior studies have found that racial differences in outcomes resolve after adjusting for confounders. A study of 423,965 patients from the CathPCI registry found that black relative to white patients following PCI had higher adjusted rates of death and MI at 30 months.[11] It is unclear why these finding differ from ours, but there are

Figure 3



Rates of DAPT adherence by race over time.This figure illustrates the proportion of black and white patients who were on DAPT at each specified time interval. Error bars represent 95% CIs.

differences between our study and the CathPCI registry to take into consideration. The CathPCI registry includes data from patients analyzed across multiple sites. It is possible that there are factors at the site level that influence outcomes that were not present in our single-center analysis. Lastly, this study included patients who received either a BMS or DES, whereas all patients in our study had a DES. They found that compared to patients who received a DES, patients who only received a BMS had worse outcomes. Consequently, the overutilization of BMS among black patients in this study may have impacted outcomes.

Percutaneous coronary intervention with DES implantation remains the gold standard for treating symptomatic CAD. Amidst a growing uncertainty of how race influences long-term outcomes following PCI, the results of our study add to the body of data addressing this topic. Nevertheless, more work is required to understand how socioeconomic factors and risk factor modification may influence outcomes after PCI and DES placement among racially and socioeconomically diverse populations.

Limitations

This study has the following notable limitations. There are potential confounders inherent to retrospective analyses that may be present that are not currently accounted for in our multivariable models. Secondly, all patients included in this study underwent PCI at a single center; therefore, it is unknown if outcomes between black and white patients are generalizable to other settings. Data regarding DAPT adherence were primarily based on patient's self-report. This form of data collection is subject to recall bias and thus may have some degree of error. Lastly, the precise household income for each individual patient was unknown, but we were able to approximate by linking patient zip codes to census data.

Conclusions

Black patients 6 years after index PCI with DES implantation have higher unadjusted rates of MI and major bleeding events relative to white patients, but there are no significant differences in MACE or other outcomes after adjusting for confounders. Racial variations in outcomes are in part explained by differences in baseline comorbidities.

CRediT authorship contribution statement

Lonnie T. Sullivan: II Conceptualization, Methodology, Writing - original draft, Writing - review & editing, Visualization, Project administration. **Hillary Mulder:** Methodology, Software, Validation, Formal analysis, Data curation, Writing - review & editing. **Karen Chiswell:** Methodology, Software, Validation, Formal analysis, Data curation, Writing - review & editing. **Linda K. Shaw:** Supervision. **Tracy Y. Wang:** Supervision, Writing - review & editing. **Larry R. Jackson:** II Supervision,

Writing - review & editing. **Kevin L Thomas:** Conceptualization, Methodology, Writing - review & editing, Validation, Supervision, Resources, Project administration, Funding acquisition.

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Conflicts of interest: Lonnie T. Sullivan II, MD—none; Kevin L. Thomas, MD—consultant for Bristol-Myers Squibb and Pfizer; advisory board member for Janssen Pharmaceuticals; Tracy Y. Wang, MD, MHS, MSc—consulting honoraria from Grifols and Gilead; DCRI research grants from Amgen, AstraZeneca, Bristol-Myers Squibb, Cryolife, Novartis, Pfizer, Portola, and Regeneron; Larry R. Jackson II, MD—none.

Appendix A. Multivariable Cox regression model adjustment variables

- Demographic: age, female gender
- Medical history: body mass index, diabetes mellitus, hypertension, hyperlipidemia, history of renal disease, previous or current smoker, previous CABG, previous MI, history of heart failure, Charlson Comorbidity Index (noncardiac factors)
- Angiographic/procedural information: year of PCI, indication for PCI, extent of CAD (number of diseased vessels)
- Socioeconomic information: median household income

Appendix B. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ahj.2019.04.005.

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