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Outcomes of mechanical circulatory support for acute myocardial infarction complicated by cardiogenic shock

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Abstract

Background: Mechanical circulatory support (MCS) with the Impella device (Abiomed, Danvers, MA) has been associated with higher in-hospital mortality than intra-aortic balloon pump (IABP) in the Premier Healthcare Database and National Cardiovascular Data Registry.

Methods: The objective of this retrospective cohort study was to describe trends and outcomes of Impella usage in acute myocardial infarction complicated by cardiogenic shock (AMICS) treated with MCS (Impella or IABP) using real-world observational data from the National Inpatient Sample (NIS) including hospitalizations for AMICS managed with MCS between January 2012 to December 2017. The primary outcomes included in-hospital mortality, transfusion, acute kidney injury, stroke, total costs, and length of stay. Propensity score matching was performed with hierarchical models using risk factor and Elixhauser comorbidity variables.

Results and Conclusion: We identified 54,480 hospitalizations for AMICS managed with MCS including 5750 (10.5%) utilizing Impella. Throughout the study period, Impella usage increased yearly to 19.9% of AMICS cases in 2017. After propensity score matching, Impella was associated with higher in-hospital mortality (odds ratio [OR] 1.74, 95% confidence interval [CI] 1.41–2.13) and transfusions (OR 1.97, 95% CI 1.40–2.78) than IABP, without association with acute kidney injury or stroke. Impella use was associated with higher hospital costs (mean difference \$22,416.80 [95% CI \$17,029–27,804]). Impella usage for AMICS increased

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CONFLICT OF INTEREST

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

significantly from 2012 to 2017 and was associated with increased in-hospital mortality and costs. Randomized controlled trials are urgently needed to assess the safety and efficacy of Impella.

Keywords

acute myocardial infarction/STEMI; cardiogenic shock; ECMO/IABP/tandem/impella; mechanical circulatory support

1 | INTRODUCTION

Acute myocardial infarction complicated by cardiogenic shock (AMICS) is associated with 30-day mortality around 50%.¹ Intravascular microaxial left ventricular assist devices can provide up to 5 liters per minute of flow, greater hemodynamic support than intra-aortic balloon pumps (IABPs).² Numerous studies confirm the hemodynamic effects of the Impella device (Abiomed, Danvers, MA) in the setting of cardiogenic shock and high-risk percutaneous coronary intervention (PCI).³⁻⁵ Whether these hemodynamic effects translate to sustained clinical survival benefit remains less well characterized.⁶⁻⁹

Current cardiogenic shock guidelines condone the use of mechanical circulatory support (MCS) devices such as Impella or IABP based on observational data suggesting improvement in mortality.¹⁰ However, the landmark IABP-SHOCK II trial (Intra-aortic Balloon Pump in Cardiogenic Shock II) showed no mortality benefit for IABP use in AMICS.^{2,11} Recently, Amin et al. published a real-world observational study comparing Impella and IABP in patients undergoing PCI: they found an association between Impella utilization and higher rates of death and stroke.⁶ Furthermore, in patients undergoing PCI for AMICS, Dhruva et al. showed increased in-hospital mortality and bleeding associated with Impella utilization.¹² Therefore, we sought to compare outcomes in a large, real-world, nationally representative dataset between Impella and IABP among patients presenting with AMICS.

2 | METHODS

2.1 | Data

The National Inpatient Sample (NIS) from the Agency for Healthcare Research and Quality (AHRQ) includes discharge-level data from approximately eight million annual hospitalizations from 28 U.S. states. Adult patients (age ≥ 18) hospitalized for AMICS from January 2012 through December 2017 were selected utilizing International Classification of Diseases, Ninth and Tenth Revision, Clinical Modification (ICD-9-CM and ICD-10-CM) codes among the first three admission diagnoses (Supplement Figure 1). From this population, we identified patients who underwent Impella or IABP placement during the hospital course. To be included in the study patients in both arms could have cardiogenic shock, cardiac arrest, or both. Propensity matching included the presence of cardiac arrest. Patients who received both devices were excluded for purposes of direct comparison. This study was exempt from the Yale University institutional review board because NIS is publicly available, deidentified data.

2.2 | Variables

Patient demographics and hospital characteristics including age, sex, race, payor, hospital location and size, and length of stay were obtained from NIS. Clinical characteristics (hypertension, diabetes, hyperlipidemia, chronic kidney disease, ST-elevation myocardial infarction) and hospital course (ventricular tachycardia, ventricular fibrillation, respiratory failure, acute kidney injury, sepsis) were determined using ICD-9-CM and ICD-10-CM codes (Supplement Table 1). Elixhauser mortality risk score was derived using 29 comorbidity classification variables, each defined by a list of ICD-9/10-CM codes.¹³ Procedures (PCI, cardiopulmonary resuscitation, transfusion of blood products) and MCS devices (Impella and IABP) were identified using the ICD-9 and ICD-10 procedure coding system (ICD-9/10-PCS). Primary outcomes were in-hospital mortality, transfusions, acute kidney injury, stroke, and length of stay. Transfusions, acute kidney injury, and stroke were derived using ICD-9/10-CM and ICD-9/10-PCS codes (Supplement Table 1).

2.3 | Statistical analysis

National admission trends were approximated using weight trends recommended by the AHRQ for analysis of survey data.¹⁴ We compared survey-specific statements (e.g., SURVEYFREQ, SURVEYMEANS) for descriptive statistics, and discharge weights were used to obtain national estimates.⁸ Temporal trends for proportion of Impella use (annual number of Impella hospitalizations divided by total hospitalizations included) were evaluated for the study time period. The Cochran-Armitage trend test was used to determine the annual trend in the proportion of Impella use. Next, we compared baseline patient characteristics and hospital course using the *Rao-Scott* χ^2 -test for categorical variables and survey-specific *t*-tests for continuous variables. Total hospital charges and cost-to-charge ratio files were used to determine average costs. Missing cost data and extreme outliers (<1% or >99%) were removed.

Lastly, we used propensity score matching to account for differences between patients who received Impella versus IABP. Hospitalizations with Impella use were matched by logit of propensity score using a greedy neighbor approach with a caliper distance of 0.25 times the SD of the logit of the propensity score using a *proc PSMATCH* statement. Propensity score matching included patient demographics (age and sex), and other risk variables (hypertension, hyperlipidemia, diabetes, coronary artery disease, chronic kidney disease, congestive heart failure, ST-elevation myocardial infarction, cardiac arrest, cardiopulmonary resuscitation, and PCI). Elixhauser comorbidity classification software was used to derive variables used in the propensity score matching (chronic pulmonary disease, peripheral vascular disease, fluid/electrolyte disorders, obesity, coagulation deficiency, and blood loss). After matching, we used survey logistic regression to compare primary outcomes. All analyses were performed using SAS version 9.4 (Cary, NC) with a 2-tailed *p* value of 0.05 for statistical significance. Regional heatmaps were generated with Python 3.6 (Wilmington, DE) using the Plotly package.

3 | RESULTS

Between January 2012 and December 2017, the NIS recorded 54,480 hospitalizations for AMICS managed with either Impella (10.6%) or IABP (89.4%). There were no significant differences in age, gender, or race between the Impella and IABP groups. Patients receiving Impella were less likely to have hypertension, hyperlipidemia, coronary artery disease, chronic obstructive pulmonary disease, congestive heart failure, and atrial fibrillation and more likely to have peripheral artery disease. Small and medium sized hospitals were less likely to use Impella during the study period than larger hospitals. Regarding in-hospital events, patients receiving Impella had more acute kidney injury, cardiac arrest, arrhythmias, respiratory failure, sepsis, and stroke; were more likely to undergo PCI, transfusions, and CPR; and had a longer length of stay. Details of patient demographics, comorbidities, and hospital courses appear in Supplement Tables 2 and 3.

MCS device utilization increased in all regions of the United States except the Northeast. The greatest increase occurred in the Southern region (Figure 1(A)). Overall, the proportion of Impella use increased approximately 5-fold from 4.1% in 2012 to 19.9% in 2017 (p for trend <0.01) (Figure 1(B)), while the proportion of IABP use declined from 92% to 76%. Based upon annual Elixhauser mortality risk scores (Supplement Figure 2), Impella use over the study period accelerated most in patients who were younger with fewer comorbidities.

After propensity score matching, there were 5750 matched pairs with mean difference of <0.05 for all matched covariates (Table 1). In the study population, 345 (8.9%) hospitalizations in the Impella arm had cardiac arrest, while 1170 (6.5%) in the IABP arm had cardiac arrest; these diagnoses were not mutually exclusive. Following propensity matching, cardiac arrest was present in 22%–23% of patients in each arm (OR 0.96, 95% CI 0.79–1.17). Overall, matched pairs showed no statistically significant differences in demographics, comorbidities, or in-hospital events except for respiratory failure (52.6% for Impella versus 46.1% for IABP, $p < 0.01$). After propensity score matching, Impella use was still associated with increased in-hospital mortality (OR 1.73 [95% CI 1.41–2.13]) and transfusions (OR 1.97 [95% CI, 1.40–2.78]) (Table 2). There were no significant differences in acute kidney injury (OR 1.12 [95% CI, 0.95–1.32]) or stroke (OR 1.10 [95% CI, 0.67–1.80]) between the groups. Impella use was associated with increased hospital costs (mean difference \$22,416.80 [95% CI \$17,029–\$27,805]) compared to IABP. Mean length of stay was numerically longer for Impella without reaching statistical significance (mean difference 0.86 days, 95% CI [–0.31 to 2.02]).

4 | DISCUSSION

In this large U.S. national database, there was a 5-fold increase in Impella implantation in patients presenting with AMICS from 2012 to 2017. However, Impella was associated with greater in-hospital mortality, blood transfusion, and hospital costs than IABP. The association with increased mortality remained in a propensity score matched analysis. The study aimed to compare outcomes of IABP and Impella as the primary strategy in a billing dataset, as such patients who received both IABP and Impella were excluded from our study. The methods and results model the prior studies performed in observational datasets, which

also excluded patients who received both devices.^{6,15} Unfortunately, given the limitations of the data available, inclusion of these patients would result in undue speculation rather than further insight. For example, the use of both devices could indicate that IABP failed, IABP caused harm, initial Impella placement attempt was unsuccessful, or the patient was too sick and Impella was used as salvage and did not further add to the risk profile. Indeed, it would be difficult to speculate as to the reasons for using both devices and, resultantly, difficult to explain the effect on mortality. Additionally, patients receiving Impella were more likely to receive care at tertiary centers. However, in a prior study, Amin et al. reported that there was wide variation in Impella use across hospitals even after propensity matching (>5 fold variation).⁶ Therefore, we did not adjust for hospital size in our propensity matching, focusing on matching at the patient level rather than at the hospital level.

Cardiogenic shock complicates between 5% and 10% of acute myocardial infarction with incidence increasing.^{16,17} Despite marked improvements in cardiac care over the past 30 years, there have been unchanging mortality rates in AMICS^{18–20} and few evidence-based therapies available for improved survival beyond early revascularization.^{19,21–23} Thus, there is clearly a need for MCS devices that can improve outcomes in this population. In line with evidence that IABP provides no survival benefit in AMICS over medical therapy alone,² we found IABP use declining over the study period. Impella provides a promising—but under-investigated—alternative.

Despite its theoretical hemodynamic superiority, Impella has been consistently associated with similar or higher mortality than IABP in this and prior smaller studies.^{6,8} Previously published data are limited to single arm registry studies, small trials, and retrospective comparisons. An initial 2013 multicenter registry feasibility study of Impella in very high-risk patients showed 30-day mortality around 64%.²⁴ A small (n = 48) exploratory randomized, open-label prospective trial (IMPRESS) showed similar survival rates between Impella (50%) and IABP (46%) at 30 days but higher bleeding rate in the Impella group among a population of patients who were critically ill with a majority having cardiac arrest.²⁰ Pooled analyses of smaller trials showed no difference in 30-day mortality between percutaneous ventricular assist devices including Impella compared to IABP.^{20,25} Subsequent retrospective data comparing matched patients from the IABP-SHOCK trial showed equivalent 30-day mortality rates with Impella (48.5%) and IABP (46.3%).²⁶ Prospective, single-arm registry data does suggest improved survival with earlier compared to later device implantation,^{4,5} however the overall survival rate to hospital discharge in one registry was 44%⁴ and 53% survival to device explant in the other,⁵ similar to mortality rates without Impella from other trials between 40% and 50%.^{2,19,27} The present study, the largest of in the field by far, builds upon the landscape of prior observational studies suggesting no improvement in AMICS mortality using Impella versus IABP.²⁸ In fact, compared to IABP, which provides no survival benefit over medical therapy,² Impella exhibited a signal for harm in this study and others.^{6,15} Building on previous studies, this study adds to existing literature adding propensity matching to help to control for unmeasured confounders.

The findings of this study indicate a pattern of increased Impella usage over the study period, and, unsurprisingly, increased costs attendant to the device usage. Although our data showed a trend toward increased mortality with Impella versus IABP, this may well

have been predominantly a function of case selection wherein sicker patients received Impella support. The intrinsic methodological limitations of the present study preclude firm conclusion whether this mortality observation reflects patient selection or actual contributions of device complications. These findings, however, underscore the need for rigorous, large-scale prospective clinical trials in AMICS patients to evaluate the safety and efficacy of Impella implantation.

5 | LIMITATIONS

This study had several limitations. First, using retrospective observational data may result in selection bias and missing unmeasured confounding factors. Propensity matching can be used to control for some selection bias, but it cannot substitute for a prospective study, where equipoise can be attempted by design. Second, reliance on administrative codes for identification of cardiogenic shock may lead to unrecognized miscoding of diagnostic and procedural information. For example, is not possible to determine whether shock was present on admission or developed during the hospital stay. Additionally, although this study utilized propensity matching, there is a possibility of unmeasured confounders that resulted in Impella patients being sicker than non-Impella patients. In summary, these observational findings underscore the need for high-quality, prospective randomized studies for patients suffering AMICS managed with MCS.

6 | CONCLUSION

This retrospective cohort study describes trends and outcomes of Impella usage in 54,480 hospitalizations for AMICS treated with MCS (Impella or IABP) using real-world observational data. Impella usage increased yearly to 19.9% of AMICS cases in 2017. After propensity score matching, Impella was associated with higher in-hospital mortality and transfusions than IABP, without association with acute kidney injury or stroke, as well as with higher hospital costs. Randomized controlled trials are urgently needed to assess the safety and efficacy of Impella.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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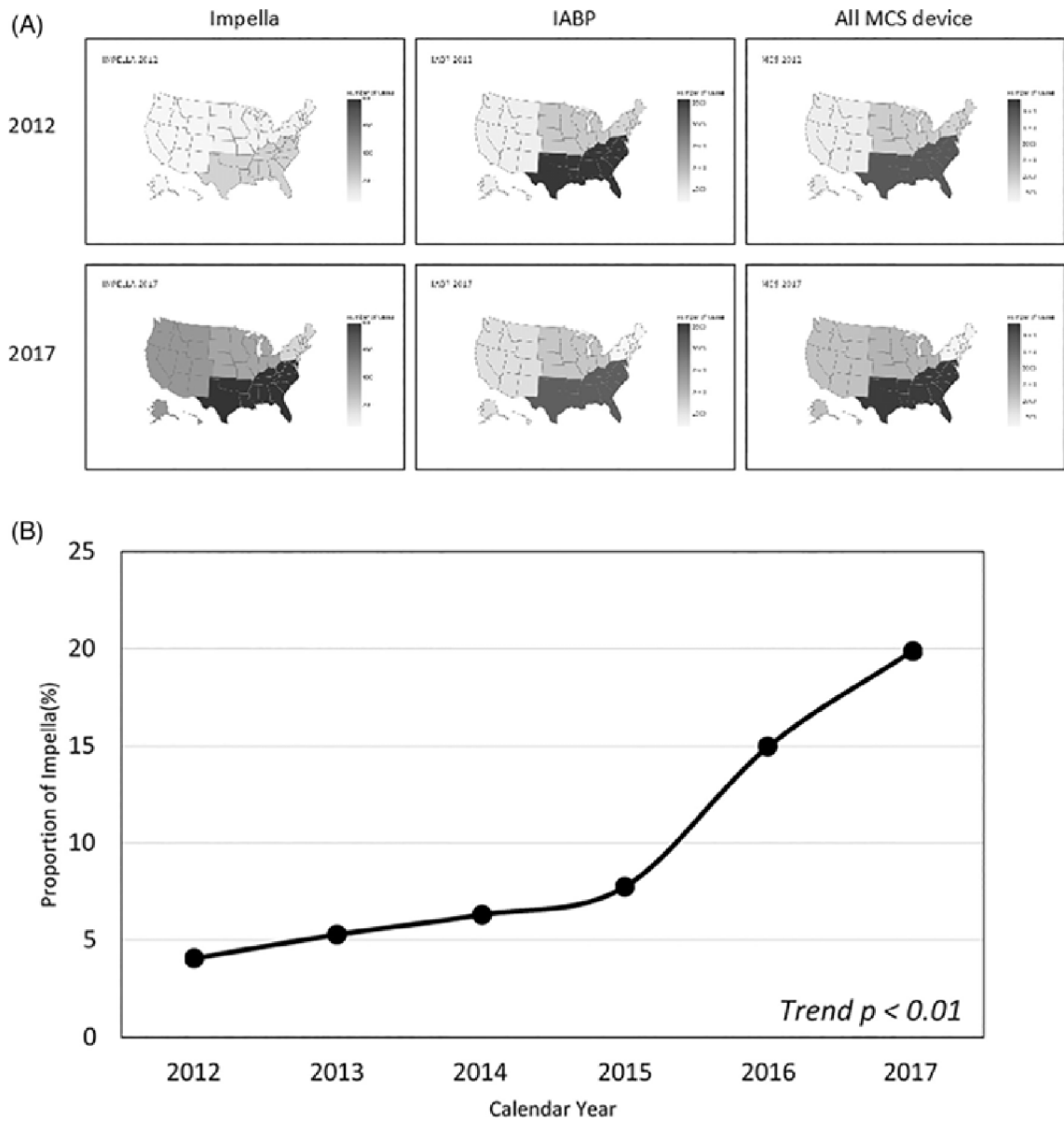


FIGURE 1. Heatmap of Impella, IABP, and total MCS device used in the United States by region in 2012 and 2017 (A) and proportion of Impella use annually (B). IABP, intra-aortic balloon pumps; MCS, mechanical circulatory support

TABLE 1

Propensity score matched patient characteristics (N = 5750 | 5750)

	Impella (%)	IABP (%)	Standardized mean difference (matched variables)	OR 95%CI^a, p-value[±]
Age (years, SD)	64.6 (13)	65.4 (13)	0.03	0.15
Female	31	31	0.00	1.00 (0.83–1.19)
White	70.5	71.0	NA	0.97(0.74–1.29)
Hypertension	44.4	45.6	0.02	0.96 (0.81–1.13)
Hyperlipidemia	46.5	46.1	0.01	1.02 (0.86–1.20)
Diabetes	39.0	38.0	0.02	1.04(0.88–1.23)
CKD	22.8	24.4	0.04	0.92 (0.76–1.11)
CAD	84.5	86.4	0.05	0.86 (0.68–1.09)
CHRN/LUNG	17.3	17.8	0.01	0.96 (0.78–1.20)
CHF	45.1	45.1	0.00	1.00 (0.85–1.18)
PVD	16.0	17.6	0.04	0.89 (0.72–1.11)
Obesity	13.6	13.7	0.00	0.99 (0.78–1.26)
Fluid disorders	50.1	49.5	0.01	1.02 (0.87–1.21)
Coagulopathy	21.7	20.1	0.04	1.01 (0.90–1.34)
Blood loss	1.4	1.8	0.04	0.76 (0.39–1.46)
STEMI	63.5	63.0	0.01	1.02 (0.86–1.21)
AKI	44.1	41.3	NA	1.12 (0.95–1.32)
Cardiac arrest	22.1	22.8	0.02	0.96 (0.79–1.17)
PCI	73.8	74.9	0.02	0.95 (0.79–1.14)
VT	21.9	19.0	NA	1.20 (0.98–1.47)
CPR	10.7	10.9	0.01	0.98 (0.75–1.28)
Transfusions	8.7	4.6	NA	1.97 (1.40–2.78)
Respiratory failure	52.6	46.1	NA	1.30(1.10–1.53)
Sepsis	7.1	7.0	NA	1.01 (0.74–1.39)
Stroke	3.0	2.7	NA	1.10 (0.67–1.80)
Length of stay ^b (days, SD)	11.4 (12)	10.5 (10)	NA	0.15
Death	24.6	15.9	NA	1.73 (1.41–2.13)
Hospital costs (USD, SD)	73,172.80 (68,730)	50,756.00 (61,805)	NA	<0.01

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Abbreviations: AKI, acute kidney injury; CAD, coronary artery disease; CHRNLUNG, chronic lung disease (Elixhauser variable); CHF, congestive heart failure; CI, confidence interval; CKD, chronic kidney disease; CPR, cardiopulmonary resuscitation; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease (Elixhauser variable); STEMI, ST-elevation myocardial infarction; USD, US dollars; VT, ventricular tachycardia.

^aBased on univariate analysis derived from 2 × 2 contingency tables

[‡]2 tailed student's *t*-test; NA, not matched by propensity score matching.

^bLength of stay evaluated only in patients discharged from hospital stay.

TABLE 2
Primary outcomes in propensity score matched cohort and unmatched study population

Outcome(s)	Matched cohort OR (95%CI) ^a	Unmatched cohort OR (95%CI)*
Death	1.74(1.41–2.13)	2.07 (1.79–2.44)
Transfusions	1.97 (1.40–2.78)	1.94 (1.55–2.44)
Acute kidney injury	1.12 (0.95–1.32)	1.36 (1.20–1.54)
Stroke	1.10 (0.67–1.80)	1.28 (0.89–1.85)
Continuous outcome (mean difference [95%CI])		
Length of stay (days)	0.9 (–0.31–2.02)	1.23 (0.41–2.05)
Total hospital cost	\$22,416.80 (17,029–27,804)	\$25,746.00 (21,632–29,859)

Abbreviations: CI, confidence interval; OR, odds ratio.

^aBased on univariate analysis.