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ORIGINAL RESEARCH

Racial and Ethnic Disparities in the Use and Outcomes With WATCHMAN FLX: A SURPASS Analysis of the NCDR Left Atrial Appendage Occlusion Registry

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BACKGROUND: Left atrial appendage occlusion (LAAO) is increasingly used as an alternative to oral anticoagulation for stroke prevention in select patients with atrial fibrillation. Data on outcomes in racial and ethnic minority individuals are limited. This analysis assessed differences in the use and outcomes of LAAO by race and ethnicity in a large national registry.

METHODS AND RESULTS: This analysis acquired data on patients who underwent WATCHMAN FLX implantation from the retrospective NCDR (National Cardiovascular Data Registry) LAAO registry through September 2022. All patients with an attempted WATCHMAN FLX implantation and known race and ethnicity were included. Baseline characteristics and 1-year event rates were compared. A total of 97 185 patients were analyzed; 87 339 were White individuals (90%), 3750 Black individuals (3.9%), and 2866 Hispanic individuals (Hispanic/Latinx), 2.9%). Black and Hispanic patients were younger, with a higher incidence of prior stroke and significant bleeding compared with White patients. Black and Hispanic patients were treated with LAAO in smaller numbers relative to their proportion of the US population. Rates of procedural success were similar between groups. Though direct oral anticoagulants were prescribed in most patients across the groups, dual and single antiplatelet therapy were prescribed more often in Black patients. Black patients had significantly higher rates of 1-year death and bleeding compared with White and Hispanic patients.

CONCLUSIONS: Patients from racial and ethnic minority groups comprise a disproportionately small fraction of all patients who undergo LAAO. Black and Hispanic patients were younger but had significantly higher comorbidities compared with White patients. Procedural success was similar among the groups, but Black patients experienced higher rates of death and bleeding at 1 year.

Key Words: atrial fibrillation ■ bleeding ■ left atrial appendage occlusion ■ racial disparity ■ stroke

Transcatheter left atrial appendage occlusion (LAAO) is an increasingly used alternative therapy to long-term anticoagulation for stroke prevention in selected patients with nonvalvular atrial fibrillation (AF). Stroke is the most devastating complication of AF, and the use of oral anticoagulation or LAAO has been shown to be effective at reducing stroke risk.[1,2] Despite the effectiveness of anticoagulation, racial and ethnic minority patients, and particularly Black patients diagnosed with AF, are less likely to be discharged on

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CLINICAL PERSPECTIVE

What Is New?

- In this study from a large US national registry of patients undergoing left atrial appendage occlusion, Black patients were younger but had higher baseline comorbidities and experienced higher rates of bleeding at 45 days and 1-year and higher 1-year mortality rates.

What Are the Clinical Implications?

- Further work is needed to enroll diverse patients into research trials and to provide equitable atrial fibrillation–related access to advanced care and intraprocedural and postprocedural care in US real-world practice.

Nonstandard Abbreviations and Acronyms

LAAO	left atrial appendage occlusion
NCDR	National Cardiovascular Data Registry
PREVAIL	Prospective Randomized Evaluation of the WATCHMAN LAA Closure Device in Patients With Atrial Fibrillation Versus Long-Term Warfarin Therapy
PROTECT-AF	WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation
SURPASS	Safety and Efficacy of the WATCHMAN FLX Device in Patients With Non-Valvular Atrial Fibrillation

oral anticoagulants, while also having a higher risk of stroke compared with White patients.[3,4] Similarly, it has been shown that there are significant racial and ethnic disparities in structural heart disease interventions, including LAAO,[5] with 1 study showing that racial and ethnic minority patients comprised less than 4% of those treated with these advanced interventions between 2011 and 2016.[5] Racial and ethnic minority individuals have also been consistently shown to be undertreated in terms of other cardiovascular procedures like transcatheter aortic valve replacement, mitral valve replacement, and implantation of implantable cardioverter-defibrillators.[6–9]

In published clinical trials and real-world experience with transcatheter LAAO, non-Hispanic White patients have represented >90% of cases; it is not clear that the efficacy in the overall population is generalizable to all racial and ethnic groups. Studies of racial and ethnic disparities in transcatheter LAAO outcomes have shown higher rates of in-hospital complications among non-Hispanic Black and Hispanic patients compared with non-Hispanic White patients.[10] However, there is a paucity of data comparing postdischarge outcomes across racial and ethnic groups.

The SURPASS (Safety and Efficacy of the WATCHMAN FLX Device in Patients With Non-Valvular Atrial Fibrillation) registry is an analysis of patients who underwent LAAO with the WATCHMAN FLX device as part of the American College of Cardiology Foundation's NCDR (National Cardiovascular Data Registry) LAAO registry. The aim of this current analysis is to examine the use of and outcomes after WATCHMAN FLX LAAO across racial and ethnic groups in a large national registry.

METHODS

The authors declare that all supporting data are available within the article and its Supplemental Material.

Data Source

This analysis included the American College of Cardiology Foundation limited data set of patients implanted with the WATCHMAN FLX device (Boston Scientific, Marlborough, MA) in the NCDR LAAO registry. This registry was initiated in December 2015 after US Food and Drug Administration approval of the first WATCHMAN device.[11] The NCDR LAAO registry serves as the formal postmarket surveillance vehicle required by the US Food and Drug Administration for the WATCHMAN device, and it is the only registry approved by Centers for Medicare and Medicaid Services to satisfy the coverage decision data submission requirement.[12] As of April 2016, US hospitals were required to submit data for all WATCHMAN procedures into the LAAO registry to qualify for Medicare reimbursement. Hospitals are encouraged to submit data on all device recipients regardless of insurance status. As previously described, per the NCDR's Institutional Review Board, a waiver of written informed consent and authorization for this study was granted.[13] The reporting of this study conforms to the Strengthening the Reporting of Observational Studies in Epidemiology statement.[14]

The LAAO registry data collection methods have been detailed previously.[11] In brief, the LAAO registry collects ≈220 data elements from the implant hospitalization, 60 for each follow-up visit, and 15 data elements to support the adjudication of adverse events. Data are collected at discharge, and follow-up visits over the first year occur at 45 days (±14 days), 180 days (–30 days/+60 days), and 365 days (±60 days). The

NCDR Data Quality Reporting process is designed to ensure that submissions are complete, valid, and accurate; it involves an annual audit of about 5% of sites that are randomly selected, during which submitted data are compared with source documentation and billing data.[15] The LAAO registry developed and validated a novel process to adjudicate adverse clinical events over follow-up. A computer-based algorithm uses discrete combinations of registry data elements based on standard event definitions to adjudicate adverse events.[16] Cases are manually adjudicated when registry data elements are incomplete or conflicting. Adjudicated adverse events in the registry include ischemic stroke, hemorrhagic stroke, undetermined stroke, transient ischemic attack, intracranial hemorrhage, systemic arterial embolism (other than stroke), major bleeding, and major vascular complications.

Study Population

This analysis used patient data collected between August 5, 2020, and September 30, 2022. All patients with attempted WATCHMAN FLX implantation were included. The data collection form of the NCDR LAAO registry has a racial category question and a Hispanic or Latinx ethnicity question. Analysis cohorts were based on the selections within these 2 questions. Race and Hispanic or Latinx ethnicity was determined by the patient/family and site reported. Groups were then defined as White (non-Hispanic White), Black (Black/African American on the Data Collection Form; [non-Hispanic Black]), Asian (non-Hispanic Asian), Native American/Pacific Islander (non-Hispanic American Indian/Alaska Native/Native Hawaiian/Pacific Islander) and Hispanic (Hispanic or Latinx). Additional groups included multiple selections (if multiple categories were selected), other (1 of the 2 questions was not answered), and no race or ethnicity reported (neither question was answered). Patient and procedure characteristics and outcomes in patients with multiple selections, other, or no selection can be found in Tables S1 through S4.

Study End Points

All-cause death, stroke (ischemic and/or hemorrhagic), and major bleeding (any bleeding requiring hospitalization and/or causing a decrease in hemoglobin level>2 g/dL or requiring blood transfusion that was not hemorrhagic stroke[11]) were evaluated at 45 days and 1 year. Additional end points evaluated at 45 days include major vascular complications, pericardial effusion, device embolization, device migration, and peridevice leak.

Statistical Analysis

Data were summarized using descriptive statistics for continuous variables and frequency tables or proportions for discrete variables. *P* values were from the Fisher exact or χ^2 test, as appropriate. Clinical event rates at 45 days and 1 year were estimated using the Kaplan–Meier method with *P* values from the log-rank test. To include patients with long enough follow-up, for the 45-day analysis, patients discharged on or before September 2022 were included, and those who were discharged on or before December 31, 2021, were included in the 1-year analysis. Adjustment or differences in baseline characteristics was performed in the 3 largest groups. Cox proportional hazards regression was performed for the comparisons between White and Black and White versus Hispanic patients. Candidate variables are included in Data S1. The following variables, based on clinical relevance and with a $P<0.02$ in univariable analyses, were included: age, sex, components of the CHA_2DS_2-VASc and/or HAS-BLED scores, type of AF, fall risk, chronic lung disease, sleep apnea, cardiomyopathy, coronary artery disease, prior ablation, and left ventricular ejection fraction. We excluded all patients with missing data in the multivariate analysis. Statistical analyses were conducted using SAS version 9.4 (SAS Institute, Cary, NC).

RESULTS

A total of 97 185 patients were implanted with WATCHMAN FLX between August 5, 2020, and September 30, 2022, at 772 sites in the United States. Most patients were White individuals (90% [n=87 339]); Black patients comprised 3.9% (n=3750), Hispanic 2.9% (n=2866), Asian 1.1% (n=1082), and American Indian/Pacific Islander 0.3% (n=274) of the patient population. Data from other groups can be found in Tables S1 through S5, including 297 patients with multiple races or ethnicities selected (0.3%), 1255 (1.3%) who did not have data for both race and ethnicity and 322 who did not have data for either race or ethnicity (0.3%). Black, Hispanic, Asian, and American Indian/Pacific Islander patients were treated with LAAO in smaller numbers relative to their proportion of the US population (Figure S1).[17]

Baseline Characteristics

Overall, there were significant differences in baseline characteristics between racial and ethnic groups. Black and Native American/Pacific Islander patients were several years younger than other groups and had the largest ratio of women to men (Table 1). The CHA_2DS_2-VASc score was highest in Black, Hispanic, and Native American/Pacific Islander patients; and HAS-BLED was highest in Black patients. Prior stroke was highest in Black and Asian patients and prior bleeding highest in Black patients.

Table 1. Baseline Characteristics

Description	White (N=87 339)	Black (N=3750)	Hispanic/Latinx ethnicity (N=2866)	Asian (N=1082)	American Indian/ Alaska Native or Native Hawaiian/ Pacific Islander (N=274)	Overall *P* value
Age, y	76.6±7.6 (87 339)	72.3±9.5 (3750)	75.0±9.1 (2866)	75.5±9.0 (1082)	73.5±9.1 (274)	<0.0001
Age group, y						<0.0001
<70	14 958 (17.1)	1352 (36.1)	698 (24.4)	263 (24.3)	85 (31.0)	
70–80	44 684 (51.2)	1658 (44.2)	1332 (46.5)	483 (44.6)	129 (47.1)	
>80	27 697 (31.7)	740 (19.7)	836 (29.2)	336 (31.1)	60 (21.9)	
Female	35 762 (41.0)	1834 (48.9)	1240 (43.3)	443 (40.9)	120 (43.8)	<0.0001
CHA_2DS_2-VASc score	4.7±1.5 (87 088)	4.9±1.6 (3745)	4.9±1.6 (2861)	4.8±1.5 (1077)	4.9±1.5 (274)	<0.0001
Congestive heart failure	32 477 (37.2)	1835 (49.0)	1101 (38.4)	347 (32.1)	116 (42.3)	<0.0001
Left ventricular dysfunction	7471 (8.6)	528 (14.1)	310 (10.8)	77 (7.1)	28 (10.2)	<0.0001
Hypertension	79 721 (91.3)	3597 (95.9)	2689 (93.8)	1000 (92.6)	256 (93.4)	<0.0001
Diabetes	29 429 (33.7)	1775 (47.4)	1462 (51.0)	508 (47.0)	122 (44.5)	<0.0001
Stroke	17 298 (19.8)	1134 (30.3)	760 (26.5)	343 (31.8)	73 (26.6)	<0.0001
Transient ischemic attack	10 015 (11.5)	377 (10.1)	297 (10.4)	108 (10.0)	44 (16.1)	<0.0001
Thromboembolic event	12 183 (14.0%)	738 (19.7%)	470 (16.4%)	183 (16.9%)	44 (16.1%)	<0.0001
Vascular disease	46 108 (52.8)	1808 (48.2)	1394 (48.7)	491 (45.5)	148 (54.0)	<0.0001
HAS-BLED score	2.8±1.1 (87 081)	3.0±1.2 (3742)	2.8±1.2 (2861)	2.8±1.1 (1077)	2.8±1.2 (273)	<0.0001
Uncontrolled hypertension	25 081 (28.7)	1314 (35.1)	904 (31.5)	270 (25.0)	70 (25.6)	<0.0001
Abnormal renal function	11 315 (13.0)	1079 (28.8)	495 (17.3)	210 (19.4)	51 (18.7)	<0.0001
Abnormal liver function	2598 (3.0)	136 (3.6)	148 (5.2)	39 (3.6)	14 (5.1)	<0.0001
Stroke	18 051 (20.7)	1162 (31.0)	774 (27.0)	361 (33.4)	82 (30.0)	<0.0001
Bleeding	56 949 (65.3)	2829 (75.5)	1929 (67.3)	745 (69.0)	194 (71.1)	<0.0001
Labile international normalized ratio	4277 (4.9)	173 (4.6)	145 (5.1)	35 (3.2)	14 (5.1)	<0.0001
Alcohol	4415 (5.1)	145 (3.9)	92 (3.2)	26 (2.4)	14 (5.1)	<0.0001
Drugs—antiplatelet	29 970 (34.4)	1325 (35.4)	879 (30.7)	305 (28.2)	101 (37.0)	<0.0001
Drugs—NSAIDS	11 418 (13.1)	498 (13.3)	288 (10.1)	106 (9.8)	24 (8.8)	<0.0001
Increased fall risk	36 969 (42.4)	1256 (33.6)	1187 (41.5)	394 (36.5)	109 (39.9)	<0.0001
Clinically relevant bleeding event	48 158 (55.3)	2712 (72.4)	1732 (60.5)	690 (63.8)	162 (59.1)	<0.0001
AF pattern						<0.0001
Paroxysmal	53 806 (62.1)	2598 (69.9)	1782 (62.9)	635 (59.2)	182 (66.9)	
Persistent	18 019 (20.8)	640 (17.2)	568 (20.0)	217 (20.2)	47 (17.3)	
Long-standing persistent	10 189 (11.8)	322 (8.7%)	312 (11.0)	137 (12.8)	30 (11.0)	
Permanent	4677 (5.4)	159 (4.3)	173 (6.1)	84 (7.8)	13 (4.8)	
Attempt at AF termination of patients with AF	40 546 (46.5)	1325 (35.4)	1018 (35.6)	368 (34.0)	102 (37.2)	<0.0001
Atrial flutter	15 980 (18.3)	720 (19.2)	425 (14.9)	163 (15.1)	46 (16.8)	<0.0001
Attempt at atrial flutter termination of patients with atrial flutter	10 834 (68.2)	436 (60.8)	282 (66.8)	103 (63.2)	34 (73.9)	0.11
Cardiac structural intervention	6824 (7.8)	240 (6.4)	218 (7.6)	73 (6.8)	18 (6.6)	0.001
Hypertrophic cardiomyopathy	880 (1.0)	70 (1.9)	25 (0.9)	15 (1.4)	4 (1.5)	<0.0001
Chronic lung disease	17 303 (19.8)	799 (21.3)	415 (14.5)	115 (10.6)	67 (24.5)	<0.0001
Coronary artery disease	38 750 (44.4)	1464 (39.1)	1183 (41.4)	429 (39.7)	126 (46.0)	<0.0001
Sleep apnea	26 587 (30.5)	1071 (28.6)	667 (23.3)	195 (18.0)	86 (31.4)	<0.0001

(*Continued*)

Table 1. Continued

Description	White (N=87 339)	Black (N=3750)	Hispanic/Latinx ethnicity (N=2866)	Asian (N=1082)	American Indian/ Alaska Native or Native Hawaiian/ Pacific Islander (N=274)	Overall *P* value
Sleep apnea treatment	19 489 (22.5)	727 (19.6)	434 (15.3)	139 (12.9)	61 (22.3)	<0.0001
LAA orifice maximal width, mm	20.9±4.3 (85 401)	22.0±4.5 (3683)	20.7±4.4 (2797)	21.5±4.3 (1064)	21.2±4.7 (270)	<0.0001
Left ventricular ejection fraction, %	54.3±9.6 (56 095)	52.5±12.1 (2532)	53.7±10.8 (1801)	55.7±10.0 (668)	53.5±10.6 (185)	<0.0001

Numbers are n (%) or mean±SD (N). AF indicates atrial fibrillation; LAA, left atrial appendage; and NSAIDS, nonsteroidal anti-inflammatory drugs.

Procedural Characteristics

Indications for LAAO were consistent across the groups and mainly related to risk of bleeding and/or stroke (Table 2). Device size tended to be larger in Black and Asian patients. Same-day discharge rates ranged from 21.5% to 38.2%. The rates of successful implantation and complete seal after the procedure were high in all groups. Direct oral anticoagulation alone and direct oral anticoagulant plus aspirin were prescribed in the majority of patients across all groups. Dual antiplatelet therapy and single antiplatelet therapy were prescribed more often in Black patients than other groups (Table 3).

Outcomes at 45 Days

Outcomes at 45 days, unadjusted for differences in baseline characteristics, are shown in Figure 1 and Table S6. Death occurred in 0.81% of patients overall at 45 days and was not statistically different across racial and ethnic groups, ranging from 0.41% in Native American/Pacific Islanders to 1.10% in Black patients. Stroke occurred in 0.29% of patients overall and was highest in Asian patients (0.80%) at 45 days. The rate of major bleeding in all patients combined was 3.11% at 45 days. There were significant statistical differences overall, and the highest rates were found in Black patients (4.92%) and Native American/Pacific Islanders (4.89%). Peridevice leak at 45 days was similar across groups.

Cox proportional hazard regression analysis to adjust for differences in baseline characteristics was performed in the 3 largest racial and ethnic groups using White patients as the reference group (Table 4 and Figure 2). After adjustment, the risk of bleeding was significantly higher at 45 days in Black compared with White patients (hazard ratio [HR), 1.30 [95% CI, 1.10–1.54). Death and stroke were similar between Black and White patients after adjustment. No differences in death, stroke, or bleeding were found in White versus Hispanic patients at 45 days after adjustment.

Outcomes at 1 Year

Outcomes at 1 year are shown in Figures 1 and 2 and Table S7. At 1 year, the rate of unadjusted death was 8.15% and was significantly different across the racial and ethnic groups. Native American/Pacific Islanders (15.79%) and Black (11.24%) had the highest rates of death at 1 year. The causes of death (defined in the NCDR LAAO registry) are listed in Table S8. Major bleeding in the overall patient cohort was 6.37% at 1 year and varied significantly among racial and ethnic groups. Major bleeding was highest in Native American/Pacific Islanders (10.32%) and Black (10.91%) patients compared with the other groups (Figures 1 and 2 and Table S6). Stroke overall at 1 year was 1.48% and, though not statistically significantly different, ranged from 1.37% in Asian patients to 2.28% in Black patients.

After adjustment, the risk of death and bleeding was significantly higher in Black compared with White patients at 1 year (death: HR, 1.26 [95% CI, 1.06–1.50); bleeding: HR, 1.36 [95% CI, 1.15–1.60). Hispanic and White patients had similar risk of death and bleeding at 1 year. The risk of stroke was similar between groups in each comparison (White versus Black or White versus Hispanic) after adjustment at 1 year.

DISCUSSION

This study is the largest analysis of racial and ethnic differences in use and outcomes of LAAO procedures in the United States to date including almost 100 000 patients. We demonstrated the following key findings: (1) Significant racial and ethnic disparities exist, with <4% of Black patients and <3% of Hispanic patients comprising patients who receive LAAO; (2) Black patients undergoing LAAO are significantly younger but with more comorbidities than White patients undergoing the procedure; and (3) the risk of death at 1 year and major bleeding at 45 days and 1 year was higher for Black patients compared with White patients.

Disparities in Access to LAAO

Relative to their proportion of the US population, Black, Hispanic, Asian, and American Indian/Pacific Islander patients were treated with LAAO in smaller numbers in SURPASS (Figure S1).[17] However, the racial and ethnic

Table 2. Procedural Characteristics

Description	White (N=87 339)	Black (N=3750)	Hispanic/Latinx ethnicity (N=2866)	Asian (N=1082)	American Indian/ Alaska Native or Native Hawaiian/ Pacific Islander (N=274)	Overall *P* value
Successful implantation	85 149 (97.5)	3688 (98.4)	2797 (97.6)	1053 (97.3)	264 (96.4)	0.051
Indication for procedure*						
Increased thromboembolic stroke risk	55 482 (63.6)	2348 (62.6)	1844 (64.3)	723 (66.8)	182 (66.7)	0.03
History of major bleeding	44 915 (51.4)	2562 (68.3)	1612 (56.3)	631 (58.3)	151 (55.3)	<0.0001
High fall risk	33 484 (38.4)	1116 (29.8)	1081 (37.7)	359 (33.2)	95 (34.8)	<0.0001
Labile international normalized ratio	3200 (3.7)	145 (3.9)	109 (3.8)	34 (3.1)	7 (2.6)	<0.0001
Patient preference	37 599 (43.1)	1322 (35.3)	1118 (39.0)	479 (44.3)	117 (42.9)	<0.0001
Noncompliance with anticoagulation therapy	2806 (3.2)	145 (3.9)	128 (4.5)	23 (2.1)	12 (4.4)	0.0003
Average number of devices used per patient	1.2±0.5 (87 339)	1.1±0.4 (3750)	1.1±0.4 (2866)	1.2±0.4 (1082)	1.2±0.55 (274)	<0.0001
Device size, mm						
20	10 604 (12.5)	253 (6.9)	340 (12.2)	79 (7.5)	28 (10.6)	
24	26 669 (31.3)	859 (23.3)	915 (32.7)	279 (26.5)	75 (28.4)	
27	27 026 (31.7)	1242 (33.7)	875 (31.3)	360 (34.2)	85 (32.2)	
31	15 163 (17.8)	898 (24.4)	475 (17.0)	212 (20.1)	54 (20.5)	
35	5687 (6.7)	436 (11.8)	192 (6.9)	123 (11.7)	22 (8.3)	
Procedure time, min	78.0±66.2 (87336)	84.9±57.5 (3750)	88.9±274.1 (2866)	84.7±86.6 (1081)	75.2±37.2 (274)	<0.0001
Contrast volume, mL	37.9±33.2 (84440)	36.5±33.9 (3558)	43.6±37.1 (2736)	38.9±34.8 (1039)	40.6±31.2 (267)	<0.0001
General anesthesia	82 633 (94.8)	3544 (94.8)	2736 (95.8)	1033 (95.8)	265 (96.7)	<0.0001
Concomitant procedure performed	1776 (2.0)	86 (2.3)	59 (2.1)	18 (1.7)	8 (2.9)	<0.0001
Length of stay, d	2.0±6.76 (87339)	2.6±9.05 (3750)	2.6±10.19 (2866)	2.2±2.75 (1082)	1.8±1.19 (274)	<0.0001
Same-day discharge	30 301 (34.7)	940 (25.1)	652 (22.8)	287 (26.5)	114 (41.6)	<0.0001
Residual leak after procedure, mm						<0.0001
0	81 155 (96.4)	3466 (94.8)	2661 (96.7)	980 (94.6)	242 (94.5)	
>0 to ≤3	2414 (2.9)	165 (4.5)	77 (2.8)	43 (4.2)	11 (4.3)	
>3 to ≤5	571 (0.7)	24 (0.7)	13 (0.5)	11 (1.1)	3 (1.2)	
>5	19 (0)	1 (0.03)	0 (0)	2 (0.2)	0 (0)	
Patients with missing leak data	3180	94	115	46	18	

Numbers are n (%) or mean±SD (N).
*Patients can have >1 indication.

representation among WATCHMAN FLX recipients in this study mirror the low enrollment of racial and ethnic minority patients in clinical trials involving these devices. The PROTECT-AF (WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation) and PREVAIL (Prospective Randomized Evaluation of the WATCHMAN LAA Closure Device in Patients With Atrial Fibrillation Versus Long-Term Warfarin Therapy) trials that led to US Food and Drug Administration approval for the WATCHMAN device had few minority patients, with 1.3% and 2.2% Black enrollment, respectively, as compared with >90% White enrollment in both trials.[18,19] Similar disparities in real-world LAAO use have been previously described in other observational studies.[10,20–22] An important consideration that affects access of racial and ethnic minority patients to LAAO procedures is the location of hospitals/centers that perform the procedures. An analysis of Medicare fee-for-service claims (2016–2019) by Reddy and colleagues revealed that between 2016 and 2019, 97.4% of new LAAO programs opened in the United States were in metropolitan areas.[7] The authors found that LAAO centers, as compared with non-LAAO centers, provided care to patients with higher median household incomes. After adjustment for socioeconomic markers, age, and clinical comorbidities, LAAO procedures were less likely to be performed in zip codes with higher proportions of Black and Hispanic patients.[7] The authors concluded that geographic proximity alone may not ensure equitable access to LAAO.

Table 3. Discharge Medication Regimens

Description	White (N=87 339)	Black (N=3750)	Hispanic/Latinx ethnicity (N=2866)	Asian (N=1082)	American Indian/ Alaska Native or Native Hawaiian/ Pacific Islander (N=274)
Direct oral anticoagulant alone	13 623 (22.7)	604 (23.0)	581 (30.7)	206 (20.2)	39 (20.4)
Direct oral anticoagulant+aspirin	29 245 (48.7)	1248 (47.5)	785 (41.5)	317 (43.4)	98 (51.3)
Direct oral anticoagulant +$P2Y_{12}$ inhibitor	3005 (5.0)	90 (3.4)	103 (5.5)	41 (5.6)	9 (4.7)
Warfarin alone	1496 (2.5)	58 (2.2)	41 (2.2)	13 (1.8)	11 (5.8)
Warfarin+aspirin	4521 (7.5)	148 (5.6)	92 (4.9)	37 (5.1)	11 (5.8)
Warfarin+$P2Y_{12}$ inhibitor	408 (0.68)	11 (0.42)	14 (0.74)	6 (0.82)	3 (1.6)
Dual antiplatelet therapy	4805 (8.0)	296 (11.3)	132 (7.0)	66 (9.0)	11 (5.8)
Single antiplatelet therapy	1482 (2.5)	110 (4.2)	65 (3.4)	25 (3.4)	2 (1.1)
Triple therapy	1.5 (1.5)	37 (1.4)	34 (1.8)	14 (1.9)	3 (1.6)
Other	233 (0.39)	10 (0.38)	19 (1.0)	3 (0.41)	0 (0.0)
No oral anticoagulant or antiplatelet therapy	403 (0.67)	16 (0.61)	24 (1.3)	2 (0.27)	4 (2.1)

Numbers are n (%) or mean±SD (N); Other=(warfarin+ direct oral anticoagulant +$P2Y_{12}$ inhibitor) or (warfarin+direct oral anticoagulant+aspirin) or (warfarin+ direct oral anticoagulant).

Another important consideration that affects the demographic composition of those who undergo LAAO procedures is that White patients have a higher risk of AF than other racial and ethnic groups.[4] However, this only explains some of the underrepresentation of racial and ethnic minority groups among patients undergoing LAAO procedures. In 1 analysis using the National Inpatient Sample (a 20% random, stratified sample of hospital discharges in the United States), there were racial and ethnic differences in adult admissions related to a diagnosis of AF where more than 80% were White individuals, 9.3% were Black individuals, 5.7% were Hispanic individuals, 2% were Asian American and Pacific Islander individuals, and 2.4% were of other races and ethnicities.[21] However, the proportions of racial and ethnic minority patients undergoing LAAO procedures was still lower than their proportions among AF admissions. Examining the racial and ethnic makeup of the patients who underwent LAAO procedures in this study, Black patients made up only 4.2% and Hispanic patients 5.0% of patients undergoing LAAO procedures.[21] Similar underrepresentation was seen in other National Inpatient Sample analyses.[10,20,22] Other studies investigating AF in the US population confirmed the lower incidence and prevalence rates of AF in Black (1.8%–6.6%), Hispanic (1.5%–7.8%), Asian (2.1%–9.9%), and Native American patients (5.4%) compared with White patients (3.4%–11.3%).[23–27] These distributions are highly dependent on the sex and ages of the patient population studied.[23]

A number of underlying reasons have been posited to explain the racial and ethnic differences in the undertreatment of underrepresented racial and ethnic groups including barriers to health care access, socioeconomic and insurance status, mistrust of the health care system, implicit bias, lack of proper training and resources among physicians, and patient preferences in treatment and health care use.[4,28–30]

Disparities in LAAO Outcomes

Prior analyses have focused on short-term outcomes and found differences in major adverse events between White patients and racial and ethnic minority patients regarding intraprocedural or immediate postprocedural complications even after adjusting for differences in baseline characteristics.[10,20–22] SURPASS patients were followed up to a year and the rates of major adverse events at 45 days and 1 year were similar in White and Hispanic patients. However, the risk of death at 1 year and major bleeding at 45 days and 1 year was higher for Black patients compared to White patients even after adjustment for differences in baseline comorbidities. Though we adjusted for known differences in baseline characteristics, the impact of the disparities leading to these differences, suggested above, was not accounted for.

The differences in outcomes in this study may be related to differences in medical comorbidities. Black and Hispanic patients had higher CHA_2DS_2-VASc and HAS-BLED scores. Additionally, Black patients had the highest incidence of prior bleeding and more than twice the incidence of abnormal renal function compared with White patients. This increase in bleeding in Black patients may be driven by worse renal function in this patient population. Both of which could have contributed to the increase in death observed at 1 year. These data echo other studies focusing on the impact

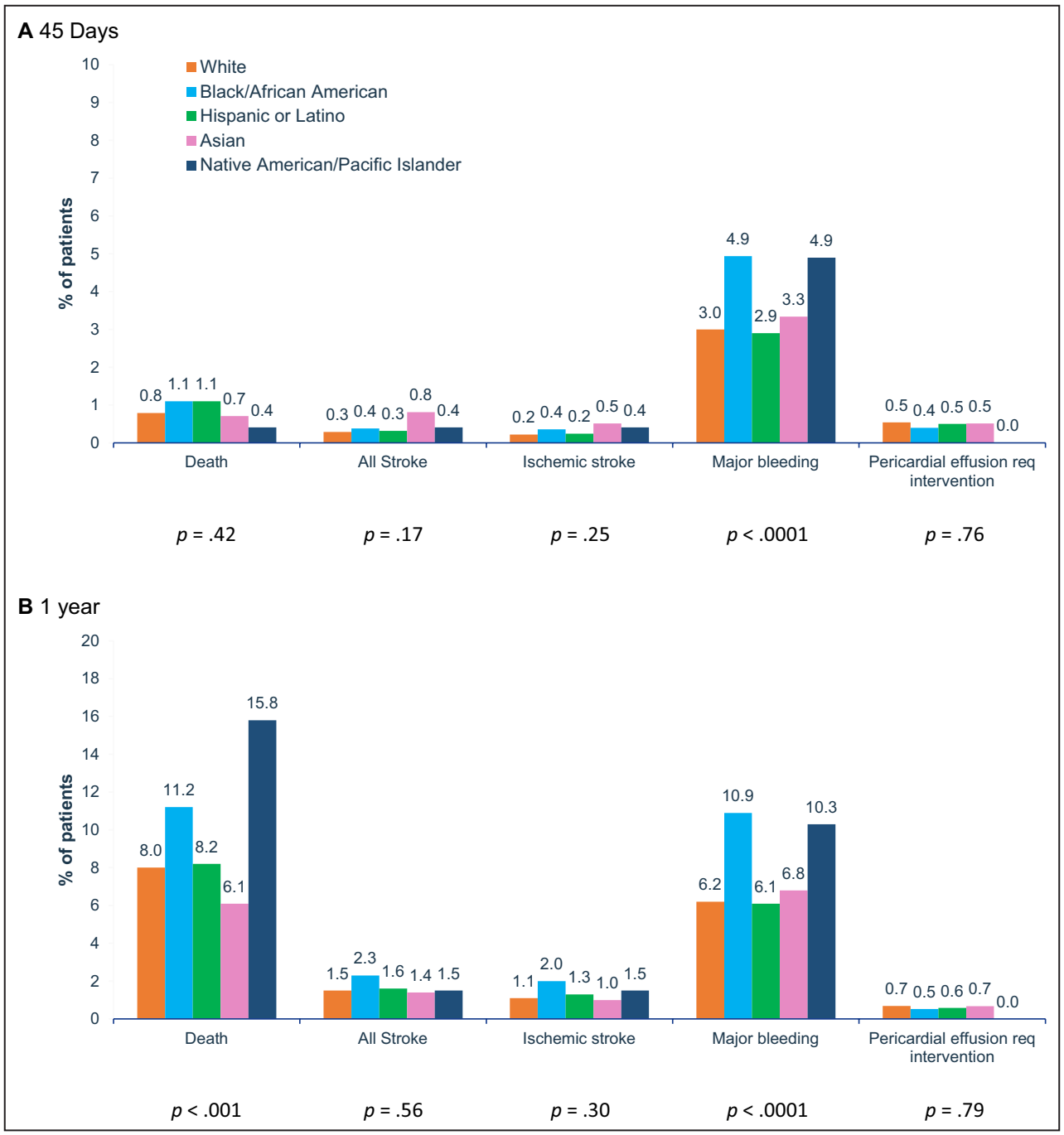

Figure 1. Outcomes at 45 days and 1 year by race and ethnicity.
Time-to-event outcomes at (**A**) 45 days and (**B**) 1 year by race and ethnicity in patients implanted with WATCHMAN FLX.

of race and ethnicity after LAAO. Compared with White patients, more Black patients; Hispanic patients; and patients of Asian, Asian American, or Pacific Islander ancestry had diabetes, chronic kidney disease, previous stroke, and deficiency anemias.[21] The higher risk factor burden in Black compared with White patients in contrast with the lower incidence and prevalence of AF is called the AF race paradox. Several theories have been proposed to explain this paradox, including larger atrial dimensions to allow for remodeling in White patients, underascertainment in Black patients due to higher likelihood of paroxysmal AF, poorer access to medical care and survival bias of White patients, and differences in genetic susceptibility between Black and White patients.[31–33]

Black patients were more commonly discharged on anticoagulation plus aspirin or dual antiplatelet therapy instead of anticoagulation alone, which has been

Table 4. Outcomes in the Adjusted Cohorts Through 45-Day and 1-Year Follow-Up Visits

	Black		Hispanic/Latinx ethnicity	
	Univariable HR (95% CI)	Multivariable HR (95% CI)	Univariable HR (95% CI)	Multivariable HR (95% CI)
45 d				
All death	1.39 (1.00–1.94)	1.18 (0.83–1.67)	1.11 (0.72–1.70)	1.15 (0.75–1.77)
All stroke	1.30 (0.74–2.28)	1.15 (0.65–2.02)	1.10 (0.54–2.23)	1.04 (0.51–2.12)
Ischemic stroke	1.69 (0.96–2.98)	1.50 (0.85–2.64)	1.07 (0.48–2.43)	1.06 (0.47–2.40)
Major bleeding*	1.64 (1.39–1.92)	1.30 (1.10–1.54)	0.99 (0.79–1.25)	0.90 (0.71–1.15)
1 y				
All death	1.37 (1.17–1.61)	1.26 (1.06–1.50)	1.04 (0.83–1.29)	0.99 (0.79–1.25)
All stroke	1.38 (0.97–1.96)	1.12 (0.77–1.63)	1.06 (0.65–1.73)	1.09 (0.67–1.79)
Ischemic stroke	1.57 (1.08–2.28)	1.24 (0.83–1.85)	1.12 (0.66–1.92)	1.13 (0.66–1.94)
Major bleeding*	1.75 (1.50–2.04)	1.36 (1.15–1.60)	0.99 (0.78–1.25)	0.89 (0.69–1.14)

HR (95% CI); reference White patients. HR indicates hazard ratio.

*Any bleeding requiring hospitalization and/or causing a decrease in hemoglobin level>2 g/dL, and/or requiring blood transfusion that was not hemorrhagic stroke. Multivariable models adjusted for age, sex, CHA_2DS_2-VASc and HAS-BLED score components, type of atrial fibrillation, diabetes, fall risk, history of bleeding, chronic lung disease, sleep apnea, cardiomyopathy, coronary artery disease, prior ablation, left ventricular ejection fraction, and postimplant device margin residual leak.

previously reported to be associated with higher rates of bleeding after LAAO.[34] The increased use of antiplatelet agents may be indicated in this population with a higher burden of cardiovascular and renal comorbidities but could impact the difference in outcomes that were found between White and Black patients. Residual confounding due to unreported patient characteristics, disparities in access to LAAO, and postprocedural care may also account for some of the differences observed in bleeding and death.

Future Directions

Disparities leading to inadequate access to structural heart interventions remains a challenge in other areas as well, as similar single-digit representation of Black and Hispanic patients were found in the transcatheter aortic valve replacement population.[5,9,35] An analysis of the Transcatheter Valve Therapy Registry of patients undergoing transcatheter aortic valve replacement in the United States revealed that only 3.8% of patients were Black individuals compared with 91.3% White patients.[9] Similar findings have been found for other cardiovascular procedures, including mitral valve replacement and implantation of implantable cardioverter-defibrillators.[6,8,9] There is a pressing need to increase enrollment of minority patients into clinical trials either by way of mandated enrollment targets, broadening the clinical trial sites to include hospitals serving predominantly racial and ethnic minoritized patients and including investigators who also serve this patient population in clinical trials. Strategies to improve access should also include efforts to train providers and help develop infrastructure at centers that provide care to mainly minority patients. Interestingly, hospitals in urban centers with a large minority population still have low treatment rates of minority patients,[7] suggesting that low enrollment rates are not just a location issue. Efforts must be made to address barriers to care even in hospitals serving predominantly minority communities. Even if trial enrollment of minority populations improves, the absolute numbers of minority patients may remain relatively modest, particularly for device trials, which tend to be smaller, precluding detailed assessments of differences in outcomes. Real-world registry data serve as a complement to smaller trials for the study of these important patient subgroups.

Limitations

As with all observational registries there are limitations to this analysis including unmeasured or residual confounders. Both race and ethnicity were defined by the subject but are social constructs that may encompass a variety of genetic and cultural backgrounds. Canceled procedures are not included in the data received from the NCDR LAAO registry and hospital location or region are not known. Patient zip code and insurance status were not available in the data set used. Dialysis status is unknown, and adjusting for estimated glomerular filtration rate stage may not capture different degrees of abnormal renal function. There is no control group, so it is difficult to determine if disparities are inherent to differences in efficacy versus differences in baseline risk. Only patients treated with WATCHMAN FLX are included, and patients are being followed for >2 years, but this analysis is limited to 1 year follow-up. The reporting of events relies on site-reported data, although algorithmic adjudication of adverse events is employed by the NCDR LAAO registry.

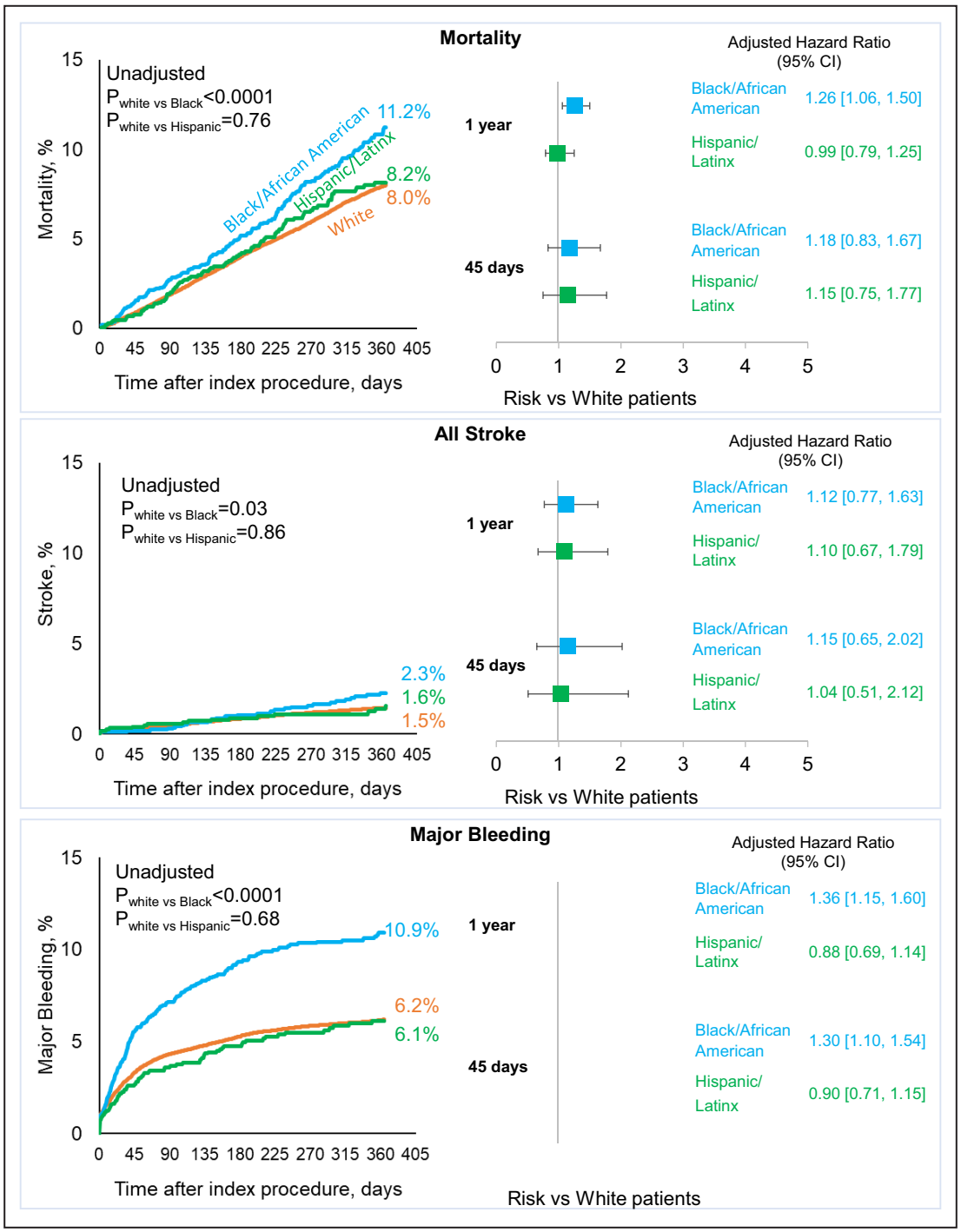

Figure 2. Unadjusted and adjusted outcomes of adverse events for White, Black, and Hispanic/Latinx patients receiving WATCHMAN FLX.

P value from the log-rank test. **HR** (95% CI); reference White patients; *Major bleeding defined as bleeding requiring hospitalization, and/or causing a decrease in hemoglobin level>2 g/dL, and/or requiring blood transfusion that was not hemorrhagic stroke. Multivariable models adjusted for age, sex, CHA_2DS_2-VASc and HAS-BLED score components, type of atrial fibrillation, diabetes, fall risk, history of bleeding, chronic lung disease, sleep apnea, cardiomyopathy, coronary artery disease, prior ablation, left ventricular ejection fraction, and postimplant device margin residual leak. HR indicates hazard ratio.

CONCLUSIONS

This study is the largest analysis of racial and ethnic disparities in LAAO procedures in the United States to date, and it revealed that minorities remain significantly underrepresented despite increasing procedural volumes nationally. Black patients were younger but had higher baseline comorbidities and experienced higher rates of bleeding at 45 days and 1 year and a higher 1-year mortality rate.

ARTICLE INFORMATION

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Supplemental Material

Data S1
Tables S1–S8
Figure S1

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