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Outcomes in Patients With Cardiogenic Shock Following Percutaneous Coronary Intervention in the Contemporary Era

An Analysis From the BCIS Database (British Cardiovascular Intervention Society)

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ABSTRACT

OBJECTIVES This study sought to determine mortality rates among cardiogenic shock (CGS) patients undergoing percutaneous coronary intervention (PCI) for acute coronary syndrome in the contemporary treatment era and to determine predictors of mortality.

BACKGROUND It is unclear whether recent advances in pharmacological and interventional strategies have resulted in further improvements in short- and long-term mortality and which factors are associated with adverse outcomes in patients presenting with CGS and undergoing PCI in the setting of acute coronary syndrome.

METHODS This study analyzed prospectively collected data for patients undergoing PCI in the setting of CGS as recorded in the BCIS (British Cardiovascular Intervention Society) PCI database.

RESULTS In England and Wales, 6,489 patients underwent PCI for acute coronary syndrome in the setting of CGS. The mortality rates at 30 days, 90 days, and 1 year were 37.3%, 40.0%, and 44.3%, respectively. On multiple logistic regression analysis, age (for each 10-year increment of age: odds ratio [OR]: 1.59, 95% confidence interval [CI]: 1.51 to 1.68; $p < 0.0001$), diabetes mellitus (OR: 1.47, 95% CI: 1.28 to 1.70; $p < 0.0001$), history of renal disease (OR: 2.03, 95% CI: 1.63 to 2.53; $p < 0.0001$), need for artificial mechanical ventilation (OR: 2.56, 95% CI: 2.23 to 2.94; $p < 0.0001$), intra-aortic balloon pump use (OR: 1.57, 95% CI: 1.40 to 1.76; $p < 0.0001$), and need for left main stem PCI (OR: 1.90, 95% CI: 1.62 to 2.23; $p < 0.0001$) were associated with higher mortality at 1 year.

CONCLUSIONS In this large U.K. cohort of patients undergoing PCI in the context of CGS, mortality remains high in spite of the use of contemporary PCI strategies. The highest mortality occurs early, and this time period may be a particular target of therapeutic intervention. (J Am Coll Cardiol Intv 2014;7:1374–85) © 2014 by the American College of Cardiology Foundation.

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Advances in the management of acute myocardial infarction (AMI), such as the introduction of early revascularization with primary percutaneous coronary intervention and use of potent adjunctive therapies have resulted in reduction in the reported overall mortality of AMI (from 18% in 1998 to 10% in 2009) (1-4). Cardiogenic shock (CGS) remains a major cause of mortality, however, with death in patients defined as suffering from CGS reported to have remained high. Mortality rates recorded in the 1990s were reported to be >50% (1-4). CGS describes the pathophysiological state in which reduced cardiac output and resultant tissue hypoxia occur in the presence of adequate intravascular volume. Hemodynamically, the definition of CGS is open to some debate but can be defined as a fall in systolic blood pressure below 90 mm Hg sustained for at least 30 min in the absence of hypovolemia, with a cardiac index below 1.8 l/min/m^2 without support or 2.0 to 2.2 l/min/m^2 with support, and in the presence of a raised pulmonary capillary wedge pressure (>15 mm Hg) (2,5). The aims of this study were to determine the contemporary 30-day, 90-day, and 1-year mortality outcomes and to determine predictors of 1-year mortality in patients undergoing percutaneous coronary intervention (PCI) in the setting of acute coronary syndrome (ACS) and CGS.

METHODS

STUDY DESIGN. This was an observational cohort study. The British Cardiovascular Intervention Society oversees the collection of data comprising all PCI performed in the United Kingdom. There are 117 centers from the 4 U.K. countries (Scotland 8, England 101, Northern Ireland 4, Wales 4). These data are encrypted and sent from each PCI center to servers now hosted by the National Institute for Clinical Outcomes Research based at University College London, as previously described (6). In summary, the BCIS (British Cardiovascular Intervention Society) registry dataset includes a total of 113 variables that describe baseline characteristics, clinical presentation, procedural details, and procedural complications. These data are prospectively collected at the end of each procedure under the responsibility of the performing interventional cardiologist. Peri- and post-procedural complications, clinical data, and discharge medications are subsequently updated on discharge. Reliable mortality tracking is possible for patients from England and Wales using their National Health Service number (a unique identifier). Tracking is performed by the Medical Research Information Service using data from the Office of National Statistics for patients in England and Wales. It was the robust nature of the follow-up outcomes with the England and Wales data that led us to use these tracked data as the basis of our observational report. An accepted definition of CGS is "persistent hypotension (systolic blood pressure <80 to 90 mm Hg or mean arterial pressure 30 mm Hg lower than baseline) with severe reduction in cardiac index (<1.8 l/min/m^2 without support or <2.0 to 2.2 l/min/m^2 with support) and adequate or elevated filling pressure (e.g., left ventricular end-diastolic pressure >18 mm Hg or right ventricular end-diastolic pressure >10 to 15 mm Hg) (2,5)." Because such hemodynamic measurements are rarely available in the clinical setting of primary and emergency PCI, in the BCIS registry, CGS was defined on clinical criteria when a patient fulfilled the following minimal conditions: persistent hypotension with clinical evidence of hypoperfusion (cool, clammy, oliguric, altered mental status) with dependence on inotropes or mechanical left ventricular support to correct this situation. Such strict clinical criteria allowed us to ensure patients entered into this registry were highly likely (in the clinical context of needing PCI for ACS), to be suffering CGS. Key definitions for variables used in the BCIS dataset are shown in the Online Appendix.

STATISTICAL ANALYSIS. Data are presented as percentages for categorical variables and as means ± SD for continuous variables. Logistic regression was applied to detect the association of baseline characteristics, angiographic, and procedural characteristics with mortality. The 30-day, 90-day, and 1-year mortality rates were calculated. Multiple logistic regressions were applied to evaluate predictors of 1-year mortality. In multiple logistic regression analysis, analysis was performed under the assumption that missing values were missing completely at random. We also performed an analysis assuming that the missing values were not missing at random using multiple imputations (7) to determine whether it makes a difference in the results. Both results are shown in tables whereas the results from not missing at random analysis are reported in the abstract and main text. Distribution of time to event was estimated by using Kaplan-Meier method. All tests in the analyses were 2-sided tests. A p value <0.05 was considered statistically significant. All statistical analyses were performed using SAS (version 9.3, SAS Inc., Cary, North Carolina).

ABBREVIATIONS AND ACRONYMS

ACS = acute coronary syndrome

AMI = acute myocardial infarction

CGS = cardiogenic shock

CI = confidence interval

IABP = intra-aortic balloon pump

MV = multiple variable

MVD = multivessel disease

OR = odds ratio

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

TIMI = Thrombolysis In Myocardial Infarction

RESULTS

The study flowchart is displayed in Figure 1. An initial dataset consisting of 501,117 PCI procedures from all centers from the BCIS database in the United Kingdom were available for consideration. Of these, 6,489 patients were used as the patient observational group because they were recorded as having undergone PCI for ACS in the setting of CGS in England and Wales and had complete 1-year mortality tracking. Figure 2 shows the incidence of shock over time. The baseline, angiographic, and procedural characteristics for all patients in this study cohort (N = 6,489), those who died (group 1: n = 2,872), and those who were alive at 1 year (group 2: n = 3,617) are displayed in Tables 1 and 2.

BASELINE CHARACTERISTICS. The baseline characteristics are displayed in Table 1. Patients in group 1 were older than those in group 2 (70.5 years vs. 64.4 years, $p < 0.0001$). Furthermore, in group 1, the following baseline parameters were more common than in group 2: female sex (30.5% vs. 28%, $p = 0.03$), history of hypertension (53% vs. 46.7%, $p < 0.0001$), diabetes (25.5% vs. 16.5%, $p < 0.0001$), previous myocardial infarction (29.9% vs. 24.3%, $p < 0.0001$), chronic renal disease (12.9% vs. 4.8%, $p < 0.0001$), acute stent thrombosis (2.0% vs. 1.2%, $p = 0.0105$), and primary PCI procedure (61.7% vs. 56.6%, $p < 0.0001$). The rate of CGS in the entire group of patients with unstable angina, non-ST-segment elevation myocardial infarction (STEMI), convalescent STEMI, and STEMI (includes primary PCI, rescue PCI, facilitated PCI, and reinfarction) was 2.6%.

ANGIOGRAPHIC AND PROCEDURAL CHARACTERISTICS. The angiographic and procedural characteristics are shown in Table 2. More patients in group 1 had TIMI (Thrombolysis In Myocardial Infarction) flow grade 0 (for definition see the Online Appendix) at the start of the PCI procedure than did those in group 2 (69.4% vs. 66.1%, $p = 0.0166$). In group 1, compared with group 2, there was a significantly higher number of lesions treated (1.7 ± 1.0 vs. 1.5 ± 0.9, $p < 0.0001$), left main PCI (19.9% vs. 9.7%, $p < 0.0001$), femoral procedures (85.0% vs. 77.8%, $p < 0.0001$), need for artificial ventilation (37.7% vs. 20.9%, $p < 0.0001$), perceived need for intra-aortic balloon pump (IABP)

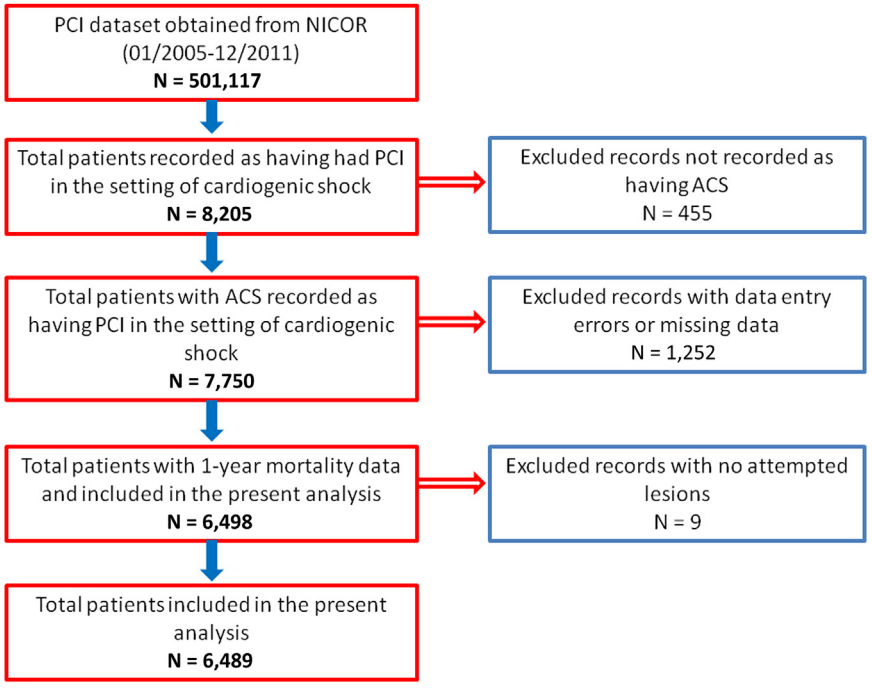

FIGURE 1 Study Flowchart

The flowchart describes the population that underwent percutaneous coronary intervention (PCI) in the setting of cardiogenic shock between 2005 and 2011. ACS = acute coronary syndrome; NICOR = National Institute for Clinical Outcomes Research.

(56.6% vs. 42%, p < 0.0001), TIMI flow grade 0 post-PCI (13.3% vs. 5.4%, p < 0.0001), incidence of reinfarction (0.8% vs. 0.3%, p = 0.0072), renal failure/dialysis (2.3% vs. 0.9%, p < 0.0001), cardiac tamponade (0.7% vs. 0.1%, p = 0.0018), heart block requiring pacing (5.5% vs. 2.5%, p < 0.0001), direct current cardioversion (6.3% vs. 2.9%, p < 0.0001), and no flow/slow flow during PCI (8.7% vs. 4.1%, p < 0.0001). Abciximab was used less frequently in group 1 than in group 2 (47.3% vs. 52.1, p < 0.0002). Multivessel PCI was performed in 28.5% of patients.

MORTALITY FOLLOWING CGS. The overall 30-day, 90-day, and 1-year mortality rates following PCI for CGS were 37.3%, 40.0%, and 44.3%, respectively. Analysis of the BCIS annual audit reports indicates that in patients without CGS, the overall 30-day, 90-day, and 1-year mortality rates following PCI in the setting of ACS were 2.0%, 2.81%, and 5.14%, respectively. Mortality rate according to the year of presentation is shown in Figure 3. The Kaplan-Meier curve for mortality is displayed in Figure 4. For patients with CGS, the 1-year mortality for patients who were known to be alive at 30 days was 11.1%. The 1-year mortality for ACS patients without CGS but with similar age-sex distribution as those of shock patients who were alive at 30 days was 5.7%.

PREDICTORS OF 30-DAY MORTALITY. Multiple regression analysis was initially performed excluding procedure-related variables (artificial ventilation, IABP use, and radial procedure) and is displayed in Table 3. Age (for each 10-year increment: odds ratio [OR]: 1.35, 95% confidence interval [CI]: 1.29 to 1.41; p < 0.0001), history of renal disease (OR: 1.63, 95% CI: 1.34 to 1.98; p < 0.0001), diabetes mellitus (OR: 1.34, 95% CI: 1.17 to 1.54; p < 0.0001), and left main disease (OR: 1.49, 95% CI: 1.28 to 1.75; p < 0.0001) were significant in predicting 30-day mortality. TIMI flow grade 3 pre-PCI (OR: 0.74, 95% CI: 0.62 to 0.88; p = 0.001), and TIMI flow grade 3 post-PCI (OR: 0.44, 95% CI: 0.38 to 0.50; p < 0.0001) were associated with reduced 30-day mortality.

When procedure-related variables were included in the multiple variable (MV) logistic regression, the following parameters were associated with a greater likelihood of dying at 30 days: age (for each 10-year increment: OR: 1.45, 95% CI: 1.38 to 1.52; p < 0.0001); history of renal disease (OR: 1.55, 95% CI: 1.25 to 1.91; p < 0.0001); diabetes mellitus (OR: 1.26, 95% CI: 1.10 to 1.45; p = 0.001); need for artificial ventilation (OR: 2.59, 95% CI: 2.28 to 2.95; p < 0.0001); IABP use (OR: 1.56, 95% CI: 1.39 to 1.76; p < 0.0001); and left main PCI (OR: 1.56, 95% CI: 1.34 to 1.83; p < 0.0001). TIMI flow grade 3 pre-PCI (OR: 0.76, 95% CI: 0.62 to 0.95; p = 0.0145), TIMI flow grade 3 post-PCI (OR: 0.41, 95% CI: 0.35 to 0.47; p < 0.0001), and radial procedures (OR: 0.71, 95% CI: 0.62 to 0.81; p < 0.0001) were associated with reduced 30-day mortality (Table 4).

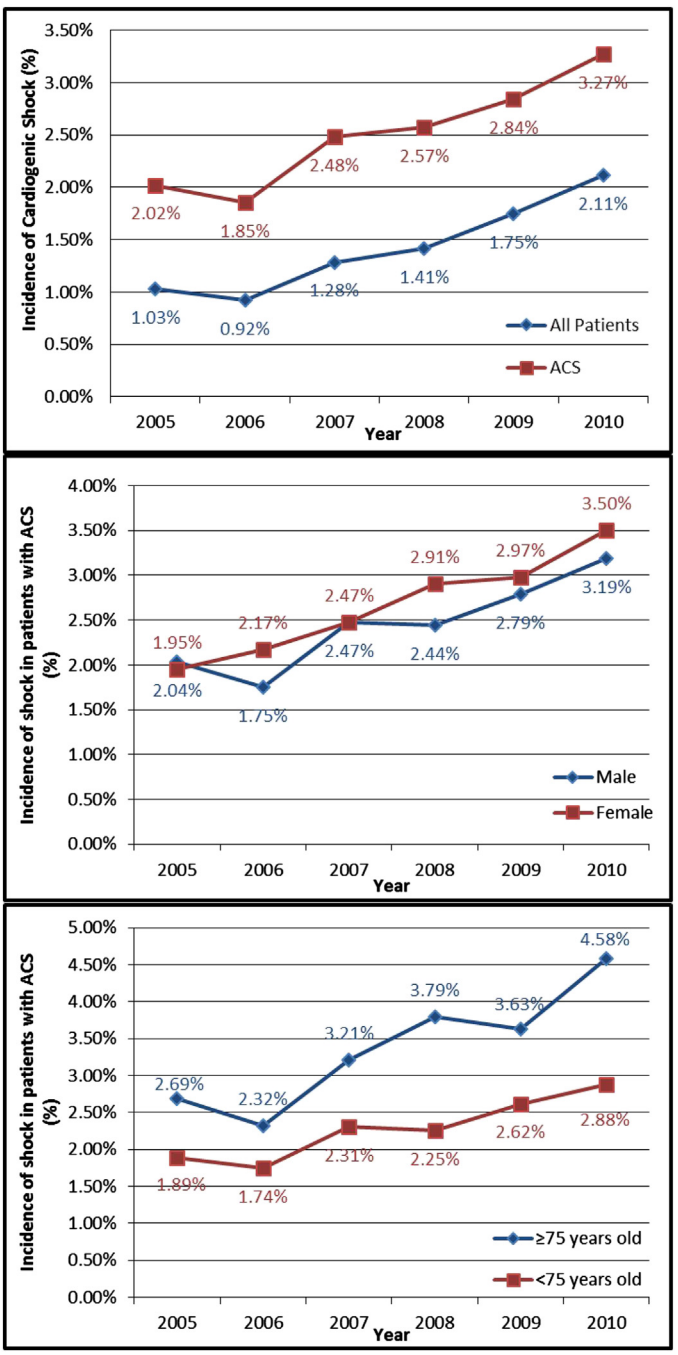

FIGURE 2 Incidence of CGS Over Time

The graphs describe the percentage of cardiogenic shock (CGS) cases over time (2005 to 2010) in the setting of acute coronary syndrome (ACS).

TABLE 1 Baseline Characteristics (Stratified by 1-Year Mortality)

	Total (N = 6,489)	Died, Group 1 (n = 2,872)	Alive, Group 2 (n = 3,617)	p Value
Variables				
Mean age, yrs	67.1 ± 12.6	70.5 ± 11.9	64.4 ± 12.5	<0.0001
Female	1,879/6,454 (29.1)	870/2,855 (30.5)	1,009/3,599 (28.0)	0.0323
Hypertension	2,903/5,877 (49.4)	1,348/2,544 (53.0)	1,555/3,333 (46.7)	<0.0001
Diabetes mellitus	1,218/5,959 (20.4)	662/2,593 (25.5)	556/3,366 (16.5%)	<0.0001
Hypercholesterolemia	2,751/5,877 (46.8)	1,216/2,544 (47.8)	1,535/3,333 (46.1)	0.1842
Previous myocardial infarction	1,493/5,596 (26.7)	722/2,419 (29.9)	771/3,177 (24.3)	<0.0001
Previous PCI	843/6,111 (13.8)	392/2,674 (14.7)	451/3,437 (13.1)	0.0839
Previous CABG	312/6,150 (5.1)	142/2,700 (5.3)	170/3,450 (4.9)	0.5550
Family history of CAD	1,824/4,730 (38.6)	703/1,941 (36.2)	1,121/2,789 (40.2)	0.0057
Smoking, ever smoker	3,485/5,138 (67.8)	1,399/2,119 (66.0)	2,086/3,019 (69.1)	0.0203
History of renal disease	472/5,686 (8.3)	315/2,437 (12.9)	157/3,249 (4.8)	<0.0001
Indication for intervention				
Acute/subacute stent thrombosis	100/6,489 (1.5)	57/2,872 (2.0)	43/3,617 (1.2)	0.0105
UA/NSTEMI/convalescent STEMI	1,642/6,489 (25.3)	670/2,872 (23.3)	972/3,617 (26.9)	0.0011
Primary PCI	3,819/6,489 (59.0)	1,771/2,872 (61.7)	2,048/3,617 (56.6)	<0.0001
Facilitated PCI	76/6,489 (1.2)	16/2,872 (0.6)	60/3,617 (1.7)	<0.0001
Rescue PCI	596/6,489 (9.2)	249/2,872 (8.7)	347/3,617 (9.6)	0.2009
Reinfarction rescue PCI	116/6,489 (1.8)	46/2,872 (1.6)	70/3,617 (1.9)	0.3144
PCI for reinfarction	140/6,489 (2.2)	63/2,872 (2.2)	77/3,617 (2.1)	0.8582
Admission route				
Direct to cardiac center	3,374/6,043 (55.8)	1,478/2,672 (55.3)	1,896/3,371 (56.2)	0.4695
Interhospital transfer	2,020/6,043 (33.4)	865/2,672 (32.4)	1,155/3,371 (34.3)	0.1226
Already in cardiac center	630/6,043 (10.4)	324/2,672 (12.1)	306/3,371 (9.1)	0.0001
Recent lysis	931/5,917 (15.7)	348/2,619 (13.3)	583/3,298 (17.7)	<0.0001

Values are mean ± SD or n/N (%).

CABG = coronary artery bypass graft; CAD = coronary artery disease; NSTEMI = non-ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; UA = unstable angina.

PREDICTORS OF 1-YEAR MORTALITY. Multiple regression analysis was initially performed excluding procedure-related variables (artificial ventilation, IABP use, and radial procedure) and is displayed in Table 5. Age (for each 10-year increment: OR: 1.48, 95% CI: 1.41 to 1.55; $p < 0.0001$), diabetes mellitus (OR: 1.54, 95% CI: 1.34 to 1.77; $p < 0.0001$), history of renal disease (OR: 2.10, 95% CI: 1.72 to 2.58; $p < 0.0001$), and left main disease (OR: 1.71, 95% CI: 1.46 to 2.01; $p < 0.0001$) were significant in predicting 1-year mortality. TIMI flow grade 3 post-PCI (OR: 0.47, 95% CI: 0.41 to 0.55; $p < 0.0001$) was associated with reduced 1-year mortality.

Using MV logistic regression including procedure-related variables such as IABP use, need for artificial ventilation, left main PCI, and radial procedure, the following parameters were associated with a greater likelihood of dying at 1 year: age (for each 10-year increment: OR: 1.59, 95% CI: 1.51 to 1.68; $p < 0.0001$); diabetes mellitus (OR: 1.47, 95% CI: 1.28 to 1.70; $p < 0.0001$); history of renal disease (OR: 2.03, 95% CI: 1.63 to 2.53; $p < 0.0001$); need for artificial ventilation (OR: 2.56, 95% CI: 2.23 to 2.94; $p < 0.0001$); IABP use (OR: 1.57, 95% CI: 1.40 to 1.76; $p < 0.0001$); and left main PCI (OR: 1.90, 95% CI: 1.62 to 2.23; $p < 0.0001$) remained associated with increased mortality at 1 year. TIMI flow grade 3 post-PCI (OR: 0.44, 95% CI: 0.37 to 0.51; $p < 0.0001$) and radial procedures (OR: 0.79, 95% CI: 0.69 to 0.90; $p = 0.0008$) were associated with reduced 1-year mortality (Table 6).

DISCUSSION

This study used an established large national database of consecutive patients presenting with CGS undergoing PCI in the contemporary era and showed that mortality remains high in this group. Despite an apparent modest fall compared with historical data, an annual mortality of 44% in these patients suggests that there remains substantial room for improvement in the management of such patients. This study has also demonstrated that age, diabetes mellitus, history of renal disease, need for artificial ventilation, perceived need for IABP, and left main disease/PCI were independently associated with increased

TABLE 2 Procedural Characteristics (Stratified by 1-Year Mortality)

	Total (N = 6,489)	Died, Group 1 (n = 2,872)	Alive, Group 2 (n = 3,617)	p Value
Pre-PCI LMS stenosis, 75%-100%	735/4,945 (14.9)	453/2,207 (20.5)	282/2,738 (10.3)	<0.0001
TIMI flow grade pre-PCI				
0	3,164/4,683 (67.6)	1,478/2,131 (69.4)	1,686/2,552 (66.1)	0.0166
1	477/4,683 (10.2)	202/2,131 (9.5)	275/2,552 (10.8)	0.1443
2	490/4,683 (10.5)	222/2,131 (10.4)	268/2,552 (10.5)	0.9256
3	552/4,683 (11.8)	229/2,131 (10.8)	323/2,552 (12.7)	0.0437
Lesions attempted	1.6 ± 0.9	1.7 ± 1.0	1.5 ± 0.9	<0.0001
Stents per lesion	1.7 ± 1.3	1.7 ± 1.4	1.7 ± 1.2	0.2235
Drug-eluting stents	0.8 ± 1.2	0.7 ± 1.2	0.9 ± 1.2	<0.0001
Radial procedure	1,428/6,340 (22.5)	526/2,812 (18.7)	902/3,528 (25.6)	<0.0001
Femoral procedure	5,133/6,340 (81.0)	2,389/2,812 (85.0)	2,744/3,528 (77.8)	<0.0001
Left main PCI	911/6,413 (14.2)	565/2,839 (19.9)	346/3,574 (9.7)	<0.0001
Graft vessel PCI	173/6,413 (2.7)	77/2,839 (2.7)	96/3,574 (2.7)	0.9488
Use of glycoprotein IIb/IIIa inhibitors				
None	2,482/6,196 (40.1)	1,172/2,736 (42.8)	1,310/3,460 (37.9)	<0.0001
Abciximab	3,099/6,196 (50.0)	1,295/2,736 (47.3)	1,804/3,460 (52.1)	0.0002
Eptifibatide	272/6,196 (4.4)	115/2,736 (4.2)	157/3,460 (4.5)	0.5256
Tirofiban	283/6,196 (4.6)	133/2,736 (4.9)	150/3,460 (4.3)	0.3225
Ventilated patients	1,655/5,828 (28.4)	981/2,602 (37.7)	674/3,226 (20.9)	<0.0001
IABP use	2,971/6,120 (48.6)	1,547/2,733 (56.6)	1,424/3,387 (42.0)	<0.0001
Lesions successful	1.4 ± 0.9	1.4 ± 1.0	1.4 ± 0.8	0.8554
TIMI flow grade post-PCI				
0	449/5,006 (9.0)	299/2,241 (13.3)	150/2,765 (5.4)	<0.0001
1	160/5,006 (3.2)	123/2,241 (5.5)	37/2,765 (1.3)	<0.0001
2	544/5,006 (10.9)	325/2,241 (14.5)	219/2,765 (7.9)	<0.0001
3	3,853/5,006 (77.0)	1,494/2,241 (66.7)	2,359/2,765 (85.3)	<0.0001
PCI hospital outcome				
Q-wave MI	37/6,184 (0.6)	20/2,753 (0.7)	17/3,431 (0.5)	0.2446
Non-Q-wave MI	14/6,184 (0.2)	4/2,753 (0.2)	10/3,431 (0.3)	0.2391
Emergency CABG	17/6,184 (0.3)	10/2,753 (0.4)	7/3,431 (0.2)	0.2393
Arterial complication	61/6,184 (1.0)	27/2,753 (1.0)	34/3,431 (1.0)	0.9678
CVA emboli	20/6,184 (0.3)	12/2,753 (0.4)	8/3,431 (0.2)	0.1690
CVA bleed	19/6,184 (0.3)	9/2,753 (0.3)	10/3,431 (0.3)	0.8014
TIA/RIND	7/6,184 (0.1)	4/2,753 (0.2)	3/3,431 (0.1)	0.5032
Reintervention PCI	82/6,184 (1.3)	36/753 (1.3)	46/3,431 (1.3)	0.9102
Repeat catheterization, no PCI	22/6,184 (0.4)	7/2,753 (0.3)	15/3,431 (0.4)	0.2357
Reinfarction	30/6,184 (0.5)	21/2,753 (0.8)	9/3,431 (0.3)	0.0072
Blood transfusion	148/6,184 (2.4)	64/2,753 (2.3)	84/3,431 (2.5)	0.7528
Renal failure/dialysis	96/6,184 (1.6)	64/2,753 (2.3)	32/3,431 (0.9)	<0.0001
GI bleed	75/6,184 (1.2)	36/2,753 (1.3)	39/3,431 (1.1)	0.5395
Tamponade	22/6,184 (0.4)	18/2,753 (0.7)	4/3,431 (0.1)	0.0018
Platelet transfusion	28/6,184 (0.5)	12/2,753 (0.4)	16/3,431 (0.5)	0.8599
Procedural complications				
Side branch occlusion	54/5,868 (0.9)	29/2,624 (1.1)	25/3,244 (0.8)	0.1844
Coronary dissection	137/5,868 (2.3)	82/2,624 (3.1)	55/3,244 (1.7)	0.0004
Coronary perforation	25/5,868 (0.4)	16/2,624 (0.6)	9/3,244 (0.3)	0.0582
Heart block requiring pacing	226/5,868 (3.9)	144/2,624 (5.5)	82/3,244 (2.5)	<0.0001
DC cardio version	259/5,868 (4.4)	165/2,624 (6.3)	94/3,244 (2.9)	<0.0001
No flow/slow flow	359/5,868 (6.1)	227/2,624 (8.7)	132/3,244 (4.1)	<0.0001

Values are mean ± SD or n/N (%).

CVA = cerebrovascular event; DC = direct current; GI = gastrointestinal; IABP = intra-aortic balloon pump; LMS = left main stem; MI = myocardial infarction; RIND = reversible ischemic neurologic deficit; TIA = transient ischemic attack; TIMI = Thrombolysis In Myocardial Infarction; other abbreviations as in Table 1.

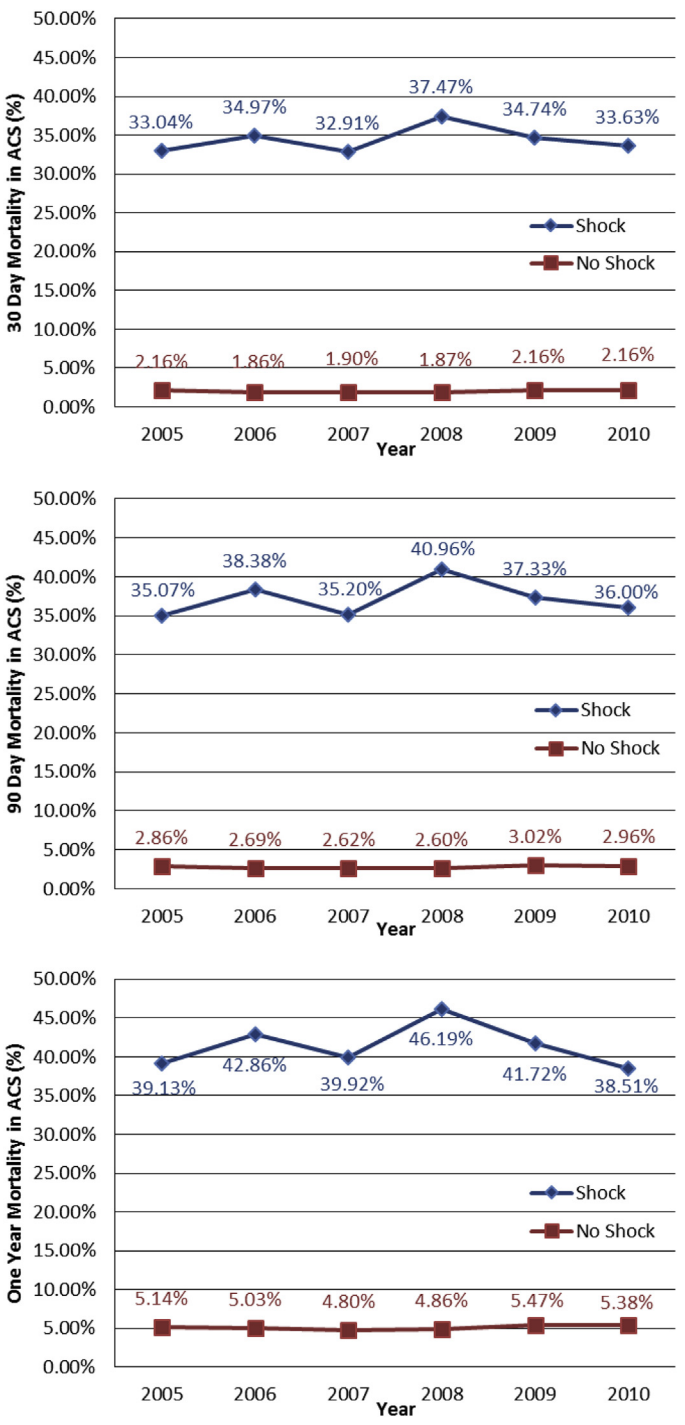

FIGURE 3 Mortality in CGS

The graphs describe the mortality in CGS cases over time (2005 to 2010) in the setting of ACS. Abbreviations as in Figure 2.

mortality rates at 1 year following PCI in the setting of CGS. Our data have also illustrated the relatively low subsequent mortality rate for those patients with CGS who survive the first 30 days. This suggests that endeavors to change the natural trajectory of this condition should focus on interventions that can be provided in the acute phase.

This study offers insights over the existing literature in 3 ways. The treatment of patients with acute coronary syndromes continues to evolve, and this study is important in reflecting contemporary practice. With 6,489 patients, it is the largest cohort of consecutive unselected patients studied in the setting of CGS. Finally our data describes mortality rates not only for the short-term (30 days and 90 days) but also in the longer term (1 year) following PCI in the setting of CGS. This comparison of 30-day and 1-year mortality data demonstrated an interesting observation on the plateau-like nature of the mortality curve over time.

These results highlight the persistently poor outcome for PCI in CGS in the contemporary period. Despite early mortality appearing to have improved when compared with historical studies, concomitant perhaps with a broader use of PCI and recommended adjunctive medications in the acute stage, the 1-year mortality remains high and appears to be influenced less than may have been expected by contemporary adjunctive treatments (8). The management of STEMI in general has evolved rapidly over the last 5 to 10 years so that the majority of patients in the United Kingdom now have access to primary PCI. However, despite the use of the same such contemporary management strategies in CGS patients over the same period, the current study shows that mortality remains disappointingly high in the short term (30-day mortality: 37.3%) with further albeit less later attrition (1-year mortality: 44.3%). Our mortality rates are comparable to a recent analysis of STEMI patients with CGS where the in-hospital mortality was 39% (9).

The size of the reported cohort allows us to describe important predictors of poor outcome in this condition. Thus, for example, age as might have been expected, was an independent predictor of mortality at 1 year in our study. This is consistent with other observational studies such as that from the GRACE (Global Registry of Acute Coronary Events) (10) and others demonstrating increased mortality with advanced age in ACS. In another small study of patients with CGS, 1 multiple predictor of in-hospital mortality was age ≥75 years (hazard ratio: 1.81, 95% CI: 1.006 to 3.27; $p = 0.04$) (11). Optimal treatment strategies for older patients presenting with CGS and undergoing PCI are not known and warrant further

study. Tailoring specific therapy toward the older patients, who may be susceptible to bleeding from access site is underconsidered in this and other conditions.

Previous studies have demonstrated that diabetes is associated with higher in-hospital and long-term mortality in patients with MI complicated by CGS (12). In our study, presence of diabetes on multiple analyses was an independent predictor of 1-year mortality, a finding that is consistent with previous observations from the PL-ACS (Polish Registry of Acute Coronary Syndromes) (12). However, our study and that of PL-ACS (both studies reflecting contemporary practice) are discrepant with the SHOCK (Should We Emergently Revascularize Occluded Coronary Arteries for CGS Trial and Registry) (which was performed in the 1990s) with the latter showing no difference in adjusted in-hospital mortality among diabetic CGS patients (13). The reasons for the differences are unclear other than the contemporary timing of the study. Our data suggests that better treatment strategies to improve survival among diabetic patients in the contemporary era are required, although some factors may be indirect in their impact, such as the extent of disease that is deemed not feasible/suitable for revascularization among the diabetic cohort, which may play an important role in the overall outcomes in such patients.

This study unsurprisingly found that need for artificial ventilation was an independent predictor of 1-year mortality using multiple analyses. Such patients most often present following out-of-hospital cardiac arrest, and their risk is compounded by the presence of other important factors, including the degree of recoverable neurological status and metabolic disturbance, which are usually not clear at the time of PCI. Strategies to improve survival among these ventilated patients are developing, including in particular therapeutic hypothermia (14), but more innovative interventions are likely to be required. Details of the extent of use of therapeutic

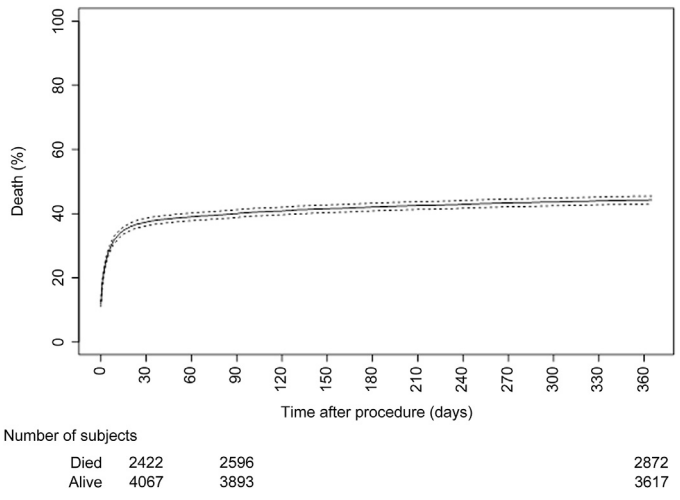

FIGURE 4 Kaplan-Meier Curve for Mortality

The graph shows 1-year mortality following percutaneous coronary intervention in cardiogenic shock.

TABLE 3 Predictors of 30-Days Survival Following PPCI in the Setting of CGS

	Odds Ratio (95% CI) (MCAR)	p Value	Odds Ratio (95% CI)* (NMAR)	p Value*	N† Missing	% Missing
Age for each 10-yr increment, yrs	1.41 (1.31–1.52)	<0.0001	1.35 (1.29–1.41)	<0.0001	2	0.00
Sex, female vs. male	1.04 (0.86–1.26)	0.6640	1.04 (0.92–1.17)	0.5178	35	0.54
Hypertension	1.17 (0.98–1.40)	0.0799	1.00 (0.89–1.12)	0.9807	612	9.43
Diabetes Mellitus	1.26 (1.02–1.56)	0.0327	1.34 (1.17–1.54)	<0.0001	530	8.17
Previous MI	1.31 (1.04–1.66)	0.0245	1.08 (0.93–1.25)	0.3009	893	13.76
Previous PCI	0.79 (0.59–1.05)	0.1053	0.94 (0.78–1.14)	0.5417	378	5.83
Previous CABG	0.97 (0.56–1.69)	0.9254	0.90 (0.67–1.22)	0.5081	339	5.22
H/O renal disease	1.97 (1.42–2.73)	<0.0001	1.63 (1.34–1.98)	<0.0001	803	12.37
Smoking status, reference group: never smokers	1.00 (0.83–1.20)	0.9982	1.03 (0.91–1.17)	0.6205	1351	20.82
Use of glycoprotein IIb/IIIa inhibitor	0.91 (0.76–1.09)	0.3197	0.95 (0.85–1.06)	0.3728	293	4.52
Graft vessel PCI	0.90 (0.45–1.82)	0.7731	0.85 (0.57–1.25)	0.4035	76	1.17
Left main disease, reference group: 0%–74%	1.42 (1.10–1.82)	0.0064	1.49 (1.28–1.75)	<0.0001	1,386	21.40
Pre-PCI TIMI flow grade 3, reference group: TIMI flow grade <3	0.62 (0.46–0.82)	0.0009	0.74 (0.62–0.88)	0.0010	1,767	27.20
Post-PCI TIMI flow grade 3, reference group: TIMI flow grade <3	0.33 (0.27–0.40)	<0.0001	0.44 (0.38–0.50)	<0.0001	1,483	22.90

Multiple logistic regressions without covariates artificial ventilation, radial procedure, and IABP use in the model. Total sample size = 6,489, sample entered into MV model without missing data = 2,687, total events = 926. *Odds ratio (95% CI) and p values after applying multiple imputation NMAR (all 6,489 subjects were used; total events = 2,422). †Case records with missing data.

CGS = cardiogenic shock; CI = confidence interval; MCAR = missing completely at random; MV = multiple variable; NMAR = not missing at random; PPCI = primary percutaneous coronary intervention; other abbreviations as in Tables 1 and 2.

TABLE 4 Predictors of 30-Days Survival Following PPCI in the Setting of CGS (Multiple Logistic Regressions)

	Odds Ratio (95% CI) (MCAR)	p Value	Odds Ratio (95% CI)* (NMAR)	p Value*	N† Missing	% Missing
Age for each 10-yr increment, yrs	1.55 (1.43–1.68)	<0.0001	1.45 (1.38–1.52)	<0.0001	2	0.00
Sex, female vs. male	1.07 (0.88–1.31)	0.4720	1.08 (0.95–1.22)	0.2512	35	0.54
Hypertension	1.16 (0.96–1.39)	0.1186	1.03 (0.91–1.16)	0.6320	612	9.43
Diabetes mellitus	1.22 (0.98–1.51)	0.0803	1.26 (1.10–1.45)	0.0010	530	8.17
Previous MI	1.32 (1.04–1.69)	0.0237	1.06 (0.91–1.23)	0.4638	893	13.76
Previous PCI	0.76 (0.56–1.02)	0.0678	0.95 (0.80–1.14)	0.5733	378	5.83
Previous CABG	0.86 (0.50–1.49)	0.6004	0.85 (0.63–1.15)	0.2979	339	5.22
H/O renal disease	2.00 (1.44–2.79)	<0.0001	1.55 (1.25–1.91)	<0.0001	803	12.37
Smoking status, reference group: never smokers	0.96 (0.80–1.17)	0.7067	1.05 (0.92–1.20)	0.4823	1351	20.82
Radial procedure	0.82 (0.67–1.01)	0.0643	0.71 (0.62–0.81)	<0.0001	149	2.30
Use of glycoprotein IIb/IIIa inhibitor	0.92 (0.77–1.11)	0.3943	0.96 (0.85–1.08)	0.4504	293	4.52
Ventilated patients	3.15 (2.57–3.86)	<0.0001	2.59 (2.28–2.95)	<0.0001	661	10.19
IABP use	1.76 (1.47–2.11)	<0.0001	1.56 (1.39–1.76)	<0.0001	369	5.69
Graft vessel PCI	1.16 (0.60–2.27)	0.6599	1.01 (0.67–1.53)	0.9436	75	1.16
Left main PCI	1.73 (1.33–2.24)	<0.0001	1.56 (1.34–1.83)	<0.0001	75	1.16
Pre-PCI TIMI flow grade 3, reference group: TIMI flow grade <3	0.61 (0.45–0.83)	0.0014	0.76 (0.62–0.95)	0.0145	1,767	27.20
Post-PCI TIMI flow grade 3, reference group: TIMI flow grade <3	0.30 (0.24–0.37)	<0.0001	0.41 (0.35–0.47)	<0.0001	1,483	22.90

Multiple logistic regressions including covariates artificial ventilation, radial procedure, and IABP use in the model. Total sample size = 6,489, sample entered into MV model without missing data = 2,783, total events = 962. *Odds ratio (95% CI) and p values after applying multiple imputation NMAR (all 6,489 subjects were used; total events = 2,422). †Case records with missing data.

Abbreviations as in Tables 1 to 3.

hypothermia in our study are not available from the dataset. The question as to whether the use of therapeutic hypothermia in the setting of CGS, within or without the context of cardiac arrest, which could lead to improved survival is so far unknown, but our study highlights that this may be an area worthy of further study.

Our study demonstrated that IABP use was an independent predictor of 1-year mortality. It is likely that IABP use is simply a marker of worse clinical state at presentation and the perception in operators' minds that it might be of value in such patients. The benefits of IABP use have recently been questioned. In 1 study, the use of IABP did not significantly reduce 30-day mortality among patients with CGS complicating AMI in whom an early revascularization strategy was planned (15). In another study, IABP was used only in one-quarter of patients with CGS treated

TABLE 5 Predictors of 1-Year Survival Following PPCI in the Setting of CGS

	Odds Ratio (95% CI) (MCAR)	p Value	Odds Ratio (95% CI)* (NMAR)	p Value*	N† Missing	% Missing
Age, yrs	1.53 (1.42–1.64)	<0.0001	1.48 (1.41–1.55)	<0.0001	2	0.00
Sex, female vs. male	0.96 (0.80–1.16)	0.6809	0.96 (0.85–1.08)	0.5143	35	0.54
Hypertension	1.04 (0.87–1.24)	0.6575	0.93 (0.83–1.04)	0.2167	612	9.43
Diabetes mellitus	1.45 (1.18–1.79)	0.0005	1.54 (1.34–1.77)	<0.0001	530	8.17
Previous MI	1.25 (0.99–1.58)	0.0582	1.10 (0.94–1.27)	0.2253	893	13.76
Previous PCI	0.88 (0.66–1.16)	0.3568	1.06 (0.89–1.27)	0.4984	378	5.83
Previous CABG	0.77 (0.45–1.33)	0.3549	0.80 (0.60–1.07)	0.1315	339	5.22
History of renal disease	2.31 (1.65–3.25)	<0.0001	2.10 (1.72–2.58)	<0.0001	803	12.37
Smoking status, reference group: never smokers	0.99 (0.83–1.19)	0.9374	1.04 (0.92–1.18)	0.5439	1,351	20.82
Use of glycoprotein IIb/IIIa inhibitor	0.96 (0.81–1.15)	0.6560	0.93 (0.83–1.04)	0.21	293	4.52
Graft vessel PCI	1.07 (0.54–2.13)	0.8451	0.88 (0.60–1.29)	0.52	76	1.17
Left main disease, reference group: 0%–74%	1.70 (1.33–2.18)	<0.0001	1.71 (1.46–2.01)	<0.0001	1,386	21.36
Pre-PCI TIMI flow grade 3, reference group: TIMI flow grade <3	0.76 (0.58–1.00)	0.0468	0.85 (0.71–1.02)	0.0745	1,767	27.20
Post-PCI TIMI flow grade 3, reference group: TIMI flow grade <3	0.34 (0.28–0.42)	<0.0001	0.47 (0.41–0.55)	<0.0001	1,483	22.90

Multiple logistic regressions without covariates artificial ventilation, radial procedure, and IABP use in the model. Total sample size = 6,489, sample entered into MV model without missing data = 2,687, total events = 1,073. *Odds ratio (95% CI) and p values after applying multiple imputation NMAR (all 6,489 subjects were used; total events = 2,872). †Case records with missing data.

Abbreviations as in Tables 1 to 3.

TABLE 6 Predictors of 1-Year Survival Following PPCI in the Setting of CGS (Multiple Logistic Regressions)

	Odds Ratio (95% CI) (MCAR)	p Value	Odds Ratio (95% CI)* (NMAR)	p Value*	N† Missing	% Missing
Age, yrs	1.68 (1.56–1.82)	<0.0001	1.59 (1.51–1.68)	<0.0001	2	0.00
Sex, female vs. male	1.02 (0.85–1.24)	0.8201	0.99 (0.88–1.12)	0.9009	35	0.54%
Hypertension	1.04 (0.87–1.25)	0.6741	0.95 (0.85–1.07)	0.4295	612	9.43
Diabetes mellitus	1.40 (1.13–1.74)	0.0022	1.47 (1.28–1.70)	<0.0001	530	8.17
Previous MI	1.29 (1.01–1.64)	0.0397	1.06 (0.91–1.24)	0.4372	893	13.76
Previous PCI	0.84 (0.62–1.12)	0.2240	1.09 (0.91–1.30)	0.3632	378	5.83
Previous CABG	0.75 (0.44–1.28)	0.2828	0.76 (0.56–1.03)	0.0792	339	5.22
History of renal disease	2.40 (1.70–3.40)	<0.0001	2.03 (1.63–2.53)	<0.0001	803	12.37
Smoking status, reference group: never smokers	0.93 (0.77–1.12)	0.4365	1.06 (0.93–1.22)	0.3617	1,351	20.82
Radial procedure	0.92 (0.75–1.12)	0.4157	0.79 (0.69–0.90)	0.0008	149	2.30
Use of glycoprotein IIb/IIIa inhibitors	0.99 (0.83–1.19)	0.9189	0.93 (0.83–1.05)	0.2546	293	4.52
Ventilated patients	3.06 (2.50–3.75)	<0.0001	2.56 (2.23–2.94)	<0.0001	661	10.19
IABP use	1.70 (1.43–2.03)	<0.0001	1.57 (1.40–1.76)	<0.0001	369	5.69
Graft vessel PCI	1.20 (0.62–2.33)	0.5810	1.11 (0.74–1.65)	0.6217	75	1.16
Left main PCI	2.04 (1.57–2.65)	<0.0001	1.90 (1.62–2.23)	<0.0001	75	1.16
Pre-PCI TIMI flow grade 3, reference group: TIMI flow grade <3	0.76 (0.57–1.01)	0.0606	0.88 (0.71–1.09)	0.2311	1,767	27.20
Post-PCI TIMI flow grade 3, reference group: TIMI flow grade <3	0.31 (0.25–0.39)	<0.0001	0.44 (0.37–0.51	<0.0001	1,483	22.90

Multiple logistic regressions including covariates artificial ventilation, radial procedure, and IABP use in the model. Total sample size = 6,489, sample entered into MV model without missing data = 2,783, total events = 1,118. *Odds ratio (95% CI) and p values after applying multiple imputation NMAR (all 6,489 subjects were used; total events = 2,872). †Case records with missing data.

Abbreviations as in Tables 1 to 3.

with primary PCI, demonstrating no benefit of IABP on outcome, which supports the findings of the randomized IABP-Shock II (Intraaortic Balloon Support for Myocardial Infarction With Cardiogenic Shock) trial (16). A meta-analysis evaluated the effect of IABP in the setting of AMI. IABP was associated with a significantly reduced risk of death in patients who received thrombolysis (risk ratio [RR]: 0.77, $p < 0.0001$), and a higher risk of death in patients who underwent PCI (RR: 1.18, $p = 0.01$) (17). Again these are observational data that may be confounded by the sickest patients being selected for IABP. Although the evidence for the use of IABP in this context is relatively weak, IABP use in CGS patients undergoing PCI in the United Kingdom remains relatively high, which may represent physician bias and their belief that it is useful.

In the randomized SHOCK trial, 60% of patients in the PCI group and 80.4% of patients in the coronary artery bypass graft group had 3-vessel coronary artery disease (18). In the SHOCK registry, 53.4% of patients had multivessel disease (MVD) (19). Despite the fact that MVD appears to be a predominant finding in patients with CGS, the best strategy of how to treat MVD identified in the setting of CGS is unknown and requires further evaluation. In patients with CGS, MVD with and without a chronic occlusion were predictors for short-term mortality (20).

We have demonstrated that history of renal disease is an independent predictor of worse outcome at 1 year. Strategies to minimize further worsening of renal function and development of contrast-induced nephropathy should be seriously considered in such patients with efficient angiography and PCI using as little contrast as possible. It is unclear but intuitive and supported by our study that multiple risk factors for mortality in patients with CGS exist and modifying each may have overall benefit. Protocol-driven intervention in the sick CGS patient, with recognition of the risk factors as demonstrated in this study and available in catheter labs, could focus care. We have also shown that TIMI flow grade 3 post-PCI and radial procedures were independent predictors of survival at 1 year. Transradial access may be a marker for patients who are less sick, because in patients with severe end organ hypoperfusion, the radial pulse may be impalpable and the femoral artery would be the only possible access route. Thus the association of lower mortality with transradial access may be partly explained by the use of radial access in patients who are less profoundly shocked.

STUDY LIMITATIONS. This is an observational study. However, it is mandatory for all institutions within the United Kingdom to submit their PCI to the national database, and the data are sufficiently robust to be used as a reference database and are publically available as an audit of outcome. The main strength is that our study represents all patients treated in England and Wales in whom complete and

independently reported mortality data are available. The strategies used by different operators in different parts of the country vary and could have implications on the outcome of patients included in our analysis. It is possible that the definition of CGS used by operators varied between centers, and in the setting of emergency PCI, the diagnosis is often based on clinical judgment rather than objective measurements of cardiac physiology. However, a recent analysis of the 2011 BCIS PCI audit demonstrated that the mortality for all units for patients presenting with CGS was within 2 SD of the funnel plot, which provides some reassurance of consistency regarding the definition of CGS across the centers within the United Kingdom (21).

Of the data that was entered into the MV regression model, there were missing values as shown in **Tables 3 to 6**. However, significant results in **Tables 3 to 6** would not be affected by the missing values under the assumption that the missing data occurred completely at random. We also conducted further analysis based on the assumption of data not missing at random and our main findings did not change much as is shown in **Tables 3 to 6** from the analysis using data missing completely at random. Furthermore, the variables entered in the MV model were included and retained as these variables are of clinical relevance in the management of patients with CGS and undergoing PCI. We did not have information regarding the following variables due to the missing data in our registry: details of resuscitation before procedure; details of mechanical complications; symptom onset to PCI time; door to balloon time; details of therapeutic hypothermia; use of extracorporeal membrane oxygenation; and the use of left ventricular assist device.

CONCLUSIONS

Mortality remains high in CGS. We can better predict which patients are at higher risk of dying as a result of this study. A novel finding is the apparent, somewhat plateau-like nature of mortality after the early initial attrition in survival; longer term survival is good, allowing the focusing of attention during the acute phase and its potential impact on longer term mortality.

In a large U.K. cohort of patients undergoing PCI in the context of CGS, mortality remains high in spite of the use of contemporary PCI strategies. Further improvements in the early detection and management of CGS are still required. This remains an area that requires focused research investment.

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KEY WORDS cardiogenic shock, mortality, primary angioplasty

APPENDIX For TIMI flow grade classifications and the definitions of arterial complications and renal failure/dialysis used in this study, please see the online version of this paper.