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Original Article

Outcomes of STEMI Complicated by Cardiogenic Shock With and Without IABP

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ABSTRACT

Background: The results of the IABP-SHOCK II trial did not encourage the use of an intra-aortic balloon pump (IABP) in cardiogenic shock (CS) with ST-elevation myocardial infarction (STEMI). We aimed to determine whether these findings may be applicable to our population in the South Asian region, as there is a paucity of data.

Methods: In this prospective cohort study, 2 independent cohorts of STEMI patients with CS were recruited based on the utilization of IABP during revascularization. The primary endpoints of in-hospital and after 30 days of major adverse cardiac events (MACE) and the secondary endpoint of any major bleed were compared between the 2 cohorts.

Results: In total, each cohort consisted of 130 patients. Demographic, clinical, and angiographic profiles were comparable in the 2 cohorts. In the IABP and non-IABP cohorts, the in-hospital and 30-day mortality rates were 19.2% vs 26.2%; *P*=0.183 and 30.8% vs 36.9%; *P*=0.358, respectively, while the MACE rates were 20.8% vs 26.2%; *P*=0.306 and 32.3% vs 36.9%; *P*=0.434, respectively. Cardiac catheterization laboratory death was 0.8% vs 5.4%; *P*=0.031 and the major bleed was 4.6% vs 3.8%; *P*=0.758, among patients managed with IABP and without IABP, respectively.

Conclusions: Our study concluded that while there was no significant difference in the overall outcome, there was a lower trend in in-hospital mortality and significantly lower cardiac catheterization laboratory death with the use of IABP. However, the in-hospital and 30-day MACE were comparable in both groups. ***(Iranian Heart Journal 2023; 24(1): 69-77)***

KEYWORDS: Acute myocardial infarction, Cardiogenic shock, Revascularization, IABP, MACE

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Treatment of ST-elevation myocardial infarction (STEMI) to decrease morbidity and mortality and improve survival has evolved in recent years. This includes a preference for primary coronary angioplasty over thrombolytics, use of drug-eluting stents, utilization of transradial access, and refinement in cardiogenic shock (CS)

management, including recommendations regarding placement of an intra-aortic balloon pump (IABP). With the advent of new devices, more complex procedures and sicker cardiogenic shock patients whose mortality remains unacceptably high are being managed. CS is a highly complex low cardiac output state that leads to hypoperfusion to vital organs of the body.[1] It is estimated to happen in 5% to 12% of acute myocardial infarction patients.[2-4] Cardiogenic shock is defined variably, based on different studies; however, in the contemporary era, it is defined as systolic blood pressure <90 mm Hg for ≥ 30 minutes or the use of pharmacological and/or mechanical support to maintain systolic blood pressure ≥90 mm Hg, with evidence of end-organ hypoperfusion (urine output of <30 mL/h, cool extremities, altered mental status, serum lactate >2.0 mmol/L).[5] This is because of extensive damage to a large part of the myocardium or secondary to mechanical complications. Mortality related to cardiogenic shock due to left ventricular failure varies from 30% to 80%.[1,2,6] SHOCK trial demonstrated the benefits of early revascularization in the reduction of short-and long-term mortality in patients with acute myocardial infarction (AMI) with cardiogenic shock.[7-10]

ACC/AHA/ESC,[11-14] guidelines recommended that patients with STEMI complicated with CS should be revascularized either with percutaneous coronary intervention (PCI) or with CABG, irrespective of time delay. IABP rapidly augments coronary flow, ameliorates systemic hemodynamics, reduces myocardial oxygen demand, and can sustain coronary patency after PCI.[15-17] Insertion of an IABP is associated with a reduction of 11% risk of death; however, this meta-analysis only encompasses cohort studies.[14] In contrast, data from the IABP-SHOCK-II trial,[1] a randomized controlled trial (RCT) revealed that insertion of an IABP did not significantly reduce cumulative 30-day mortality in acute STEMI patients complicated with cardiogenic shock, who underwent early revascularization, which is why in the recent ESC and AHA/ACC guidelines, the recommendation for placement of IABP has decreased to class IIb.[18]

With the recent evidence of increased incidence of acute coronary syndrome patients at a very young age in the South Asian region, 2.1% up to 30 years and 6.2% up to the age of 35 years,[19] we were curious about results from the IABP-SHOCK-II trial, whether they are translatable for our patients' population too. Moreover, the data on the use of IABP in cardiogenic shock in our region is quite limited. This is why we chose to study whether the insertion of an IABP in patients with STEMI complicated by cardiogenic shock and undergoing early revascularization improves outcomes in our population compared to early revascularization without the use of IABP.

METHODS

The current study was a prospective cohort study conducted at the National Institute of Cardiovascular Diseases (NICVD) Karachi, located in the province of Sindh, in the southern region of Pakistan. NICVD is the largest public sector for cardiac care in Pakistan, with an average annual PCI volume of more than 10,000, and provides 24/7 free-of-cost services supported by the provincial government. Two independent equal-sized cohorts were recruited from consecutive patients presenting to the cardiac catheterization laboratory for revascularization with a diagnosis of STEMI complicated by cardiogenic shock between September 2020 and August 2021. The cohorts were classified as revascularization with IABP and revascularization without IABP, based on the utilization of IABP. The placement of an IABP was at the discretion of the primary operator. All the IABP devices were deployed

in the catheterization laboratory pre or post-diagnostic angiography but before PCI.

The sample size for the study was calculated based on data reported by Thiele et al [1] in their study, mortality at 30 days in the IABP group was 39.7% as against 41.3% in the control groups with a relative risk of 0.96 [0.79–1.17]. Using this information at a 95% confidence level and 30% relative precision, a minimum required sample size of 89 patients in each IABP and non-IABP group was calculated. To address the observation bias, the expected loss to follow-up, and time constraints, the sample size was inflated by a factor of 45%. Although there were no specific matching criteria for the 2 cohorts, 2 independently selected cohorts consisting of 130 consecutive patients in each group, as in the IABP and non-IABP groups, were enrolled.

The study was approved by the ethical review committee of the institution (ERC-37/2019), and informed consent was obtained from all patients at the time of recruitment before reaching the catheterization laboratory. The inclusion criteria of the study were adult patients (≥18 y) presenting with STEMI or transferred from other facilities, complicated by cardiogenic shock (CS), and undergoing early revascularization. Patients who refused to participate in the study, had preexisting congenital or valvular heart disease or pericarditis, died before reaching the catheterization laboratory, were resuscitated >30 minutes, cardiogenic shock secondary to mechanical causes (eg, ventricular septal defects or papillary muscle ruptures), and the onset of shock >12 hours, were excluded from this study.

Cardiogenic shock was defined as patients with a systolic blood pressure of less than 90 mm Hg for more than 30 minutes or needing an infusion of inotropes/vasopressor to maintain a systolic pressure ≥90 mm Hg, having clinical signs of pulmonary congestion, and impaired end-organ perfusion. Impaired end-organ perfusion was defined as patients with at least one of the criteria: altered mental status, cold clammy skin and extremities, oliguria with urine output of <30 mL per hour, or serum lactate level >2.0 mmol per liter. [1]

The demographics, clinical, laboratory, and angiographic profiles of the study participants were recorded and compared in the 2 cohorts, including the biological sex ratio and individual patient family history of premature CAD; Patient hemodynamics, instances of hypertension and diabetes mellitus, dyslipidemia, chronic kidney disease, a history of a prior MI or a prior intervention, smoking status; prior cerebrovascular accidents, and baseline laboratory investigations, as shown in Table 1. Also documented and compared between the 2 groups were the angiographic profile (the number of diseased vessels and culprit vessels), access site, and pre-and post-procedural TIMI flow, as shown in Table 2.

All patients were managed and discharged from the hospital upon attaining clinical and hemodynamic stability after assessment by experienced cardiologists, as per the clinical practice guidelines and institutional protocols. All patients were monitored during their hospital stay and up to 30 days after discharge via physical or telephonic follow-up. Major adverse cardiac events (MACE) were recorded as the primary endpoint, which included cardiovascular mortality, re-infarction (nonfatal MI or stent thrombosis), stroke (nonfatal ischemic stroke or transient ischemic attack), and emergency coronary artery bypass grafting (CABG) surgery. Major bleeding was defined according to the ISTH (International Society on Thrombosis and Haemostasis) as clinically overt bleeding accompanied by a decrease in the Hb level ≥2 g/dL or transfusion ≥2 units of packed red cells, occurring at a critical site, or resulting in death, was recorded as a secondary endpoint, as shown in Table 3.

The data were analyzed using IBM SPSS, version 21. The collected information was summarized using appropriate mean ± SD, median (IQR), or frequency and percentages. Both groups, IABP and non-IABP, were compared for quantitative (continuous) variables with the help of an independent sample *t* test or the Mann–Whitney *U* test where appropriate. The association of the IABP and non-IABP groups with the categorical response variables was assessed by applying the χ^2 test or the Fisher exact test. The significance criterion was a 2-sided *P* value ≤0.05 in all analyzes.

Table 1: Demographic characteristics, clinical presentation, risk factors, baseline management and assessments, and angiographic findings of IABP and non-IABP group

Characteristic	IABP	Non-IABP	*P* value
Total, N	130	130	-
Age, y	59.13 ± 9.79	59.02 ± 12.5	0.934
≤ 65	75.4% (98)	74.6% (97)	0.886
> 65	24.6% (32)	25.4% (33)	
Sex			
Male	82.3% (107)	76.9% (100)	0.281
Female	17.7% (23)	23.1% (30)	
Chest pain to ER time, min	165 [97-270]	183 [85-342]	0.261
ER to lab time, min	75 [55-120]	91 [54-145]	0.08
Baseline hemodynamic			
Systolic blood pressure, mm Hg	84.18 ± 7.38	84.38 ± 7.04	0.862
Diastolic blood pressure, mm Hg	56.38 ± 8.16	56.57 ± 8.54	0.89
Heart rate, bpm	100.77 ± 24.31	97.02 ± 26.78	0.249
SCAI SHOCK Classification			
B	20.8% (27)	28.5% (37)	0.150
C	79.2% (103)	71.5% (93)	
Risk profile			
Hypertension	61.5% (80)	50.8% (66)	0.080
Diabetes mellitus	49.2% (64)	43.1% (56)	0.320
Smoking	33.8% (44)	33.1% (43)	0.895
Family history of CAD	5.4% (7)	6.9% (9)	0.606
Dyslipidemia	3.8% (5)	2.3% (3)	0.473
Chronic kidney disease	3.8% (5)	3.8% (5)	>0.999
Prior myocardial infarction	13.8% (18)	14.6% (19)	0.859
Prior intervention	10% (13)	10.8% (14)	0.839
Cerebrovascular accident	3.8% (5)	3.1% (4)	0.734
Use of Inotrope	92.3% (120)	94.6% (123)	0.452
CPR/ Defibrillation	17.7% (23)	17.7% (23)	>0.999
Routine labs			
Hemoglobin, mg/dL	13.39 ± 2.51	13.08 ± 2.51	0.32
White blood cells, 10^9/L	18.37 ± 6.49	18.2 ± 9.09	0.859
Random blood sugar, mg/dL	214 [148-287]	195 [142-240]	0.333
Creatinine, mg/dL	1.41 ± 0.86	1.41 ± 1.22	0.953
Urea, mg/dL	39 [28-55]	36 [28-48]	0.459

IABP, Intra-aortic balloon pump; ER, Emergency room; SCAI, Society for Cardiovascular Angiography and Interventions; STEMI, ST-elevation myocardial infarction; NSTEMI, Non-ST-elevation myocardial infarction; CAD, Coronary artery diseases; CPR, Cardiopulmonary resuscitation; LAD, Left anterior descending artery; RCA, Right coronary artery; LCX, Left circumflex artery; TIMI, Thrombolysis in myocardial infarction

Table 2: Distribution of angiographic findings of IABP and non-IABP group

Characteristic	IABP	Non-IABP	*P* value
Total, N	130	130	-
Access to the procedure			
Femoral	76.9% (100)	71.5% (93)	0.321
Radial	23.1% (30)	28.5% (37)	
Number of vessels involved			
Single-vessel disease	19.2% (25)	24.6% (32)	0.302
Two-vessel disease	30% (39)	22.3% (29)	
Three-vessels disease	50.8% (66)	53.1% (69)	
Culprit coronary artery			
Left anterior descending artery	65.4% (85)	56.2% (73)	0.118
Right coronary artery	20% (26)	30.8% (40)	
Left circumflex	13.1% (17)	13.1% (17)	
Left main	1.5% (2)	0% (0)	
Pre-procedure TIMI flow			
0	75.4% (98)	66.2% (86)	0.107
I	19.2% (25)	21.5% (28)	
II	5.4% (7)	12.3% (16)	
III	0% (0)	0% (0)	
Postprocedural TIMI flow			
0	0.8% (1)	2.3% (3)	0.674
I	2.3% (3)	3.1% (4)	
II	10% (13)	7.7% (10)	
III	86.9% (113)	86.9% (113)	
Pre-procedure LVEF (angiogram)	29.16 ± 9.33	30.35 ± 9.31	0.305
Post-procedure LVEF (echocardiogram)	31.53 ± 7.37	32.59 ± 8.53	0.283

IABP, Intra-aortic balloon pump; TIMI, Thrombolysis in myocardial infarction; LVEF, Left ventricular ejection fraction

Table 3: In-hospital and 30-day outcomes of IABP and non-IABP group

Characteristic	IABP	Non-IABP	*P* value
Total, N	134	134	-
In-hospital outcomes			
MACE	20.8% (27)	26.2% (34)	0.306
Emergency CABG	1.5% (2)	0% (0)	0.156
Stent thrombosis	1.5% (2)	0% (0)	0.156
Stroke	2.3% (3)	0.8% (1)	0.314
Mortality	19.2% (25)	26.2% (34)	0.183
Bleeding	4.6% (6)	3.8% (5)	0.758
Table death	0.8% (1)	5.4% (7)	0.031*
Length of stay, d	5.55 ± 3.53	5.68 ± 3.39	0.761
30-day outcomes			
MACE	32.3% (42)	36.9% (48)	0.434
Emergency CABG	1.5% (2)	0% (0)	0.156
Stent thrombosis	1.5% (2)	0% (0)	0.156
Stroke	2.3% (3)	1.5% (2)	0.652
Mortality	30.8% (40)	36.2% (47)	0.358

IABP, Intra-aortic balloon pump; MACE, Major adverse cardiac events; CABG, Coronary artery bypass grafting
*significant

RESULTS

Each cohort consisted of 130 patients, with the mean age being 59.13 ± 9.79 years in the IABP cohort and 59.02 ± 12.5 years in the non-IABP cohort. The median duration of IABP support was 96 [72–120] hours. Physical or telephonic follow-up at 30 days of discharge was successful for all patients in both the IABP and non-IABP groups.

The demographics, clinical, and laboratory profiles of the 2 cohorts were comparable and revealed no statistical difference in the distribution of biological sex ratio, individual patient family history of premature CAD; Patient hemodynamics, instances of hypertension and diabetes mellitus, dyslipidemia, chronic kidney disease, a history of a prior MI or a prior intervention, smoking status; prior cerebrovascular accidents, and baseline laboratory investigations, as shown in Table 1. Inotropes, including dobutamine, dopamine, and norepinephrine, were used in 92.3% vs 94.6%; *P*=0.452 in the IABP and non-IABP cohorts, respectively.

In the angiographic profile, the preprocedural TIMI 0 flow was 75.4% vs 66.2%; *P*=0.107 and the LAD-culprit STEMI was 65.4% vs 56.2%; *P*=0.118, in the IABP and non-IABP cohorts, respectively; however, the rest of the parameters were well-matched in the 2 groups, as shown in Table 2.

With regard to outcomes, in the IABP and non-IABP cohorts, the in-hospital and 30-day mortality rates were 19.2% vs 26.2%; *P*=0.183 and 30.8% vs 36.9%; *P*=0.358, while MACE rates were 20.8% vs 26.2%; *P*=0.306 and 32.3% vs 36.9%; *P*=0.434, respectively. Cardiac catheterization laboratory death was 0.8% vs 5.4%; *P*=0.031 and the major bleed was 4.6% vs 3.8%; *P*=0.758 among patients managed with IABP and without IABP, respectively (Table 3 and Figure 1). No significant difference in 30-day event-free survival was observed between the IABP and non-IABP groups with Log-Rank test *P* value=0.402 and hazard ratio of 0.841 [0.556-1.273] (Fig. 2).

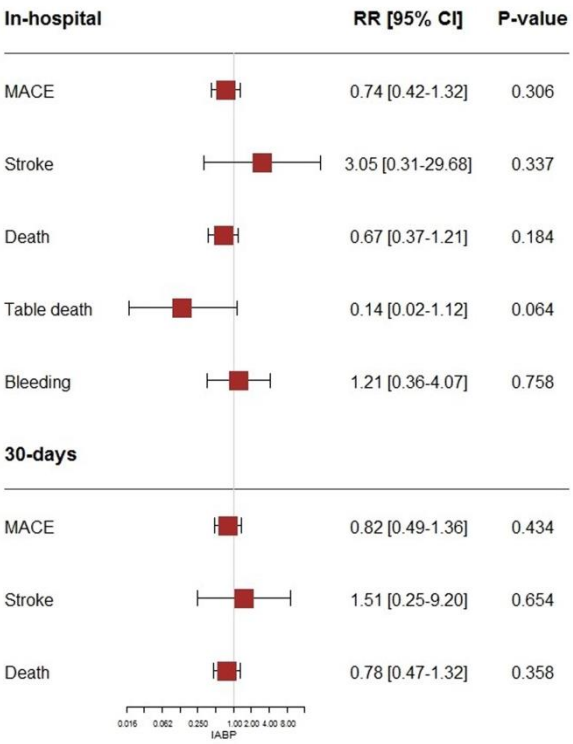

Figure 1: The image presents the in-hospital and 30-day outcomes of the IABP and non-IABP groups.

IABP, Intra-aortic balloon pump; MACE, Major adverse cardiac events; RR, Risk ratio; CI, Confidence interval
*significant

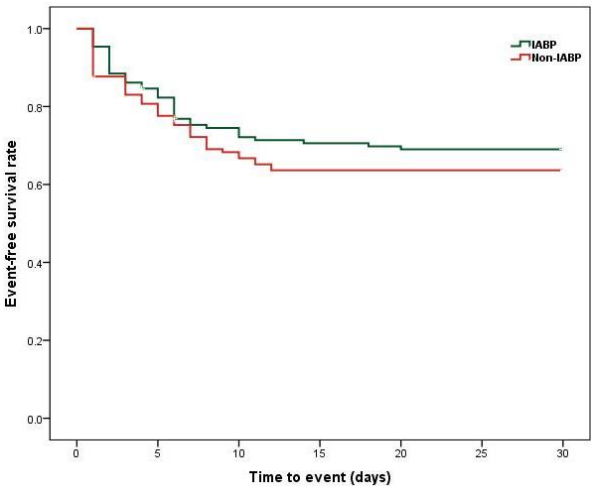

Figure 2: The image depicts Kaplan-Meier survival curves comparing the IABP and non-IABP groups.
IABP, Intra-aortic balloon pump

DISCUSSION

Cardiogenic shock is a devastating and lethal complication that develops after myocardial infarction and carries very high mortality and morbidity rates. Death in patients with acute myocardial infarction complicated by cardiogenic shock has been found to result either from multiorgan failure, hemodynamic impairment, arrhythmogenic, or mechanical complications. Urgent coronary revascularization with the intent of achieving TIMI III flow as early as possible has been shown to reduce mortality.[20]

The use of an IABP was once thought to be beneficial and crucial for managing acute cardiogenic shock patients and reducing mortality as it augments coronary perfusion, reduces afterload, and was given a class 1 recommendation for its use by different international societies.[12-14] However, contemporary data from clinical and experimental studies failed to show significant benefits of the use of IABP in these patients for reducing mortality.[1,21] The Euro Heart Survey,[22] which involved 33 different European countries, many registries,[23,24] and a meta-analysis by Sjauw et al, [25] showed no mortality benefits for IABP placement in cardiogenic shock patients, which explains why recently IABP use has been notably reduced to less than 25%. The current study showed similar results in terms of overall outcomes and is in line with the IABP-SHOCK-II trial; still, there was a trend toward lower mortality and overall MACE with the use of IABP, as depicted in Figure 1. Of note, the significantly low instances of table death in the IABP cohort compared to the non-IABP cohort were observed; however, that difference could not be extended to short-term and long-term outcomes, as shown in the survival curve in Figure 2. Partially similar findings were observed in a meta-analysis of nine cohort studies where 30-day mortality was reduced in STEMI patients treated with thrombolysis.[26]

As shown in Table 2, the use of IABP trended more in the LAD-culprit STEMI, where the preprocedural TIMI flow was zero. These are the situations where one would think of taking all possible measures, at least to support the revascularization procedure. These findings are partially supported by a study conducted by Helgestad OK et al [27] in 2020, where mortality was improved with the use of mechanical circulatory support.

When compared with the IABP-SHOCK-II results, the current study is not fully against the use of IABP devices in the setting of cardiogenic shock, especially in very high-risk patients. As can be appreciated from Figure 1, the overall MACE trended to be higher in the non-IABP cohort, and the major bleed trended to be higher in the IABP cohort, although it could not achieve statistical significance. By and large, these findings are not distinctive from the IABP-SHOCK-II study, where the use of IABP did not reduce short-term and 12-month all-cause mortality.

This study is thus far the largest local study to the best of our knowledge and was conducted at a tertiary care cardiac hospital, which is the largest public sector cardiac care facility, with a steady flow of patients from across the country. The single-center coverage of the study remains its main limitation. Other limitations include the observational study design and small sample size, which prevented multivariable analysis and left the main comparison unadjusted.

CONCLUSIONS

This study concluded that IABP did not reduce mortality and overall MACE both in-hospital and at 30 days; however, there is a trend to lower both in-hospital and short mortality and MACE with its use in STEMI patients complicated by cardiogenic shock and a significantly lower cardiac catheterization laboratory death.

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