***Title page***

**Ethnicity in Complex High-risk but Indicated Percutaneous Coronary Intervention (CHiP) Types and Outcomes?**

Running Title: **CHiP Types and Outcomes Amongst Races.**

Warkaa Shamkhani (MRCP) a, b, Tim Kinnaird (MD)c, a, Harindra C. Wijeysundera (MD, PhD) d, Peter Ludman (MD)e, Muhammad Rashid (PhD)a, b\*, Mamas A. Mamas (DPhil)a, b\*

1. Keele Cardiovascular Research Group, Centre for Prognosis Research, Institutes of Primary Care and Health Sciences, Keele University, UK
2. Royal Stoke University Hospital, Stoke-on-Trent, U.K.
3. Department of Cardiology, University Hospital of Wales, Cardiff, UK.
4. Sunnybrook Health Sciences Centre, Toronto, Canada.
5. Queen Elizabeth Hospital, Birmingham, UK.

\*Joint senior authors

Correspondence to:

Mamas A. Mamas

Keele Cardiovascular Research Group, Centre for Prognosis Research,

Keele University,

Newcastle Road

ST5 5BG, U.K.

Phone: [01782 732000](https://www.google.com/search?gs_ssp=eJzj4tTP1TcwzLAoTjNg9BLITk3NSVUozcssSy0qziypBACDCgnM&q=keele+university&oq=keele+unive&aqs=chrome.2.69i57j35i39j46i433j0j69i60l2j69i65j69i60.5968j0j7&sourceid=chrome&ie=UTF-8)

[mamasmamas1@yahoo.co.uk](mailto:mamasmamas1@yahoo.co.uk)

**Abstract**

Complex High-risk but indicated Percutaneous coronary interventions (CHiP) is increasingly common in contemporary practice. However, data on ethnic differences in CHiP types, outcomes, and trends in patients with stable angina are limited; this is pertinent given the population of Black, Asian, and other Ethnic Minorities (BAME) in Europe is increasing. We conducted a retrospective analysis of CHiP procedures undertaken in patients with stable angina using data obtained from the **British Cardiovascular Intervention Society** (BCIS) registry **(2006-2017).** CHiP cases were identified, categorized by ethnicity into White and BAME groups. We then performed multivariable regression analysis and propensity score matching to determine adjusted odds (aOR) of in-hospital mortality, bleeding, and major adverse cardiovascular and cerebral events (MACCE) in BAME compared to Whites. Out of **424,290** procedures’ records, 105,949 **(25.0%) were CHiP [White:** 89,038 (84%)**,** BAME:16,911 (16%)]**. BAME patients were younger (median: 68.1 vs 70.6 years). Previous coronary artery bypass surgery (33.4%vs. 38.3%), followed by CTO PCI (31.9% vs 32%) were common CHiP variables in both groups. The third common variable was age>80 (23.6%) in White patients, severe vascular calcifications in BAME patients (18.8%). BAME patients had higher rates of diabetes (41.1 vs. 23.6 %), hypertension (68 vs. 66.5 %), previous PCI (43.7 vs. 37.6 %), and previous MI (44.9 vs. 42.5 %), (p<0.001 for all). Mortality (aOR, 1.07 (95% CI** 0.8-1.5**) and MACCE (aOR, 0.9 (95% CI** 0.8-.1.1**) odds were similar amongst the groups. Bleeding odds (aOR, 0.69 (95% CI** 0.6-0.9**) were lower in BAME. In conclusion, CHiP procedures differed amongst the ethnic groups. BAME patients were younger, had worse cardiometabolic profiles. Similar odds of death and MACCE were seen in BAME compared to their White counterparts. Bleeding odds were 30% less in the BAME group.**

KEYWORDS: Complex PCI, High-risk PCI, RACE differences, stable angina

**Introduction**

The first reports of racial/ethnic differences in coronary artery disease (CAD) management and clinical outcomes emerged more than three decades ago1, 2. Since then, data derived from trials and observational studies demonstrated that CAD risk profile and outcomes post coronary intervention varies amongst races 3-5. Some demonstrated similar outcomes 3, 4, others suggested that Blacks, Asians, and other Minority Ethnic groups (BAME) have a higher incidence of CAD and poorer clinical outcomes 5-7. Complex, high-risk but indicated Percutaneous coronary intervention (CHiP) refers to a group subset with specific patients’ and procedural’s characteristics that put patients at higher risk of periprocedural complications 8. Previous studies around CHiP by ethnicity were limited to data that examined outcomes in highly selected cohorts (specific types of CHiP cases only)8-11, or certain geographical areas 12 . This is of interest given CHiP cases are growing, and the BAME population, which represents 13% of the population of England and Wales 13 is expected to increase to 20% by 2050 14, 15. This analysis sought to study the ethnic differences in CHiP undertaken in patients with stable angina over 12 years, using data from a national PCI registry in the UK.

**Methods**

The data were collected from the British Cardiovascular Intervention Society (BCIS) registry. The BCIS is managed by the National Institute of Cardiovascular Outcomes and Research (NICOR). Data from over 95% (112 out of the 117 PCI centres in the U.K) PCI procedures undertaken in England and Wales are collected annually. The BCIS data includes a wide range of clinical characteristics, important cardiovascular comorbidities, interventional and pharmacological treatments, in-hospital procedural complications and mortality16. As part of a NICOR national audit initiative, all data are collected prospectively and encrypted before transferring to database services. Also, all data have section 251 approval of NHS Act 2006, which allows the dataset to be used for audit purposes and research without seeking patients consent. Hence, ethical approval was not required for this study17. The BCIS data entry is mandated as part of the professional revalidation 16. The accuracy and quality of the BCIS dataset have been previously ascertained 18.

We analyzed data obtained from all patients who had undergone PCI for CAD in England and Wales between 1st January 2006 and 31st December 2017 on the BCIS registry. Based on our previous work8, 19, 20, a CHiP case was defined as any PCI case that has met at least one of the following patients’ characteristics (age≥80years, previous coronary artery bypass graft (CABG), severely impaired left ventricular (LV) function, and chronic renal failure(CRF)) or procedural’s characteristics (left main (LM) PCI, chronic total occlusion PCI, use of laser atherectomy, use of rotational atherectomy, or need for LV support). The collected CHiP data was then categorized into White and BAME groups. We required a sample size of >13628 to provide a power of 0.8 at alpha (p<0.05).

Severe LV impairment was defined as LV function with an estimated ejection fraction of 30% or less, LV support use as cases where Impella or Intra-aortic balloon (IABP) was used, chronic renal failure as any patient with chronic creatinine elevation of more than 200 umol/l, history of renal transplant, or chronic dialysis, which is predefined in the dataset. Extensive vascular calcification was defined as any PCI that required cutting balloons rotational or laser atherectomy.

The primary outcome of interest was in-hospital all-cause mortality. Secondary outcomes included were a) in-hospital major adverse cardiovascular and cerebral events (MACCE); defined as the cumulative incidence of in-hospital death, peri-procedural myocardial infarction MI or cerebrovascular accidents (CVA), or in-hospital CVA; b) In-hospital major bleeding events. We defined peri-procedural MI as a composite of Q-wave MI, non-Q-wave MI, reinfarction, and reintervention (emergency PCI or CABG) predefined within the BCIS registry. Major bleeding events are defined as radiological evidence of intracranial bleed, access site bleeding requiring intervention, clinically evident gastrointestinal tract bleeding, retroperitoneal bleed/hematoma, any transfusion of blood or blood products, or any access site complications requiring intervention or surgery). We defined access site complication as the presence of any of the following: retroperitoneal hematoma, false aneurysm, hemorrhage without hematoma, arterial dissection.

Patients’ variables were summarized as median and interquartile range for continuous variables, and as frequencies and percentages for categorical variables. The patients' baseline and comorbidity characteristics and procedural details were then compared using Pearson's Chi-squared test for categorical and binary variables and the Kruskal Wallis test for continuous data. The information about missing data for each variable included in the study is reported in Supplementary Table 1. We used multiple imputations with chained equations to impute missing data to create 10 datasets, assuming that data were missing at random. We used logistic regression for binary variables, multinomial for nominal, ordinal logistic regression for ordered, and linear regression for continuous variables in our multiple imputation framework. The variables included in our model were: ethnicity, age, body mass index (BMI), history of dyslipidaemia, previous CABG, previous PCI, previous MI, previous CVA, hypertension, diabetes mellitus, renal failure, peripheral vascular disease (PVD), clopidogrel, family history of CAD, vascular access, left main PCI, IABP, rotational atherectomy, number of treated lesions, and number of stents used. We performed subsequent analyses on the imputed dataset, and results were pooled using Rubin’s rule 21. Finally, we used multivariable logistic regression analyses to determine the adjusted odds ratios (aOR [95% confidence interval (CI)]) of outcomes between White and BAME groups. To control for differences and imbalances in the baseline clinical and procedural characteristics between the groups, we used multiple imputations with propensity score matching PSM (mi estimate:teffects psmatch). We used the PSM to estimate the average treatment effect using all the covariates used in our main regression analysis.We then converted the coefficients to odds ratios to help with better interpretation of the results. To better assess the consistency of the results obtained, we performed a sensitivity analysis on the non-imputed dataset. Stata version 14.1 was used to conduct the analyses (StataCorp, College Station, Texas). Statistical significance was assessed at a type I error rate of 0.05.

**Results**

**The study cohort consisted of** 105,949 **CHiP (24.97%) out of 424,290** Stable CAD **PCI cases performed in England and Wales (January 2006 to December 2017). The process of patients' inclusion and exclusion for this analysis is presented in Figure 1. Figure 2 shows the prevalence of each CHiP factor, stratified by ethnicity. Supplement Figure 1 demonstrates the temporal changes in the prevalence of CHiP procedures stratified by ethnicity, where CHiP cases increased from 5073 procedures in 2006 to 9131 in 2017. Supplement Figure 1 also shows how the proportion of BAME patients changed throughout the study years, ranging between 13-18%. Supplement figure 2 shows the absolute number of each CHiP factor.**

**Table 1 provides an overview of CHiP factors (types), cardiovascular risk factors, pharmacology, and procedural characteristics according to their ethnic background. Overall,** 89,038 (84%) of the **CHiP procedures were performed in White patients, and** 16,911 (16%) **were performed in BAME patients. Whites were on average 1.5 years older than BAME patients (median age: Whites, 70.6; BAME, 68.1). Amongst cardiovascular risk factors,** BAME patients had a higher prevalence of hypertension, diabetes, and previous history of both PCI and MI. On the other hand, White patients had a higher prevalence of CVA, PVD, and current and former smokers.

Temporal changes in patients’ characteristics and CHiP types by ethnicity are shown in Supplementary Table 2. **Supplementary Table 3 details the baseline clinical and procedural characteristics stratified into** White, Black, Asian, and other Ethnic Minorities. Of the BAME, Asian patients represented the majority (7.7%), whereas Black patients represented 0.8% of the cases.

CHiP factors (types) frequencies differed amongst the groups. The three most common CHiP factors in White patients were prior CABG (33.4%), CTO PCI (31.9%), and age 80 years and above (23.6%). Whilst in BAME patients, they were prior CABG (38.3%), CTO PCI (32%), and severe vascular calcification (18.8%) (Table 1). Figure 3 shows the temporal trends in each CHiP factor according to ethnicity. Overall, in both groups, the number of procedures undertaken in those 80 years of age and above, history of chronic renal failure, poor LV function, LM PCI, and severe vascular calcification increased gradually (see also Supplementary Table 2). **Of the BAME patients, Asians had the highest rates of previous CABG (47.5%), followed by PCI to a CTO lesion (31.5%) (Supplementary Table 3).**

Procedural characteristics varied as well. BAME patients had higher rates of LM PCI, whilst White patients had higher rates of graft PCI (Table 1). Of the BAME patients, the Asians had the highest rates of LM PCI (15.3%) and PCI to a graft vessel (11.4 %) (Supplementary Table 3). Overall, BAME patients had more extensive CAD than Whites. BAME patients were more likely to have more than one lesion treated and or multivessel PCI than white patients. However, White patients had more extensive calcific lesions as evidenced by higher rates of rotational atherectomy therapy and cutting balloons use. The radial access was used less frequently in BAME (37.5 vs 46.8% respectively), with fewer procedures in BAME patients utilizing more than one access site. Changes in procedural characteristics over time are shown in Supplementary Table 2.

Variations in pharmacotherapy prescription amongst ethnic groups were observed. Higher prescription rates of Warfarin and Glycoprotein IIb/IIIa inhibitors were observed in the White patients. In contrast, BAME patients were treated more frequently with prasugrel and ticagrelor. Similar findings were seen when stratified into 4 ethnic groups (Supplementary Table 3).

Crude and adjusted outcomes, stratified by ethnicity, are shown in Table 2. Overall, crude in-patient mortality and MACCE did not differ between the groups. However, BAME patients had lower bleeding rates (0.5 vs 0.9%, respectively, p<0.001). Following adjustment for differences in baseline covariates, BAME patients had similar mortality (**(aOR, 1.07 (95% CI** 0.8-1.5)**; p=0.659)** and MACCE odds **(aOR, 0.9 (95% CI** 0.8-1.1)**; p=0.564) but** had 30% lower odds for bleeding compared to White patients. Further stratification into four groups (supplementary Table 5) showed that the lowest odds of bleeding seen in BAME patients were mainly recorded in the “Other” ethnic minorities (aOR, 0.5 (95% CI, 0.4-0.8); p=0.002). No differences in outcomes between the groups were again confirmed with propensity score matching analysis (Supplement Table 6).

The temporal trends of crude outcomes amongst the ethnic groups demonstrated stable mortality rates with no significant differences amongst the groups, whereas MACCE rates gradually decreased. Bleeding rates remained unchanged in White patients, while a gradual decline was seen amongst the BAME patients (Supplementary Table 7).

**Discussion**

This analysis of a national cohort of 105,949 procedures’ records is the first to examine ethnic differences in the risk profile, procedural characteristics and clinical outcomes of CHiP procedures undertaken in patients with stable angina. The study findings can be summarised as follows: 1) BAME patients were younger, had a worse cardiometabolic risk profile and were more likely to have multivessel PCI. 2) Common CHiP in BAME patients were previous CABG, PCI to a CTO vessel and treatment of calcific disease. 3) The adjusted in-hospital mortality and MACCE did not differ amongst the ethnic groups, although bleeding odds were significantly lower in the BAME patients.

Differences in baseline characteristics between ethnic groups have been reported in previous studies 22, 23. The ethnic case mix in our study is different from that seen in contemporary PCI studies from the USA, reflecting societal differences, with Asians representing the majority of patients in the UK, as opposed to Black patients in the USA. Nevertheless, the cardiovascular risk profile of BAME patients in our study was comparable to that generally seen in the USA studies24. BAME patients were younger and had worse cardiometabolic profiles, with higher rates of hypertension, diabetes mellitus, CRF, and heart failure. Amongst BAME patients, Asian patients had the worse cardiometabolic burden.

Previous studies examining outcomes in specific CHiP procedure categories reported no significant differences amongst ethnic groups in clinical outcomes. For example, observational studies from the Pan-London PCI Registry examining PCI outcomes in patients with a history of CABG, the commonest CHiP factor in our study, found that Asian and White patients have comparable mortality risks (Multivariable, aOR 1.07 (0.97-1.17))25.

PCI to a CTO vessel was the second commonest CHiP factor in our analysis in both groups. Interestingly, a retrospective analysis from the USA found that Black ethnicity was a predictor for lower success in a CTO PCI (HR 0.6, (0.50- 0.92); p=0.013)26 . In our analysis, White patients had more extensive vascular calcification than BAME, which may relate to the fact that White patients were older and hence more likely to have heavier vascular calcifications; this was also seen in a multicentre retrospective analysis on 12,445 patients from the USA (aOR for vascular calcifications, 1.57 (1.42,1.73); p<0.001) in 27. The same study found that old age (aOR, 1.04 (1.03, 1.04), p<0.001) and history of PVD (aOR, 1.32 (1.13, 1.54), p=0.0004) were also associated with severe vascular calcification, both of which were more prevalent in White patients in our study. The impact of ethnicity on the angiographic characteristics and clinical outcomes following PCI were examined in 1863 females with CAD pooled from the PLATINUM Diversity and PROMUS ELEMENT PLUS post-approval studies 22; the study found differences between African American females (larger reference vessels diameter and fewer lesion calcifications) and Hispanic females (longer and more calcific disease) compared to White females. Despite differences, odds for death and MACCE were similar between the groups22.

More BAME patients, in our study, had PCI to LM than Whites. A previous retrospective analysis from a single centre in the USA reported that African American ethnicity is an independent risk factor for worse outcomes in LM PCI (HR 2.71, 1.44-5.10; p=0.002) for both short- and long-term outcomes5. We also observed that a greater proportion of BAME patients had chronic renal failure, similar to findings from a retrospective study on 474 chronic dialysis patients from 4 centres in the USA, where ethnicity per se was found to be not associated with worse outcomes (p=0.069)12.

Despite the significant differences mentioned earlier amongst the groups, our study showed that Mortality and MACCE odds were comparable, suggesting that ethnicity was not a marker for worse short-term outcomes, similar to findings from many studies around non-CHiP procedures 3, 4, 28. We report that bleeding risk was significantly lower in the BAME patients than Whites. This could be related to the fact that BAME patients were younger, had lower rates of severe vascular calcifications and had lower utilization of calcium modification devices, meaning their risk of coronary perforation (and hence bleeding complications) was lower. On the contrary, a higher proportion of White patients in our study met some of the criteria for high bleeding risk as per The Academic Research Consortium (ACR) definition29; such as age above 80 years, use of anticoagulation (warfarin) and glycoprotein IIb IIIa inhibitors, and history of stroke. In support of this, an analysis on 9244 patients from a single centre in the USA demonstrated a larger proportion of White patients meeting high bleeding risk criteria and experiencing major bleeding events than BAME patients30. Nevertheless, the rates for using the femoral access, IABP, and more potent antiplatelets (Ticagrelor and Prasugrel) were higher amongst the BAME patients.

The observation in which younger BAME patients with worse cardiometabolic profiles experience similar outcomes to older White patients has been reported in other studies focussed on non-complex PCI in the short term. However, the same is often not true when comparing longer-term outcomes31. For example, a retrospective study from a multicentre complex in the USA comparing outcomes of non-complex PCI amongst African American and White patients demonstrated no significant short-term outcomes; but significant worst outcomes were only seen at five years follow-ups in the African American group (adjusted HR 1.44, 95% CI 1.03-2.00; p0.03)31. This raises the question of whether longer-term outcomes will be worse in BAME patients following CHiP procedures. Nevertheless, our findings are reassuring in that in a universal healthcare system with universal coverage of patients irrespective of ethnicity, complex PCI outcomes are similar. This highlights that disparities observed in other healthcare systems may reflect disparities in healthcare provision.

Our analysis should be considered in light of the following strengths and limitations: to the best of our knowledge, this is the first study that has examined ethnicity stratified CHiP outcomes in a real-world, unselected setting at a national level. Over 99% of cases performed in England and Wales are recorded in the BCIS database. The sample size was large enough to provide sufficient statistical power to determine whether there is a real difference in ethnicity-based CHiP outcomes. As with all observational studies, there are several limitations. Firstly, there is the potential for the presence of unmeasured confounders in both clinical and procedural variables such as socioeconomic status, frailty, control and duration of cardiovascular risk factors such as diabetes, and lesion complexity that may impact on clinical outcomes that we report. Secondly, there is always the risk of reporting and coding errors that could represent a potential bias, such as the underreporting of other comorbidities, and complications are self-reported with no external validation. Thirdly, the BCIS dataset captures ethnicity as Asian, Black, White, and Other, and so the “Other” category is likely to represent a heterogenous racially diverse population. Lastly, the BCIS dataset only captures in-hospital outcomes, and we cannot rule out significant differences in the longer term.

In conclusion, this nationwide analysis has shown significant differences in the types of CHiP procedures undertaken and in the ethnicity case-mix and baseline clinical and procedural characteristics. BAME were younger, with a greater comorbid burden, and had more complex coronary disease. Despite these differences, we found no differences in in-hospital mortality and MACCE following CHiP once differences in baseline characteristics were adjusted. Bleeding risk was significantly lower in the BAME patients. Ethnicity should not be considered as a barrier in the decision-making process around CHiP PCI procedure.

**Funding**

An unrestricted educational grant from Abbott supports Warkaa Shamkhani salary. However, the company had no role in the study design, manuscript preparation, or access to the manuscript's contents before submission. The authors are solely responsible for this study design and conduct and all analysis, drafting, and editing of the manuscript and its final content.

**Disclosures**

The authors have nothing to disclose.

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**Figure Legends**

**Figure 1**: Flow diagram illustrates **the process of patients' inclusion and exclusion for the CHiP analysis, stratified by ethnicity.**

**Figure 2:** Prevalence of CHiP factors in patients with stable angina, stratified by ethnicity (percentage).

**Figure 3:** Temporal changes in prevalence of each CHiP factor amongst patients with stable angina and per cent change over time, stratified by ethnicity.