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Defining Percutaneous Coronary Intervention Complexity and Risk

An Analysis of the United Kingdom BCIS Database 2006-2016

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ABSTRACT

OBJECTIVES The authors used the BCIS (British Cardiovascular Intervention Society) database to define the factors associated with percutaneous coronary intervention (PCI) procedural complexity.

BACKGROUND Complex high-risk indicated percutaneous coronary intervention (CHIP-PCI) is an emerging concept that is poorly defined.

METHODS The BCIS (British Cardiovascular Intervention Society) database was used to study all PCI procedures in the United Kingdom 2006-2016. A multiple logistic regression model was developed to identify variables associated with in-hospital major adverse cardiac or cerebrovascular events (MACCE) and to construct a CHIP score. The cumulative effect of this score on patient outcomes was examined.

RESULTS A total of 313,054 patients were included. Seven patient factors (age ≥80 years, female sex, previous stroke, previous myocardial infarction, peripheral vascular disease, ejection fraction <30%, and chronic renal disease) and 6 procedural factors (rotational atherectomy, left main PCI, 3-vessel PCI, dual arterial access, left ventricular mechanical support, and total lesion length >60 mm) were associated with increased in-hospital MACCE and defined as CHIP factors. The mean CHIP score/case for all PCIs increased significantly from 1.06 ± 1.32 in 2006 to 1.49 ± 1.58 in 2016 ($P < 0.001$ for trend). A CHIP score of 5 or more was present in 2.5% of procedures in 2006 increasing to 5.3% in 2016 ($P < 0.001$ for trend). Overall in-hospital MACCE was 0.6% when the CHIP score was 0 compared with 1.2% with any CHIP factor present ($P < 0.001$). As the CHIP score increased, an exponential increase in-hospital MACCE was observed. The cumulative MACCE for procedures associated with a CHIP score 4+ or above was 3.2%, and for a CHIP score 5+ was 4.4%. All other adverse clinical outcomes were more likely as the CHIP score increased.

CONCLUSIONS Seven patient factors and 6 procedural factors were associated with adverse in-hospital MACCE and defined as CHIP factors. Use of a CHIP score might be a future target for risk modification.
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ABBREVIATIONS AND ACRONYMS

AUC = area under the curve

CABG = coronary artery bypass grafting

CHIP = complex high-risk indicated PCI

CTO = chronic total occlusion

EF = ejection fraction

LV = left ventricular

MACCE = major adverse cardiac or cerebrovascular event(s)

MI = myocardial infarction

NSTEMI = non-ST-segment elevation myocardial infarction

PCI = percutaneous coronary intervention

Much has been made in recent years of the concept of complex high-risk indicated percutaneous coronary intervention (CHIP-PCI). A recent consensus statement suggested that among the patient factors that might define complexity, advanced age (often defined as ≥80 years), chronic renal failure, and previous coronary artery bypass grafting (CABG) were important (1). Procedural factors that might define CHIP-PCI included treatment of the left main stem or chronic total occlusions and/or interventions associated with severe calcification. Adverse hemodynamics were also suggested to contribute to case complexity marked by those with poor left ventricular (LV) function, the need to use LV support, and severe concurrent valve disease (2-4). Enthusiasm in the interventional community for the concept of CHIP-PCI has been driven by both its potential to facilitate comparative research, and because it contextualizes case discussion for collaboration and refinement of service delivery (5). Despite this, there are few studies of CHIP-PCI aside from commentaries and white papers (1). One limitation to studying the CHIP-PCI concept thus far is the lack of robust criteria with which to define CHIP-PCI, and the parameters thus far been defined by expert clinical opinion and historical studies (1,6-9).

Therefore, we used the BCIS (British Cardiovascular Intervention Society) National PCI dataset to examine the factors that adversely affected in-hospital post-percutaneous coronary intervention (PCI) morbidity and mortality, and thus to define criteria for a novel CHIP-PCI complexity score. Second, we examined the size of the defined CHIP-PCI population, followed temporal changes in the prevalence of CHIP factors, and assessed the cumulative impact of these factors on outcomes by developing a CHIP score.

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METHODS

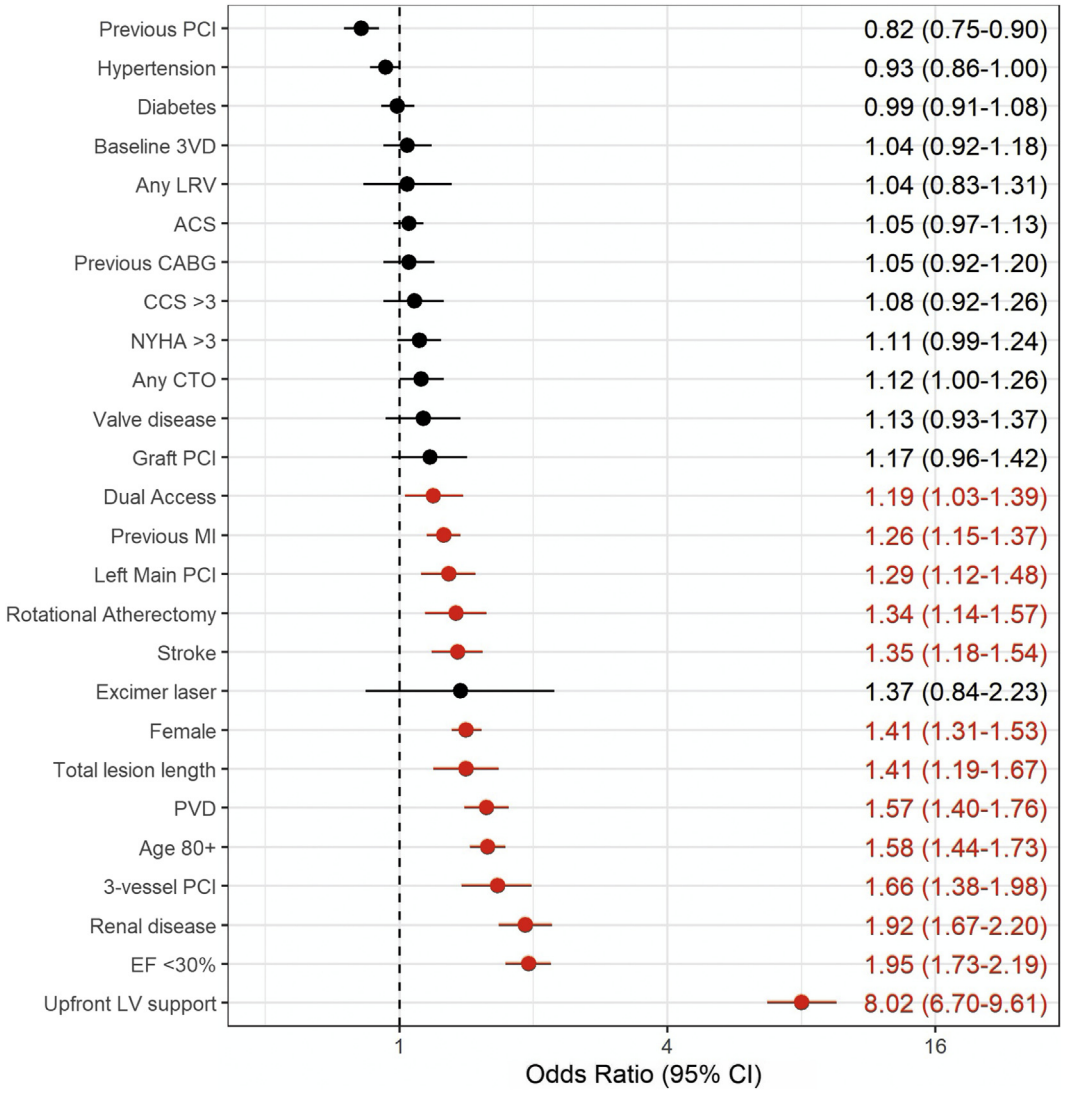
STUDY DESIGN AND PARTICIPANTS. We analyzed data from all patients undergoing PCI in the United Kingdom between January 2006 and December 2016. In selecting the patient population for analysis, we considered the premise of the study, namely that pre-PCI identification of certain characteristics that define complexity and risk might enable operators to individualize treatment and, based upon the appropriate informed discussion and shared decision-making, facilitate tailoring of management accordingly. As such, we excluded patients undergoing primary PCI, undergoing emergency PCI for non-ST-segment elevation myocardial infarction (NSTEMI), and/or presenting in cardiogenic shock as the ability to spend time in such considerations is necessarily limited in these cases (Supplemental Figure 1). Ethical approval for the project was granted by the NICOR (National Institute for Cardiovascular Outcomes Research) Advisory Group.

STUDY SETTING AND SOURCES OF DATA. Data were analyzed on patients and procedures from the BCIS dataset, which records over 120 variables detailing patient demographics, clinical and procedural characteristics, and in-hospital outcomes. Data collection and management are facilitated by BCIS in collaboration with NICOR, with approximately 100,000 new records currently added annually. Entry into the dataset of PCI procedures by UK interventional operators (the vast majority of which are performed within the National Health Service) is mandated as part of professional revalidation. The accuracy and quality of the BCIS dataset has previously been ascertained (10,11).

STUDY DEFINITIONS AND ENDPOINTS. Study definitions were used as in the BCIS-NICOR database. In considering how to study what defines complexity, we chose to focus on risk, that is, which factors were associated with adverse patient outcomes after PCI. Accordingly, we chose to use in-hospital major adverse cardiac and cerebrovascular events (MACCE)—a composite of death, periprocedural cerebral vascular accident, or periprocedural myocardial infarction (MI)—as the primary outcome measure of complexity/risk and defined any factor independently associated with increased MACCE as a CHIP factor. Full study definitions are listed in the Supplemental Appendix.

DATA ANALYSES. Statistical analysis was performed using the R coding environment (R Foundation for Statistical Computing). Records with incomplete MACCE data or unknown ejection fraction were excluded from analysis (Supplemental Figure 1). Multiple imputations were carried out for each dataset using the *mice* package to reduce the potential bias from missing data (Supplemental Table 1), assuming missingness at random mechanisms. We used chained equations to impute the data for all variables with missing information and generated 5 datasets to be used in the analyses. A multiple logistic regression model was developed to identify variables associated with in-hospital MACCE. The potential predictor variables in the model included female sex,

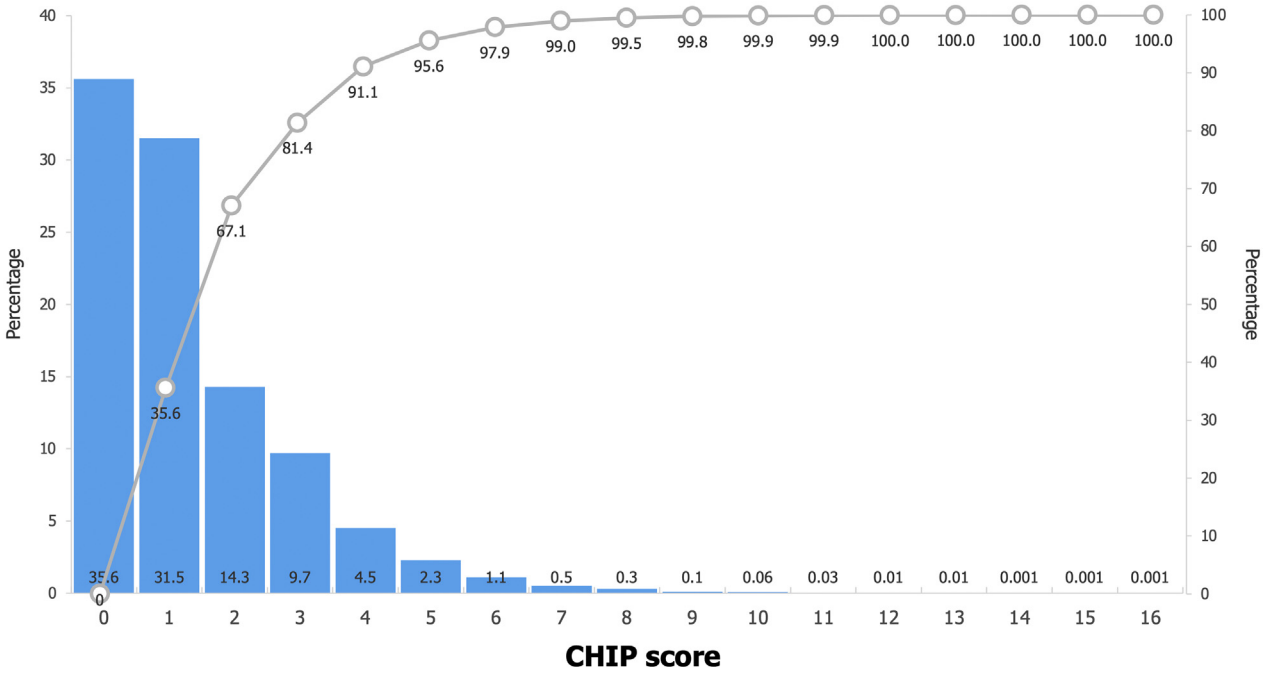
FIGURE 1 **Multivariate Adjusted Baseline and Procedural Covariates Associated With In-Hospital MACCE**



Multivariate adjusted baseline and procedural covariates associated with in-hospital MACCE in patients undergoing PCI in the United Kingdom 2006-2016 (**red highlight** indicates statistically significant variables associated with in-hospital MACCE). 3VD = 3-vessel disease; ACS = acute coronary syndrome; CABG = coronary artery bypass grafting; CCS = Canadian Cardiovascular Society; EF = ejection fraction; LRV = last remaining vessel; LV = left ventricular; MACCE = major adverse cardiac or cerebrovascular event(s); MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PVD = peripheral vascular disease.

age >80 years, smoking history, ejection fraction (EF) <30%, history of renal disease, hypertension, cerebrovascular disease, severe valvular heart disease, peripheral vascular disease, acute coronary syndrome, Canadian Cardiovascular Society score, New York Heart Association functional classification, previous MI, previous CABG, previous PCI, diabetes, baseline 3-vessel disease, left main PCI, 3-vessel PCI, rotational atherectomy use, excimer laser atherectomy use, dual access, last remaining vessel PCI, graft PCI, chronic total occlusion (CTO) attempted, stent longer than 60 mm, and planned LV mechanical support. A sensitivity analysis for the associates of in-hospital MACCE for the most contemporary study years (2014-2016, n = 104,578) was also undertaken. We developed an integer-based CHIP score using methodology as previously studied (12). We assigned an integer score to each CHIP factor based on its effect size on the observed OR for MACCE compared with baseline as follows: >2.0 = 3 points, 1.5-2.0 = 2 points,

FIGURE 2 Distribution of CHIP Factors/Case



Distribution of CHIP factors/case in patients undergoing PCI in the United Kingdom 2006-2016. CHIP = complex high-risk indicated PCI; PCI = percutaneous coronary intervention.

1.0-1.5 = 1 point. We then summed the totals to generate a CHIP score for each procedure. Data are presented with the CHIP score as a continuous variable, but also arbitrarily, we defined a CHIP threshold as the score observed to be associated with a >5 times increase in in-hospital MACCE when compared with the baseline rate observed when no CHIP factors were present. Individual MACCE rates for each factor and cumulative MACCE rates for all procedures including that number of factors and higher were then calculated. Linear changes in CHIP factors were analyzed using the Pearson's chi-square test for trend.

Finally, in a separate analysis, we randomly split the original dataset with complete outcomes (N = 313,053) into a training (66% of procedures, n = 206,614) and testing (34% of procedures, n = 106,439) datasets. Next, we ran a generalized linear model with all variables on the training dataset. We took all significant variables (OR: >1.00; $P < 0.05$), and retrained the model to use them only before applying the model to the test dataset and calculating the area under the curve (AUC) (C-statistic) using receiver-operating characteristic curve analysis.

RESULTS

Between January 2006 and December 2016, 839,508 PCI procedures were recorded in the BCIS National PCI database. Following exclusions, a total of 313,054 patients were included in the analysis.

RISK FACTORS FOR IN-HOSPITAL MACCE POST-PCI IN THE UNITED KINGDOM 2006-2016. Using multiple logistic regression, the variables independently associated with increased in-hospital MACCE were identified (Figure 1). In total, 7 patient factors (age ≥80 years, female sex, previous stroke, previous MI, peripheral vascular disease, EF <30%, and chronic renal disease) and 6 procedural factors (rotational atherectomy, left main PCI, 3-vessel PCI, dual arterial access, planned LV mechanical support, and total lesion length >60 mm) were associated with increased in-hospital MACCE and thus were defined as CHIP factors. Based on the observed OR, planned LV mechanical support scored 3 points; age ≥80 years, peripheral vascular disease, EF <30%, and chronic renal disease scored 2 points; and the remaining factors, 1 point. A sensitivity analysis for the associates of in-hospital MACCE for the most

TABLE 1 Temporal Trends in CHIP Score and CHIP Factors During PCI in the United Kingdom 2006-2016

	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	*P* Value[a]
Any CHIP factor	58.8	60.0	60.4	61.5	62.8	63.6	64.6	66.2	67.3	67.6	68.6	<0.001
CHIP score/case	1.06 ± 1.32	1.12 ± 1.38	1.19 ± 1.45	1.23 ± 1.47	1.27 ± 1.50	1.31 ± 1.53	1.38 ± 1.58	1.42 ± 1.58	1.46 ± 1.58	1.45 ± 1.57	1.49 ± 1.58	<0.001
CHIP 4+ of all PCI	5.4	6.0	7.2	7.7	8.2	8.6	9.8	10.5	10.3	10.3	10.8	<0.001
CHIP 5+ of all PCI	2.5	3.1	3.6	3.9	4.2	4.3	4.9	5.1	5.0	5.0	5.3	<0.001
Female	26.3	26.1	26.1	25.8	25.7	25.5	25.9	25.1	25.5	25.3	25.0	<0.001[b]
Age ≥80 y	7.0	7.6	8.6	9.5	10.4	11.9	12.7	13.2	13.6	13.6	14.1	<0.001
Previous stroke	3.3	3.6	3.9	4.7	4.7	4.6	4.6	4.8	4.6	4.7	4.3	<0.001
PVD	4.7	4.7	5.5	6.0	6.7	6.2	6.4	6.3	6.3	5.7	5.2	<0.001
Previous MI	30.4	32.2	32.0	32.5	33.9	34.5	34.1	34.5	34.4	34.5	35.6	<0.001
Chronic renal disease	2.4	2.8	2.8	2.8	3.2	2.8	3.2	3.4	3.6	3.5	3.4	<0.001
Ejection fraction <30%	4.0	4.5	5.3	4.9	4.1	4.0	4.5	4.7	4.5	4.6	4.7	0.340
Rotational atherectomy	0.9	1.2	1.8	2.0	2.5	2.9	3.6	3.9	3.9	3.6	4.1	<0.001
Left main stem PCI	3.0	2.9	3.1	3.7	3.7	4.7	4.8	6.1	6.5	6.4	6.8	<0.001
Lesion length ≥60 mm	2.0	2.1	3.0	3.1	3.5	4.0	4.7	5.0	6.1	6.6	6.8	<0.001
Three-vessel PCI	1.3	1.8	2.0	1.9	1.9	2.1	2.2	2.1	2.3	2.3	2.7	<0.001
Dual arterial access	1.7	3.3	2.3	2.8	3.2	3.5	4.2	2.9	5.4	6.1	6.2	<0.001
Planned LV support	0.7	0.6	0.7	0.5	0.5	0.5	0.5	0.4	0.3	0.3	0.2	<0.001[b]

Values are % or mean ± SD. [a]*P* value for trend. [b]significance for downward trend.
CHIP = complex high-risk and indicated PCI; LV = left ventricular; MI = myocardial infarction; PCI = percutaneous coronary intervention; PVD = peripheral vascular disease.

contemporary study years (2014-2016, n = 104,578) was consistent with the outcome of the complete 2007-2016 cohort. In the training AUC analysis, exactly the same predictors as the full model were identified as predictive of in-hospital MACCE. Using receiver-operating characteristic curve analysis, the AUC (C-statistic) for the testing cohort was 0.654 (Supplemental Figure 2).

DISTRIBUTION OF AND TEMPORAL CHANGES IN CHIP SCORE DURING PCI IN THE UNITED KINGDOM 2006-2016. A CHIP factor was present in 64.1% of all PCI procedures undertaken between 2006 and 2016. The distribution of the CHIP scores ranged from 0 to 16 (**Figure 2**). There were significant increases in case complexity between 2006 and 2016 (**Table 1**). A CHIP factor was present in 58.8% of all procedures in 2006, increasing to 68.6% of cases in 2016 ($P < 0.001$ for trend). The mean score/case also increased significantly from 1.06 ± 1.32 in 2006 to 1.49 ± 1.58 in 2016 ($P < 0.001$ for trend). A score of 5+ was present in 2.5% of procedures in 2006 increasing to 5.3% in 2016 ($P < 0.001$ for trend). The frequency of individual factors differed significantly over time (**Table 1**).

OUTCOMES BY CHIP SCORE FOLLOWING PCI IN THE UNITED KINGDOM 2006-2016. Overall, in-hospital MACCE was 0.6% when no CHIP factors were present compared with 1.2% with any associated CHIP factor ($P < 0.001$) (**Table 2, Central Illustration**). However, as the CHIP score increased, there was an exponential increase in observed in-hospital MACCE with steeper increases observed between CHIP 3 and CHIP 5. The observed MACCE for CHIP 5 was 3.2% and as such, based on a >5× increase in the observed MACCE compared with a CHIP score of 0, a CHIP score threshold of 5 was arbitrarily defined as a CHIP case. The cumulative MACCE for procedures associated with a score of CHIP 4+ (ie, all cases with a score of 4 or more) was 3.2%, and for CHIP 5+ (ie, all cases with a score of 5 or more) was 4.4% (**Central Illustration**). Similar patterns were observed for in-hospital mortality with an exponential increase in observed in-hospital mortality as the CHIP score increased with steeper increases between CHIP 3 and CHIP 5 (**Figure 3**). The cumulative mortality for procedures associated with a score of CHIP 4+ was 2.2%, and for CHIP 5+ was 3.3% (**Figure 3**). Increases in all other clinical endpoints recorded by the BCIS database including major bleeding and acute procedural complications (Figure 4), emergency revascularization, acute kidney injury, and access site complications were also observed as the CHIP score increased (Supplemental Figure 3). Procedural success and completeness of revascularization decreased as CHIP score increased (Supplemental Figure 4). Median length of stay for the entire cohort was 1 day (IQR: 0-1 day). The crude clinical outcomes for each CHIP factor are presented in **Table 2**.

TABLE 2 Crude Clinical Outcomes for Each CHIP Factor During PCI in the United Kingdom 2006-2016

	In-Hospital MACCE, %	In-Hospital Mortality, %	In-Hospital Major Bleeding, %	Acute Procedural Complication, %
Overall outcomes in study population	1.0	0.4	0.7	4.0
No CHIP factor/procedure	0.6	0.1	0.3	3.1
Any CHIP factor/procedure	1.2	0.6	0.8	4.4
Previous MI	1.2	0.6	0.7	4.0
Female	1.3	0.6	1.2	4.7
Total lesion length ≥60 mm	1.5	0.7	1.1	9.4
Age ≥80 y	1.9	1.2	1.2	4.6
Previous stroke	1.9	1.1	0.9	4.8
Dual arterial access	1.9	1.0	2.0	7.4
PVD	2.2	1.3	1.1	5.0
Rotational atherectomy	2.3	1.3	2.0	7.1
Left main stem PCI	2.5	1.6	1.3	6.7
Chronic renal disease	2.8	2.0	1.1	4.0
Ejection fraction <30%	3.0	2.2	0.9	4.5
Three-vessel PCI	3.0	1.7	1.2	7.1
Planned LV support	15.2	11.4	6.6	14.8

Abbreviations as in Table 1.

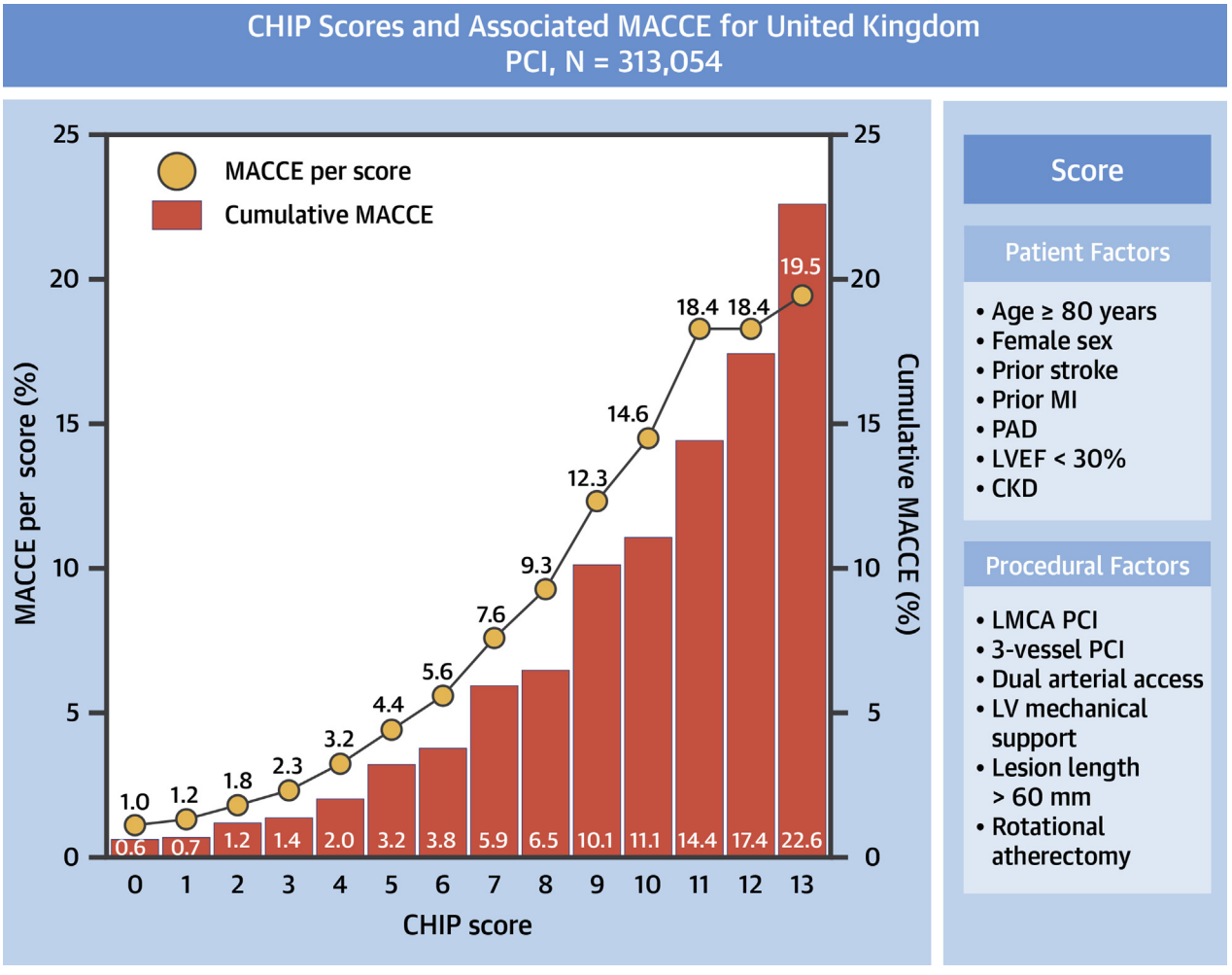
DISCUSSION

In this study, we have described a novel CHIP score for defining the complexity and outcome risk for patients undergoing nonemergency PCI using a large national dataset. The study findings can be summarized as follows: 1) When using in-hospital MACCE as a marker of complexity/risk, 7 patient factors (age ≥80 years, female sex, previous stroke, previous MI, peripheral vascular disease, EF <30%, and chronic renal disease) and 6 procedural factors (rotational atherectomy, left main PCI, 3-vessel PCI, dual arterial access, LV mechanical support, and total lesion length >60 mm) were defined as CHIP factors; 2) The mean CHIP score/case for all PCIs increased significantly from 1.06 ± 1.32 in 2006 to 1.49 ± 1.58 in 2016; 3) In-hospital MACCE increased exponentially as the CHIP score increased, and only minor increases adverse outcomes were observed with single CHIP criteria; 4) All other adverse clinical outcomes including major bleeding, acute kidney injury, and periprocedural coronary complications were more frequent as the number of CHIP factors increased.

Although risk scores such as EuroSCORE and EuroSCORE II are well-established in surgical revascularization, risk prediction in PCI is less well established. A previous analysis of the National Cardiovascular Data Registry in all-comer PCI identified 8 patient characteristics that were predictive of in-hospital mortality (9). However, as all indications for PCI were included, ST-segment elevation on presentation, cardiogenic shock, and an emergency indication were strongly associated with increased mortality. However, the CHIP population would typically not include such patients with the premise of the CHIP concept being that pre-PCI identification of certain characteristics might define complexity and risk, and this might enable operators to individualize treatment and tailor management accordingly. As such, the current study excluded patients undergoing primary PCI, undergoing emergency PCI for NSTEMI, and/or presenting in cardiogenic shock. Thus, this is the first study to our knowledge to attempt to define the factors predictive of MACCE in the CHIP-eligible population.

In the current study, we have focused on the *risk* component of PCI—rather than the looser concept of complexity—and used clinical endpoints to ensure that the findings were patient-centered rather than technically orientated. The findings in some part are intuitive, and the observation of an association between age ≥80 years, disease in other vascular beds, low EF <30%, and chronic renal disease with increased MACCE are consistent with previous data (13-19). Also notably, the prevalence of several factors increased over time. One driver of these temporal changes may be patient age. An analysis of global cardiovascular deaths found a 40% increase in the number of cardiovascular deaths due to the increasing age of the world's population (20). Further studies have demonstrated a doubling in the number of patients over the age of 80 years who underwent PCI during the same period (13). Advancing patient age is associated with greater likelihood of low EF (21), vascular calcification, and chronic renal disease (22,23). Additionally, although female sex has not previously featured as a conventional CHIP-PCI factor, numerous previous studies have highlighted adverse outcomes in women undergoing PCI (24,25). It is interesting to observe that previous CABG was not independently associated with increased MACCE, a factor that has often previously been considered a conventional CHIP factor (1). It also notable that ACS presentation was not independently associated with increased MACCE. One possible explanation for this observation is that we removed the highest risk ACS patients by excluding primary PCI, cardiogenic shock, and the small number of the highest-risk cases who underwent NSTEMI-PCI on an emergent basis. Excluding these patients on the basis that optimizing service provision for emergency patients will be a greater systemic challenge than for non-emergency patients likely identified a lower-risk ACS cohort.

CENTRAL ILLUSTRATION **In-Hospital Major Adverse Cardiac or Cerebrovascular Events**



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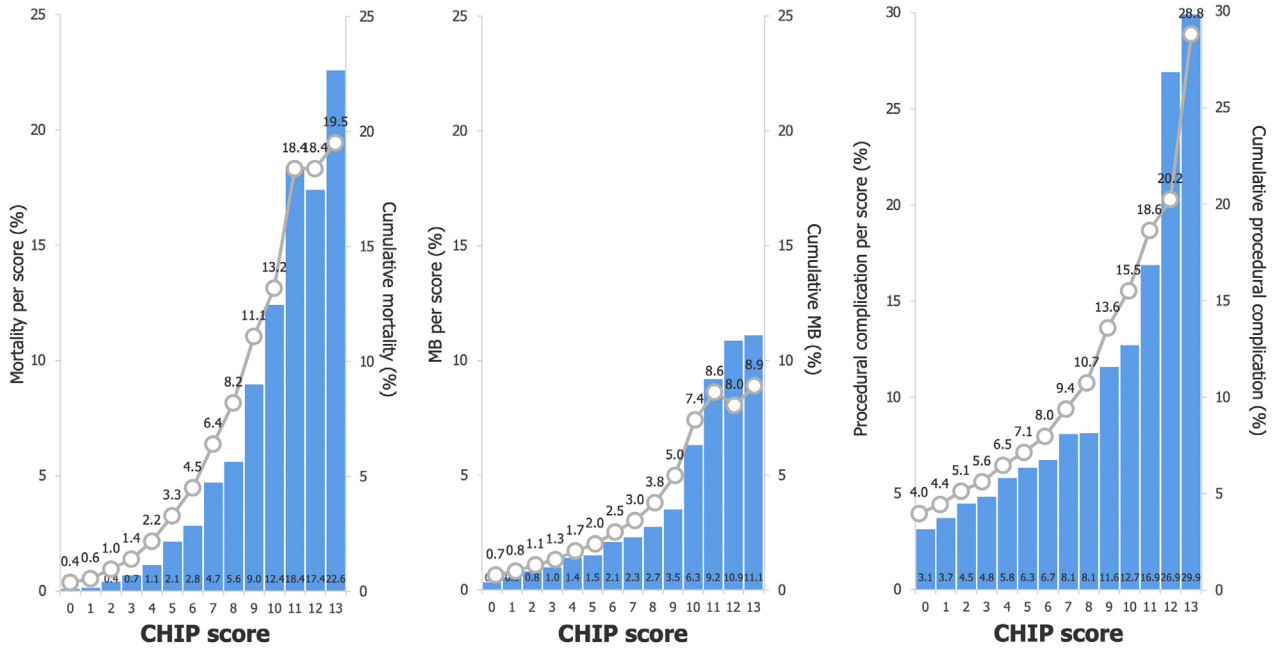
Red bars plot in-hospital major adverse cardiac or cerebrovascular events (MACCE) by the number of complex high-risk indicated PCI (CHIP) factors present in patients undergoing percutaneous coronary intervention (PCI) in the United Kingdom 2006-2016. **Yellow circles** plot cumulative in-hospital MACCE of that number of factors or more/case, that is, cumulative in-hospital MACCE of 3 or more CHIP factors/case is 3.0%.

Of the 6 procedural factors defined as key factors for our scoring tool, several such as rotational atherectomy, left main PCI, and total lesion length >60 mm have in previous studies been associated with increased complications (26-30). However, it is interesting to note that contrary to previous arbitrary definitions of CHIP-PCI, CTO as a whole was not associated with increased MACCE. Potential explanations for this novel finding might include a predominance of straightforward lower-risk CTO-PCI, a miscategorization of lesion severity, or that historically, many CTO-PCI interventions were not fully committed attempts. Consistent with this is the observation that dual arterial access (in which the majority of cases were also CTO-PCI) was independently associated with increased MACCE. It is interesting to observe that use of planned LV support was the factor most strongly associated with in-hospital MACCE, presumably reflecting the underlying comorbidity of the patient such as low EF and multivessel disease including the left main stem. Although guidelines support the use of mechanical LV support during high-risk PCI, the observed reduction in the prevalence of use of planned LV support is likely driven by increasing operator comfort in high-risk PCI over time, a lack of robust clinical evidence

FIGURE 3 In-Hospital Mortality and Major Bleeding, and Procedural Complications by the Number of CHIP Factors Present



(Left) Bars indicate in-hospital mortality by the number of CHIP factors present. The cumulative mortality for procedures associated with a score of CHIP 5+ was 3.3%. **(Middle)** Bars indicate in-hospital major bleeding (MB) by the number of CHIP factors present. The cumulative in-hospital MB of that number of factors or more/case. **(Right)** Bars indicate procedural complication by the number of CHIP factors present. The cumulative procedural complications of that number of factors or more/case.

supporting their use, cost, and concerns regarding the safety and morbidity of the devices themselves (8,31,32).

The inclusion of both anatomical and patient characteristics as markers of risk in our analysis acknowledges that both influence patient outcomes. Therefore, although a Type A lesion in a patient with multiple comorbidities may be technically straightforward to treat with PCI, such patients remain at high risk of adverse outcomes. Therefore, in considering the implications of the current study, the development of tailored pathways for PCI cases, regardless of whether the CHIP score is driven by procedural or patient complexity, might lead to improvements in the clinical outcomes of these high-risk cases. As observed, over 60% of all PCI procedures were associated with at least 1 CHIP factor, and aside from planned LV support, a single factor was associated with only modest increases in MACCE. Therefore, our analysis may facilitate the ability to define more clearly those patients and procedures that are genuinely high risk. These data clearly illustrate that aside from upfront LV support, a single CHIP criterion has a minimal effect on patient outcomes. Therefore, these data support the use of multiple CHIP factors to define complexity. For practical purposes, arbitrary thresholds would need to be applied to the curvilinear relationship observed between the CHIP score and in-hospital MACCE to define a high-risk case, and such thresholds are likely to vary between individuals, centers, and health care systems. Accordingly, the data are presented in a continuous fashion to facilitate informed consent, multidisciplinary discussion, and appropriate decision-making. In considering where to draw an arbitrary line to define a CHIP case, a compromise needs to be made between cases with multiple CHIP factors (but which occur infrequently and thus would be less relevant to service optimization) and cases with fewer CHIP factors (and thus which occur more frequently but in which there may be less relative outcome benefit with service reconfiguration). In attempting to balance these considerations, we have proposed—based on a >5× increase in the observed MACCE—that a CHIP score of 5 or more be considered as defining a CHIP case. As a result, in contemporary

PCI practice, 5% to 10% of PCI procedures in the relevant patient cohort would be considered truly complex and high risk.

Notwithstanding the challenge of definition, utilizing a CHIP score may identify patients who could benefit from specific strategies such as referral to a recognized operator or center with expertise in undertaking either the complexity component of the PCI procedure or managing the complexity aspect of the patient (5). These data are relevant because procedural success and completeness of revascularization—variables that are observed to be unfavorably associated with CHIP score—might be improved by complex operator expertise. Additionally, interventions that might improve patient outcomes include the routine use of imaging in cases defined as CHIP cases (33). For example, intravascular ultrasound use in left main PCI and long lesions has already been demonstrated to be associated with improved outcomes (32). Other interventions that might improve outcomes include routine radial access where possible (although the paradox of lower use in higher complexity cases is well reported), optimizing periprocedural and postprocedural pharmacology, mandated discussion in a multidisciplinary format, detailed preprocedural planning, buddying up with colleagues, and the avoidance of ad hoc PCI where practical (1,34-37). The findings of the current study highlight the importance of risk assessment and the unmet clinical need in optimizing in-hospital outcomes of complex PCI, and are worthy of further study.

STUDY LIMITATIONS. First, as with any registry, these data are observational and thus subject to unmeasured confounders. Second, in excluding emergency indications such as primary PCI, our findings only apply to patients undergoing PCI for stable angina and NSTEMI presentations. Third, the BCIS dataset is not exhaustive in fields recorded and does not include certain anatomical factors (such as tortuosity and bifurcation) and patient factors (such as hemoglobin or pulmonary function) that might also have an independent impact on outcomes and thus be considered as CHIP factors. Fourth, although the C-statistic performed only moderately well in the testing model, the identification of CHIP factors was not intended to be used to predict outcomes. Rather, the premise of the study was to identify the highest risk patients undergoing PCI in order to support service and procedural optimization. Occasional low frequency MACCE events in a large number of non-complex patients will likely dilute down the predictive power of CHIP-PCI modelling. Finally, the BCIS database in the years studied did not capture intravascular lithotripsy or orbital atherectomy use and therefore the influence of these technologies on in-hospital MACCE cannot be assessed. Because the latest iteration of the BCIS database will capture these technologies, this question may be addressed in future studies.

CONCLUSIONS

Seven patient factors (age ≥80 years, female sex, previous stroke, previous MI, peripheral vascular disease, EF <30%, and chronic renal disease) and 6 procedural factors (rotational atherectomy, left main PCI, 3-vessel PCI, dual arterial access, planned LV mechanical support, and total lesion length >60 mm) were independently associated with adverse in-hospital MACCE. These factors were used to define the concept of CHIP. As the CHIP score increased, an exponential increase in in-hospital MACCE and other adverse clinical outcomes was observed. The identification of CHIP factors and scores may facilitate personalized assessment and management of complex and high-risk patients undergoing PCI.

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PERSPECTIVES

WHAT IS KNOWN? Much is made of complex PCI, but as a concept, it is poorly defined with most criteria based on expert consensus. Little data exist on the cumulative impact of patient and procedural complexity on clinical outcomes.

WHAT IS NEW? From data derived from over 300,000 PCI procedures, 7 patient factors and 6 procedural factors were associated with increased in-hospital MACCE and defined as CHIP factors. As the number of the CHIP score increased, an exponential increase in-hospital MACCE was observed.

WHAT IS NEXT? Assessing cumulative CHIP factors and scores might be future target for risk modification such as focusing complex PCI to specific operators/centers, optimizing access site, intravascular imaging, and pharmacology.

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KEY WORDS CHIP-PCI, complex PCI, national database, patient outcomes

APPENDIX For supplemental figures and a table, please see the online version of this paper.