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ORIGINAL STUDIES

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Vascular complications associated with intraaortic balloon pump supported percutaneous coronary intervention (PCI) and clinical outcomes from the British Cardiovascular Intervention Society National PCI Database

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Abstract

Introduction: The impact of a vascular complication (VC) in the setting of intraaortic balloon pump (IABP) supported PCI on clinical outcomes is unclear.

Methods: Using data from the BCIS National PCI Database, multivariate logistic regression was used to identify independent predictors of a VC. Propensity scoring was used to quantify the association between a VC and outcomes.

Results: Between 2007 and 2014, 9,970 PCIs in England and Wales were supported by IABP (1.6% of total PCI), with 224 femoral VCs (2.3%). Annualized rates of a VC reduced as the use of radial access for PCI increased. The independent predictors of a VC included a procedural complication (odds ratio [OR] 2.9, $p < .001$), female sex (OR 2.3, $p < .001$), PCI for stable angina (OR 3.47, $p = .028$), and use of a glycoprotein inhibitor (OR 1.46 [1.1:2.5], $p = .04$), with a lower likelihood of a VC when radial access was used for PCI (OR 0.48, $p = .008$). A VC was associated with a higher likelihood of transfusion (OR 5.7 [3.5:9.2], $p < .0001$), acute kidney injury (OR 2.6 [1.2:6.1], $p = .027$), and peri-procedural MI (OR 3.2 [1.5:6.7], $p = .002$) but not with adjusted mortality at discharge (OR 1.2 [0.8:1.7], $p = .394$) or 12-months (OR 1.1 [0.76:1.56], $p = .639$). In sensitivity analyses, there was a trend towards higher mortality in patients experiencing a VC who underwent PCI for stable angina (OR 4.1 [1.0:16.4], p value for interaction .069).

Discussion and Conclusions

Although in-hospital morbidity was observed to be adversely affected by occurrence of a VC during IABP-supported PCI, in-hospital and 1-year survival were similar between groups.

Abbreviations: BCIS, British Cardiovascular Intervention Society; CABG, coronary artery bypass surgery; FA, femoral access; IABP, intraaortic balloon pump; IVUS, intravascular ultrasound; LAD, left anterior descending; LMS, left main stem; MACCE, major adverse cardiac or cerebrovascular events; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; uLMS-PCI, unprotected left main stem percutaneous intervention.

KEYWORDS
bleeding, complications, intraaortic balloon pump, patient outcomes, vascular complications

1 | INTRODUCTION

The evolution of revascularization for coronary artery disease has resulted in percutaneous coronary intervention (PCI) becoming more complex in contemporary practice with advancing patient age necessitating increasingly the utilization of calcium modification strategies.[1] Despite recent controversies regarding the Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease (EXCEL) trial, PCI for left main disease also continues to represent an increasingly large percentage of the total PCI procedures undertaken.[2,3] Furthermore, in parallel with increasing patient age and the uptake of transaortic valve replacement (TAVR), severe concomitant valve disease is also more prevalent.[4] With increasing patient and procedural complexity comes an increased likelihood of potential complications such as coronary perforation, persistent no reflow, and arrhythmias leading to hemodynamic instability.[5]

As a result of the well-documented increase in procedural complexity, interest has arisen in the use of left ventricular support devices as an adjunct to PCI. Although intraaortic balloon pumps are historically the dominant LV support device, recent interest has focused on the Impella device and the significant augmentation of cardiac output that it provides.[6,7] However, two recent studies have identified significant bleeding and vascular risks associated with Impella use.[8,9] Furthermore, although the significant hemodynamic support provided by the Impella remains attractive, their prohibitive cost in many healthcare systems means that IABP remains the dominant device used. Although historical studies of most patient subsets undergoing PCI have identified vascular complications as correlating closely with adverse short-term and medium-term outcomes, little is known about the temporal changes in vascular complications and bleeding associated with IABP use, and the subsequent impact such as complication has on medium term survival.[10-13] One unexplored hypothesis is that the morbidity associated with such LV support devices might offset any benefit gained from improved hemodynamics.

Therefore, the aims of the present study were to use the British Coronary Intervention Society (BCIS) National PCI Database to study the temporal changes in vascular complications occurring during IABP-supported PCI, examine the independent predictors of vascular complications, and to assess the impact of a vascular complication on 12-month survival.

2 | METHODS

2.1 | Study design and participants

We analyzed data from all patients undergoing PCI in England and Wales between January 1, 2007 and December 31, 2014. The study patient flow is illustrated in Figure S1 with the study cohort consisting of all patients who underwent PCI for any indication with IABP support. Participants with missing information on vascular complication status were excluded from the study. The final study population of 9,790 procedures was then classified as to whether a vascular complication had occurred or not.

2.2 | Study setting and sources of data

The BCIS maintains data prospectively on PCI procedures throughout United Kingdom, a process overseen by the National Institute of Cardiovascular Outcomes Research (NICOR). Entry of all PCI procedures by UK interventional operators is mandated as part of their professional revalidation. The governance and quality of these data have previously been validated and published.[14,15] In 2014, approximately 98% of all PCI procedures performed in the National Health Service (NHS) hospital in England and Wales were recorded on this National database (www.bcis.org.uk/). The BCIS database consists of over 120 clinical, demographical, procedural, and outcomes variables with approximately 80,000 new entries uploaded each year.[15,16] BCIS records are linked with Office of National Statistics (ONS) data for postdischarge mortality tracking in all patients from England and Wales by using their unique National Health Service (NHS) numbers. Patients from Scotland and Northern Ireland were not included in this study due to the absence of the ONS-linked postdischarge mortality data.

2.3 | Study definitions

The BCIS National PCI Audit records use of an intraaortic balloon pump during PCI although does not record whether use is in a planned fashion or consequent to hemodynamic collapse during the procedure. Study definitions were used as in the BCIS National PCI Audit (available at https://www.bcis.org.uk/resources/bcis-ccad-database-resources/datasets-history/). For the purposes of the study, a vascular complication was defined as an arterial dissection, arterial occlusion, retroperitoneal hemorrhage, any complication requiring surgical intervention, a false aneurysm (with conservative, surgical, thrombin injection, or compressive management separately recorded), or arterial hemorrhage with delayed discharge. In the BCIS database, to fulfill the cardiogenic shock criteria, patients must have both systemic hypotension (systolic BP of ≤90 mmHg) and evidence of peripheral hypoperfusion such as a weak pulse, pallor, cool peripheries, or diaphoresis. Pre-PCI or post-PCI disease severity was defined as vessels with a stenosis ≥70% in the case of the LAD, circumflex or right coronary arteries, or ≥50% in the case of the left main artery. Chronic renal failure was defined as chronic dialysis, history of renal transplant, or a creatinine >200 μmol/L. An acute coronary complication was

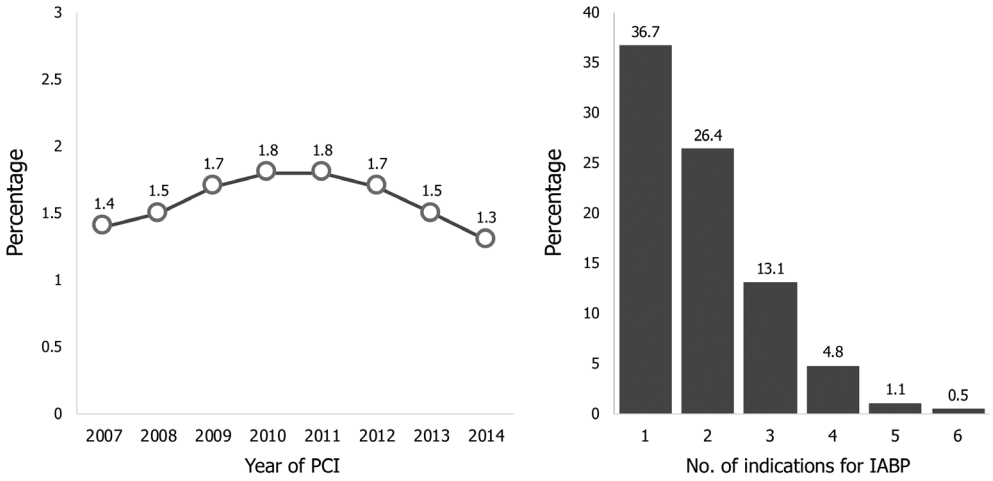

FIGURE 1 Left: Annual rate of IABP use to support PCI in England and Wales 2007–2014, $p = .325$ for trend; Right: Number of indications for IABP use

defined as a coronary perforation, coronary/aortic dissection, major side branch loss, severe no/slow flow, or shock induced by the procedure. In-hospital major adverse cardiac or cerebrovascular events (MACCE) were defined as a combination of death, stroke, or myocardial infarction after PCI.

2.4 | Data analyses

Trends for the use of IABP, access site and VC over time were constructed and significance was examined using linear regression. We examined the baseline and procedural characteristics of patients by vascular complication status. We tested for associations between each categorical variable and coronary perforation using a Chi-squared test, and for continuous variables we used one-way analysis of variance. We then performed separate multivariate analyses of the predictors of a vascular complication using multivariate logistic regression to investigate the influence of variables that have the potential for being included in the linear component of a proportional hazard model. We first imputed missing data on baseline covariate using multiple imputations with chained equation (missing data points are presented in Table S1). We selected a final model for each outcome by using forward stepwise variable selection and an inclusion criterion of $p < .1$. Variables included in this analysis were age, sex, clinical presentation, emergency indication, cardiogenic shock, angina score, dyspnea score, recent thrombolysis, previous MI, previous CABG, previous PCI, diabetes, body mass index, ejection fraction (EF), baseline disease severity, left main stem intervention, number of stents used, glycoprotein inhibitor use, rotational atherectomy, embolic protection, use of inotropes, closure device, history of smoking, hypertension, previous stroke, peripheral vascular disease, severe valve disease, ventilated preprocedure, Q wave on ECG, chronic renal failure, and radial use. We also included the occurrence of an acute coronary complication in this modeling (rather than as an outcome event), as it seemed more likely that an IABP was used as a result of an acute coronary complication, that is, that the reverse scenario was rather unlikely.

We then explored the association between a VC and clinical outcomes. We initially calculated the crude rates by VC status. Then using a Cox proportional hazard mode, we estimated the corresponding hazard ratio. To adjust for baseline imbalances, we performed a propensity score analysis in order to balance for important covariates that might bias estimates for causal inferences. The following variables were used in the propensity score analysis: age, sex, clinical presentation, emergency indication, cardiogenic shock, previous MI, previous CABG, previous PCI, diabetes, EF, baseline disease severity, left main stem intervention, use of intracoronary imaging, glycoprotein inhibitor use, rotational atherectomy, use of inotropes, use of cardiopulmonary support, hypertension, previous stroke, peripheral vascular disease, severe valve disease, ventilated preprocedure, Q wave on ECG, and chronic renal failure. As above, we also adjusted outcomes for the occurrence any acute coronary procedural coronary complication. The propensity scores for each patient was derived using the inverse probability of treatment weight (IPTW). More precisely, one estimates the probability that a particular patient is assigned to one of the two groups as a function of that individual's covariates (the propensity score). Each individual observation was then given a weight equal to the inverse of this propensity score to create two pseudo-populations of exposed and unexposed patients who now represent what would have happened to the entire population under those two "treatment" conditions. The advantage of this method is that it is inclusive as it uses all patients in a study; therefore, no loss of sample occurs as in other conditioning methods such as matching or stratification. We also normalized the weights by dividing them by the mean weight. Those weights were then used to derive weighted hazard ratios. A sensitivity analysis examining the effect of a VC by access site (radial vs. femoral) was also undertaken. Subgroup analyses for gender, age >75, shock, stable angina, EF <30, acute coronary complication and left main PCI were also performed. Finally, an outcome analysis including only patients with hemorrhage, that is, with exclusion of patients with a vascular complication but without hemorrhage, was also undertaken.

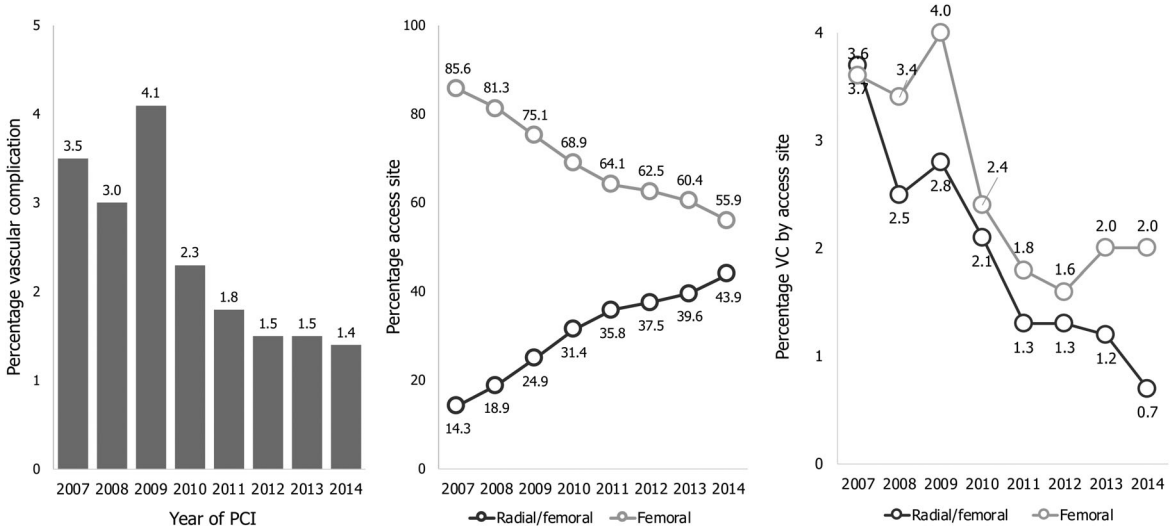

FIGURE 2 Left panel: Annual rate of vascular complications during IABP use to support PCI in England and Wales 2007–2014 ($p < .001$ for trend); Middle panel: Temporal change in the access site for PCI used during IABP supported PCI ($p < .001$ for trend); Right panel: Annual rate of vascular complications by access site during IABP use to support PCI in England and Wales 2007–2014

3 | RESULTS

3.1 | Temporal changes in IABP use and vascular complications between 2007 and 2014

Between 2007 and 2014, there were 9,970 IABP-supported PCI procedures undertaken (1.6% of total PCI) with no significant trend in the frequency of IABP use (Figure 1, left panel). The most frequent indications for IABP use were cardiogenic shock (54.8%), multivessel coronary artery disease (27.6%), EF less than 30% (23.4%), left main PCI (19.8%), acute procedural complication (19.1%) and PCI to the last remaining vessel (5.1%). The mean number of indications for IABP use was 1.87 ± 0.97 with many patients having multiple reasons for IABP use (Figure 1, right panel). In total, there were 224 vascular complications (2.3%) with major arterial hemorrhage, femoral artery aneurysm, and femoral artery dissection the most common events. There was a significant reduction in the annualized rates of a VC from 4.1% in 2007 to 1.4% in 2014 ($p < .001$ for trend) which mirrored a significant increase in radial approach over the same period was observed (14.3–43.9%, $p < .001$ for trend, Figure 2 left and center panel). When analyzed by access site for PCI, annualized rates of a VC were consistently lower when radial access was used, although the annualized VC rates dropped significantly in both access groups (Figure 2 right panel).

3.2 | Baseline demographics, and procedural data by vascular complication status during IABP-supported PCI between 2007 and 2014

In general, there were few baseline characteristics associated with a vascular complication. Only female sex, previous CABG, stable angina indication, clopidogrel use, and baseline disease severity were observed to be associated with a greater frequency of a vascular complication (Table 1). However procedural characteristics differed between the two cohorts with no. vessels/lesions attempted, glycoprotein inhibitor use, radial access for PCI, left main PCI, size and number of stents used, and the occurrence of an acute coronary complication all observed to be associated with a significant increase in vascular complications (Table 2). In multivariate analysis of the independent predictors of a vascular complication, an acute coronary complication (OR 2.86, 95% confidence interval 1.94–4.22, $p < .001$), female sex (OR 2.03, 95% confidence interval 1.38–3.00, $p < .001$), stable angina indication (OR 3.47, 95% confidence interval 1.14–10.40, $p \leq .028$) and glycoprotein inhibitor use (OR 1.46, 95% confidence interval 1.00–2.19, $p = .050$) were associated with a greater likelihood of a vascular complication, whilst diabetes mellitus (OR 0.60, 95% confidence interval 0.36–0.99, $p = .046$) and use of the radial artery for PCI (OR 0.48, 95% confidence interval 0.28–0.83, $p = .008$) were associated with a lower likelihood (Table 3). Use of a closure device, patient age, body mass index, or a history of peripheral vascular disease were not associated with a differing risk of a vascular complication.

3.3 | Clinical outcomes by vascular complication status during IABP-supported PCI between 2007 and 2014

Clinical outcomes for the whole IABP-supported PCI cohort was poor with an observed in-hospital mortality of 28.4% and a 12-month mortality of 41.0%. For those who survived, median LOS was 5 days (IQR 2–10 days). In unadjusted analysis, although transfusion (19.8 vs. 2.7%, $p < .001$), periprocedural CVA (2.4 vs. 0.6% $p = .011$),

TABLE 1 Baseline characteristics by vascular complication status after IABP-supported PCI performed in England and Wales between 2007 and 2014

Variable	No vascular complication (*n* = 9,566)	Vascular complication (*n* = 224)	*p*-value
Age (years) ± *SD*	67.7 ± 12.3	67.9 ± 11.9	.390
Female sex, no. (%)	2,621 (27.5)	82 (37.6)	<.001
BMI (kg/m^2) ± *SD*	27.1 ± 5.0	27.3 ± 5.2	.422
History of hypertension, no. (%)	4,494 (50.8)	116 (56.3)	.134
Diabetes mellitus, no. (%)	2,053 (22.9)	45 (21.3)	.657
History of smoking, no. (%)	4,915 (62.4)	115 (59.5)	.466
Previous MI, no. (%)	2,459 (28.3)	55 (27.1)	.746
Previous stroke, no. (%)	538 (6.1)	17 (8.3)	.255
Peripheral vascular disease, no. (%)	767 (8.7)	12 (5.8)	.189
Chronic renal disease, no. (%)	641 (7.4)	18 (8.7)	.597
Previous PCI, no. (%)	1,373 (15.0)	25 (11.7)	.207
Previous CABG, no. (%)	645 (7.0)	26 (12.2)	.007
EF (%), ±*SD*	34.3 ± 14.0	35.2 ± 15.5	.244
EF <30%, no. (%)	2,300 (45.9)	61 (46.9)	.894
Recent thrombolysis, no. (%)	573 (6.7)	13 (6.6)	.999
Stable angina indication, no. (%)	478 (4.9)	18 (8.2)	.046
Clopidogrel use, no. (%)	5,797 (70.2)	165 (82.5)	<.001
Out of hospital cardiac arrest, no. (%)	186 (19.9)	3 (23.1)	.775
Cardiogenic shock on presentation, no. (%)	5,364 (56.8)	102 (47.0)	.004
Ventilated preprocedure, no. (%)	2,224 (25.0)	31 (14.9)	.001
Mean NYHA class, ±*SD*	2.36 ± 1.62	2.01 ± 1.57	.020
No. vessels diseased ±*SD*	1.93 ± 1.00	2.11 ± 1.04	.005

periprocedural MI (6.1 vs. 1.6%, $p < .001$), and acute kidney injury (4.7 vs. 1.5%, $p < .001$) were more likely when a VC occurred, in-hospital death, MACCE and 12-month mortality were similar between both groups (Table 4). There was a trend for median length of stay to be longer when a VC occurred although this difference did not reach statistical significance. In adjusted analysis, a vascular complication during IABP-supported PCI was associated with an increase in blood transfusion (OR 5.72, [3.54:9.23], $p < .001$), periprocedural MI (OR 1.58, [1.51:6.73], $p = .002$), and acute kidney injury (OR 2.60, [1.11:6.11], $p = .027$) but not increased in-hospital (OR 1.17, [0.81:1.70], $p = .394$) or 12-month mortality (OR 1.09, [0.76:1.58], $p = .639$) (Table 5). Adjusted Kaplan Meier curves by vascular complication status are presented in Figure 3. When the outcome analysis was restricted to patients with major hemorrhage, that is, with exclusion of patients with a vascular complication but without hemorrhage, the findings were similar to the whole cohort with an excess of transfusion (OR 6.41, [3.12:13.1], $p < .001$) and periprocedural MI (OR 4.27, [1.52:11.96], $p = .006$) but similar survival at 12-months follow-up (OR 1.20, [0.65:2.21], $p = .554$) (Table S2). In sensitivity analyses, in the radial sub-group, patient outcomes were similar to the overall group with no difference in 12-month survival observed between patients with or without a vascular complication (OR for 12-month mortality 0.84 [0.43–1.92], $p = .601$). Although the 12-month mortality for several subgroups including female sex, age >75 years, EF >30% and left main PCI did not differ from the overall study findings, there was a trend for a vascular complication in the setting of stable angina PCI to be associated with increased 12-month mortality (OR 4.07, [1.01:16.39], $p = .048$, p value for interaction = .069) (Figure 4).

4 | DISCUSSION

The findings of the current study can be summarized as follows: (a) Vascular complications occurred in 2.3% of all IABP-supported PCI; (b) There was a significant reduction in the annualized rates of a VC which mirrored a significant increase in radial artery access for PCI in the same period; (c) The independent predictors of an increase in VC were a procedural complication, female sex, PCI for stable angina, and use of a glycoprotein inhibitor, whilst a lower likelihood of a VC occurred when radial access was used; (d) Although a VC was associated with a higher likelihood of transfusion, acute kidney injury, and periprocedural MI, its occurrence was not associated with a higher rate of in-hospital or 12-month mortality; (e) In sensitivity analyses, there was a trend toward higher mortality in patients who sustained a vascular complication during ABP-supported PCI for stable angina.

The observed frequency of vascular complications complicating IABP-supported PCI varies widely in the literature. In a meta-analysis of 20 studies, the overall rate of vascular complications varied

TABLE 2 Procedural variables by vascular complication status after IABP-supported PCI performed in England and Wales between 2007 and 2014

Variable	No vascular complication (*n* = 9,566)	Vascular complication (*n* = 224)	*p*-value
On-site surgical cover, no. (%)	6,191 (70.0)	147 (70.2)	.988
No. vessels attempted ±*SD*	1.47 ± 0.74	1.63 ± 0.81	.001
No. lesions attempted ±*SD*	1.64 ± 0.91	1.80 ± 1.09	.004
No. chronic total occlusions attempted, no. (%)	885 (9.9)	30 (14.5)	.037
Radial access for PCI, no. (%)	3,032 (32.6)	50 (23.0)	.028
Closure device, no. (%)	1,908 (23.7)	46 (24.6)	.831
Glycoprotein inhibitor, no. (%)	4,725 (51.9)	130 (60.5)	.016
Intra-coronary imaging, no. (%)	677 (8.1)	14 (7.1)	.719
Vessel attempted, no. (%)			
Left main	1,943 (20.4)	67 (30.7)	<.001
Left anterior descending	5,456 (57.4)	126 (57.8)	.979
Circumflex	2,643 (27.8)	71 (32.6)	.144
Right	2,937 (30.9)	67 (30.7)	.949
Graft	293 (3.1)	10 (4.6)	.231
Left main protected, no. (%)	244 (3.4)	11 (7.4)	.015
Aspiration thrombectomy, no. (%)	3,090 (33.6)	70 (32.9)	.892
Rotational atherectomy, no. (%)	284 (3.7)	11 (5.6)	.216
Inotrope use, no. (%)	2,360 (24.6)	55 (25.1)	.937
Largest stent (mm) ±*SD*	3.40 ± 0.66	3.54 ± 0.75	.001
Longest stent (mm) ±*SD*	27.7 ± 16.6	27.3 ± 14.3	.371
No. stents used ±*SD*	1.77 ± 1.35	2.10 ± 1.61	<.001
Acute procedural complication, no. (%)	1,866 (20.9)	90 (43.9)	<.001
No. successful lesions ±*SD*	1.46 ± 0.94	1.53 ± 1.17	.126

TABLE 3 Significant associations between covariates and a vascular complication status after IABP-supported PCI performed in England and Wales between 2007 and 2014

Variable	OR for vascular complication vs. no vascular complication	[95% CI]	*p*-value
Procedural complication	2.86	[1.94:4.22]	<.001
Female sex	2.03	[1.38:3.00]	<.001
Stable angina	3.47	[1.14:10.4]	.028
Glycoprotein inhibitor	1.46	[1.00:2.19]	.050
Diabetes mellitus	0.60	[0.36:0.99]	.046
Radial access for PCI	0.48	[0.28:0.83]	.008

between 0.94 and 31.1% in published studies a finding driven in part by differing clinical scenarios, variable study sizes, and the inclusion of historical studies with outdated practice.[16] In the first randomized trial of IABP to support primary PCI, the Second Primary Angioplasty in Myocardial Infarction (PAMI-II) Trial investigators observed major bleeding and/or vascular complications in over 20% of patients in the IABP arm.[17] In a more contemporary study, the IABP-SHOCK II trial investigators observed severe bleeding occurred in 3.3%, and peripheral ischemic complications in 4.4% of the IABP arm. Therefore, in the present study the vascular complication rate was lower than previously reported, albeit with a significant temporal reduction in its observed frequency.[18-20]

Use of both Impella and IABP to support PCI remains controversial given the lack of robust randomized data confirming improving patient outcomes when used. In the IABP-SHOCK II trial, 12-month survival was similar between IABP and control arms.[18-20] Similarly, in the Balloon Pump-Assisted Coronary Intervention Study trial, survival at 6-months was not statistically different between the two arms.[21] In an attempt to improve patient outcomes, the pivotal PROTECT II trial randomized patients undergoing complex PCI to support with Impella or

TABLE 4 Unadjusted outcomes by vascular complication status after IABP supported PCI performed in England and Wales between 2007 and 2014

Variable	No vascular complication (*n* = 9,566)	Vascular complication (*n* = 224)	*p*-value
Transfusion, no. (%)	242 (2.7)	42 (19.8)	<.001
Gastrointestinal bleed, no. (%)	90 (0.9)	4 (1.8)	.351
Periprocedural CVA, no. (%)	59 (0.6)	5 (2.4)	.011
Periprocedural MI, no. (%)	148 (1.6)	13 (6.1)	<.001
Acute kidney injury, no. (%)	140 (1.5)	10 (4.7)	<.001
Emergency CABG, no. (%)	123 (1.4)	7 (3.3)	.038
Median length of hospital stay, (IQR)	5 (2–10)	6 (2–12)	.083
In-hospital death, no. (%)	2,667 (28.4)	62 (28.7)	.998
In-hospital MACCE, no. (%)	2,813 (29.6)	74 (34.1)	.170
Mortality at 12-months, no. (%)	3,231 (41.1)	71 (36.7)	.259

TABLE 5 Adjusted clinical outcomes by vascular complication status after IABP supported PCI performed in England and Wales between 2007 and 2014

Variable	OR for vascular complication vs. no vascular complication	[95% CI]	*p*-value
Transfusion	5.72	[3.54:9.23]	<.001
Gastrointestinal bleed	0.82	[0.15:4.50]	.822
Periprocedural CVA	1.58	[0.31:8.01]	.580
Periprocedural MI	3.19	[1.51:6.73]	.002
Acute kidney injury	2.60	[1.11:6.11]	.027
Emergency CABG	1.40	[0.40:4.92]	.597
In-hospital death	1.17	[0.81:1.70]	.394
In-hospital MACCE	1.37	[0.96:1.96]	.078
Mortality at 12-months	1.09	[0.76:1.58]	.639

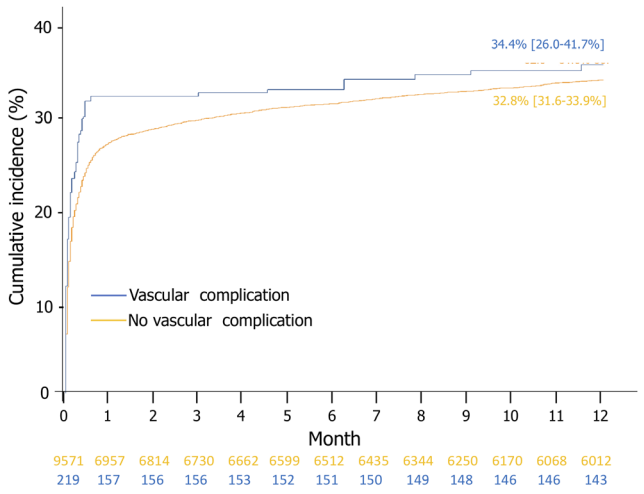

FIGURE 3 Mortality by vascular complication status during IABP-supported PCI in England and Wales 2007–2014 [Color figure can be viewed at wileyonlinelibrary.com]

IABP, with no statistical difference observed between the two arms.[22] The controversy of LV support during PCI has deepened further with two recent registries identifying adverse outcomes in patients receiving Impella augmentation.[8,9] One hypothesis underpinning these observations is that the morbidity associated with such LV support devices might offset any benefit gained from improved hemodynamics.

Therefore, a major strength of the current study, aside with the number of procedures included and the longitudinal data entry allowing study of temporal trends, is that it is the first study of a national registry investigating whether vascular complications associated with IABP use independently predict adverse in-hospital and 12-month survival. The observation that vascular complications were associated with increased periprocedural MI and acute kidney injury might be explained by their adverse hemodynamic consequences, the deleterious effects of a transfusion, and complications arising from reparative interventions and imaging.[23] However, the lack of a mortality signal associated with a vascular complication in the overall cohort is at odds with most other studies where major bleeding and/or a vascular complication were strongly predictive of higher short-term and medium-term mortality.[24,25] The likely explanation for this lack of an association is that the life-threatening pathology underpinning the need for IABP support overwhelms any adverse consequences of a vascular complication. One caveat to these observations is that the reported rates of vascular complications were relatively low and, therefore, the total event rates were relatively small. Nevertheless, given

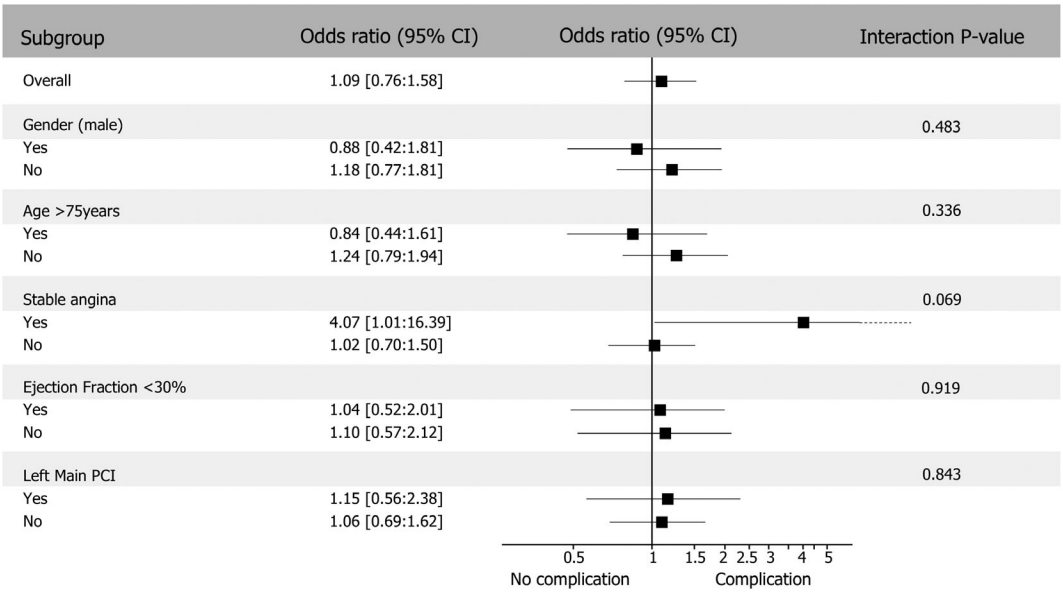

FIGURE 4 Forest plot of 12-month survival by vascular complication status during IABP-supported PCI in study subgroups of gender, age >75 years, clinical presentation, EF, and left main PCI

the overall high MACCE and mortality, and the narrow odds ratios, it seems unlikely that a type II error is present.

Notwithstanding the lack of a robust survival advantage offered by IABP to support PCI, it is reassuring that in the acute setting at least, there is no mortality cost of a vascular complication. However, it is noteworthy that in the stable angina setting, there was a strong trend for excess mortality when a vascular complication occurs. This observation combined with the temporal signal for vascular complications to occur less frequently when the radial artery was used for PCI, supports the concept that radial access should be used for PCI whenever possible even when a single femoral artery puncture is still required for LV support. These observations are in keeping with the Radial versus femoral approach comparison in percutaneous coronary intervention with intraaortic balloon pump support (RADIAL PUMP UP) registry in which high-risk patients undergoing PCI and requiring IABP support appeared to have fewer adverse events if transradial access was used for PCI instead of transfemoral access.[26] Although small case series have reported successful introduction of IABP to support patients using brachial or subclavian access, whether this results in improved patient outcomes versus femoral access is uncertain in the absence of randomized trial data.[27,28]

5 | LIMITATIONS

As with any registry, these data are observational, subject to unmeasured confounders and therefore cannot be used to imply causality. Additionally, the timing of IABP insertion not recorded and whether its use was up-front or as bail-out. The duration of IABP use is also not recorded, a factor which has been correlated with complications in previous studies. As data is self-reported, clinical events may be underreported. We have made assumptions that under-reporting is randomly distributed but it remains a possibility that nonrandom under-reporting is an unmeasured confounder. Finally, limb or gut ischemia are not recorded in the BCIS database although any surgical repair is, and therefore the effect of this complication in outcomes cannot be assessed.

6 | CONCLUSIONS

Vascular complications associated with IABP use have declined in frequency as radial access use for PCI increased. Although increases in several in-hospital nonfatal outcomes were observed with the occurrence of a vascular complication, in-hospital and 1-year survival was not affected.

CONFLICTS OF INTEREST

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SUPPORTING INFORMATION

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

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