# Outcomes Among Patients Transferred for Revascularization With Impella for Acute Myocardial Infarction With Cardiogenic Shock from the cVAD Registry

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**The outcomes for patients transferred with cardiogenic shock and later treated with revascularization and Impella support have not previously been studied. To evaluate these outcomes, patients in cardiogenic shock were recruited from the catheter-based ventricular assist device registry, a prospective registry enrolling patients who underwent percutaneous coronary intervention with hemodynamic support using Impella 2.5 or CP. Analysis was performed on subgroups of patients who were characterized as those directly admitted to a tertiary care hospital (direct), or those transferred from an outside hospital (transfer). Patients who were transferred with acute myocardial infarction with cardiogenic shock (AMICS) more often presented in shock were in shock longer than 24 hours, and were more likely to be on intra-aortic balloon pump but were less likely to sustain cardiac arrest. The number of pressors, EF, diseased, and treated vessels were similar between the 2 groups. Despite baseline differences, the mortality was similar in the transfer versus direct patients (47.0% vs 53.5% p = 0.19). In a multivariate model, the factors independently associated with 30-day mortality in AMICS treated with revascularization and Impella support were cardiopulmonary resuscitation (CPR) (p <0.01), age (p <0.01), and ST-segment elevation myocardial infarction (STEMI) (p = 0.02). Whether the patient was transferred or directly admittedly with AMICS was not an independent predictor of death. In conclusion, these findings suggest that considerations should be given to transfer patients with AMICS to allow them to be treated in a contemporary manner.**  **(Am J Cardiol 2019;123:1214−1219)**

Acute myocardial infarction with cardiogenic shock (AMICS) remains a highly lethal condition for those treated medically.[1] The SHOCK trial demonstrated improved survival at 6 months for those patients who were revascularized versus medical therapy alone.[2] Recent randomized trials in shock have failed to demonstrate improvement from planned intra-aortic balloon pump (IABP) counterpulsation.[3] More advanced left ventricular support systems like the Impella microaxial flow circulatory assist device (Abiomed, Danvers, MA), are mostly available in tertiary care settings, thus necessitating transfer of AMICS patients. Our analysis means to explore the outcomes of patients with AMICS who were transferred to a tertiary care center where an Impella device was placed. We compared the outcomes in this unique group with those who had AMICS but were directly admitted and treated with an Impella device.

## Methods

The catheter-based ventricular assist device (cVAD) registry is an on-going multicenter voluntary registry open to centers in the United States and Canada. The registry design and method were published elsewhere.[4] In brief, institutional review board (IRB) approval has been granted at each participating site. To avoid bias, all patients identified in a commercial database maintained by the manufacturer are enrolled at each cVAD site. The diagnosis of acute myocardial infarction (AMI) was made by analysis of ECG changes, cardiac enzymes, and/or identification of an infarct-related coronary occlusion on emergency angiography. The central clinical events committee confirmed the presence of AMICS based on chart information collected. Cardiogenic shock was defined as a (1) systolic blood pressure ≤90 mm Hg or need for inotropic support to maintain systolic blood pressures ≥90 mm Hg, (2) signs of peripheral hypoperfusion, and (3) cardiac index <2.2 L/min/$m^2$ and pulmonary capillary wedge pressure ≥15 mm Hg. We sought to compare the outcomes of patients who were treated

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for shock at the primary admission (direct group) versus those who were transferred from another center (transfer group).

Data are expressed as mean ± standard deviation (SD) or median as appropriate. Qualitative data are presented as proportion. Categorical variables were tested using Pearson's chi-square test for contingency tables or Fisher's exact test, as appropriate. Continuous variables were analyzed by one-way analysis of variance (ANOVA). All statistical tests and/or confidence intervals, as appropriate, were performed with a 2-sided p value = 0.05. Kaplan-Meier estimates of survival through 30 days were performed, and a Log-rank test was used to compare the curves between the study groups. Multivariate regression model was employed for determination of 30 days independent predictors of mortality. Statistical analysis was performed using SAS Software v10.

## Results

Between December 2007 and December 2014, 273 patients were directly admitted to a tertiary care center (direct group) and 202 patients were transferred (transfer group) to a tertiary care center where the Impella was used (Table 1). There was on average 18 hours delay for the percutaneous coronary intervention (PCI) from MI onset in the transfer group. Similarly, the duration of cardiogenic shock was longer in the transfer group compared with the direct admission group with nearly a third with shock duration over 24 hours (Table 1). Patients in both groups were similar in age, gender, previous coronary artery bypass grafting, and society of thoracic surgeons score. More patients in the transfer group presented with

Table 1
Patient baseline characteristics

| Characteristics | All (N = 475 patients) | Direct (N = 273 patients) | Patients transferred (N = 202 patients) | p Value |
|---|---|---|---|---|
| Age (Years) | | | | |
| Mean ± SD (N) | 64.71 ± 12.1 | 63.91 ± 12.6 (273) | 65.80 ± 11.4 | 0.09 |
| Men % | 361 (76.0 %) | 206 (75.5%) | 155 (76.7%) | 0.83 |
| Smoker % | 445 (49.0%) | 119 (47.2%) | 99 (51.3%) | 0.44 |
| Hyperlipidemia % | 258 (57.1%) | 136 (53.1%) | 122 (62.2%) | 0.06 |
| Hypertension % | 331 (72.4%) | 183 (70.1%) | 148 (75.5%) | 0.21 |
| Diabetes mellitus % | 199 (43.7%) | 101 (38.7%) | 98 (50.5%) | 0.01 |
| Renal insufficiency % | 107 (23.9%) | 58 (22.6%) | 49 (25.8%) | 0.44 |
| Prior AICD/pacer implanted % | 39 (8.6%) | 24 (9.3%) | 15 (7.7%) | 0.61 |
| Prior PCI % | 142 (31.3%) | 83 (31.9%) | 59 (30.4%) | 0.76 |
| Prior CABG % | 53 (11.5%) | 30 (11.4%) | 23 (11.7%) | 1.00 |
| PVD % | 69 (15.7%) | 30 (11.9%) | 39 (20.9%) | 0.01 |
| STS mortality score | | | | |
| Mean ± SD (N) | 19.7 ± 17.2 | 18.9 ± 17.9 | 20.7 ± 16.4 | 0.29 |
| Patient was supported with an IABP prior to Impella support % | 160 (34.5%) | 82 (30.6%) | 78 (39.8%) | 0.05 |
| Patient required inotropes or pressors prior to Impella support, % | 372 (78.3%) | 211 (77.3%) | 161 (79.7%) | 0.57 |
| If yes, maximum number of different inotropes | | | | |
| Mean ± SD (N) | 2.0 ± 1.1 (372) | 2.0 ± 1.1 (211) | 1.9 ± 1.0 (161) | 0.09 |
| Hours between MI onset and start of PCI (Hours) | | | | |
| Mean ± SD (N) | 21.4 ± 50.7 | 14.0 ± 47.9 | 32.6 ± 52.9 | 0.01 |
| Anoxic brain injury | 85 (19.0%) | 58 (22.1%) | 27 (14.5%) | 0.05 |
| Cardiac arrest | 243 (52.5%) | 159 (59.3%) | 84 (43.1%) | <0.01 |
| CPR | 238 (51.7%) | 152 (57.0%) | 86 (44.6%) | 0.01 |
| STEMI | 301 (70.3%) | 196 (79.0%) | 105 (58.3%) | <0.01 |
| NSTEMI | 127 (30.0%) | 52 (21.0%) | 75 (41.7%) | <0.01 |
| Shock was present on admission % | 268 (58.3%) | 132 (50.0%) | 136/196 (69.4%) | <0.01 |
| Duration of shock (hours) | | | | |
| <6 | 241 56.2% | 161 65.7% | 80 43.5% | <0.01 |
| 6-12 | 46 (10.7%) | 20 (8.2%) | 26 (14.1%) | 0.06 |
| 12-24 | 45 (10.5%) | 22 (9.0%) | 23 (12.5%) | 0.27 |
| >24 | 97 (22.6%) | 42 (17.1%) | 55 (29.9%) | <0.01 |
| HR (bpm) | | | | |
| Mean ± SD (N) | 93.9 ± 33.5 | 93.4 ± 35.5 | 94.6 ± 30.7 | 0.69 |
| Mean arterial pressure (mm Hg) | | | | |
| Mean ± SD (N) | 74.5 ± 22.5 | 74.7 ± 25.0 | 74.3 ± 18.5 | 0.86 |
| Cardiac index (L/min/$m^2$) | | | | |
| Mean ± SD (N) | 2.0 ± 0.8 | 1.9 ± 0.8 | 2.1 ± 0.8 | 0.13 |
| PCWP (mm Hg) | | | | |
| Mean ± SD (N) | 28.2 ± 9.7 | 28.3 ± 9.7 | 28.2 ± 9.9 | 0.96 |

AICD = automatic internal cardiac defibrillator; BPM = beats per minute; CABG = coronary artery bypass grafting; CPR = cardiopulmonary resuscitation; Hyperlipidemia = patient is on at least one lipid lower medication; Hypertension = patient is on at least one anti-hypertensive medication; IABP = intra-aortic balloon pump; MI = myocardial infarction; mm Hg = millimeters of mercury; NSTEMI = non-ST segment elevation MI; PCI = percutaneous coronary intervention; PCWP = pulmonary capillary wedge; PVD = peripheral vascular disease; SD = standard deviation; STEMI = ST-segment elevation MI; STS = Society of Thoracic Surgery.

non-STEMI, whereas the majority of patients in the direct admission had STEMI.

Hemodynamic variables are also listed in Table 1. The patients who were transferred were more likely to be supported by an IABP before Impella support. The mean cardiac index was 2.0 ± 0.8 L/min/$m^2$ which were similar between groups. This dire hemodynamic status was observed, although the patients with AMICS were on an average of 2 inotropes and 1/3 were on IABP. Patients transferred to a tertiary care center had lower rates of anoxic brain injury and cardiac arrest before their PCI in cardiogenic shock and Impella use.

Procedural characteristics are listed in Table 2. Patients transferred had longer times from onset of cardiogenic shock to Impella placement. The left ventricular ejection fraction was severely depressed overall and similar in both groups. There were similar rates of TIMI III flow after PCI in both groups. The majority of patients in both groups were supported by the Impella 2.5 by a femoral approach. The duration of Impella support was on average 1.5 days in both groups.

Adverse events to discharge are listed in Table 3. Rates of myocardial reinfarction and stroke were low and similar in both groups. The rates of vascular complications requiring surgery and patients needing blood transfusion were low and similar between groups. ICU stay was on average 4 days longer in the patients that were transferred in, but the overall hospitalization duration at the destination hospital was only increased marginally by 2 days (p = 0.08; Table 2.)

The in-hospital and 30-day mortality rates were similar among patients transferred in and directly admitted in AMICS (Figure 1). To evaluate the association between baseline clinical variables and mortality, a multivariable model was constructed. The factors independently associated with 30-day mortality were age, CPR, and STEMI at the time of admission (Table 4). However, neither duration of cardiogenic shock before Impella insertion nor whether patients were transferred was associated with 30-day mortality.

## Discussion

Patients with AMCIS continue to have a high mortality despite the benefits of coronary artery revascularization. Efforts to reduce this mortality using the IABP have proved unsuccessful.[3] A meta-analysis comparing IABP to Impella

Table 2
Procedural characteristics

| Characteristics | All (N = 475 patients) | Direct (N = 273 patients) | Patients transferred (N = 202 patients) | p Value |
|---|---|---|---|---|
| LVEF (%) | | | | |
| Mean ± SD (N) | 25.2 ± 13.3 (358) | 25.6 ± 14.0 (193) | 24.7 ± 12.4 (165) | 0.56 |
| Number of diseased vessels (at least one lesion with ±50% stenosis) | | | | |
| Mean ± SD (N) | 1.7 ± 0.7 (441) | 1.7 ± 0.7 (255) | 1.7 ± 0.7 (186) | 0.28 |
| Number of vessels treated (at least one lesion treated per vessel) | | | | |
| Mean ± SD (N) | 1.5 ± 0.6 (428) | 1.5 ± 0.6 (248) | 1.6 ± 0.6 (180) | 0.07 |
| TIMI flow pre PCI, | | | | |
| 0 | 200 (52.6%) | 141 (58.5%) | 59 (42.5%) | <0.01 |
| 1 | 46 (12.1%) | 21 (8.7%) | 25 (18.0%) | 0.01 |
| 2 | 43 (11.3%) | 20 (8.3%) | 23 (16.6%) | 0.02 |
| 3 | 91 (24.0%) | 59 (24.5%) | 32 (23.0%) | 0.80 |
| TIMI flow post PCI, | | | | |
| 0 | 16 (3.4%) | 10 (3.7%) | 6 (3.0%) | 0.80 |
| 1 | 3 (0.6%) | 0 (0.0%) | 3 (1.5%) | 0.08 |
| 2 | 62 (13.2%) | 31 (11.5%) | 31 (15.5%) | 0.22 |
| 3 | 388 (82.7%) | 228 (84.8%) | 160 (80.0%) | 0.22 |
| Angiographic success (as residual stenosis <30% after stent implant) | 469 (98.7%) | 270 (98.9%) | 199 (98.5%) | 0.70 |
| Impella type | | | | |
| Impella 2.5 | 274 (57.7%) | 58.2 (159) | 56.9 (115) | 0.78 |
| Impella CP | 201 (42.3%) | 41.8 (114) | 43.1 (87) | 0.78 |
| Impella access | | | | |
| Femoral | 393 (98.5) | 233 (99.2) | 160 (97.6) | 0.23 |
| Sub-clavian or axillary | 6 (1.5) | 2 (0.9) | 4 (2.4) | 0.23 |
| Onset of AMI to first balloon inflation (hours) | | | | |
| Mean ± SD (N) | 22.2 ± 51.6 (206) | 14.9 ± 48.7 (125) | 33.4 ± 54.2 (81) | 0.01 |
| Onset of CS to Impella start (hours) | | | | |
| Mean ± SD (N) | 19.3 ± 50.5 (211) | 12.3 ± 45.8 (130) | 30.6 ± 55.8 (81) | 0.01 |
| Duration of device support (hours) | | | | |
| Mean ± SD (N) | 35.9 ± 44.2 (406) | 34.8 ± 48.3 (226) | 37.4 ± 38.6 (180) | 0.55 |
| ICU stay (days) | | | | |
| Mean ± SD (N) | 9.0 ± 13.0 (390) | 7.4 ± 8.4 (222) | 11.1 ± 17.1 (168) | 0.01 |
| Duration of Index hospitalization (days) | | | | |
| Mean ± SD (N) | 11.8 ± 17.5 (471) | 10.6 ± 16.8 (271) | 13.5 ± 18.3 (200) | 0.08 |

AMI = acute myocardial infarction; CPR = cardiopulmonary resuscitation; ICU = intensive care unit; LVEF = left ventricular ejection fraction; NSTEMI = non-ST segment elevation myocardial infarction; STEMI = ST-segment elevation myocardial infarction.

Table 3
In-hospital adverse events

| Characteristics | All (N = 475 patients) | Direct (N = 273 patients) | Patients transferred (N = 202 patients) | p Value |
|---|---|---|---|---|
| Death | 241 (50.7%) | 146 (53.5%) | 95 (47.0%) | 0.19 |
| Myocardial infarction | 5 (1.1%) | 1 (0.4%) | 4 (2.0%) | 0.17 |
| CVA/Stroke | 17 (3.6%) | 10 (3.7%) | 7 (3.5%) | 1.00 |
| Acute Renal dysfunction | 119 (25.1%) | 64 (23.4%) | 55 (27.2%) | 0.40 |
| Revascularization (including emergent CABG) | 7 (1.5%) | 3 (1.1%) | 4 (2.0%) | 0.47 |
| Bleeding requiring transfusion | 60 (12.6%) | 35 (12.8%) | 25 (12.4%) | 1.00 |
| Vascular complication requiring surgery | 35 (7.4%) | 16 (5.9%) | 19 (9.4%) | 0.16 |

Acute renal dysfunction is defined as “Abnormal kidney function requiring dialysis (including hemofiltration) in patients who did not require this procedure prior to implant, or a rise in serum creatinine of greater than 2 times baseline or greater than 2.5 mg/dL” CVA indicates cerebrovascular accident.

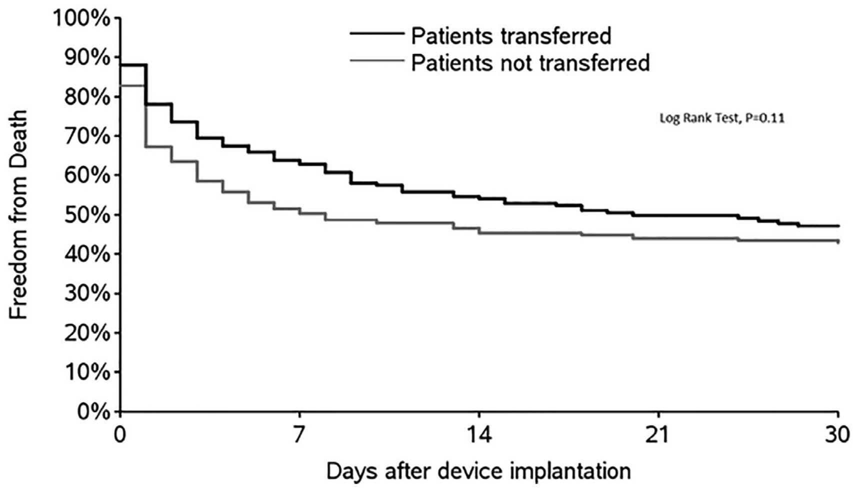


Figure 1. Kaplan-Meier curve for freedom from death (to 30 days).

in shock showed similar all-cause mortality at 30 days.[5] To date, no large randomized trials of mechanical circulatory support with Impella have been reported. In addition, a comparison of routine Impella support for patients directly admitted to the hospital in AMICS versus those transferred and treated has not occurred. Our experience, the largest of its kind in patients in cardiogenic shock with the Impella support device, offers this opportunity. Several important trends emerge in this registry.

First, transfer of critically ill patients in shock for Impella supported PCI is a viable strategy. A previous analysis from the ACC/NCDR Cath PCI registry has shown that more patients in AMICS are being treated with PCI at lower volume centers.[6] This is despite a direct relation between volume and survival in cardiogenic shock.[7] This volume survival relation has also been demonstrated with Impella from the (IQ) registry.[8] The benefits of a regional transfer strategy have been shown for STEMI and include an increased proportion of patients who are transferred to PCI capable hospitals and improvement in door-to-balloon time delays of transfer.[9] It is because of these successes that the American Heart Association has recommended similar research into a hub-and-spoke care system for cardiogenic shock in the form of prospective registries, such as cVAD.[4,10]

Second, patients who are in prolonged shock may still derive benefit from treatment. This group of patients has historically been excluded from randomized trials of AMICS. The SHOCK trial excluded patients who were diagnosed with shock and were not randomized within 12 hours.[2] Both IABP-SHOCK II and CULPRIT-SHOCK had similar exclusion criteria for those patients in shock beyond 12 hours.[3,11] In our study, the average time from onset of shock to Impella start in the transferred group was 30.6 ± 55.8 hours. In addition, shock >24 hours was not an independent predictor of death. Further insights into the impact of time to shock on outcomes will be elucidated from studies investigating the protocolized care of AMICS patients.[12]

The similar mortality between groups seen in our registry differs from previous data with Impella in AMICS. An earlier analysis of the cVAD registry suggested that early initiation of mechanical support may improve outcomes.[13] A meta-analysis of the reported trials of Impella in AMICS showed similar findings.[14] Finally, data from the IMPRESS trial which randomized patients in AMICS to IABP versus Impella showed a trend, although not statistically significant, of improved survival when support was initiated prerevascularization.[15] One explanation for this difference may be selection bias, in that patients who are considered unlikely to survive with advanced hemodynamic support due to co-morbidities are not transferred regardless of time in shock. This phenomenon has been shown in a previous registry comparing outcomes of patients with AMICS who were transferred versus treated at the admitting hospital.[16] In

Table 4
Univariate and multivariate logistic regression of in-hospital mortality and transfer status in AMICS

| Variable | Univariate OR and (95% CI) | p Value | Multivariate OR and (95% CI) | p Value |
|---|---|---|---|---|
| CPR | 3.79 (2.58-5.59) | <0.01 | 4.02 (2.64-6.12) | <0.01 |
| Age (per year) | 1.04 (1.02-1.05) | <0.01 | 1.05 (1.03-1.07) | <0.01 |
| Diastolic BP (per mm Hg) | 0.99 (0.98-1.00) | 0.01 | 1.00 (0.99-1.01) | 0.36 |
| STEMI | 1.62 (1.11-2.37) | 0.01 | 1.71 (1.10-2.67) | 0.02 |
| Systolic BP (per mm Hg) | 0.99 (0.99-1.00) | 0.07 | | |
| Duration of shock to Impella (hours) | | | | |
| 6-12 | 1.17 (0.62-2.22) | 0.18 | | |
| 12-24 | 0.66 (0.34-1.25 | 0.32 | | |
| >24 hours | 0.66 (0.41-1.06) | 0.19 | | |
| Male | 0.79 (0.51-1.20) | 0.27 | | |
| Heart rate (per beat) | 1.00 (0.99-1.01) | 0.33 | | |
| Diabetes | 1.20 (0.83-1.73) | 0.34 | | |
| PVD | 0.81 (0.49-1.36) | 0.25 | | |
| Transferred vs not transferred | | | 0.91 (0.59-1.38) | 0.64 |

CPR = cardiopulmonary resuscitation; PVD = peripheral vascular disease; STEMI = ST-segment elevation myocardial infarction.

our study, patients treated at their index hospital had higher rates of CPR, and were more often in shock on admission.

This was a retrospective analysis and therefore suffers from survivor bias. However, the outcomes in this analysis are very similar to recent quality initiative that included all patients with AMICS.[8] The high frequency of anoxic brain injury seen in this registry (almost 20%) may have affected the outcomes seen in this report. We are currently working on a report that will address this important group of patients in AMICS.

## Conclusion

Patients who are transferred for treatment of AMICS with Impella supported PCI have similar mortality to those patients who are treated directly at the tertiary hospital. This is despite a prolonged time in cardiogenic shock. Further study of the impact of "door to support" on mortality in AMICS is warranted.

## Author Disclosures

Dr. Cohen is a consultant for Abiomed, Dr. Basir has received research funding from Abiomed, Dr. Schreiber serves as a consultant to Abiomed and is on the steering committee for the CVAD registry, Dr. Kapur has received research funding from Abiomed and is on steering committee for the CVAD registry, Dr. Dixon is on the steering committee for the CVAD registry, Dr. Ohman is on the steering committee for the CVAD registry, Dr. William O'Neill serves as a consultant to Abiomed and is on the steering committee for the CVAD registry, Dr. Brian O'Neill, Dr. Khandelwal and Dr. Grines have no relevant financial disclosures to this article.

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## Supplementary materials

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