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Cardiogenic Shock Complicating Acute Myocardial Infarction Treated With Percutaneous Coronary Intervention Supported by Impella: Implications of Advanced Age and Refractory Shock on Outcomes

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OBJECTIVES: With percutaneous left ventricular mechanical circulatory support devices becoming increasingly available for patients with cardiogenic shock due to acute myocardial infarction and the lack of a clear mortality benefit to date, identifying optimal candidates for this technology is crucial. We studied the effectiveness of Impella Cardiac Pow (Abiomed, Danvers, MA) in various stages of cardiogenic shock and elderly cohorts.

DESIGN: Retrospective review.

SETTING: Data were collected for patients at a single community hospital between January 1, 2018, and December 31, 2019.

SUBJECTS: Thirty-one consecutive adult patients with cardiogenic shock due to acute myocardial infarction who received Impella Cardiac Pow support. Shock stages were defined by the Society for Cardiovascular Angiography and Intervention (Stages A–E).

INTERVENTIONS: None.

MEASUREMENTS AND MAIN RESULTS: The primary outcome was in-hospital death across Society for Cardiovascular Angiography and Intervention cardiogenic shock stages and in patients greater than or equal to 80 and less than 80 years old. Secondary outcomes were Valve Academic Research Consortium-2 vascular and bleeding complications, stroke, and renal failure requiring dialysis. The median age of the study population was 64 years, with seven patients (23%) being greater than or equal to 80 years old. No patients were in Society for Cardiovascular Angiography and Intervention Stage A, whereas there were seven in B, eight in C, six in D, and 10 (32%) in E. Overall in-hospital mortality occurred in 61% of patients. All 10 patients in Stage E died before hospital discharge. Mortality occurred in 54% of patients (13/24) age less than 80 years compared with 86% of those 80 years or older (6/7). A total of 38.7% of patients (12/31) and 32.3% of patients (10/31) experienced Valve Academic Research Consortium-2 bleeding and vascular events, which were evenly distributed across Society for Cardiovascular Angiography and Intervention cardiogenic shock Stages.

CONCLUSIONS: In conclusion, patients with shock in extremis and those 80 years old and older may have a prohibitively high mortality despite Impella use. These findings merit further prospective investigation in a larger number of patients to evaluate the effectiveness of Impella (and other left ventricular mechanical circulatory devices) and the inherent resource utilization in advanced cardiogenic shock and the elderly.

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KEY WORDS: age; cardiogenic shock; Impella; mechanical support; myocardial infarction; Society for Cardiovascular Angiography and Intervention

Cardiogenic shock (CS) occurs in approximately 8% of patients with acute myocardial infarctions (AMIs) (1) and carries an in-hospital mortality rate of 70–90% if untreated. Revascularization has improved survival in these patients, although the prognosis remains poor with 50% of these patients dying in-hospital (2). Thus, there has been a keen interest in developing and evaluating the efficacy of newer treatment strategies to decrease mortality in these patients. Of these, the intraaortic balloon pump has failed to demonstrate an added benefit to revascularization in decreasing mortality. More recently, percutaneous left ventricular mechanical circulatory device (pVAD) support with the Impella devices (Abiomed, Danvers, MA) has demonstrated improved hemodynamics with their use in CS due to AMI (CS-AMI) patients (3, 4). However, although observational studies have suggested improved survival with use of this device in CS-AMI patients, small randomized trials in this cohort thus far have shown no mortality benefit when compared with control groups (3, 4). These disparate findings may be related to a potential increase in serious complications such as access site bleeding and vascular complications or perhaps may also be a result of inappropriate patient selection, factors more prominent in centers without a standardized shock team and specific protocol-driven approach in the management of these patients. Specific to patient selection, it is important to recognize that CS in AMI represents a spectrum from a preshock state to refractory shock, and not all patients presenting with CS-AMI are at the same stage of the disease, a fact that was not accounted for in the majority of prior studies of pVAD support. In a recently published retrospective analysis of Mayo Clinic Cardiovascular ICU patients, CS was staged using a five-stage classification scheme (A–E) proposed by the Society for Cardiovascular Angiography and Intervention (SCAI) for risk stratification (5). The effectiveness of Impella in various stages of CS has not been comprehensively studied. Similarly, data on outcomes of Impella in CS-AMI with advanced age are not available. Accordingly, we performed a retrospective analysis of patients in our community hospital setting with AMI complicated by CS to understand how various stages of shock and advanced age would be related to in-hospital outcomes among patients receiving Impella support.

MATERIALS AND METHODS

Data on 31 consecutive patients greater than 18 years old who had AMI complicated by CS and who underwent pVAD support with the Impella Cardiac Power (CP) device (Abiomed) at our institution between January 1, 2018, to December 31, 2019, were retrospectively evaluated. Patients were categorized into various stages of CS as defined by SCAI (5). Baseline demographics including age, gender, comorbidities, body mass index, ejection fraction, and cardiac arrest status were collected for the entire cohort. Clinical characteristics gathered included acute coronary syndrome classification, number of vessels revascularized, baseline vitals, and hemodynamics. The primary outcome of interest was in-hospital all cause death across SCAI CS stages and in patients greater than or equal to 80 years old or less than 80 years old. Secondary outcomes of interest were defined according to the Valve Academic Research Consortium (VARC)–2 (6) and included vascular complications (such as limb ischemia, dissection, perforation, pseudoaneurysm, stenosis, or thrombosis), isolated bleeding (subcategorized into life threatening, major, or minor), overt bleeding with hemolysis, isolated hemolysis, cerebrovascular accident, and need for continuous renal replacement therapy. Hemolysis was defined as a plasma-free hemoglobin greater than 20 mg/dl, a haptoglobin level less than 10 mg/dl, and/or a serum lactate dehydrogenase level greater than 2.5 times the upper limit of normal range at the implanting center.

CS stages were defined in accordance with the SCAI as cited in the study by Jentzer et al (5) and were determined based on clinical and laboratorial data at the moment immediately prior to pVAD insertion: Stage A (at risk) were patients without hypotension, tachycardia, or hypoperfusion; Stage B (beginning) were patients with hypotension or tachycardia without hypoperfusion; Stage C (classic) were patients with hypoperfusion without deterioration; Stage D (deteriorating) were patients with hypoperfusion with deterioration but not refractory shock; and Stage E

(extremis) were patients with hypoperfusion with deterioration and refractory shock (5). Hypoperfusion was defined as a lactate greater than 2 mmol/L or urine output less than 720 mL during the first 24 hours or creatinine increase by greater than or equal to 0.3 mg/dL during the first 24 hours. Deterioration was defined as worsening lactic acidosis or pressor requirements during hospitalization when compared with admission but not meeting criteria for refractory shock. Refractory shock was defined as a mean systolic blood pressure less than 80 mm Hg on pressor support, mean arterial pressure less than 50 mm Hg and on pressor support, or lactate greater than or equal to 10 mmol/L (5).

Descriptive statistics are presented to characterize the study group. Continuous variables are presented as medians with interquartile ranges. Categorical variables are reported as frequency distributions. For display purposes, we provided information on patients who expired versus those who survived. The Ascension St. John Hospital Institutional Review Board (IRB) has determined that this project, with reference number 1560900, is exempt from IRB review according to federal regulations and has waived the need for informed consent (see **Supplemental File**, http://links.lww.com/CCX/A662).

RESULTS

Demographics and Clinical Characteristics

A total of 31 patients had Impella CP implanted for AMI and CS during the study period. The median age of patients was 64 years with seven patients (22.6%) being greater than or equal to 80 years old. The median age was 63 years in those who survived and 64 years in those who died. The majority of the patients were male. Approximately half of the patients were smokers, previously diagnosed with diabetes mellitus, coronary artery disease, and/or heart failure with a reduced ejection fraction, and one eighth of the patients were on hemodialysis at presentation. The prevalence of diabetes mellitus was higher whereas that of previous cardiovascular disease (coronary artery disease, myocardial infarction, congestive heart failure) lower among patients who died (**Table 1**).

TABLE 1.
Baseline Demographics for the Study Cohort of Cardiogenic Shock Due to Acute Myocardial Infarction Patients

Characteristics	CS After AMI Total (*n* = 31)	CS After AMI–Survived (*n* = 12)	CS After AMI–Deceased (*n* = 19)
Age (yr), median (interquartile range)	64.0 (53.0–75.0)	63.0 (53.5–72.5)	64.0 (50.3–77.8)
Gender (male), *n* (%)	19 (61.3)	5 (41.7)	14 (73.7)
Body mass index (kg/m^2), median (interquartile range)	29.5 (25.4–33.7)	29.5 (25.4–33.7)	29.5 (25.9–33.2)
Hypertension, *n* (%)	25 (80.6)	9 (75.0)	16 (84.2)
Hyperlipidemia, *n* (%)	23 (74.2)	10 (83.3)	13 (68.4)
Smoking, *n* (%)	14 (45.2)	6 (50.0)	8 (42.1)
Diabetes, *n* (%)	15 (48.4)	5 (41.7)	10 (52.6)
Coronary artery disease, *n* (%)	15 (48.4)	7 (58.3)	8 (42.1)
Cerebrovascular accident, *n* (%)	6 (19.4)	2 (16.7)	4 (21.1)
Chronic obstructive pulmonary disease, *n* (%)	5 (16.1)	2 (16.7)	3 (15.8)
Heart failure with reduced ejection fraction, *n* (%)	14 (45.2)	7 (58.3)	7 (36.8)
Prior myocardial infarction, *n* (%)	7 (22.6)	4 (33.3)	3 (15.8)
Prior coronary artery bypass grafting, *n* (%)	5 (16.1)	1 (8.3)	4 (21.1)
Peripheral vascular disease, *n* (%)	5 (16.1)	2 (16.7)	3 (15.8)
Chronic kidney disease, not on dialysis, *n* (%)	9 (29.0)	3 (25.0)	6 (31.6)
End-stage renal disease on dialysis, *n* (%)	4 (12.9)	2 (16.7)	2 (10.5)

AMI = acute myocardial infarction, CS = cardiogenic shock.

Approximately 70% of patients (22/31) presented due to a ST elevation myocardial infarction, with over half suffering a cardiac arrest prior to and/or during device insertion. The median ejection fraction was estimated at 20%. No patients were in SCAI Stage A, whereas there were seven in Stage B, eight in Stage C, six in Stage D, and 10 (32%) in Stage E. A higher proportion of the deceased patients suffered a cardiac arrest

TABLE 2.
Clinical Characteristics and Invasive Hemodynamics for the Study Cohort of Cardiogenic Shock Due to Acute Myocardial Infarction Patients

Variables	CS after AMI Total (*n* = 31)	CS After AMI–Survived (*n* = 12)	CS After AMI–Deceased (*n* = 19)
Pre-PCI implantation, *n* (%)	18 (58.0)	6 (50.0)	12 (63.0)
Pre-PCI implantation by SCAI stage distribution, *n* (%)	A–NA B–5/7 (71.4) C–5/8 (62.5) D–3/6 (50.0) E–5/10 (50.0)	A–NA B–4/6 (66.7) C–2/4 (50.0) D–0/2 (0) E–N/A	A–NA B–1/1 (100) C–3/4 (75.0) D–3/4 (75.0) E–5/10 (50.0)
Cardiac arrest, *n* (%)	17 (54.8)	5 (41.7)	12 (63.2)
Left ventricular ejection fraction (%), median (interquartile range)	20.0 (12.5–27.5)	20.0 (15.0–25.0)	20.0 (12.5–27.5)
Creatinine clearance (mL/min/1.73 m^2), median (interquartile range)	52.0 (33.3–70.7)	73.5 (47.6–99.5)	44.0 (31.2–56.9)
ACS class (ST elevation myocardial infarction/non-ST elevation-ACS), *n* (%)	22 (71.0)/9 (29.0)	8 (66.7)/4 (33.3)	14 (73.7)/5 (26.3)
Number of vessels revascularized	1	1	1
Heart rate (beats/min), median (interquartile range)	98.5 (79.1–117.9)	112.5 (101.1–123.9)	90.0 (68.4–111.7)
Mean arterial pressure (mm Hg), median (interquartile range)	56.5 (37.8–75.3)	57.5 (47.1–67.9)	56.5 (35.1–77.9)
Systolic blood pressure (mm Hg), median (interquartile range)	98.0 (81.0–115.0)	96.5 (82.3–110.8)	101.0 (80.4–121.7)
Left ventricular end-diastolic pressure (mm Hg), median (interquartile range)	32.0 (26.0–38.0)	35.5 (26.3–44.8)	30.0 (26.5–33.5)
Mean pulmonary arterial pressure (mm Hg), median (interquartile range)	34.5 (26.5–42.5)	34.5 (29.9–39.2)	36.5 (27.4–45.7)
Pulmonary artery occlusion pressure (mm Hg), median (interquartile range)	26.0 (18.5–33.5)	24.0 (16.5–31.5)	26.5 (21.4–31.7)
Cardiac index (L/min/m^2), median (interquartile range)	1.9 (1.3–2.6)	2.4 (1.8–3.0)	1.8 (1.2–2.4)
Cardiac power index (W/m^2), median (interquartile range)	0.32 (0.25–0.40)	0.31 (0.28–0.35)	0.32 (0.22–0.42)
SCAI stage distribution, *n* (%)	A–0 (0) B–7 (22.6) C–8 (25.8) D–6 (19.4) E–10 (32.3)	A–0 (0) B–6 (50.0) C–4 (33.3) D–2 (16.7) E–0 (0)	A–0 (0) B–1 (5.3) C–4 (21.1) D–4 (21.1) E–10 (52.6)

ACS = acute coronary syndrome, AMI = acute myocardial infarction, CS = cardiogenic shock, NA = not applicable, PCI = percutaneous coronary intervention, SCAI = Society for Cardiovascular Angiography and Intervention.

prior to device insertion and had lower baseline creatinine clearance and lower median cardiac index compared with those who survived. Other hemodynamic and clinical characteristics in those who survived and those who died are as noted in **Table 2**. Rates of prepercutaneous coronary intervention (PCI) Impella CP insertion for the entire cohort as well as by SCAI stage distribution in those who survived and those who died are as noted (Table 2).

Outcomes and Clinical Events

A total of 12 of 31 patients suffered blood loss, three of which were life-threatening bleeds, four major bleeds, one minor bleed, and four overt bleeds with evidence of coexisting intravascular hemolysis. There was no clear trend toward increased bleeding events when comparing those who died with those who survived. Ten of the 31 patients suffered vascular complications, eight of which were major and two of which were minor complications. Vascular complications occurred at a higher rate in those who died (7/19; 36.8%) versus those who survived (3/12; 25.0%) (**Table 3**).

Overall in-hospital mortality was 61%. Mortality increased with advanced SCAI stage, with all 10 patients dying in Stage E (100%) despite Impella CP support. A high death rate was also noted in those greater than or equal to 80 years old (6/7; 86%). There was a decline in hemoglobin after device insertion among all categories, with 20 of the 31 patients suffering a decline in hemoglobin greater than 3 g/dL postdevice insertion compared with their preprocedural value. Overall, there was no clear trend toward increased bleeding events or vascular complications across SCAI stages. There was no trend toward increased cerebrovascular accidents and need for continuous renal replacement therapy across progressively worsening SCAI Stages (**Table 4**).

DISCUSSION

Our study was a small retrospective analysis with the aim of gaining insight into patient-related factors that may portend a dismal prognosis in CS-AMI and in whom we may hypothesize that pVAD support may or may not be beneficial. A particular focus was placed on performing this analysis in the context of the SCAI categories of shock as identified by Jentzer et al (5) and in those with advanced age. We found that all 10 patients in SCAI stage E (in extremis) died despite receiving pVAD support. Similarly, six of seven patients greater than or equal to 80 years old died despite Impella CP

TABLE 3.
Outcomes for the Study Cohort of Cardiogenic Shock Due to Acute Myocardial Infarction Patients

Outcomes	CS After AMI Total (*n* = 31)	CS After AMI–Survived (*n* = 12)	CS After AMI–Deceased (*n* = 19)
Hemoglobin prior to insertion (g/dL), median (interquartile range)	11.8 (10.1–13.5)	12.0 (9.6–14.5)	11.7 (10.2–13.3)
Hemoglobin after insertion (g/dL), median (interquartile range)	7.3 (5.8–8.9)	7.0 (5.9–8.1)	7.8 (6.0–9.6)
Vascular complication, *n* (%)	10 (32.3)	3 (25.0)	7 (36.8)
Life-threatening bleed, *n* (%)	3 (9.7)	1 (8.3)	2 (10.5)
Major bleed, *n* (%)	4 (12.9)	1 (8.3)	3 (15.8)
Minor bleed, *n* (%)	1 (3.2)	0 (0.0)	1 (5.3)
Overt blood loss with hemolysis, *n* (%)	4 (12.9)	3 (25.0)	1 (5.3)
Isolated hemolysis, *n* (%)	5 (16.1)	4 (33.3)	1 (5.3)
Cerebrovascular accident, *n* (%)	2 (6.5)	0 (0.0)	2 (10.5)
Continuous renal replacement therapy, *n* (%)	5 (16.1)	2 (16.7)	3 (15.8)
Death, *n* (%)	19 (61.3)	0 (0.0)	19 (100.0)

AMI = acute myocardial infarction, CS = cardiogenic shock.

TABLE 4.

Outcomes Stratified Based on Society for Cardiovascular Angiography and Intervention and Age Categories in the Study Cohort of Cardiogenic Shock Due to Acute Myocardial Infarction Patients

Outcomes	CS after AMI (*n* = 31)	SCAI B (*n* = 7)	SCAI C (*n* = 8)	SCAI D (*n* = 6)	SCAI E (*n* = 10)	Age < 80 yr Old (*n* = 24)	Age ≥ 80 yr Old (*n* = 7)
Hemoglobin prior to insertion (g/dL), median (interquartile range)	11.8 (10.1–13.5)	12.1 (10.8–13.5)	10.2 (8.6–11.8)	11.5 (8.4–14.7)	12.8 (11.8–13.9)	12.3 (10.5–14.2)	10.5 (9.1–11.9)
Hemoglobin after insertion (g/dL), median (interquartile range)	7.3 (5.8–8.9)	7.1 (5.9–8.4)	6.6 (6.3–7.0)	7.2 (6.5–7.9)	10.3 (9.4–11.2)	8.3 (6.7–10.0)	6.7 (5.9–7.5)
Vascular complication, *n* (%)	10 (32.3)	3 (42.9)	2 (25.0)	3 (50.0)	2 (20.0)	7 (29.2)	3 (42.9)
Life-threatening bleed, *n* (%)	3 (9.7)	0 (0.0)	2 (25.0)	0 (0.0)	1 (10.0)	1 (4.2)	2 (28.6)
Major bleed, *n* (%)	4 (12.9)	1 (14.3)	0 (0.0)	0 (0.0)	3 (30.0)	4 (16.7)	0 (0.0)
Minor bleed, *n* (%)	1 (3.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (10.0)	1 (4.2)	0 (0.0)
Overt blood loss with hemolysis, *n* (%)	4 (12.9)	1 (14.3)	2 (25.0)	1 (16.7)	0 (0.0)	3 (12.5)	1 (14.3)
Isolated hemolysis, *n* (%)	5 (16.1)	2 (28.6)	2 (25.0)	1 (16.7)	0 (0.0)	5 (20.8)	0 (0.0)
Cerebrovascular accident, *n* (%)	2 (6.5)	1 (14.3)	0 (0.0)	0 (0.0)	1 (10.0)	2 (8.3)	0 (0.0)
Continuous renal replacement therapy, *n* (%)	5 (16.1)	1 (14.3)	3 (37.5)	1 (16.7)	0 (0.0)	4 (16.7)	1 (14.3)
Death, *n* (%)	19 (61.3)	1 (14.3)	4 (50.0)	4 (66.7)	**10 (100)**	13 (54.2)	**6 (85.7)**

AMI = acute myocardial infarction, CS = cardiogenic shock, SCAI = Society for Cardiovascular Angiography and Intervention.
Boldface values identify results of main importance in the study, which are those highlighted in the abstract as well.

support. Other adverse events such as VARC-2 bleeding occurred in a considerable number of patients, 12 of 31 (39%), with eight of these being isolated bleeding events and four being overt bleeding associated with hemolysis. Additionally, VARC-2 vascular complications occurred in 10 of 31 patients (32%), with eight of these being major complications and 2 being minor complications. Bleeding and vascular complications occurred in all stages of the SCAI spectrum of shock severity and in both those less than 80 years old and older.

Since the mortality reduction from 70% to 50% demonstrated by revascularization in CS-AMI patients (2, 7), no further adjunctive therapy has shown clear additive benefit in reducing adverse outcomes in these patients. Randomized trials of the intraaortic balloon pump and PCI versus PCI alone in CS-AMI showed no further mortality benefit from the intraaortic balloon pump over that observed with PCI alone (8, 9). Initial Impella studies were small, testing for feasibility rather than efficacy, or were discontinued due to poor enrollment, ultimately never demonstrating a significant mortality benefit in CS-AMI patients when compared with the intraaortic balloon pump (3, 4). Recent data from registries studying Impella use prior to PCI in CS-AMI are promising. The U.S. Impella registry reported a survival to discharge of 65% in 63 patients who underwent Impella support prior to PCI compared with a survival of 41% in the 91 patients who received Impella support post-PCI (10). The Detroit CS Initiative reported a survival to discharge of 75% in 30 of 40 consecutive patients with CS-AMI who underwent mechanical circulatory support before PCI (11). Recently, data from the National CS Initiative on the SCAI classification of 300 CS-AMI patients undergoing early Impella support were

retrospectively analyzed and reported an overall survival to discharge of 71%, yet a mortality of over 80% for those who were in refractory shock (SCAI Stage E) upon reevaluation at 24 hours (12). Compared with these registries, our data represent our early experience with utilization of the Impella device. The higher survival rates demonstrated in these larger registries may reflect employment of a more protocol-driven approach for patient evaluation and selection for early implantation of mechanical circulatory support, more experienced operators, and adoption of standardized techniques for vascular access management, factors that were not consistently present in our institution's early experience.

Given that outcomes of CS have been variable and its management largely unstandardized and costly, several studies have attempted to establish prognostic predictors to better understand this complex disease and to provide guidance as to how to more effectively care for these patients. Factors that portend higher mortality in CS include, but are not limited to, renal insufficiency/dialysis (13, 14), diabetes mellitus (13), elevated lactate levels (13) or poor lactate clearance (15), low cardiac power output/index (13, 16), extended need for vasopressor support (13, 14), and cardiac arrest (5, 15, 17). Our analysis extends this paradigm to suggest a very high mortality in those with CS in extremis and those 80 years old or older. CS is now increasingly recognized as a disease spectrum, as delineated in a recent five-stage CS classification scheme proposed by SCAI for the purpose of risk stratification (5). Jentzer et al (5) applied this five-stage SCAI CS model to 10,004 patients, 43% of which had ACS, in the Mayo Clinic Cardiovascular ICU between 2007 and 2015. In the 4,267 patients they analyzed with CS-AMI, of whom no more than 0.5% received Impella support, Jentzer et al (5) reported that in-hospital mortality rates in CS-AMI patients increased as a function of CS SCAI stage severity, ranging between 7% and 80% in SCAI Stages B–E (5). These results were consistent both in the subset of CS-AMI patients as well as CS due to heart failure. Similarly, prior studies have cited increasing age as a predictor of worse outcomes in CS-AMI patients (13, 15, 18, 19), although cautioned that age alone should not be the determining factor in dictating management strategies (20). In an observational study by Tehrani et al (13) of 204 consecutive patients with CS, age greater than or equal to 71 years was a predictor of 30-day mortality on univariate analysis with an odds ratio of 3.17 (CI, 1.59–6.34; $p < 0.01$). In the Acute Myocardial Infarction in Switzerland Plus Registry of 4,090 patients with CS, age per additional year was an independent predictor of in-hospital mortality with an odds ratio of 1.04 (CI, 1.03–1.05) (19). However, guidance on the management of the very elderly (≥ 80 yr) presenting with CS is scarce, specifically as it relates to the use of pVAD support to improve their grim outcomes.

Our findings although not allowing for direct comparison with prior studies suggested that similar to studies by Jentzer et al (5) and Hanson et al (12), mortality is higher among patients with more advanced SCAI stages of CS, with all patients in SCAI Stage E (in extremis) dying despite Impella CP support among all patients, unlike those in the study by these investigators. That age predicts increased death among those with CS-AMI despite use of the Impella device has been shown in prior studies. In the Impella-EUROSHOCK registry, age greater than 65 years was an independent predictor of 30-day mortality in patients with refractory CS receiving the Impella 2.5 device (21). Our findings suggest that outcomes were dismal among those age greater than or equal to 80 years, with only one of seven patients surviving even after receiving Impella CP support.

Our study may have some clinical implications that we could speculate. Percutaneous ventricular assist device use is associated with significant cost in patients with CS-AMI. In addition, its use in these patients is not risk-free and can be associated with serious bleeding and vascular complications in already critically ill patients presenting with CS-AMI; this may not only increase resource utilization but also adversely influence in-hospital outcomes. Data from the U.S. Impella registry cited a combined rate of 13.6% for limb ischemia and vascular complications requiring surgical repair, 20.1% for bleeding requiring transfusion and/or surgery, and 10.3% for hemolysis (10). Data from the Percutaneous Mechanical Circulatory Support Versus Intra-Aortic Balloon Pump in Cardiogenic Shock After Acute Myocardial Infarction (IMPRESS) trial reported a rate of 4% for major vascular complications, 33.3% for bleeding, and 8.3% for hemolysis in the Impella arm (3). In our study, rates of major vascular complications and hemolysis were higher (25.8% and 29%, respectively) than those reported in previous studies; likely due to the lack of a systematic

protocol for patient selection, the presence of newly seasoned implanting operators, unstandardized vascular access site management, or a combination thereof early in our institution's experience with Impella utilization. The overall rate of bleeding in our study (39%) was comparable with that of the IMPRESS trial, and the rate of major/life-threatening bleeding (at least 22.6%) comparable with that reported in the U.S. Impella registry. Thus, our data suggested that selection of appropriate patients with CS-AMI may be key to improving outcomes of CS-AMI and justify resource utilization with Impella use. Although we cannot be definitive in our inferences given the observational nature and small number of patients at a single center in our study, our data raised an important hypothesis that the use of Impella among those with Stage E CS-AMI or those very elderly may not be beneficial in these patients. Clearly, these findings in a small number of patients merit further evaluation in future studies involving a much larger number of older patients and those with advanced CS-AMI before adopting a ubiquitous strategy of using these devices in all patients with these characteristics.

Our study findings must be viewed in light of the study's limitations. Besides involving a small number of patients at a single center in this observational analysis, the use of Impella or adjunctive treatment was neither mandated nor driven by a unified protocol. As such, the timing of insertion of the Impella CP device (whether pre- or post-PCI) was not standardized. Furthermore, alternative forms of mechanical circulatory support, such as venoarterial extracorporeal membrane oxygenation, were not as readily available at the time of this analysis. It would be interesting to determine whether these factors will contribute meaningfully on patient outcomes in further prospective trials. In addition, influence of unmeasured confounders on outcomes cannot be ascertained from our study. Our findings and the association of other important factors on outcomes in CS-AMI with the use of Impella need to be evaluated in future studies.

CONCLUSIONS

Our early experience suggests that patients with CS in extremis and those 80 years old and older have a prohibitively high mortality despite Impella use. Whether the institution of more standardized patient selection and vascular management protocols will alter these outcomes remains to be elucidated. These findings merit further prospective investigation in a larger number of patients to evaluate the effectiveness of Impella (and other pVAD devices) and the inherent resource utilization in advanced CS and the elderly.

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Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website (http://journals.lww.com/ccejournal).

Dr. Kaki is a proctor and speaker on behalf of Abiomed, Abbott, Cardiovascular Systems, Inc., and Terumo. Dr. Schreiber has consulted with Abiomed. The remaining authors have disclosed that they do not have any conflicts of interest.

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