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ABSTRACT

Objective: This study aimed to explore the correlates for mortality in patients treated with both primary percutaneous coronary intervention (PCI) and intra-aortic balloon pump counter-pulsation (IABP). Background: Acute myocardial infarction (AMI) complicated by cardiogenic shock (CS) is associated with high mortality rates.

Methods: From a cohort of patients with AMI, treated with both primary PCI and IABP and who met strict definitions for CS to identify correlates associated with mortality, the study compared patients who died inhospital to those who survived to discharge.

Results: A cohort of 93 patients met the inclusion/exclusion criteria. Of them, 66.7% were male, and the average age was 64.96 ± 13.06 years. The overall in-hospital mortality rate for this cohort was 33%. The baseline characteristics were balanced save for older average age and left ventricular ejection fraction in those who died (p = 0.049 and p = 0.014, respectively). Insertion of IABP pre-PCI and cardiac arrest at the catheterization lab were more frequent in those who died (p = 0.027 and p = 0.008, respectively). The insertion of IABP pre-PCI, cardiac arrest at the cath lab, and lower ejection fraction were correlated with inhospital mortality (ORs 2.68, 5.93, and 0.02, respectively).

Conclusions: In the era of primary PCI and IABP as standard of care in AMI complicated by CS, patients with low EF, those who necessitate IABP insertion pre-PCI, and those who necessitate cardiopulmonary resuscitation during PCI are at higher risk for in-hospital mortality and should be considered for more robust hemodynamic support devices with an attempt to improve their prognosis.

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1. Introduction

Cardiogenic shock (CS) complicates 5–15% of all acute myocardial infarction (AMI), with mortality rates of 30–50% [1]. Although the rates of CS developed during hospitalization have decreased during the last decade, the rates of CS at presentation remain constant [2], even in the current era of rapid reperfusion with both pharmacological and mechanical support. Several predictors for mortality in this clinical setting were previously reported and include age, left ventricular function, diabetes mellitus, and renal insufficiency [3]. Most of the previously published studies focused on the outcomes of CS patients, including different patient populations with different definitions of CS applied. In most of these trials, only part of the patients had received optimal, evidence-based therapy. In a recent, large-scale registry of CS patients, only 50% had percutaneous

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coronary intervention (PCI) and 17% were supported by intra-aortic balloon pump (IABP) counterpulsation [4]. Similar results were reported in the Global Registry of Acute Coronary Events (GRACE) [1]. Thus, the aim of the present analysis was to examine the correlates for mortality in patients presenting with AMI complicated by CS when all patients were treated with evidence-based therapy including IABP and PCI.

2. Methods

This retrospective analysis utilized our medical center's database to identify patients with AMI complicated by CS. Pre-specified clinical and laboratory data during hospitalization periods were obtained from hospital records by independent research personnel blinded to the study objectives. All clinical events and angiographic data were adjudicated by independent cardiologists.

Patients were eligible if they met the inclusion criteria, which included both AMI [defined as creatine kinase-MB (CK-MB) elevation ≥ 2 times the upper limit of normal and/or the presence of ischemic electrocardiographic (ECG) change including new Q-wave or ST elevation ≥ 1 mm in > 2 contiguous leads] and CS treated with

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standard therapy defined as primary PCI (or urgent PCI in the case of CS in non-ST elevation) and with IABP. CS was defined by systolic blood pressure <90 mm Hg for >30 minutes, the need for infusion of catecholamines to maintain a systolic pressure >90 mm Hg or clinical signs of pulmonary congestion [5]. Patients were excluded if they had undergone resuscitation for >30 minutes, had no intrinsic cardiac activity, had shock onset >12 hours, had a mechanical etiology for cardiogenic shock (e.g. ruptured chordea or ventricular septal defect), or other established etiology for shock.

PCI was performed according to guidelines current at the time of the procedure. Patients were loaded pre-procedurally with aspirin 325 mg and either 300- or 600-mg clopidogrel and were recommended to continue aspirin indefinitely and to continue clopidogrel 75 mg for 12 months. During the procedure, patients were treated with bivalirudin (0.75 mg/kg bolus followed by a 1.75 mg/kg/hour infusion) or unfractionated heparin (40 U/kg bolus with an additional dose to achieve an active clotting time of 250–300 seconds). The use of Ilb/IIIa antagonists was at the operator's discretion as was the selection of interventional therapy (e.g., balloon angioplasty/stent). All patients routinely underwent 12-lead ECG before and after the procedure. Blood samples were taken at 6 and 24 hours after PCI to assess CK-MB fraction. The analysis was conducted in accordance with the local institutional review board regulations.

Comparisons were made between those patients who survived to discharge and those who did not. Demographics, medical history, clinical and laboratory indices were evaluated.

Statistical analyses were performed using SAS version 9.1 (SAS Institute Inc., Cary, North Carolina). Continuous variables were compared using Student's t tests and are expressed as mean \pm SD. Categorical variables were compared using chi-square or Fisher's exact tests, as appropriate, and are expressed as numbers and percentages. Statistical significance was defined as p < 0.05. Univariable logistic regression model was applied to analyze independent correlates for mortality with confidence intervals (CI) of 95%. The variables used in this model were selected based on clinical relevance and their potential to be associated with mortality. These included demographic data (age, gender, body mass index), relevant medical history (ejection fraction, history of diabetes mellitus, history of heart failure, history of coronary artery bypass grafting surgery, history of myocardial infarction, number of diseased vessels, timing of cardiogenic shock, timing of cardiac arrest, timing of IABP insertion) and CK-MB fraction maximal values.

3. Results

A total of 209 patients admitted from September 2007 to May 2012 with a clinical diagnosis of CS made by cath lab operators were screened for inclusion in the present analysis. Of them, 93 met the criteria for AMI and CS and were subsequently analyzed. The average age was 64.96 ± 13.06 years with 66.7% men and 59.1% Caucasians. In this cohort, 79% of patients were hypertensive, 39% had diabetes mellitus, 32% had family history of coronary artery disease, and 72% had hyperlipidemia. The average left ventricular ejection fraction (EF) was $34\pm16\%$ and the mean CK-MB fraction was $158.2\pm177.3~\mu\text{gr/L}$. On angiography, the patients in this cohort had an average of 2.02 ± 0.89 diseased vessels with 47.1% of the culprit lesions in the left anterior descending (LAD) artery; 45.2% of lesions were defined as proximal lesions. The operators defined 63% of the lesions as type C while the prevalence of types A and B was 31% and 7%, respectively.

The baseline characteristics (Table 1) were similar in the patients who died versus those who survived to discharge, save for older age (68.73 \pm 10.14 vs. 63.08 \pm 14.0 years, respectively; p = 0.049). EF was lower in the patients who died (0.28 \pm 0.15 vs. 0.36 \pm 0.15; p = 0.014). Also noted was a higher prevalence of cardiac arrest at the time of PCI in the patients who died (29.0% vs.

Table 1Baseline Characteristics.

Variable	Died	Survived	p value
	(n = 31)	(n = 62)	
Demographics			
Men	20 (64.5%)	42 (67.7%)	0.756
Age (years \pm SD)	68.73 ± 10.14	63.08 ± 14.0	0.049
Caucasian	19 (61.3%)	36 (58.1%)	0.765
Diabetes mellitus type II	13 (41.9%)	23 (37.1%)	0.652
Hypertension	25 (83.3%)	48 (77.4%)	0.511
Hyperlipidemia	21 (70.0%)	45 (72.6%)	0.797
Previous acute myocardial infarction	7 (23.3%)	13 (21.0%)	0.797
Family history of coronary artery disease	9 (32.1%)	20 (32.3%)	0.991
History of tobacco abuse	16 (51.6%)	36 (58.1%)	0.555
Body mass index (mean \pm SD)	26.30 ± 4.75	28.76 ± 5.61	0.055
Clinical Parameters			
ST-elevation myocardial infarction	21 (70.0%)	48 (77%)	0.452
Ejection fraction (mean \pm SD)	0.28 ± 0.15	0.36 ± 0.15	0.014
Maximum creatine kinase-MB (µgr/L)	175.43 ± 191.86	150.63 ± 171.64	0.548
Number of diseased vessels	2.17 ± 0.95	2.04 ± 0.90	0.268
IABP inserted pre-cath lab	0	1 (1.6%)	1.0
IABP inserted pre-PCI	19 (61.3%)	23 (37.1%)	0.027
IABP inserted post-PCI	12 (38.7%)	35 (56.5%)	0.107
Cardiac arrest pre-PCI	8 (25.8%)	21 (33.9%)	0.429
Cardiac arrest at PCI	9 (29.0%)	4 (6.5%)	0.008
Pre-hospital cardiogenic chock	16 (51.6%)	23 (37.1%)	0.181
Cardiogenic shock at the cath lab	10 (32.3%)	32 (51.6%)	0.077
Time from shock to PCI $(min. \pm SD)$	110.29 ± 103.42	89.08 ± 145.81	0.421
Time from shock to IABP (min. \pm SD)	113.90 ± 112.69	62.34 ± 174.61	0.090
Laboratory Indices at Baseline			
Hematocrit (% \pm SD)	38.91 ± 7.15	39.71 + 5.60	0.605
Platelet (K/Ul \pm SD)	247.33 ± 91.89	237.25 ± 76.84	0.626
Creatinine (mg/dl \pm SD)	1.98 ± 1.91	1.27 + 0.64	0.020
White blood cells (K/Ul \pm SD)	13.85 ± 5.99	13.36 ± 5.79	0.746

IABP, intra-aortic balloon pump; PCI, percutaneous coronary intervention.

6.5%; p = 0.008). No differences were noted in the baseline laboratory indices, CK-MB levels, number of diseased vessels, the prevalence of pre-hospital cardiogenic shock, and the prevalence of cardiac arrest pre-PCI. When evaluating the angiographic characteristics of the treated lesions in both groups, the only significant difference was a lower prevalence of significant coronary lesions in the right coronary artery (RCA; 14.6% (died) vs. 30.7% (survived); p=0.038). The in-hospital mortality rate in this cohort was 33% (31/91) (Table 2).

Fig. 1 depicts the univariable logistic regression model for correlates of mortality. Among the co-variables examined, the correlates for mortality were low EF (OR = 0.02 (0.0–0.5); p = 0.018), cardiac arrest in the cath lab (OR = 5.93 (1.66–21.2); p = 0.006) and IABP insertion pre-PCI (OR = 2.68 (1.11–6.52); p = 0.006)

Table 2Angiographic Lesion Characteristics.

Died(n = 48)	Survived (n = 88)	p value
7 (14.6%)	27 (30.7%)	0.038
4 (8.3%)	6 (6.8%)	0.742
26 (54.2%)	38 (43.2%)	0.220
11 (22.9%)	16 (18.2%)	0.508
25 (52.1%)	36 (41.4%)	0.232
13 (27.1%)	22 (25.3%)	0.870
5 (10.4%)	19 (21.8%)	0.097
4 (8.3%)	4 (4.6%)	0.454
43 (89.6%)	87 (97.8%)	0.051
11 (22.9%)	31 (35.2%)	0.138
35 (72.9%)	50 (56.8%)	0.064
	7 (14.6%) 4 (8.3%) 26 (54.2%) 11 (22.9%) 25 (52.1%) 13 (27.1%) 5 (10.4%) 4 (8.3%) 43 (89.6%) 11 (22.9%)	7 (14.6%) 27 (30.7%) 4 (8.3%) 6 (6.8%) 26 (54.2%) 38 (43.2%) 11 (22.9%) 16 (18.2%) 25 (52.1%) 36 (41.4%) 13 (27.1%) 22 (25.3%) 5 (10.4%) 19 (21.8%) 4 (8.3%) 4 (4.6%) 43 (89.6%) 87 (97.8%) 11 (22.9%) 31 (35.2%)

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