**Outcome of femoral-popliteal bypass procedures in different ethnic groups in England:**

**A retrospective analysis of Hospital Episode Statistics**

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**Abstract**

*Background*: Previous studies, mainly from the United States, have reported worse outcomes from lower limb bypass procedures in ethnic minority populations. Limited nationwide data are available from ethnic minority populations from Europe. The aim of this study is to investigate outcomes from lower limb bypass procedures in ethnic minorities from England.

*Methods*: We enquired the “Hospital Episode Statistics” database, using ICD-10 codes to identify all cases of femoral-popliteal bypass operations from English NHS Hospitals from 01/01/2006 to 31/12/2015. Every case was followed up for 2 years for subsequent events. The primary outcomes were mortality and major leg amputation. Patients were broadly categorised according to Black, Asian and White ethnicity. Chi-square test was used to the ethnic groups and odds ratios (OR) were calculated using White ethnic group with the largest numbers of participants as a reference category.

*Results*: In the examined 10-year period, 20825 femoral-popliteal bypass procedures (250 of Black, 167 of Asian, and 20.408 of White ethnicity) were recorded. Thirty-day and 2-year mortality were 2.8% and 16.8% with no significant ethnic differences. Patients of Black ethnicity had higher risk of limb loss compared to Whites (23.2% vs 15.6%, OR =1.63, 95% confidence interval (CI) 1.21-2.19, p<0.01). There was no significant difference in amputation rates between Asians and Whites (16.2% vs 15.6%, p=0.94).

 *Conclusion*: Patients of Black ethnicity are at higher risk of limb loss after a femoropopliteal bypass procedure. Further research is needed to identify the causes of this discrepancy.

Key words: ethnicity, peripheral arterial disease, bypass

# Introduction

Peripheral arterial disease (PAD) is a global pandemic associated high morbidity and mortality, poor quality of life, and disability.1–3 Different ethnic groups vary in epidemiology and natural history of the disease, and prevalence of atherosclerotic risk factors. Black ethnicity is associated with higher rates of PAD4 and higher risk of lower limb amputation in studies from the United States (US)5,6 and the United Kingdom (UK)7. On the other hand patients of Asian ethnicity present with lower rates of PAD and amputations despite higher prevalence of diabetes4,7.

Ethnic minority patients in the US, specifically of African-American and Hispanic origin, have worse outcomes after lower limb bypass operations.8 Several genetic, environmental and socioeconomic factors have been investigated without fully justifying this discrepancy. However, the US health care system differs from those in the UK and Europe and it is not clear whether the observed ethnic differences in the US also exist in the UK. Data from the UK are limited with one single centre/ single surgeon series reporting no significant difference in distal bypass graft patency between Caucasians and Afro- Caribbeans9.

Given the limited nationwide data are available from ethnic minority populations from Europe, the aim of this study is to investigate outcomes from lower limb bypass procedures in ethnic minorities.

# Methods

This is a retrospective study of the Hospital Episode Statistics (HES). The HES is the administrative dataset for the English National Health Service (NHS), which contains information regarding every admission of any patient to English NHS hospitals. HES data are anonymised by the allocation of a unique identifier to each patient, so individuals can be tracked as their care moves from consultant to consultant on any particular admission, and between hospital admissions. The dataset therefore allows long term follow up of individual patients with respect to multiple hospital admissions. The HES database is linked with the Office of National Statistics (ONS) mortality data, so that deaths are recorded in the database even when they occur outside of hospital.10 Advantages of such data sets have been documented in literature as they encompass large populations, they are easily available and amenable to computerised data extraction11. International Classification of Diseases (ICD-10) codes12 were used to detect corresponding clinical diagnoses and different treatments. Ethnicity is self-defined by patients on admission, and as reported before, it is recorded in the HES database in 79.4% of hospital admissions13.

We enquired HES to detect all femoropopliteal bypass operations performed in English NHS Hospitals during the 10-year period between 01/01/2006 and 31/12/2015, including procedures with either vein or prosthetic graft. Based on recorded ethnicity, patients were broadly categorized in one of the three most numerous ethnic groups of UK population, White, Asian, and Black (including African and Caribbean)14. Patients with recorded “Mixed Ethnicity” or missing ethnicity were excluded from the study. Demographic characteristics and previous diagnosis of hypertension, diabetes, heart failure, ischaemic heart disease, and atrial fibrillation were recorded using relevant ICD-10 codes. Every patient’s records were studied for a two-year period after the initial operation and the outcomes of death, second open or endovascular procedure and major amputations were recorded.

In order to better assess the durability of the initial femoropopliteal bypass, decision was made to look for subsequent procedures in the same arterial territory; only infrainguinal open and endovascular procedures were therefore recorded. A comparison of baseline characteristics and outcomes was made between patients of different ethnic groups using descriptive statistics. Analysis was done with MedCalc Version 14.8.1. Chi-squared test was used and p value was calculated to demonstrate significant differences, defined as p<0.05. Odds ratios (OR) were calculated using White ethnic group as reference.

An attempt was made to match the side of the initial bypass operation with the side of subsequent events based on laterality codes; this was not possible for 23% of open, 26.5% of endovascular reinterventions and 33.4% of amputations due to lack of laterality codes. In addition, according to HES data sharing policy we could not report outcomes in small absolute numbers of patients, less than 5, which was the case for ethnic minority patients receiving a prosthetic graft. With these limitations an initial analysis was made including the whole cohort regardless of laterality codes and then further analysis was performed on the subgroup of patients with available laterality information receiving a vein graft.

# Results

In the time period 2006 to 2015, a total number of 23.269 femoropopliteal bypass procedures were performed with 20825 (89.5%) having ethnicity data: 20.408 (98%) White, 167 (0.8%) Asian and 250 (1.2%) Black ethnicity. Asian patients were significantly younger, were more likely to be male and had higher prevalence of diabetes and ischaemic heart disease compared to other ethnic groups. Whites had higher prevalence of AF, while there was no significant difference in rates of heart failure and hypertension. Prosthetic graft was used in 27% of cases with no significant difference among ethnic groups (Table 1).

Overall, 30-day and 2-year mortality in this population were 2.8% and 16.8% with no statistically significant difference between ethnic groups. When the whole cohort was analysed regardless of procedure laterality codes, Asians were submitted in more endovascular procedures in the follow up period compared to Whites (33.5% vs 25%, p= 0.01). On the other hand, Black patients were at higher risk of major amputation compared to Whites (23.2% vs 15.6%, OR=1.63, 95% CI 1.21-2.19, p<0.01) and Asians. There was no significant difference in the rates of second open arterial procedure (Table 2).

When only procedure with laterality codes were included, bypass procedures with vein conduit were matched with outcomes on the same limb. There was no significant difference in the rates of subsequent open or endovascular procedures among ethnic groups. However, Black patients were at higher risk of limb loss compared to Whites (14.3% vs 7.9%, OR=1.95 95% CI 1.27-2.99, p<0.01) and Asians (7.5%), (Table 3).

# Discussion

The principal finding of this study is the high risk of limb loss in patients of Black ethnicity undergoing femoropopliteal bypass operation in England. This observation would have implications for risk assessment and mitigation, to reduce the risks of poor outcomes in these Black ethnicity patients.

This finding is in accordance with previous studies comparing the outcomes of lower limb bypass between patients of black and white ethnicity in the US. Black patients have been reported to have higher rates of 30-days graft failure8,15–17, 5-year graft failure8, 30-day limb loss18, 1-year limb loss17 and 5 year limb loss8. However, one trial on 125 patients submitted to distal bypass procedures from UK, does not identify any significant difference in 1-year patency or 1-year amputation free survival in Blacks9.

Thirty-day and 2-year mortality rates in this population are comparable to figures from previous publications19,20. Additionally there was no significant difference in mortality among the three ethnic groups included, which is in agreement with previous studies8,9,17. Patients of Asian ethnicity had similar outcomes with White patients despite their different risk factor profile. To the best of our knowledge there is no previous study comparing the outcomes of lower limb bypass between these ethnic groups.

The factors that generate worst outcomes in Black patients are not fully understood. Risk factor profile varies among ethnic groups. Black ethnicity is associated with high rates of hypertension and higher values of mean systolic and diastolic blood pressure, in general population studies from the US21,22 and the UK23. In addition, Black patient tend to develop hypertension at younger age and have different response to antihypertensive treatment24. Prevalence of diabetes in Blacks appears to be considerably higher when compared to Whites but lower compared to Asians22,25,26. Those differences apply in our study population and also in previous cohorts of patients submitted to lower limb revascularization8,16,18,27. In addition, ethnic groups present with differences in epidemiology and distribution of atherosclerotic disease, with Black patients showing higher prevalence of PAD4 and a predisposition to more distal patterns of the disease, which is not completely explained by the higher rates of diabetes and other risk factors28,29. Whether those differences can explain the worse outcomes of revascularization procedures in Black patients is controversial. In a retrospective study of 834 male patients receiving lower limb revascularization, Rivero et al demonstrated that Black patients have higher rates of diabetes, dialysis dependence, hypertension, infrapopliteal disease, gangrene and foot sepsis. In multivariate analysis, the effect of race in limb loss was not significant with authors making the conclusion that worse limb salvage in Black patients is related to anatomic factors, advanced disease and other negative prognostic factors30. On the other hand, studies have shown that despite different risk factor profile, Black ethnicity independently predicts worse outcomes after lower limb bypass.

In a study by Robinson et al, including 1646 patients, after controlling for demographic, medical, anatomic factors and disease severity, Black patients were at higher risk of graft failure (HR 1.33 95% CI 1.02-1.73, p=0.035) and limb loss (HR 1.45 95% CI 0.97-2.17, p=0.073)8. Similarly in a retrospective review of 16,276 cases, Selvarajah et al report higher rates of early graft failure in Black patients (adjusted OR 1.26, 95% CI 1.05-1.51, p=0.011) after controlling for above confounders16. In addition, when specifically investigating selected populations with certain comorbidities, those differences in outcomes remain: among patients on dialysis, Black ethnicity was related to higher rates of graft failure and limb loss after lower limb bypass31 and among diabetic patients receiving revascularization, Black patients with diabetes had higher rates of limb loss regardless of type of revascularization32.

Racial disparities in outcomes of surgical treatment and healthcare overall are a known problem. A systematic review of previous studies originating mainly from the US, demonstrates that race can be related to socioeconomic status and insurance status of patients. This can result in inequalities in access to healthcare, delayed or suboptimal surgical treatment and poorer outcomes. In addition, Black patients in the US have been reported as less likely to receive surgical treatment in a high-volume centre, less willing to undergo surgery in small number of studies and more prone to late presentation with more advanced disease33. In their study Arya et al confirm that low socioeconomic status is related to more amputations in PAD, however even when socioeconomic status was the same, Black patient still suffered more amputations. This observation suggests that Black race has direct effect on negative outcomes, not totally mediated by socioeconomic factors34. In an attempt to eliminate healthcare provider bias, it has been demonstrated that even after controlling for hospital performance, Black patients with PAD were at higher risk for amputation. That was also the case when specifically investigating patients treated in high-volume, teaching hospitals35. In this study, taking into account that England has a free national health service, access to healthcare is unlikely to be a factor that significantly contributed to the worse outcomes in Black patients. Proactive surveillance and risk factor modification of patients of Black ethnicity is therefore highly recommended and further research is needed to identify the causes of the observed outcome discrepancy.

Comparing the ethnic distribution in our study population (98% Whites, 0.8% Asians and 1.2% Blacks) there is an obvious difference to the corresponding figures in general population of the UK as per 2011 Census (86% Whites, 7.5% Asians, 3.3% Blacks).14 This is partially explained by the exclusion of a proportion of ethnic minority patients who were recorded as “mixed” or “unknown” ethnicity according to the study methodology. This could also be attributed to the lower prevalence of PAD in Asians and also the different distribution of PAD among ethnic groups; Blacks and Asians present more often with distal distribution of the disease in the infrapopliteal segment, and would therefore be less likely to be offered femoral-popliteal bypass. In addition, another study of UK Hospital Statistics has shown that Blacks are more likely to be submitted to primary amputation without prior revascularization.7

*Limitations*

This study has certain limitations. It is retrospective and based on administrative data, which lack the accuracy of clinical data. Despite the large total number of patients, the ethnic minority groups are relatively underrepresented and a significant proportion of cases (11.5%) was excluded due to missing ethnicity data or “mixed ethnicity”. Significant number of cases lacked laterality data, however in the subgroup where laterality data was available, results were similar. There have been no data on the clinical severity of the disease or the presence of critical ischaemia at the time of intervention and no information about distribution of arterial disease in other segments. The main limitation is that despite the obvious differences in risk factor profiles, the nature of available data would not allow further statistical analysis with either regression or propensity score analysis to eliminate the effect of those confounders.

**Conclusion**

Patients of Black ethnicity are at higher risk of limb loss after a femoral-popliteal bypass procedure. This study adds on the evidence that Black ethnicity is related with higher failure rates after lower limb bypass operations. There was no difference in mortality among patients of different ethnic groups undergoing femoropopliteal bypass.

**Declarations of interest**: none.

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Table 1 Baseline characteristics in different ethnic groups.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | White | Asian | Black | p\* | p\*\* |
| N | 20408 | 167 | 250 |  |  |
| Mean age (SD) | 68.9 (11.1) | 63.9 (13.7) | 68.2 (12.5) | <0.01 | 0.32 |
| Male % | 70.4 | 85.0 | 64.4 | <0.01 | 0.04 |
| Diabetes % | 29.7 | 63.5 | 48.4 | <0.01 | <0.01 |
| Hypertension % | 52.9 | 52.7 | 58.4 | 0.96 | 0.08 |
| Ischaemic Heart Disease % | 26.4 | 43.1 | 21.6 | <0.01 | 0.09 |
| Heart Failure % | 4.8 | 6.0 | 6.0 | 0.47 | 0.38 |
| Atrial Fibrillation % | 11.6 | 6.0 | 8.8 | 0.02 | 0.17 |
| Prosthetic graft | 27.0 | 28.7 | 25.2 | 0.62 | 0.52 |

*\*comparing White with Asian ethnicity*

 *\*\* comparing White with Black ethnicity*

Table 2 Outcomes of femoropopliteal bypass in different ethnic groups (2 year follow up). Data not specific for laterality.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | White | Asian | Black | p\* | p\*\* |
| N | 20408 | 167 | 250 |  |  |
| 30-day mortality, % | 2.8 | 4.2 | 2.0 | 0.28 | 0.45 |
| 2-year mortality, % | 16.8 | 20.4 | 18.0 | 0.22 | 0.61 |
| 2nd open procedure, % | 20.9 | 24.6 | 18.8 | 0.25 | 0.46 |
| Endovascular procedure, % | 25.0 | 33.5 | 30.4 | 0.01 | 0.06 |
| Major amputation, % | 15.6 | 16.2 | 23.2 | 0.94 | <0.01 |

*\*comparing White with Asian ethnicity*

 *\*\* comparing White with Black ethnicity*

Table 3 Outcomes of femoropopliteal bypass using vein graft in different ethnic groups (2 year follow up).

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | White | Asian | Black | p\* | p\*\* |
| N | 13825 | 106 | 175 |  |  |
| 2nd open procedure % | 9.1 | 5.7 | 11.4 | 0.22 | 0.30 |
| Endovascular procedure % | 12.3 | 15.1 | 16.0 | 0.38 | 0.14 |
| Major amputation % | 7.9 | 7.5 | 14.3 | 0.90 | <0.01 |

*Matched laterality of initial procedure and related outcomes.*

*\*comparing White with Asian ethnicity*

 *\*\* comparing White with Black ethnicity*

# Supplementary Material

Codes used to identify femoropopliteal bypass and subsequent outcomes

|  |  |
| --- | --- |
| ICD-10 code | Diagnosis |
| Femoropopliteal bypass |
| L59.3  | Bypass of femoral artery by anastomosis of femoral artery to popliteal artery using vein graft |
| L58.3 | Emergency bypass of femoral artery by anastomosis of femoral artery to popliteal artery using vein graft  |
| L59.2 | Bypass of femoral artery by anastomosis of femoral artery to popliteal artery using prosthesis  |
| L58.2 | Emergency bypass of femoral artery by anastomosis of femoral artery to popliteal artery using prosthesis |
| Open reintervention |
| L58\* | Other emergency bypass of femoral artery  |
| L59\* | Other bypass of femoral artery |
| L60\* | Reconstruction of femoral artery |
| L62.2 | Open embolectomy of femoral artery |
| L65.3 | Revision of reconstruction involving femoral artery |
| Endovascular reintervention |
| L63\* | Transluminal operations on femoral artery |
| Amputation |
| X09.3 | Amputation of leg above knee  |
| X09.4 | Amputation of leg through knee |
| X09.5 | Amputation of leg below knee |

(\*Including subcategories)