**Use of prasugrel and clinical outcomes in African-American patients treated with percutaneous coronary intervention for acute coronary syndromes**

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**ABSTRACT**

**Objective:** To investigate the use of prasugrel after percutaneous coronary intervention (PCI) in AA patients presenting with acute coronary syndrome (ACS).

**Background**: African American (AA) patients are at higher risk for adverse cardiovascular outcomes after PCI and may derive greater benefit from the use of potent antiplatelet therapy.

**Methods**: Using the multicenter PROMETHEUS observational registry of ACS patients treated with PCI, we grouped patients by self-reported AA or other races. Clinical outcomes at 90-day and 1-year included non-fatal myocardial infarction (MI), major adverse cardiac events (composite of death, MI, stroke or unplanned revascularization) and major bleeding.

**Results**: The study population included 2,125 (11%) AA and 17,707 (89%) non-AA patients. AA patients were younger, more often female (46% vs 30%) with a higher prevalence of diabetes mellitus, chronic kidney disease, and prior coronary intervention than non-AA patients. Although AA patients more often presented with troponin (+) ACS, prasugrel use was much less common in AA vs. non-AA (11.9% vs. 21.4%, respectively p=0.001). In addition, the use of prasugrel increased with the severity of presentation in non-AA but not in AA patients. Multivariable logistic regression showed AA race was an independent predictor of reduced use of prasugrel (0.42 [0.37-0.49], p<0.0001). AA race was independently associated with a significantly higher risk of MI at 90-days and 1 year after PCI.

**Conclusions**: Despite higher risk clinical presentation and worse 1-year ischemic outcomes, AA race was an independent predictor of lower prasugrel prescription in a contemporary population of ACS patients undergoing PCI.

ABBREVIATIONS

AA African-American

ACS Acute coronary syndrome

CABG Coronary artery bypass graft

CKD chronic kidney disease

CVD cerebrovascular disease

DES Drug eluting stent

MACE Major adverse cardiac events

MI Myocardial infarction

NSTEMI non-ST segment elevation myocardial infarction

PCI Percutaneous coronary intervention

STEMI ST segment elevation myocardial infarction

INTRODUCTION

Racial and ethnic differences can influence the risk of cardiovascular diseases and adverse events after acute coronary syndromes (ACS) and coronary interventions([1](#_ENREF_1)). Prior research has indicated that African American (AA) patients have the highest risk of cardiac events compared to any other race in the United States([2](#_ENREF_2)). The excess risk is mostly attributed to the higher prevalence of cardiovascular risk factors and comorbidities in AA patients ([3](#_ENREF_3)). In addition, socioeconomic factors, potential barriers to healthcare access and genetic variants are also thought to play a role. For instance, it has been reported that AA patients presenting with ACS are less likely to be referred to coronary artery revascularization([4](#_ENREF_4)).

Even when treated with percutaneous coronary intervention (PCI), small observational studies suggest the rate of short- and long-term adverse events is higher in AA patients([5](#_ENREF_5)). In part, this might be attributed to the high on-treatment platelet reactivity with clopidogrel observed in AA([6](#_ENREF_6)). Genetic studies have found a higher proportion of at least one loss of function CYP2C19 allele in AA that may lead to a suboptimal biotransformation of clopidogrel into its active compound([6](#_ENREF_6)). The use of novel P2Y12 inhibitors might therefore be preferable in these patients to overcome the low responsiveness to clopidogrel. However, few clinical data are available on the prescription and effect of prasugrel in AA patients in real world practice where several cofactors such as physicians perception of patients’ risk of adverse events and socioeconomic factors influence the prescription of P2Y12 inhibitors. PROMETHEUS is a prospective multicenter US registry that comprises a relatively large dataset on AA patients presenting with ACS and treated with PCI. Here, we describe the use of prasugrel and clopidogrel and the clinical outcomes in AA and non-AA patients after PCI.

METHODS

Study Population

Prometheus is a multicenter prospective registry comprising data from 19,914 all-comer patients presenting with ACS and treated with PCI in any of the 8 academic medical centers in the US involved in the study between 1st January 2010 and 30th June 2013. All patients enrolled were treated with either clopidogrel or prasugrel. PROMETHEUS evaluated the comparative effectiveness of a treatment strategy with prasugrel compared to clopidogrel at the time of PCI. For the purpose of this study we subdivided the study population according to their self-reported race at admission into African American (AA) and non-African Americans (non-AA). Non-AA included white Caucasian and Asians. The use of prasugrel and clopidogrel was described in AA and non-AA patients. Additionally, all patients were stratified according to the “Patterns of non-adherence to anti-platelet regimens in stented patients” (PARIS) registry coronary thrombotic risk score and the PARIS bleeding risk score, to investigate whether the treatment choice in each study group was motivated by the patient’s estimated ischemic and bleeding risk. The PARIS risk score has been previously described ([7](#_ENREF_7)). In brief, the thrombotic PARIS risk model is based on the following variables: diabetes mellitus, ACS presentation, current smoking habit, creatinine clearance, prior PCI and prior coronary artery bypass graft (CABG). The PARIS bleeding risk model is based on age, body mass index (BMI), current smoking habit, anemia, creatinine clearance, and triple therapy at discharge. Finally, we described the 90 day and 1-year clinical outcomes in AA and non-AA after PCI: information on the clinical follow-up at 90 days and 1 year was obtained from the participating centers. No adjudication was performed as all diagnoses were provided through the participating centers from the treating physician in charge of the follow up. Occurrence of clinical endpoints was obtained from medical records.

Clinical endpoint definitions

The primary clinical endpoint was a composite of major adverse cardiac events (MACE), including all-cause death, non-fatal myocardial infarction (MI), stroke or unplanned coronary revascularization at 90 days from index hospital PCI. The secondary endpoints included individual components of MACE. The primary safety endpoint was major bleeding, defined as any clinically overt hemorrhage requiring hospitalization or blood transfusion. The rate of clinical endpoints was evaluated at 90 days and 1 year after index PCI.

Statistical analysis

Continuous variables are reported as mean ± SD and were compared between the study groups using Student’s t-test. Categorical variables were reported as numbers and percentages and compared with the χ2test. The cumulative incidence of adverse events was estimated using the Kaplan-Meier method of time to first event and groups were compared using the log-rank test. To evaluate the adjusted associations between race and clinical outcomes, hazard ratios and confidence intervals were calculated using multivariable Cox proportional hazards regression. The variables used in the model were the following: age, BMI, diabetes mellitus, hypertension, chronic kidney disease, previous MI, previous PCI, previous cerebrovascular disease (CVD), clinical presentation (unstable angina, non-ST elevation MI -NSTEMI- and ST elevation MI-STEMI-) multivessel disease, stent type, stent length and participating center. Similarly, hazard ratios and confidence intervals were generated for adjusted risks of 90-day and 1-year outcomes associated with prasugrel use (with clopidogrel as a reference) using Cox regression model with the following variables: age, BMI, diabetes mellitus, hypertension, CKD, previous MI/PCI, previous CVD, clinical presentation, multivessel disease stent type, stent length and center. Data were analyzed using Stata version 14.0 (StataCorp, College Station, Texas).

RESULTS

The study included 19,832 ACS patients treated with PCI between January 2010 and June 2013 with information available on race. We identified 2,125 (10.7%) AA patients and 17,707 (89.3%) non-AA patients comprising 74% Caucasians and 26% who identify themselves with other races. Demographic and clinical characteristics by AA and non-AA race are listed in table 1. In brief, compared to non-AA, AA patients were younger, more often females, more often had a history of tobacco smoking, and had a higher BMI. The prevalence of diabetes mellitus, hypertension, CKD and anemia was higher in AA patients. AA were also more likely to have a history of coronary artery disease, prior PCI, prior CABG, and history of cerebrovascular and peripheral artery disease. On presentation, AA had a higher rate of STEMI and NSTEMI compared to non-AA with lower rates of unstable angina (Fig. 1). Consequently, AA were more often treated with urgent PCI. Angiographic characteristics are shown in table 2, AA patients presented with less multivessel disease, calcific coronary disease, long and complex B2/C lesions, bifurcation lesions as well as PCI of the left main and the LAD compared with non-AA patients. Compared to non-AA, AA patients more frequently received bare-metal stents and 1st generation drug eluting stents (DES) (Table 2).

At discharge, prescription of aspirin, P2Y12 inhibitors, beta blockers and statins did not significantly differ between AA and non-AA. ACE inhibitors were prescribed less frequently in AA patients, despite the higher rate of hypertension in this group (Supplementary Table 1). Importantly, prasugrel was prescribed in 21% of non-AA and in 11.9% of AA patients overall, p<0.01, (Fig. 2A). At multivariable logistic regression AA race emerged as an independent predictor of reduced use of prasugrel (0.42 [0.37-0.49], Z-stat= -11.92, p<0.0001) in the entire study population. When stratified according to severity of clinical presentation, the use of prasugrel increased significantly in non-AA (19% for unstable angina –UA-, 23% for NSTEMI and 25% for STEMI patients, p<0.001) but not in AA (12% for UA, 8.5% for NSTEMI and 14.4% for STEMI, p=ns) (Fig. 2B).

Next, patients were stratified by race and by estimated risk of thrombotic and bleeding events using the PARIS score (Fig. 3 A - B). AA had significantly greater estimated risk for coronary thrombotic events than non-AA with a similar estimated bleeding risk. Importantly, in both AA and non-AA the use of prasugrel decreased with the increase of ischemic risk score however, regardless of risk stratum, it remained constantly lower in AA than non-AA (Fig. 3A). A similar pattern was observed when use of prasugrel was stratified by the estimated bleeding risk (Fig. 3B).

Post-procedural complications were rare and their incidence did not differ by race (Table 3). In particular, peri-procedural MI and bleeding events occurred in 282 (1.6%) non-AA vs. 39 (1.8%) AA patients and in 252 (1.4%) non-AA vs. 33 (1.6%) AA patients, respectively (p=ns). At 90 days and 1 year after PCI, unadjusted rates of all ischemic and bleeding events were significantly higher in AA (Fig. 4 and Supplementary Fig. 1), with the exception of stent thrombosis which was rare in both groups, n=80 (0.52%) in non-AA and n=8 (0.42%) in AA patients. Upon multivariable adjustment, the risk of MACE, all-cause mortality, myocardial revascularization and bleeding were similar between the study groups at 90 days (Fig. 4). Only the adjusted risk of MI was higher in AA compared to non-AA. Similar adjusted outcomes were observed at 1-year, (Supplementary Fig. 1). At 90 days, use of prasugrel was associated with a lower adjusted risk of death in non-AA patients but a higher risk of MACE and revascularization in AA, a finding possibly reflective of a selection bias. Nevertheless, at 1-year, use of prasugrel was associated with a similar risk of ischemic and bleeding events as clopidogrel in AA patients. (Fig. 5)

DISCUSSION

This analysis from a large patient-level pooled multicenter database show that AA patients have a higher risk of 90-day and 1-year ischemic adverse events after ACS PCI as determined by both systemic comorbidities and severity of clinical presentation. Despite the higher estimated and observed risk of coronary thrombotic events, and the higher rate of STEMI presentation, AA race was an independent predictor of less frequent prescription of prasugrel compared to non-AA. This behavior was not justified by bleeding concerns since both the estimated and the observed risk of bleeding was comparable to non-AA. Since other cardiovascular medications, necessary for an optimal medical management after ACS, are equally prescribed across the study population the lower prescription of prasugrel might be due to the drug cost and socioeconomic factors requiring further investigation.

The higher prevalence of cardiovascular risk factors and comorbidities among AA patients is well known([8](#_ENREF_8)). Clinical presentation in the current analysis was more severe in AA than non-AA. In particular, the rate of STEMI was significantly higher in AA patients in our analysis. Despite higher rates of risk factors and comorbidities in AA, the extent of coronary artery disease was less severe in AA patients who had lower rates of multivessel disease, coronary calcification, bifurcation lesions, and ACC/AHA type B2/C lesions ([9](#_ENREF_9),[10](#_ENREF_10)). In non-AA, diabetes, hypertension and CKD are usually associated with a higher rate of diffuse, multivessel coronary artery disease, complex B2/C lesions with tortuosity and calcifications([11](#_ENREF_11),[12](#_ENREF_12)). Interestingly, even though diabetes, hypertension and CKD were more frequent in AA in our database, these patients were more likely to present with less complex angiographic characteristics, which may partly be explained by the younger age at presentation of AA patients in our cohort.

Nevertheless, these results are consistent with observations on atherosclerosis in other vascular territories. It has been shown, for instance, that AA have a higher risk of cerebrovascular accidents despite a lower burden of macroscopic extracranial carotid artery disease ([13](#_ENREF_13),[14](#_ENREF_14)). In part, this can be explained with an increased expression of atherosclerosis in the intracranial carotid arteries. Similarly, we observed that despite less complex angiographic characteristics the rate of spontaneous MI is significantly higher in AA already at 90 days after PCI. While epicardial coronary artery disease seems less complex in AA, it is possible abnormalities in the microcirculation might contribute to ischemic events after PCI. Other elements that could in part be responsible for the different rate of MI between the study groups are the stent choice and the pharmacological treatment. AA were significantly more likely to receive bare metal stents or first-generation DES than non-AA. In addition, there was a preferential use of clopidogrel in AA. It has previously been reported that high platelet reactivity (HPR) on clopidogrel treatment is more frequent in AA thus increasing the risk of in stent restenosis and progression of atherosclerotic disease([15](#_ENREF_15)). On the other hand, HPR might also contribute to reduce the bleeding events in AA patients. The rate of bleeding events in AA patients after PCI might therefore be underestimated compared to non-AA who are more likely to respond to clopidogrel. In aggregate, these elements can in part be responsible for the higher rate of short and long-term MI in AA compared to non-AA. However, higher rates of MI in AA did not result in an excess of all cause death nor coronary revascularization compared to non-AA.

One limitation of this study is the lack of information on reasons that led to the P2Y12 inhibitor selection at discharge, the type of antiplatelet treatment used during the follow-up and the potential switch to a different P2Y12 inhibitor. This is true for both AA and non-AA patients. However, it is likely that socioeconomic factors might result in disparities in the access to high cost medications in AA patients compared to non-AA([16](#_ENREF_16),[17](#_ENREF_17)). A recent study on ethnic and racial disparities in health insurance coverage has shown that from 2010 to 2014, a time range similar to PROMETHEUS, the rate of uninsured AA decreased from 27.1% in 2010 to 20.7% in 2014 vs 15.7% to 11.7% in Caucasians([18](#_ENREF_18)). It should be noted, however, that all patients presenting with ACS in the United States have medical coverage for at least 30 days after discharge. Therefore, prescription of potent P2Y12 drugs during the hospital stay for ACS should not be contingent on patients’ socioeconomic and insurance status. Moreover, the primary endpoint of PROMETHEUS was at 90 days to ensure little switching and fairly good adherence to treatment at that time point ([19](#_ENREF_19)).

Nevertheless, prescription of prasugrel was lower in AA overall. It is worth noting that in the PROMETHEUS population as a whole, younger patients and patients with STEMI were more likely to receive prasugrel. Although these two factors were more common in AA, it did not lead to increased use of prasugrel. In particular, use of prasugrel was around 60% lower compared to non-AA in NSTEMI and around 50% lower in STEMI patients. A study collecting data on patients enrolled in the Blue Cross Blue Shield of Michigan Cardiovascular Consortium and receiving PCI for any indication between 2010 and 2011 showed a significantly lower prescription of prasugrel (10% vs 14.5%, p<0.01) in AA patients compared to Caucasians([20](#_ENREF_20)), consistent with our results. This finding is even more important because the PROMETHEUS population comprised only ACS patients for whom prasugrel has a strong recommendation in clinical practice guidelines. Surprisingly, use of prasugrel was not higher in AA patients with STEMI compared to NSTEMI/ UA as opposed to non-AA who were more likely to receive prasugrel in STEMI. In addition, surprisingly, prasugrel prescription was inversely related to the PARIS estimated coronary ischemic risk in both AA and non-AA patients.

Limitations

The PROMETHEUS registry did not capture information on compliance to drug treatment including dual antiplatelet therapy during the follow up. Similarly, information on drug switch to a different P2Y12 inhibitor after PCI is not available. Since PROMETHEUS comprised only patients treated with either prasugrel or clopidogrel, no information is available on the use of ticagrelor in AA and non-AA patients. In addition, the prescription of P2Y12 inhibitor was not randomized, instead the choice of medication was at the discretion of the treating physician. Finally, PROMETHEUS did not collect information on insurance or socioeconomic status, that might influence not only the prescription but also patients’ long- term compliance to any treatment for the secondary prevention of ischemic events.

CONCLUSIONS

Compared to non-AA patients, AA patients had a significantly higher risk for 1-year MI after ACS PCI, but a similar risk of bleeding. Despite a higher clinical risk and a more severe clinical presentation in AA patients undergoing PCI for ACS, they were less likely to be treated with prasugrel then non-AA. Lower intra-hospital prescription of prasugrel might be a function of cost, socioeconomic and other factors that that warrant systematic investigation in future studies.

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**Figure legends**

**Figure 1**: Clinical presentation in African-American (AA) and non-African American (non-AA)

**Figure 2**: Prasugrel prescription by race (A) and by clinical presentation (B)

**Figure 3**: Distribution of AA and non-AA according to estimated PARIS risk of thrombotic coronary events (A lower panel) and bleeding events (B lower panel). Percentage of patients receiving prasugrel according to estimated thrombotic and bleeding risk (A and B upper panels)

**Figure 4:** Adjusted 90-day risk of clinical adverse events in AA patients. Non-AA are used as reference

**Figure 5**: Ninety-day and 1-year clinical outcomes in AA and non-AA patients by thienopyridine type. AA, African American; CI, confidence interval; Clop, clopidogrel; HR, hazard ratio; inter, interaction; MACE, major adverse cardiac event; Pras, prasugrel.