5-6-2021

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Recommended Citation
Haddad A, Bocchese M, Garber R, O'Neill B, Yesenosky GA, Patil P, Keane MG, Islam S, Sherrer JM, Basil A, Gangireddy C, Cooper JM, Cronin EM, and Whitman IR. Racial and ethnic differences in left atrial appendage occlusion wait time, complications, and periprocedural management. Pacing Clin Electrophysiol 2021.

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Medtronic

Received: 16 February 2021 | Revised: 1 April 2021 | Accepted: 11 April 2021

DOI: 10.1111/pace.14255

PACE WILEY

ORIGINAL - ELECTROPHYSIOLOGY

Racial and ethnic differences in left atrial appendage occlusion wait time, complications, and periprocedural management

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Abstract

Purpose: Non-white patients are underrepresented in left atrial appendage occlusion (LAAO) trials, and racial disparities in LAAO periprocedural management are unknown.

Methods: We assessed sociodemographics and comorbidities of consecutive patients at our institution undergoing LAAO between 2015 and 2020, then in adjusted analyses, compared procedural wait time, procedural complications, and post-procedure oral anticoagulation (OAC) use in whites versus non-whites.

Results: Among 109 patients undergoing LAAO (45% white), whites had lower CHA_2DS_2VASc scores, on average, than non-whites (4.0 vs. 4.8, $p = .006$). There was no difference in median time from index event (IE) or initial outpatient cardiology encounter to LAAO procedure (whites 10.5 vs. non-whites 13.7 months, $p = .9$; 1.9 vs. 1.8 months, $p = .6$, respectively), and there was no difference in procedural complications (whites 4% vs. non-whites 5%, $p = .33$). After adjusting for CHA_2DS_2VASc score, OAC use at discharge tended to be higher in whites (OR 2.4, 95% CI [0.9-6.0], $p = .07$). When restricting the analysis to those with prior gastrointestinal (GI) bleed, adjusting for CHA_2DS_2VASc score and GI bleed severity, whites had a nearly five-fold odds of being discharged on OAC (OR 4.6, 95% CI [1-21.8], $p = 0.05$). The association between race and discharge OAC was not mediated through income category (total mediation effect 19% 95% CI [-.04-0.11], $p = .38$).

Conclusion: Despite an increased prevalence of comorbidities amongst non-whites, wait time for LAAO and procedural complications were similar in whites versus non-whites. Among those with prior GI bleed, whites were nearly five-fold more likely to be discharged on OAC than non-whites, independent of income.

KEYWORDS
atrial fibrillation, cerebrovascular accident, left atrial occlusion device, mediation analysis, racial disparities, Watchman

1 | INTRODUCTION

Atrial fibrillation (AF) is the most common cardiac arrhythmia in the United States, and its prevalence is projected to increase as the population ages.[1] It affects approximately 1% of the United States population and is the most common cause of embolic stroke.[2–4] The primary treatment strategy for stroke risk reduction is with chronic oral anticoagulation (OAC).[5] Left atrial appendage occlusion (LAAO) has emerged as a stroke risk reduction strategy for patients in whom long-term OAC use is contraindicated and been demonstrated to be non-inferior to OAC.[6–9] LAAO by Watchman (Boston Scientific, St. Paul, Minnesota, USA) has emerged as the most common non-surgical LAAO strategy in the United States.[10]

Despite blacks with AF having a greater risk of embolic stroke,[11] and being more likely to have subtherapeutic anticoagulation and higher risk of hemorrhage when treated with warfarin for stroke prevention,[12] large trials examining the benefits of Watchman implant have markedly underrepresented blacks, who comprise less than 2% of study cohorts.[6,7,9,13] This may be, in part, due to a diminished referral pattern in blacks relative to whites for LAAO[14] and that whites may be more likely to embrace new therapeutic medical technologies.[15] These findings reflect a general trend in racial disparities in access to medical care, whereby non-white and indigent patients face greater barriers to continuity of care and medical care,[16–18] including advanced therapies such as percutaneous coronary intervention,[19] and coronary bypass and valvular surgery.[14,20,21]

Given the diverse socio-demographics in the United States, understanding disparities in the delivery of care across races and socioeconomic groups is essential. In white versus non-white patients undergoing LAAO, we compared patient socioeconomic and medical characteristics, examined differences in procedural wait time, procedural complications, post-LAAO anticoagulation regimen, and post-procedural follow-up parameters.

2 | METHODS

We identified consecutive patients undergoing LAAO (Watchman) at our urban medical center between May 2015 and March 2020 through retrospective review of our electronic medical record, and patients were entered into an institutional clinical registry. In white versus non-white patients, we compared socio-demographic factors, medical comorbidities, procedural wait time from index event (IE), defined as time from event when a patient was deemed to be a poor candidate for long-term anticoagulation, and cardiology encounter to implant procedure, procedural complications, post-procedure anticoagulation regimen, adherence to protocoled 45-day follow-up transesophageal echocardiogram (TEE), and prevalence of LAAO leak.

The Watchman implant procedure has been previously described.[22] Pre-procedural left atrial appendage sizing was done via cardiac computed tomography or TEE, and subsequently confirmed intra-procedurally by TEE. The implantation procedure was done under TEE and fluoroscopic guidance. Device implantation procedures were performed jointly by an interventional cardiologist and cardiac electrophysiologist (five total implanting physicians at our institution), with an advanced fellow in training present during the majority of procedures. Safety outcomes related to device implantation were defined as cardiac perforation, pericardial effusion, cardiac tamponade, stroke, myocardial infarction, or death during the index hospitalization. There was no protocol for the use of anticoagulation aside from what was done in prior clinical trials.[7] Post-procedural anticoagulation regimen was determined on an individual basis according to the treating physician.

Normally distributed continuous variables were reported as means ± standard deviation and were compared using Student's *t*-test. Categorical variables were reported as proportions and were compared using the chi-square test. Income data were obtained by publicly available median income figures by zip code, and incorporated into the mediation analysis as a binary variable of above or below the poverty line.[23] Times from IE and cardiology referral to device implant were reported as medians with interquartile range and comparisons between groups were performed using Cox regression models. Adjustments in time from IE and cardiology referral to device implant, and post implantation anticoagulation regimen were made for CHA_2DS_2VASc score. Adjustments for regressions comparing post-procedural anticoagulation regimen were made for CHA_2DS_2VASc score and severity of gastrointestinal (GI) bleed (severe vs. less than severe). Variables included in the CHA_2DS_2VASc score were not individually adjusted for to avoid statistical redundancy and reduction in power. GI bleed was defined as severe if the patient required blood transfusion, or Type 3 bleed according to the Bleeding Academic Research Consortium definition for bleeding.[24] Income was treated as a mediator on the forward pathway from race to anticoagulation use on discharge.[25] Its effect on the relationship between race and OAC at discharge was assessed using maximum likelihood estimation in a structural equation model. We also examined whether there was any association in the OAC prescription pattern in those with ESRD versus non-ESRD patients using a logistic regression model. A two-tailed *p*-value of $< .05$ was considered statistically significant. All analyses were performed using STATA 15.1 Statistical Software (StataCorp, College Station, Texas, USA).

3 | RESULTS

We identified 109 consecutive patients undergoing LAAO during the study period. Patient characteristics, including comorbidities and socio-demographics, are shown in Table 1. Non-white patients ($n = 60$, 55%) were mostly black ($n = 42$, 39% of total cohort), and of similar age to white patients. Overall, non-white patients were sicker than white patients, more frequently reported a prior history of stroke, and had higher average CHA_2DS_2VASc and HAS-BLED scores compared to whites. The cohort overall had a high prevalence of poverty ($n = 40$, 38%), and non-white patients were markedly more likely to be

TABLE 1 Baseline characteristics in white versus non-white patients

	White (N = 49)	Non-white (N = 60)	P-value
Age, year	75.3 ± 7.6	72.5 ± 9.8	.10
Sex, female	27 (55)	25 (42)	.16
Race/ethnicity White African American Hispanic AsianOther	49 (100)	42 (70)15 (25) 2 (3)1 (2)	
Hypertension	38 (78)	50 (83)	.45
Diabetes mellitus	19 (39)	32 (53)	.13
Cerebrovascular accident	7 (14)	26(43)	.001
Coronary artery disease	16 (41)	19 (42)	.91
Peripheral vascular disease	9 (18)	10 (17)	.82
Congestive heart failure	9 (18)	29 (48)	.001
End stage renal disease	0 (0)	12 (20)	<.001
AF pattern Paroxysmal Persistent PermanentUnknown	29 (59)7 (14) 10 (20)3 (6)	36 (60)7 (12) 9 (15)8 (13)	.38
CHA2DS2VASc Score (continuous)	4.06 ± 1.27	4.80 ± 1.47	.01
CHA2DS2VASc Score (categorical) 1 2 3 4 5 6 78	1 (2)5 (10) 10 (20) 13 (27) 14 (29) 6 (12) 0 (0)0 (0)	0 (0)3 (5) 7 (12) 20 (33) 9 (15) 13 (22) 6 (10)2 (3)	.05
HAS-BLED Score (continuous)	3.47 ± 0.84	4.18 ± 0.95	<.001
Insurance provider Medicaid MedicarePrivate	1 (2)46 (94)1 (4)	6 (10)51 (85)3 (5)	.23
Mean annual income (dollars)	51,859 ± 25,241	29,714 ± 12,038	<.001
Below poverty line	7 (15)	33 (55)	<.001
Indication for Watchman Major bleeding Labile INR Falls[a]Bruising[b]Other[b]	37 (76)2 (4) 4 (8) 4 (8)2 (4)	53 (88)0 (0) 2 (3) 0 (0)5 (8)	.04
Type of bleeding GI bleed Intracranial hemorrhage Epistaxis HematuriaOther	23 (62)3 (8) 3 (8) 5 (14)3 (8)	38 (70)5 (9) 6 (11) 0 (0)5 (9)	.09

Values are in N (%), mean ± SD. The *p* values are based on *t*-tests for continuous variables and chi-square tests for dichotomous variables.

CHA_2DS_2VASc Score: sum of congestive heart failure (+ 1), hypertension (+ 1), age 65 to 74 years (+ 1) and > 75 years (+ 2), female sex (+ 1), diabetes mellitus (+ 1), previous stroke/transient ischemic attack (+ 2), and vascular disease (+ 1).

HAS-BLED Score: sum of (+ 1 for each) hypertension, renal disease, liver disease, previous stroke/transient ischemic attack, prior major bleeding or disposition to bleeding, labile INR if on warfarin, age > 65 years, medication use predisposing to bleeding, alcohol consumption of > 7 drinks/week.

Abbreviations: INR, international normalized ratio; AF, Atrial fibrillation.

[a]In these patients, oral anticoagulation was felt unsafe and therefore Watchman was offered.

[b]These patients refused lifelong oral anticoagulation and therefore Watchman was offered.

TABLE 2 Comparisons of time to implant, procedural complications, post LAAO implant anticoagulation use, and adherence to 45-day follow up transesophageal echocardiogram between white and non-white patients

	White	Non-white	*p*-value
Time from IE to implant, months	10.5 (5.7-39.7)	13.7 (5.1-38.9)	.9[a], 1[b]
Time from cardiology referral to implant, months	1.9 (1.1-4.0)	1.8 (1.0-3.1)	.9[a], .6[b]
Discharge anticoagulation OAC DAPT	40 (81.6) 9 (18.4)	40 (66.7) 20 (33.3)	.08[c], .05[d]
OAC Warfarin DOAC	22 (55) 18 (45)	20 (51) 19 (49)	.74[e]
Complications pericardial effusion cardiac perforation tamponade	2 (4) 2 (100) 0 (0) 0 (0)	3 (5) 1 (33) 1 (33) 1 (33)	.33[e]
Follow up TEE ≤ 45 days	42 (91)	51 (88)	.58[e]

Values are in n (%), time data are in median (IQR1-IQR3).
Abbreviations: DOAC, direct oral anticoagulants; OAC, oral anticoagulants; DAPT, dual antiplatelet therapy; TEE, transesophageal echocardiogram; GI, gastrointestinal; LAAO, Left atrial appendage occlusion; IE, index event.
[a]*p* values based on a univariable Cox regression model.
[b]*p* values based on a multivariable Cox regression model adjusting for CHA2DS2VASc score.
[c]*p* value is based on a univariable logistic regression model.
[d]*p* value is based on a multivariable logistic regression model, restricted to those with prior GI bleed, adjusting for CHA_2DS_2VASc and GI bleed severity.
[e]*p* value is based on chi-square test.

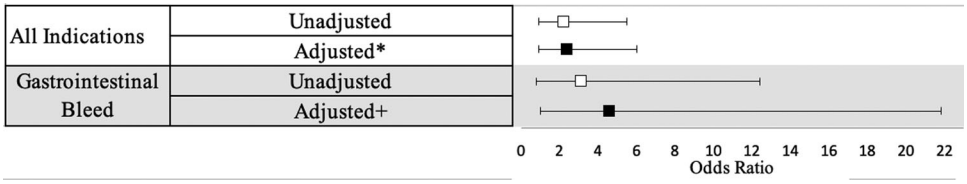

FIGURE 1 Odds of oral anticoagulation use in whites versus non-whites after LAAO, stratified by indication. White patients are the referent group. Unadjusted analyses were conducted using univariable logistic regression models and adjusted analyses were conducted using multivariable logistic regression models *adjusting for CHA_2DS_2VASc score or + CHA_2DS_2VASc score and GI bleed severity

in poverty than whites. There was no significant difference between the two groups in terms of medical insurance providers, with the vast majority of patients having Medicare. When comparing blacks and Hispanics, there was no significant difference in the baseline characteristics between the two groups (Supplementary Table S1). Compared to whites, non-white patients had similar times from IE, the majority of which were GI bleeds, and cardiology referral appointment to device implant (Table 2).

All patients had successful LAAO. Five patients experienced a procedural complication, all of which were pericardial effusions. One patient required pericardial drainage due to tamponade. One patient underwent emergent surgical intervention due to cardiac perforation. Of the five patients, two were white, and three were non-white; there was no difference in complication rates between groups (whites 4% vs. non-whites 5%, $p = .33$).

After adjusting for CHA_2DS_2VASc score, white patients were twice as likely as non-white patients to be discharge on OAC rather than dual antiplatelet therapy. This observation did not meet statistical significance (unadjusted OR 2.2, 95% CI [0.9-5.5], $p = .08$; adjusted OR 2.4, 95% CI [0.9-6.0], $p = .07$). However, when restricting the analysis to those with prior GI bleed as the indication for LAAO, after adjusting for CHA_2DS_2VASc and severity of GI bleed, whites were nearly five times more likely to be discharged on OAC versus dual antiplatelet therapy compared to non-whites (unadjusted OR 3.1, 95% CI [0.76-12.4], $p = .1$; adjusted OR 4.6, 95% CI [1-21.8], $p = .05$) (Figure 1). In those who were discharged on OAC, warfarin was prescribed for 22 (55%) of white patients compared to 20 (50%) of non-white patients and there was no statistical difference between the two groups ($p = .74$).

In our study cohort, there were 12 patients with end stage renal disease (ESRD), all of whom were black. Most of our ESRD patients, 67% (eight patients) were discharged on OAC regimen. There was no significant difference in the use of OAC when comparing ESRD patients versus non-ESRD patients (OR 1.4, 95% CI [0.4-5.2], $p = .6$).

In examining the extent to which income may mediate the racial difference on OAC use at discharge, income did not statistically influence

the relationship between race and discharge anticoagulation regimen ($p = .38$). Income only accounted for 19% (95% CI [- 0.04-0.11]), $p = .38$) of the total effect of race on discharge OAC regimen.

Excluding patients who had their 45-day follow-up TEE postponed due to the SARS-CoV-2 pandemic (white, $n = 3$; non-white, $n = 2$), protocoled 45-day follow-up TEE was done within 45 days in 91% of whites and 88% of non-whites ($p = .58$). Three patients had peri-device leak of > 5 mm at the follow-up TEE, all of whom were non-white ($p = .1$).

4 | DISCUSSION

In the context of national racial disparities in medical care and underrepresentation of minority races and ethnicities in major LAAO trials,[6,7,9,13] we examined a racially diverse group of consecutive patients undergoing LAAO procedures at our urban institution. We compared patient comorbid and socio-demographic characteristics, procedural wait times, complications, discharge medical regimen, and follow up TEE results in white versus non-white patients. Although non-white patients were markedly sicker and more frequently living in poverty, procedural wait times and complications between whites and non-whites did not significantly differ. However, post-procedural medical management demonstrated more prevalent use of OAC in whites than in non-whites, particularly in a subset of patients with a history of GI bleed.

AF is more common in whites compared with non-whites,[26–28] despite a greater incidence of risk factors for AF amongst non-whites, who also suffer greater morbidity associated with AF, including stroke.[11,29] As LAAO is the preferred alternative for stroke prevention in patients with a contraindication to OAC understanding racial disparities in those undergoing LAAO is critical.

Consistent with national trends in racial disparity,[30] we found that non-white patients had more medical co-morbidities at baseline than whites. Hispanics had a similar prevalence of co-morbidities when compared to black patients. Given that patient co-morbidity is strongly associated with differences in race and ethnicity, the higher risk of procedural complications in sicker patients may disproportionately affect minority races and ethnicities.[31,32] In fact, our racially diverse population had more co-morbidities compared to the patient cohorts in the PROTECT AF and PREVAIL trials with regard to congestive heart failure (34.9% vs. 23.4% and 26.8%, respectively), stroke (30.3% vs. 17.7% and 27.5%) and diabetes (46.8% vs. 24.4% and 33.8%)..[6,7,9] In addition to being sicker than whites, non-white patients in our study were more likely to be impoverished, and may be more representative of urban populations in the United States.[33] The morbidity of patients in our study was similar to that which was found examining LAAO patients among different racial groups in the National Inpatient Sample, suggesting that our population may be more representative of what is observed outside clinical trials.[14]

While it has been reported that blacks may have reduced access to LAAO,[14,34] we found that non-whites, who were also poorer than whites in our study, had similar wait times for LAAO when compared to whites once they had been referred. Impoverished patients often have more obstacles to advanced forms of therapy such as LAAO,[16–18] and race-related healthcare disparities in the United States persist after accounting for income.[35] Longer procedural wait times have correlated with worse outcomes and lower patient satisfaction.[36,37] Disparities in procedural wait times along racial lines have been reported.[38] However, we did not observe a significant difference LAAO wait time according to race, with any difference perhaps mitigated by prevalent relative uniformity in health insurance provider in our population, or other system factors related to serving an impoverished community.

While there was no difference in procedural wait times between whites and non-whites, most patients across races had government based medical coverage (i.e. Medicare or Medicaid). As there is an interplay between race and insurance that contributes to access to care,[39] it may be that insurance coverage serves as an equalizer in leveling procedural wait times. It may also be that at a hospital such as ours where the large majority of patients are minorities and on government based medical coverage, the system is more adept in navigating the challenges of progressing from hospitalization to outpatient referral to elective procedural intervention. It is provocative that in some contexts, there are differences in wait time across race or income,[38,40] but in other scenarios, as in the present study, this is not the case. Whether these differences in socioeconomic disparities are related to bias or an effect of the degree of heterogeneity in patient mix, or something else, is unknown. In a population with greater heterogeneity in insurance coverage, and thus more variability in prior authorization practices and reimbursement policies, differences in procedural wait times may be exaggerated.

Despite there being no difference between race groups in procedural wait times, it is notable that the overall median wait times from IE to LAAO procedure and cardiology referral to LAAO procedure were 13.5 and 1.85 months, respectively. This represents a period of time, off of OAC, prior to LAAO, during which patients were vulnerable to cardio-embolic events. Relative uniformity of insurance coverage across patients, urban geography, and service of an underserved community may be equalizers in procedural wait times, but may be in and of themselves be tied to delays in care.

We found no difference in acute procedural complications in LAAO when comparing whites versus non-whites. The incidence of procedural complications across racial and socioeconomic lines has been shown in catheter based and cardiac procedures,[41,42] although is not a uniform observation in other procedural populations.[43] A recent analysis of the National Inpatient Sample to assess racial and ethnic disparities in the utilization of structural heart disease interventions in the United States, including LAAO, revealed that while TAVR and LAAO may be under-utilized in minorities, outcomes across racial lines are similar.[14] In our racially diverse population of consecutive patients undergoing LAAO, there was no difference in acute complications after LAAO, despite an increased prevalence of co-morbidities. Our overall complication rate is similar to that of previous published studies of LAAO with Watchman.[6,7]

Watchman implantation guidelines stipulate that OAC is recommended for the 45 days after LAAO to protect against device-related thrombus as endothelialization over the occlusion device occurs with no difference in the safety profile when using Direct Oral Anticoagulation (DOAC) or warfarin.[7,44] However, in a multicenter prospective trial, the use of OAC was contraindicated in 73% of patients undergoing Watchman placement,[45] although the threshold for when OAC is "contraindicated" is somewhat subjective and often incorporates patient preference.[46] When discharging a patient in whom OAC is contraindicated after Watchman implant, dual antiplatelet therapy is suggested.[47] In our analysis, the majority of the patients were discharged on OAC. However, there was a trend toward more prevalent use of dual antiplatelet therapy in non-white patients when compared to whites. When restricting the analysis to patients with prior GI bleed, in whom the decision to discharge on OAC versus dual antiplatelet therapy is most pertinent, whites were nearly three-fold more likely to be discharged on OAC than non-whites (non-significant). This trend became statistically significant and the racial difference more marked after adjusting for both stroke risk and severity of GI bleed.

The risk versus benefit of anticoagulation in ESRD patients with AF is controversial and recently investigated in large trials.[48–50] Nonetheless, the presence of underlying ESRD in patients undergoing LAAO implant had no association with the post implant anticoagulation regimen. Therefore, despite all ESRD patients in our cohort being black, the presence of ESRD alone could not account for the differences between OAC use non-whites and whites.

Although there was a significant difference in the income between whites and non-whites, income category was not a significant mediator in the relationship between race and discharge OAC regimen. This could be explained by the fact that all patients had medical coverage, mostly government based medical insurance, which could have mitigated the effect of income gap between the two groups on post-Watchman OAC regimen.

This study had several limitations. The single center, observational design allows for regional selection bias, other unmeasured biases, and potentially identifies associations, but not causation. Nonetheless, sampling a large, urban, largely impoverished population provides data that may be generalizable to other urban centers. Importantly, we did not capture community referral patterns for LAAO, and therefore how race or income disparity may be associated with utilization of LAAO was not examined. Income was not measured on an individual level but rather obtained from publicly available income data by zip code. Further study is warranted to understand the degree to which non-white or impoverished patients are under-referred for LAAO. Because our study was not powered specifically to address differences in rare procedural complications between groups, there exists the possibility of Type II error. Moreover, complications after discharge from the procedural hospitalization were not captured. There was no specific protocol for post-procedure OAC regimen. The decision making for the use of OAC versus dual antiplatelet post-procedurally was not identified, but as each decision is patient and proceduralist specific, these findings may nonetheless be generalizable. The lack of significant difference in the

5 | CONCLUSION

Significant differences in baseline patient characteristics and co-morbidities between white and non-white patients undergoing LAAO implantation do exist. However, these differences did not translate into longer procedural wait times, acute procedural complications, or disparate results on follow-up 45-day TEE. However, upon discharge immediately after LAAO, OAC versus dual antiplatelet therapy is more common in whites versus non-whites, a relationship that is markedly more pronounced in those with prior GI bleed and independent of level of income.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

CODE AVAILABILITY

Stata 15.1

ORCID

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: Haddad A, Bocchese M, Bocchese M, et al. Racial and ethnic differences in left atrial appendage occlusion wait time, complications, and periprocedural management. *Pacing Clin Electrophysiol*. 2021;1—8