Comparison of Long-Term Clinical Outcomes After Drug-Eluting Stenting in Blacks-vs-Whites

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Patients of different racial backgrounds may have socioeconomic, cultural, or genetic differences that impact outcomes after percutaneous coronary intervention (PCI). There are limited data beyond 2 to 3 years for Blacks to inform discussions and perhaps improve outcomes. We studied consecutive limus-stent treated patients, having their first PCI at our institution January 2003 to March 2010 in 2 cohorts; Cohort 1: standard 3-year follow-up (n = 3,782, 12.4% Blacks) and Cohort 2: from nearby zip codes with intended detailed follow-up through 8 to 13 years (n = 616, 31.8% Blacks). The primary outcomes of interest were mortality and death/MI/revascularization (DMIR) (Cohort 1) or major adverse cardiac events (cardiac DMIR) (Cohort 2). In all cohorts, Blacks had a higher prevalence of many risk factors. In Cohort 1, 3-year mortalities were 14.6% and 9.6% (p = 0.001) and DMIR were 32.1% and 25.0% (p = 0.001), for Blacks and Whites, respectively. In Cohort 2, over 9.5 ± 2.0 years, treatment intensity was as high or higher for Blacks, but they continued to have higher low-density lipoprotein-cholesterol and blood pressure values. Major adverse cardiac events and mortality at 10 years were higher for Blacks (59.0% vs 48.1%, p = 0.024 and 44.3% vs 23.0%, p < 0.001). Differences in outcomes, except 10 year mortality, were not significantly different after adjustment for baseline characteristics. Blacks have a higher risk profile at the time of PCI and worse long-term outcomes after drug-eluting stent, most of which is explained by baseline differences. **(Am J Cardiol 2019;124:1179−1185)**

Differences in socioeconomic status, access to medical care, and physician and patient biases might lead to different clinical outcomes after coronary revascularization in patients of different racial backgrounds.[1−6] Although some studies have found no difference in short-term outcomes[7,8] or 2 to 3 year mortality[9,10] others have found a higher 1 to 2 year mortality after percutaneous coronary intervention (PCI) in Blacks than Whites.[11,12] Longer term assessment and a comprehensive analysis of the relation between treatment differences and outcomes have not been fully pursued.

Methods

From our prospective institutional PCI follow-up database, consecutive patients treated for the first time at our institution with any limus-eluting drug-eluting stent were identified. Two cohorts were specified: Cohort 1: PCI January 2003 to June 2010, routine 3-year follow-up; Cohort 2: PCI January 2003 to June 2010, detailed and extended follow-up for patients from Cuyahoga, Ashtabula or western Geauga counties. Race was assigned per patient group identification (Figure 1).

The Electronic medical record (EMR) was reviewed and patients were routinely sent a letter querying their status for specific endpoints annually for 3 years, with phone call follow-up when necessary. For longer follow-up, the EMR (including Care Everywhere) was extensively reviewed, supplemented by internet search and phone follow-up (n = 58), as needed. Vital signs, patient weight, medication prescription, and labs were recorded at 1 ± 0.5, 2 ± 0.5, 5 ± 1, and 8 ± 1 years, using data closest to the target date as possible. For Cohort 2 follow-up was completed June to September 2018.

Data was collected by trained research nurses, technicians or physicians on dedicated case report forms, using standard definitions. Estimated annual patient income was derived from the median household income reported within the patient's zip code using 2017 dollars. SYNTAX and residual SYNTAX scores were calculated by a single physician from the Angiographic Core laboratory, masked to clinical outcome. For Cohort 2 death was assumed to be cardiac unless it could be demonstrated otherwise (for Cohort 1 cause of death was not tracked).

Data are presented as mean ± SD, median and interquartile range, or proportion, as appropriate. Multivariable Cox proportional hazards regression analysis was used to evaluate possible correlates of the primary (mortality and death/MI or revascularization [Cohort 1], and mortality and major adverse cardiac events (MACE) [Cohort 2]), and other prespecified outcomes (cardiac death, Target lesion failure (TLF), and stent thrombosis). Propensity score covariate adjustment, considering differences in baseline characteristics between Blacks and Whites, was also performed. In Cohort 2, 2-year

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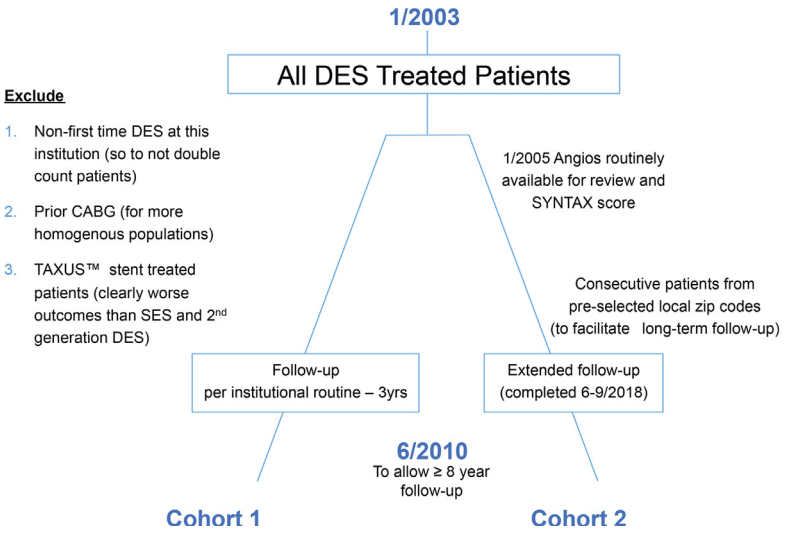

Figure 1. Origin of the patient cohorts

and 5-year landmark studies were performed to assess the impact of medical treatments during the first 2 to 5 years after stenting. Principal comparisons were of Blacks versus Whites, adjusted and unadjusted, for the end points of interest. Covariates to be tested for correlation with outcomes were chosen on the basis of likelihood based upon previous data, attempting, in general, to keep covariate:event ratio <1:10. Post-hoc analyses to assess the potential explanatory effect of income were performed for all end points for which racial status was an independent correlate of outcome. Statistical analysis was performed using STSTAT software, version 13.0 (Richmond, CA).

Results

Cohort 1 comprises 3,782 consecutively treated patients, whose baseline White and Black patient characteristics are provided in Table 1. They should be considered a composite of local and distant referred patients. Three-year lost to follow up was 9.3%.

Cohort 2 comprises 616 local patients, whose baseline and extended follow up findings are provided in Tables 2 and 3. Patients from these local zip codes tended to have less advanced disease than those referred from a greater distance (e.g., Type C lesion 21.8% vs 39.9% [$p < 0.001$]). Seven White (1.7%) and 3 (1.5%) Black patients were lost to follow up ($p = 0.90$). Twenty-five White (5.9%) and 15 (7.6%) Black patients required phone contact for successful completion of outcome assessment ($p = 0.42$).

For Cohorts 1 and 2 substantial baseline differences between races were seen, most notably for age, gender, diabetes, renal insufficiency, ejection fraction, and presentation with acute coronary syndrome. Baseline lesion complexity (SYNTAX scores) were similar, but residual SYNTAX score was modestly higher for blacks (Tables 1 and 2).

Over the ensuing follow-up, high intensity statin and dual antiplatelet therapy prescription were similar, but Blacks were given more antihypertensive medications (Table 3).

For Cohort 1 patients, Black and White Kaplan-Meier rates, respectively, for mortality were, 14.6% and 9.6% ($p = 0.001$), and for death/myocardial infarction (MI)/revascularization were 32.1% and 25.0% ($p = 0.001$; Figure 2). These differences were no longer statistically different once baseline characteristics were considered (Table 3).

Table 1
Baseline characteristics—Cohort 1

Patient characteristic	White (n = 3,238)	Black (n = 462)	p Value
Age (years)	64.2 (11.4%)	62.8 (11.7)	0.014
Men	2197 (67.9%)	244 (52.8%)	<0.001
Acute MI			
STEMI	223 (6.9%)	63 (13.6%)	<0.001
NSTEMI	78 (2.4%)	25 (5.4%)	0.003
Cardiogenic shock	31 (0.9%)	7 (1.5%)	0.27
COPD	391 (12.1%)	68 (14.7%)	0.11
Diabetes mellitus	969 (30.0%)	210 (45.5%)	<0.001
Hemoglobin (mg/%)	13.8 ± 1.8	12.8 (±1.9)	<0.001
Hypertension	2477 (76.5%)	414 (89.6%)	<0.001
LVEF	51.5 (11.6%)	49.8 (11.7%)	0.011
Peripheral artery disease	341 (10.5%)	54 (11.7%)	0.45
Prior MI	1076 (33.2%)	173 (37.4%)	0.07
Creatinine >2.0 mg/dl	138 (4.3%)	54 (11.7%)	<0.001
Smoker, at baseline	575 (17.8 %)	138 (29.9%)	<0.001
Unstable angina pectoris	984 (30.4%)	155 (32.2%)	0.19
Number of narrowed coronary arteries			
1	1214 (37.5%)	137 (29.6%)	<0.001
2	1266 (39.1%)	154 (33.3%)	
3	758 (23.4%)	178 (37.0%)	
Left coronary descending artery	1934 (56.5%)	216 (46.8%)	<0.001
Left circumflex artery	1052 (32.5%)	158 (34.2%)	0.46
Right coronary artery	1197 (37.0%)	183 (39.6%)	0.27
In-hospital outcomes			
Procedural success	3156 (97.5%)	446 (96.5%)	0.24
Bleeding requiring transfusion	84 (2.6%)	14 (3.0%)	0.59
Death, myocardial infarction, Urgent revascularization	116 (3.6%)	14 (3.0%)	0.55

% or mean ± SD, as shown.

Table 2
Baseline characteristics−Cohort 2

Patient characteristic	White (n = 420)	Black (n = 196)	p Value
Age (years)	63.0 (11.2)	62.2 (10.1)	0.38
Men	302 (71.9%)	101 (51.5%)	<0.001
Acute MI			
STEMI	44 (10.5%)	24 (12.2%)	0.51
NSTEMI	15 (3.6%)	10 (5.1%)	0.37
BMI (kg/m^2)	30.3 (6.4)	31.4 (6.6)	0.08
Cardiogenic shock	10 (2.4%)	2 (1.0%)	0.26
COPD	37 (8.8%)	23 (11.7%)	0.26
Diabetes mellitus	127 (30.4%)	96 (49.0%)	<0.001
Hemoglobin	13.8 (2.0%)	12.7 (1.9%)	<0.001
HbA1C*	6.7 (1.7)	6.7 (1.6)	0.95
Hypertension	324 (77.1%)	173 (88.3%)	0.002
Income, household (2017/thousand$)	62.8 (48.4)	22.8 (42.1)	<0.001
LDL Cholesterol (mg/%)	101.1 (40.4)	106.6 (45.0)	0.18
LVEF (%)†	52.3 (10.9)	49.2 (12.3)	0.007
Peripheral artery disease	48 (11.4%)	33 (16.8%)	0.06
Prior MI	97 (29.9%)	72 (39.6%)	0.028
Creatinine >2.0 mg/dl	16 (3.8%)	34 (17.3%)	<0.001
Smoker, at baseline	61 (18.9%)	48 (26.8%)	0.04
Unstable angina	82 (19.5%)	60 (30.6%)	0.002
Narrowed coronary arteries			
1	180 (42.6%)	74 (37.7%)	0.009
2	160 (38.1%)	63 (32.1%)	
3	80 (19.0%)	59 (30.1%)	
LAD	230 (54.8%)	90 (45.9%)	0.04
LCX	122 (29.0%)	57 (29.1%)	0.98
RCA	141 (33.6%)	75 (38.3%)	0.26
Mean RVD (mm)	3.14 (0.49)	3.06 (0.45)	0.05
Baseline SYNTAX Score	10.1 (6.9)	11.1 (7.6)	0.11
Residual SYNTAX Score	2.9 (4.5)	3.7 (5.2)	0.07
In-hospital treatment			
IVUS	68 (16.2%)	27 (13.8%)	0.44
Treated sites	1.6 (1.0)	1.6 (0.8)	0.73
Number of stents	2.2 (1.5)	2.3 (1.6)	0.48
Stent length (mm)	34.2 (25.2)	32.4 (20.7)	0.33
In-hospital outcomes			
Procedural success	414 (98.5)	193 (98.5)	0.92
Bleeding requiring transfusion	10 (2.4%)	4 (2.0%)	0.08
Death, MI, urgent revascularization	27 (6.4%)	10 (5.1%)	0.52

% or mean ± SD, as shown.
* Available in 215 White and 137 Black patients.
† Available in 313 White and 155 Black patients.

For Cohort 2 patients, detailed treatment and lab results at 5 years are provided in Table 4 (findings at years 2 and 8 were similar). Blacks tended to have worse risk factor control, despite prescription of equal or more intense treatments (e.g., blood pressure, low-density lipoprotein cholesterol.).

Unadjusted 10-year Kaplan-Meier MACE was substantially higher for Blacks (59.0% vs 48.1%, p = 0.024; Figure 3). Mortality for Blacks was nearly double that of Whites (44.3% vs 23.0%, p < 0.001; Figure 3), as was cardiac mortality (36.0 vs 15.8%, p < 0.001; Figure 3). Risk of MI at 10 years was higher in Blacks (26.6% vs 14.0%, p = 0.006), but there was no difference in risk of stent thrombosis (3.5% vs 4.1%, p = 0.45.) Differences for cardiac mortality, MACE and MI, but not overall mortality were eliminated or attenuated after correction for other covariates (Table 4) (these findings were confirmed in propensity analyses [data not shown]).

Kaplan-Meier noncardiac mortality rates at 10 years were not statistically different (8.3% for Blacks and 7.2% for Whites, p = 0.21). Leading noncardiac causes of death for Blacks were cancer (34.6%) and sepsis (23.1% of noncardiac deaths). For Whites, cancer was by far and away the leading noncardiac cause of death (43.2%.) (Table 5).

Landmark studies in Blacks found, in addition to the continued influence of baseline characteristics such as renal insufficiency and residual SYNTAX score, that several treatments or treatment−related outcomes seemed to impact risk of MACE (1 to 2 year HbA1c [p = 0.006], 5-year systolic blood pressure [p = 0.003]) and of mortality (3 to 5 year statin intensity [p = 0.012], 5-year systolic blood pressure [p = 0.039]) (Tables 6 and 7).

Discussion

Although cardiovascular death rates are falling for Blacks and Whites in the United States, age-adjusted rates for Blacks still exceed those for Whites by 25%.[13] Inadequate screening and under treatment have been suggested as the leading causes of this continued discrepancy.[14−17] Although one large 30 month follow up study using administrative data has reported a 28% excess risk of MI or

Table 3
Independent correlates of 3 year death and death/MI/revascularization in Cohort 1

Death	Est	Std error	Z	p	Death, MI, revascularization	Est	Std error	Z	p
Age	0.041	0.006	7.11	<0.001	Renal insuff	0.740	0.132	5.60	<0.001
COPD	0.914	0.132	6.95	<0.001	Diabetes	0.353	0.083	4.25	<0.001
Hb	−0.188	0.034	−5.54	<0.001	LVEF	−0.013	0.003	−4.24	<0.001
LVEF	−0.024	0.004	−5.50	<0.001	Hb	−0.082	0.023	−3.60	<0.001
Renal insuff	0.770	0.170	4.52	<0.001	COPD	0.333	0.101	3.28	0.001
Diabetes	0.420	0.127	3.31	0.001	PVOD	0.333	0.105	3.18	0.001
Shock	0.994	0.352	2.83	0.005	RVD	−0.283	0.091	−3.11	0.002
PVOD	0.407	0.145	2.81	0.005	Lesion ACC Score (1-4)	0.154	0.052	2.96	0.003
Proximal LAD	0.288	0.138	2.09	0.037	Number of Diseased Vessels	0.150	0.063	2.37	0.018
Black	−0.003	0.168	−0.02	0.987	Black	0.052	0.113	0.46	0.644

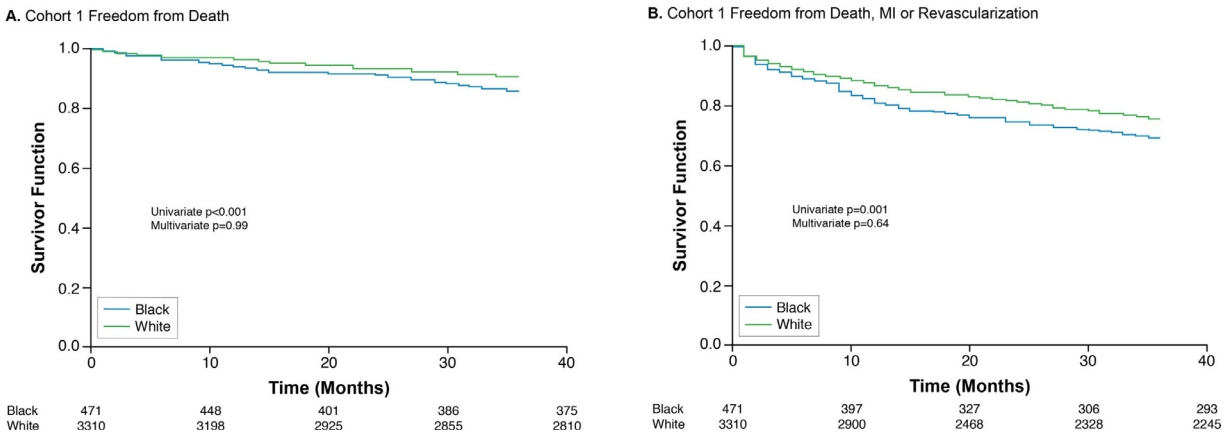

Figure 2. (*A*) Unadjusted 3 year Kaplan-Meier curves for survival for Blacks and Whites in cohort 1 (univariate p = 0.001), (*B*) Unadjusted 3 year Kaplan-Meier curves for freedom from major adverse cardiac events for Blacks and Whites in cohort 1 (univariate p = 0.001).

mortality for Blacks,[18] long-term granular data are not available to delve into the details of these issues.

The principal findings of this long term longitudinal study utilizing a relatively large 3 year follow-up cohort and a much more detailed but smaller 10-year cohort are (1) at the time of initial coronary revascularization, Blacks were more likely to have diabetes, lower hemoglobin, renal insufficiency, lower left ventricular ejection fraction, hypertension, and be female than Whites, (2) extent of coronary artery disease as assessed by SYNTAX score, was modestly, but not statistically, higher for Blacks both at baseline and after completion of the procedure, (3) despite prescription for more antihypertensive and a similar prescription of high-intensity statin medications, Blacks had higher blood pressures and low-density lipoprotein-c at 2, 5, and 8 years of follow up (there was no discernable difference in diabetes or smoking cessation rates), (4) Blacks status was an independent risk factor for mortality at 10 years, but not MI, MACE or stent thrombosis, (5) household income, despite a strong correlation with 10-year mortality, was a weaker correlate of that outcome than Blacks status, and (6) 4 modifiable treatment-related factors: Residual SYNTAX score and intensity of statin treatment, blood pressure and HbA1C, correlated with long-term adverse outcomes in Blacks.

Novel findings of this study are worse control of some risk factors despite the apparent prescription of more aggressive therapy, and the link between poor risk factor control and adverse outcomes in the poststent Blacks cohort over a protracted period of time (although, of course, there is ample epidemiological and clinical trial support for the importance of coronary artery disease risk factors and their control in more generalized populations.[19]

One has to ask how generalizable these data might be. Median Black and White household income in the United States are estimated at $36,650 and $55,300.[20,21] Comparable figures in this study are $34,400 and $58,800. Data on patients who have coronary disease severe enough to need revascularization, stratified by race, are challenging to find.

This report is limited by the relatively small number of patients studied beyond 3 years of follow up, possible lack of generalizability due to the limited geographic origin of the patients (e.g., there are several reports finding worse control of risk factors and in cardiovascular outcomes in Blacks from the Southeastern US compared with elsewhere in the United States,[22,23] imperfections in patient recall (phone calls required in 9.7% of Blacks and 9.3% of Whites in Cohort 2), some incomplete data, limitations of inferring causation from the correlations found in the landmark studies, difficulties in

Table 4
Follow up in Cohort 2

Follow-up characteristic	All patients	White	Black	p Value
5 years	n = 522	n = 368	n = 154	
BMI (kg/m^2)	30.5 ± 6.1	30.5 ± 6.1	30.9 ± 6.3	0.60
Office SBP (mm Hg)	130 ± 18	127 ± 16	136 ± 22	<0.001
Number of blood pressure medications	2.0 ± 1.2	1.8 ± 1.2	2.4 ± 1.3	<0.001
HbA1C	7.1 ± 1.9	7.1 ± 1.9	7.0 ± 2.0	0.77
Number of oral diabetes medications	0.4 ± 0.7	0.4 ± 0.7	0.4 ± 0.7	0.54
Insulin	14.6	12.5	19.3	0.072
LDL cholesterol (mg/dl)	83 ± 37	78 ± 30	96 ± 48	0.001
Smoker	14.1%	13.5%	17.3%	0.29
DAPT	51.3%	50.1%	50.7%	0.95
Statin	91.7%	90.9%	93.3%	0.91
High intensity statin	52.2%	52.8%	51.7%	0.71

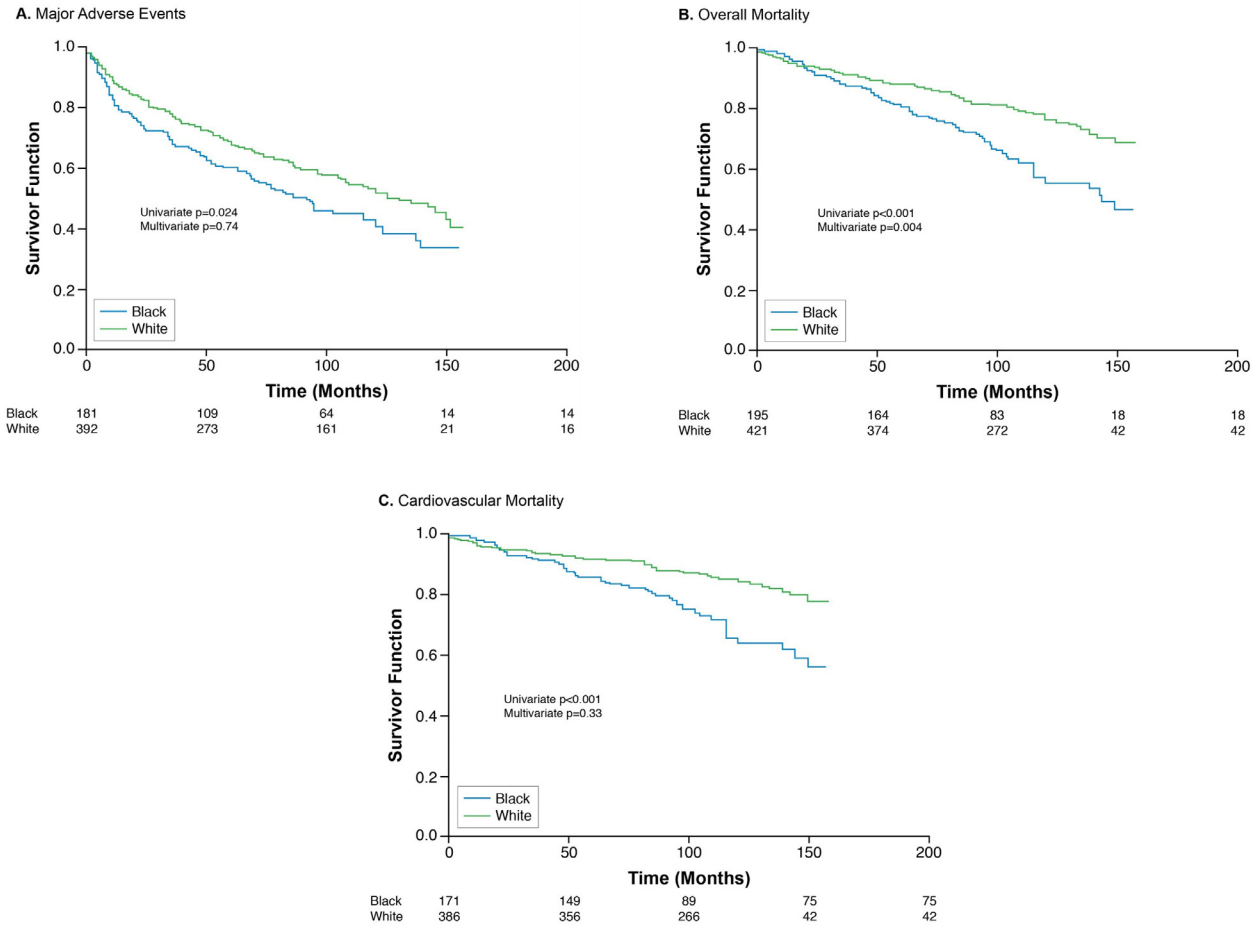

Figure 3. (*A*) Unadjusted 10 year Kaplan-Meier curves for freedom from major adverse cardiac events for Blacks and Whites from cohort 2 (univariate $p < 0.001$), (*B*) Unadjusted 10 year Kaplan-Meier curves for survival for Blacks and Whites from cohort 2 (univariate $p < 0.001$), (*C*) Unadjusted 10 year Kaplan-Meier curves for freedom from cardiac death for Blacks and Whites from cohort 2 (univariate $p < 0.001$).

discerning exact cause of death, the fact that medications prescribed were not necessarily taken, that median zip code income is only an approximation for actual household income and its single health system origin.

The strengths of this report are its much longer period of follow up than previously and completeness of follow up, granularity of data and the fact that treatments were provided within a single healthcare system, perhaps mitigating in part differences in approach to and quality of care received by Black and White patients.

The therapeutic implications of these findings appear to be simple yet profound, that even in a very highly regarded cardiac system and examining contemporary health care, Blacks would seem likely to benefit from both earlier diagnosis and more aggressive post-drug-eluting stent treatment.

Table 5
Independent correlates of 10 year death and MACE in Cohort 2

Death	Est	Std error	Z	p	MACE	Est	Std error	Z	p
Age	0.067	0.009	7.45	<0.001	Renal insufficiency	0.876	0.226	3.87	<0.001
COPD	0.918	0.224	4.11	<0.001	PVOD	0.681	0.180	3.79	<0.001
LVEF	−0.023	0.008	−3.05	0.002	Residual SYNTAX score	0.048	0.013	3.55	0.001
Residual SYNTAX score	0.051	0.016	3.11	0.002	Hemoglobin	−0.103	0.031	−3.30	0.001
Black	0.589	0.205	2.87	0.004	LVEF	−0.017	0.007	−2.61	0.009
Renal insufficiency	0.684	0.246	2.77	0.006	Black	0.050	0.153	0.33	0.743
Hemoglobin	−0.113	0.041	−2.76	0.006					
Clinical shock	1.516	0.634	2.39	0.017					
PVOD	0.429	0.214	2.01	0.044					

p Value for income (continuous): univariate p = 0.007; multivariate p = 0.57.
Above/below median: univariate p = 0.13;multivariate p = 0.25.

Table 6
Baseline and intermediate term independent correlates of landmark mortality in Blacks in Cohort 2

	Assessed At	Landmark from	Estimate	Std Error	z	p
SYNTAX Score	residual	2 yrs	0.088	0.027	3.23	0.001
Age	baseline	2 yrs	0.057	0.019	3.03	0.002
LVEF	baseline	2 yrs	−0.039	0.015	−2.56	0.010
Statin Intensity	3-5 yrs	5 yrs	−0.817	0.326	−2.50	0.012
SYNTAX score	residual	5 yrs	0.083	0.037	2.24	0.025
Systolic BP	3-5 yrs	5 yrs	0.017	0.008	2.07	0.039

Table 7
Baseline and intermediate term independent correlates of landmark MACE in Blacks in Cohort 2

	Assessed At	Landmark from	Estimate	Std error	z	p
HbA1C	1-2 yrs	2 yrs	0.268	0.098	2.27	0.006
SYNTAX score	residual	5 yrs	0.119	0.038	3.12	0.002
Systolic BP	3-5 yrs	5 yrs	0.023	0.007	3.02	0.003
Renal insuff	baseline	5 yrs	1.303	0.535	2.43	0.015

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