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ORIGINAL RESEARCH

National Use Patterns and Comparative Effectiveness of Extracorporeal Membrane Oxygenation in Myocardial Infarction–Related Cardiogenic Shock

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BACKGROUND: Extracorporeal membrane oxygenation (ECMO) provides bi-ventricular support for patients with myocardial infarction–related cardiogenic shock (MI-CS); comparative effectiveness data relative to other mechanical circulatory support remain limited. We characterize contemporary ECMO utilization for MI-CS and compare short-term mortality across ECMO and non-ECMO treatment strategies.

METHODS: We compared baseline characteristics and temporal trends in mechanical circulatory support utilization among Medicare beneficiaries hospitalized with MI-CS from 2016 to 2023 and treated with ECMO, Impella, intra-aortic balloon pump, or medical management alone. Patient outcomes for each group were evaluated using inverse probability of treatment weighting, G-formula approach, and grace period analysis. The primary endpoint was 30-day all-cause mortality.

RESULTS: The cohort included 102 718 patients: 1165 (1.1%) treated with ECMO, 10 064 (9.8%) Impella, 24 631 (24.0%) intra-aortic balloon pump, and 66 858 (65.1%) medical management alone. From 2016 to 2023, ECMO use for MI-CS increased from 0.8% to 1.8%. The percentage of hospitals using ECMO increased from 9.2% to 17.1%. Unadjusted 30-day mortality was higher for ECMO (69%) compared with Impella (60%), intra-aortic balloon pump (39%), and medical management (46%) (all $P<0.0001$). Adjusted inverse probability of treatment weighting and G-formula analyses revealed a 30-day mortality rate of 68%–70% for ECMO, which was higher than that for other therapies. The grace period analysis revealed similar mortality between patients treated with ECMO (54%) and Impella (54%).

CONCLUSIONS: ECMO use in a contemporary Medicare cohort of patients with MI-CS was infrequent (1.1%) and associated with high 30-day mortality. Despite use of complementary causal inference methods, we were unable to establish valid causal inferences on ECMO use and patient survival.

Key Words: cardiogenic shock ■ comparative effectiveness ■ ECMO

Despite advancements in the care of patients with myocardial infarction–related cardiogenic shock (MI-CS), mortality rates remain as high as 30%–50%. MI-CS is often managed with percutaneous mechanical circulatory support (MCS) devices to provide hemodynamic support and increase tissue perfusion.[1–4] There are a variety of MCS device platforms, including intra-aortic balloon pumps (IABPs)

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RESEARCH PERSPECTIVE

What Is New?

- In this study of Medicare beneficiaries with myocardial infarction–related cardiogenic shock, extracorporeal membrane oxygenation use was infrequent, but increased from 0.8% to 1.8% between 2016 and 2023.
- Despite the use of complementary causal inference methods including inverse probability treatment weighting, G-formula analyses, and grace period analyses, we were unable to establish valid causal inferences on extracorporeal membrane oxygenation use and patient survival because of limitations in the granularity of Medicare administrative claims.

What Question Should Be Addressed Next?

- It will be important for future studies to evaluate the feasibility of using purpose-built cardiogenic shock registries to evaluate the comparative effectiveness of mechanical circulatory support devices among Medicare-age adults.

Nonstandard Abbreviations and Acronyms

CS	cardiogenic shock
FDA	US Food and Drug Administration
IABP	intra-aortic balloon pump
MI-CS	myocardial infarction–related cardiogenic shock
MCS	mechanical circulatory support

and percutaneous microaxial flow pumps, both of which are intended to support the left ventricle. Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) has increasingly been used in MI-CS in recent years and can provide biventricular support and oxygenation, which may be advantageous in circumstances such as biventricular dysfunction and profound hypoxemia.[5–8]

Because of the acute presentation of cardiogenic shock (CS), need for rapid clinical decision making, and frequent inability of CS patients to participate in the informed consent process, CS clinical trials are very challenging to run.[9] These challenges have limited the completion of adequately powered, US-based, randomized clinical trials in patients with MI-CS over the past 2 decades. The ECLS-SHOCK (Extracorporeal Life Support in Cardiogenic Shock) trial, the largest randomized controlled trial to evaluate VA-ECMO in MI-CS, was only conducted outside the United States, in Germany and Slovenia. This trial revealed that the routine use of VA-ECMO did not result in an improvement in mortality for patients with MI-CS compared with medical therapy alone.[6] ECLS-SHOCK, while informative, enrolled a highly selected population of younger patients, almost 80% of whom required cardiopulmonary resuscitation, and may have limited generalizability to the broader US MI-CS population. The enrollment of exclusively younger patients is a particularly important limitation given that age is one of the most important risk factors for developing MI-CS and for mortality in MI-CS.[10] Furthermore, analyses of other MCS devices suggest that older adults may derive less benefit from routine MCS use in MI-CS, highlighting the need for age-specific evidence.[11] Additionally, ECLS-SHOCK primarily compared VA-ECMO to medical therapy and not to other mechanical circulatory support (MCS) devices (such as microaxial flow pumps).

As of June 30, 2026, based on publicly available sources, we are unaware of planned randomized trials designed to examine VA-ECMO in MI-CS in the United States, which makes leveraging observational data to inform practice critical. However, observational studies evaluating MCS devices in cardiogenic shock patients may be particularly susceptible to both residual confounding and immortal time bias.[12] In this study, our objectives were to: (1) examine the contemporary utilization of VA-ECMO in patients with MI-CS using a large national US-based data set; (2) explore the feasibility of estimating the treatment effect of VA-ECMO compared to alternative MI-CS therapies using causal inference techniques.

METHODS

The data underlying this analysis are not publicly available because of data use agreement restrictions. The statistical analysis plan was pre-specified and collaboratively developed by researchers at the Smith Center for Outcomes Research at Beth Israel Deaconess Medical Center and the FDA.

Study Aims

MI-CS is a rapidly evolving disease state with a large proportion of cases progressing to more severe shock stages during the index hospitalization.[13,14] Our first aim was to describe trends and patterns of MCS use in MI-CS. Next, we sought to evaluate the comparative effectiveness of VA-ECMO in 3 ways: 1) comparing patients treated with VA-ECMO within the first 2 days of admission to those treated with alternative strategies, 2) comparing the outcomes of VA-ECMO versus alternatives

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within the first 2 days of admission among patients for whom the treatment received was driven by local practice preferences at a given hospital, and 3) comparing patients treated with VA-ECMO within the first 7 days of admission to those treated using alternative strategies (Table S1). Comparator groups included patients treated with IABP, microaxial flow pump, or medical treatment only. For all analyses, time zero was designated as the time of hospital admission. Hereafter, the VA-ECMO configuration will be referred to as "ECMO" and the microaxial flow pump platform will be referred to as "Impella."

Study Population

We used 100% inpatient Centers for Medicare & Medicaid Services claims files for Medicare fee-for-service patients between January 1, 2016, and December 31, 2023, to identify our patient population. The study began in 2016 to ensure *International Classification of Diseases, Tenth Revision (ICD-10)* codes were fully established and ended in 2023 since that was the latest data available at the time of the analysis. Patients were identified as MI-CS if they had a primary diagnosis code of MI (*ICD-10* code I21.XX) and a secondary diagnosis code of cardiogenic shock (*ICD-10* code R57.0). The *ICD-10* codes used to identify ECMO were "5A15223" and "5A1522G," Impella were "5A0221D" and "5A0211D," and IABP were "5A02210" and "5A02110." For the comparison of baseline characteristics and trends in MCS use over time, we excluded patients who did not have Medicare claims data for 1 year before the index hospitalization. For the comparative effectiveness analysis, we used data from 2016 to 2022 and additionally excluded patients for the following reasons: (i) missing covariates; (ii) admission to hospitals caring for <10 patients with MI-CS during the study period; and (iii) admission to hospitals that did not provide all treatment modalities [medical therapy, IABP, Impella, and ECMO]. We also selected a subset of the patients with MI-CS who could be linked to the American Hospital Association hospital survey file and had complete covariate information (Figure S1).

Covariates and Outcomes

Information on patient demographics including age, sex, and race was obtained from the Master Beneficiary Summary File. Patient comorbidities were obtained from the Medicare Chronic Conditions Warehouse. Patients were characterized by the most intensive MCS support received on the day of initial receipt of MCS with ECMO > Impella > IABP. The primary outcome of interest was 30-day all-cause mortality. We also evaluated the 30-day rate of the composite of all-cause mortality and all-cause rehospitalizations, both of which were obtained using vital status and claims data.

Statistical Analysis

To demonstrate temporal trends in ECMO use in MI-CS, we first evaluated the annual rate of use of each MCS type among all patients who were admitted with MI-CS from 2016 to 2023 and had ≥1 year of Medicare claims data. To assess overall MCS utilization across hospitals, we evaluated the percentage of hospitals using each MCS type during each year of the study period. Then, using data from 2016 to 2022, we compared baseline characteristics between individuals receiving each MCS type and determined how often individuals received multiple MCS therapies. In patients who received >1 MCS device, we determined the sequence of addition of each therapy.

To evaluate the comparative effectiveness of initiating treatment within 2 days of admission, inverse probability treatment weighting (IPTW) was first employed to adjust for measured differences between treatment groups. Treatment groups were defined as follows: initiation of ECMO, IABP, Impella, or no MCS within 2 calendar days of admission. Patients were categorized according to whichever device treatment they received first; if they received no MCS after 2 days, they were categorized as medical therapy only. To compare individual treatment strategies (ECMO versus no-MCS, IABP, Impella), we used a generalized IPTW analysis allowing for multiple treatment groups. The propensity scores were estimated using a multinomial regression model with the treatment strategies included as a nominal outcome variable and all covariates as the predictors. Each observation was weighted by the inverse of the estimated probability of the treatment received. To improve the statistical efficiency, the top 1% of weights in each treatment group were truncated. Standardized mean differences were used to compare patient characteristics in the original and re-weighted samples, and a standardized mean difference >10% was used to represent a significant difference between groups.

Next, given the potential for misspecification of the propensity score model, we performed a similar comparison using the G-formula approach as a sensitivity analysis. The G-formula approach is a causal inference method that estimates marginal treatment effects by modeling the outcome as a function of treatment and covariates, then standardizing predicted outcomes over the covariate distribution of the full study population.[15] Unlike IPTW, which achieves confounding adjustment through a correctly specified propensity score model, the G-formula relies on a correctly specified outcome model; because the 2 approaches depend on different modeling assumptions, agreement between them provides greater confidence in the resulting estimates. The same risk differences reported from the IPTW approach were calculated, allowing direct comparisons against the IPTW analysis, under different modeling

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assumptions. To estimate the marginal risks, a logistic regression model was built for each treatment strategy using all baseline covariates. For each treatment strategy, the corresponding outcome regression model was employed to estimate the predicted probabilities for all individuals included in the analysis cohort had they been treated by this treatment strategy. The average of these predicted probabilities is the marginal risk of the treatment strategy among the analysis cohort. The same processes were applied to estimate the marginal risk of each treatment strategy.

In the above approach, 2 important sources of potential bias included confounding attributable to unmeasured differences among treatment groups and immortal time bias attributable to post-time zero factors governing treatment group membership. We examined the feasibility of using an instrumental variable approach based on variation in hospital preferences for use of ECMO versus alternative treatments, which, under certain assumptions, can provide valid estimates of treatment effects even in the presence of unmeasured treatment confounders. This approach would help identify the treatment effect among patients whose treatment strategy is "induced" by their presentation at different hospitals. Unfortunately, there was insufficient variation across hospitals in the use of ECMO for MI-CS, which violated the relevance assumption and precluded use of this approach.

Finally, a grace period approach was performed to assess the effectiveness of initiating treatment within 7 days of admission. The 7-day grace period was chosen because 90% of patients in the sample received ECMO within 7 days of hospital admission. Compared with the IPTW and G-formula approaches, grace period analyses are specifically designed to address immortal time bias in conditions such as MI-CS where early mortality rates are high and there is often delayed initiation of treatment. The grace period approach allows for strategy comparisons in which treatment initiation occurs after time zero by cloning each patient into all treatment strategies from time zero and applying censoring only as patients deviate from a given strategy (Data S1).[16,17] This analytical approach helps ensure that early deaths among patients who died before planned receipt of ECMO are not misclassified. The 95% CIs from IPTW, G-formula, and grace period approaches were computed using the nonparametric bootstrap resampling method based on 500 resamplings. All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc, Cary, NC). A P value of <0.05 was selected for statistical significance. This study was reviewed by the Institutional Review Board of Beth Israel Deaconess Medical Center and exempted from oversight under 45 CFR 46.101(b)(4). As this was a retrospective study conducted under an IRB exemption, informed consent was not required.

RESULTS

Trends in ECMO and Other MCS Use in MI-CS

Of the 175 222 Medicare patients admitted with MI-CS from 2016 to 2022, 102 718 patients had ≥1 year of Medicare claims data and were included in the comparison of baseline characteristics among each MCS therapy. Among this cohort, 1165 patients (1.1%) received ECMO, 10064 (9.8%) received Impella, 24 631 (24.0%) received IABP, and 66 858 (65.1%) received medical therapy alone as their most intensive therapy. Patients who received ECMO were younger (mean age ECMO: 68.8 years, Impella: 72.9 years, IABP: 73.7 years, medical therapy: 75.6 years) and more likely to have presented with an ST-segment–elevation myocardial infarction (STEMI) than those who received other therapies (Table 1). Patients who received ECMO were also less likely to have comorbidities including Alzheimer's disease and stroke/transient ischemic attack than other groups. In terms of hospital characteristics, patients who received ECMO were more likely to receive care at hospitals that were larger, metropolitan teaching hospitals, and located in the northeast than patients who did not receive ECMO. Only 2.2% of patients received 2 or more MCS therapies within 2 days of hospital admission (Table 2). Among those who received 2 devices, the most frequent sequence was IABP and Impella on the same day. Out of the 100 patients who received 3 MCS devices, 47% received all devices on the same day.

Temporal trends in the use of each device are shown in Figure 1. The proportion of ECMO use in MI-CS increased from 0.8% of all MI-CS to 1.8% between 2016 and 2023. Use of medical therapy remained relatively constant during the same time period while there was a decrease in IABP use (from 28.0% to 19.6%) and increase in Impella use (from 5.7% to 12.4%) (Figure 1). Most hospitals did not use ECMO throughout the study period but there was a slow increase in the percentage of hospitals offering ECMO (from 9.2% to 17.1%) (Figure 1).

In unadjusted analyses, patients who received ECMO had a higher rate of 30-day all-cause mortality and the composite outcome (death or all-cause readmission) than patients who received Impella, IABP or medical therapy (Table S2). Unadjusted 30-day mortality was 69% for ECMO, 60% for Impella, 39% for IABP and 46% for medical therapy (all P<0.0001 for differences between ECMO and alternative therapies).

Comparative Effectiveness Analysis

Out of the 102 718 patients in the MI-CS sample, 23 658 patients were linked to the American Hospital Association hospital survey file of which 723 (3.1%)

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Table 1. Patient and Hospital Characteristics Stratified by Mechanical Circulatory Support Received

Subject characteristic	ECMO n=1165	Impella n=10 064	IABP n=24 631	Medical therapy n=66 858	SMD (%) ECMO-Impella	SMD (%) ECMO-IABP	SMD (%) ECMO-medical therapy
Demographics							
Age (y)							
Mean±SD	68.8±7.7	72.9±8.8	73.7±9.1	75.6±10.3	−50.0	−57.8	−74.2
Male	70.6%	68.5%	64.6%	58.4%	4.7	12.9	25.8
Race							
White	85.5%	85.5%	85.2%	84.4%	0.1	0.7	3.0
Black	7.5%	6.7%	7.2%	8.4%	3.0	1.4	−3.2
Other	7.0%	7.8%	7.6%	7.2%	−3.1	−2.4	−0.7
Comorbidities							
Prior myocardial infarction	23.9%	26.4%	17.2%	12.0%	−5.8	16.5	31.4
Prior PCI	8.5%	11.7%	10.7%	14.6%	−10.8	−7.6	−19.2
Prior CABG	2.2%	2.7%	2.5%	4.5%	−3.0	−1.7	−12.7
Atrial fibrillation	6.3%	10.4%	8.7%	8.5%	−15.0	−9.4	−8.5
Heart failure	26.4%	37.2%	27.5%	20.8%	−23.4	−2.6	13.1
Stroke/transient ischemic attack	6.1%	12.8%	10.3%	8.8%	−23.2	−15.5	−10.2
Hypertension	40.0%	54.1%	44.4%	31.9%	−28.6	−8.9	16.9
Diabetes	27.5%	38.0%	28.6%	21.6%	−22.6	−2.6	13.7
Alzheimer's disease	1.8%	6.8%	6.6%	6.2%	−24.9	−24.1	−22.4
Chronic kidney disease	23.3%	37.3%	27.6%	22.7%	−30.6	−9.8	1.6
Chronic obstructive pulmonary disease	11.9%	19.6%	17.0%	15.2%	−21.0	−14.5	−9.5
Cancer	6.7%	9.9%	8.8%	6.1%	−11.7	−7.7	2.2
Cardiogenic shock–related factors							
Presenting AMI type							
STEMI	70.4%	65.1%	61.0%	41.1%	11.4	19.8	61.6
NSTEMI	29.6%	34.9%	39.0%	58.9%	−11.4	−19.8	−61.6
Cardiac arrest on presentation	21.1%	18.3%	11.8%	11.3%	7.2	25.5	26.8
RHC/PA catheters	13.4%	12.4%	5.5%	2.5%	2.9	27.1	41.0
Intubation	47.1%	44.7%	27.2%	14.8%	4.9	42.2	74.6
Hospital characteristics							
Hospital size (No. of beds)							
Mean±SD	519.7±342.5	433.6±320.1	412.2±315.9	394.5±305.9	26.0	32.6	38.6
Teaching status							
Metropolitan teaching	77.7%	68.1%	65.8%	63.6%	21.7	26.5	31.2
Metropolitan non-teaching	22.0%	31.4%	33.5%	35.0%	−21.4	−26.0	−29.1
Rural	0.4%	0.5%	0.7%	1.4%	−2.9	−4.4	−11.2
JCAHO accredited	87.0%	85.7%	84.9%	85.0%	3.8	6.2	5.7
Region							
Northeast	28.0%	14.3%	17.0%	16.8%	34.2	26.8	27.3
Midwest	12.5%	16.0%	15.1%	14.1%	−10.0	−7.3	−4.8
South	44.3%	49.8%	49.8%	49.2%	−11.0	−10.9	−9.8
West	15.1%	19.9%	18.2%	19.8%	−12.6	−8.4	−12.6
Racial and ethnic minority-serving hospital	18.8%	22.5%	20.2%	20.9%	−9.3	−3.7	−5.4

AMI indicates acute myocardial infarction; CABG, coronary artery bypass graft; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; JCAHO, Joint Commission on Accreditation of Healthcare Organizations; NSTEMI, non-ST-segment–elevation myocardial infarction; PA, pulmonary artery; PCI, percutaneous coronary intervention; RHC, right heart catheterization; SMD, standardized mean difference; and STEMI, ST-segment–elevation myocardial infarction.

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Table 2. Pattern of Mechanical Support Devices Used in Combination With ECMO

Device use pattern	All patients (n=102 718)
No. of MCS device types used within 2 d of admission	
0	65.1% (66 858/102718)
1	32.7% (33 614/102718)
2	2.1% (2146/102718)
3	0.1% (100/102718)
Single device	
ECMO only	0.9% (311/33614)
Impella only	25.8% (8672/33614)
IABP only	73.3% (24 631/33614)
2 devices	
IABP or Impella with escalation to ECMO*	12.5% (268/2146)
ECMO with secondary device added for venting/additional support†	22.7% (486/2146)
IABP and Impella‡	64.9% (1392/2146)
3 devices	
ECMO with additional devices for venting/additional support§	62.0% (62/100)
Escalation to ECMO‖	38.0% (38/100)

ECMO indicates extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; and MCS, mechanical circulatory support.

*IABP or Impella with escalation to ECMO includes the following device sequences: Impella → ECMO; IABP → ECMO.

†ECMO with secondary device added for venting/additional support includes: Impella and ECMO on same day; ECMO → Impella; IABP and ECMO on same day; ECMO → IABP.

‡IABP and Impella includes: IABP → Impella; IABP and Impella on same day; Impella → IABP.

§ECMO with additional devices for venting/additional support includes: IABP, Impella, and ECMO on same day; IABP and ECMO on same day → Impella; Impella and ECMO on same day → IABP; ECMO → Impella → IABP; ECMO → IABP → Impella; ECMO → IABP and Impella on same day.

‖Escalation to ECMO includes: IABP and Impella on same day → ECMO; IABP → Impella and ECMO on same day; Impella → ECMO → IABP; Impella → IABP and ECMO on same day; IABP → Impella → ECMO; IABP → ECMO → Impella; Impella → IABP → ECMO.

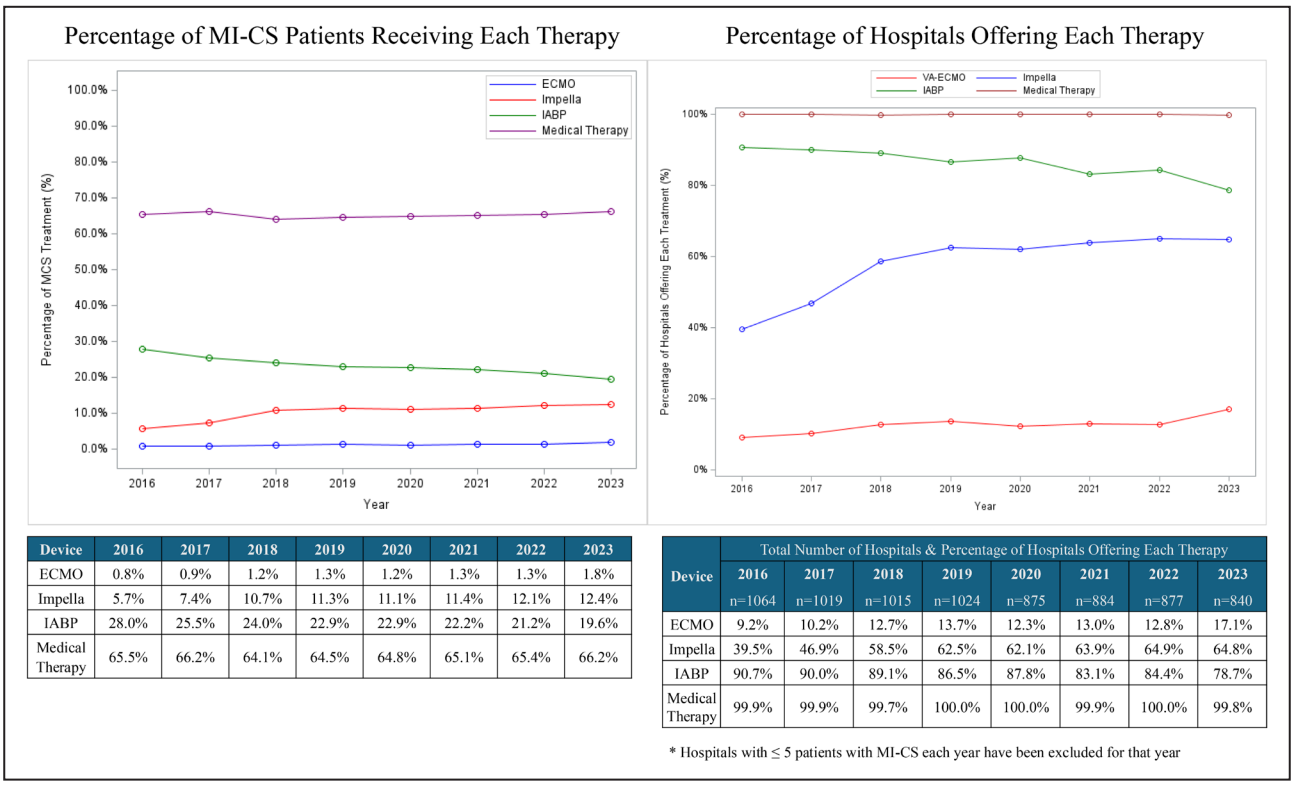
were treated with ECMO, 6042 patients (25.5%) with IABP, 2597 patients (11.0%) with Impella, and 14 296 patients (60.4%) with medical management only (Table S3). Among patients treated with ECMO, 68.5% (n=495) were also treated with at least one additional MCS device (Table S4).

For the IPTW analysis, weighting balanced several differences between the ECMO group and other treatment groups that were present at baseline (Tables S3 and S5). However, there remained some important imbalanced characteristics, including age, heart failure, prior coronary artery bypass graft, hypertension, Alzheimer's disease, chronic kidney disease, and diabetes. The propensity score distributions showed that most patients had a low propensity to receive ECMO (Figure S2). After weighting for baseline confounders, patients who received ECMO had a higher 30-day mortality rate (68.6%, 95% CI: 64.1%–73.6%) compared with Impella (57.4%, 95% CI: 55.0%–59.9%), IABP (36.2%, 95% CI: 35.0%–37.5%), and medical management (43.7%, 95% CI: 43.0%–44.6%) patients (Table 3). The rate of the composite outcome of death or all-cause readmissions at 30 days was also highest in the ECMO group (Table S6). The G-formula approach demonstrated similar findings to the IPTW approach (Figure 2). The grace period analysis showed a 30-day mortality rate of 53.6% (95% CI: 45.1%–64.4%) for ECMO, 53.5% (95% CI: 45.0%–63.5%) for Impella, 39.3% (95% CI: 35.2%–42.3%) for IABP, and 37.9% (95% CI: 35.9%–38.8%) for medical management. In the grace period analysis, there was no difference in the rate of the composite outcome between the ECMO and Impella groups, but the rate was higher in ECMO than in IABP and medical therapy (Table S6).

DISCUSSION

There are limited data on contemporary utilization patterns and outcomes of patients with MI-CS treated with ECMO in the United States. We sought to examine these factors in Medicare patients and explore the use of different causal inference techniques to determine the association of ECMO and clinical outcomes in MI-CS. Our study had 4 key findings: (1) ECMO was infrequently employed as a treatment modality for older adults with MI-CS (1.1%), although its overall use increased from 0.8% to 1.8% from 2016 to 2023. (2) ECMO was often (68.5%) used in conjunction with at least one additional MCS device (IABP or Impella). (3) The observed unadjusted 30-day mortality for patients with MI-CS treated with ECMO was very high at 69% and higher than the mortality rates in patients receiving other MI-CS treatments: Impella (60%), IABP (39%), and medical management (46%). (4) Despite using several methodologies (IPTW, G-formula approach, and grace period analysis), the differing mortality rates across treatment strategies persisted. It is unknown the extent to which these differences reflect true differences versus residual/unmeasured confounding by indication; however, the similar mortality rates across treatment groups observed in recent trials suggest a significant component of confounding in our results. We conclude that Medicare claims data do not capture a sufficient degree of granularity about cardiogenic shock severity, diagnosis, and treatment to allow for advanced statistical methodologies to overcome key biases in comparative effectiveness analyses of MCS use in MI-CS.

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Device	2016	2017	2018	2019	2020	2021	2022	2023
ECMO	0.8%	0.9%	1.2%	1.3%	1.2%	1.3%	1.3%	1.8%
Impella	5.7%	7.4%	10.7%	11.3%	11.1%	11.4%	12.1%	12.4%
IABP	28.0%	25.5%	24.0%	22.9%	22.9%	22.2%	21.2%	19.6%
Medical Therapy	65.5%	66.2%	64.1%	64.5%	64.8%	65.1%	65.4%	66.2%

Device	Total Number of Hospitals & Percentage of Hospitals Offering Each Therapy							
	2016 n=1064	2017 n=1019	2018 n=1015	2019 n=1024	2020 n=875	2021 n=884	2022 n=877	2023 n=840
ECMO	9.2%	10.2%	12.7%	13.7%	12.3%	13.0%	12.8%	17.1%
Impella	39.5%	46.9%	58.5%	62.5%	62.1%	63.9%	64.9%	64.8%
IABP	90.7%	90.0%	89.1%	86.5%	87.8%	83.1%	84.4%	78.7%
Medical Therapy	99.9%	99.9%	99.7%	100.0%	100.0%	99.9%	100.0%	99.8%

* Hospitals with ≤ 5 patients with MI-CS each year have been excluded for that year

Figure 1. Trends in MCS use and hospital utilization of MCS for MI-CS between 2016 and 2023.
Percentage of patients with MI-CS who received ECMO, Impella, IABP, and medical therapy per year and the percentage of hospitals offering each type of MCS over the time period from 2016 to 2023. MI-CS, myocardial infarction cardiogenic shock; ECMO, extracorporeal membrane oxygenation; and IABP, intra-aortic balloon pump.

Our findings add important contextual data to the contemporary MCS utilization practice patterns among older adults in the United States. Although the overall rate of ECMO utilization remains low, this is not unexpected since age, as it pertains to the risk of complications, is often a key consideration in decisions to initiate ECMO. This practice is consistent with findings from the ECLS-SHOCK trial, which suggest that ECMO be reserved as a bailout strategy for patients with MI-CS.[6] There are several reasons why early ECMO may not have improved survival for patients with MI-CS in the ECLS-SHOCK trial, including a high rate of complications and increasing afterload with a corresponding rise in myocardial oxygen demand.[18,19] Observational data suggest that among patients with MI-CS treated with ECMO, actively unloading the left ventricle with a microaxial flow pump may be associated with a reduced risk of mortality.[20,21] Our data show that about 2/3 of patients who received ECMO were treated with concomitant IABP or Impella, both of which can be employed as a left ventricular venting device. The optimal timing and device selection for left ventricular venting have yet to be defined.[18]

The substantial differences in baseline characteristics across MCS treatment groups in our study reflect the clinical and systemic factors that drive device selection. For example, patients who received ECMO were substantially younger than patients receiving other therapies, reflecting physicians' tendency to reserve ECMO for patients with a lower risk of complications from the therapy. Notably, rates of Alzheimer's disease were lower among ECMO-treated patients compared with all other treatment groups, and rates of cancer were lower among ECMO-treated patients compared with Impella-treated patients, further reflecting the tendency to reserve ECMO for patients with lower frailty burden. ECMO-treated patients also had higher rates of features associated with high acuity presentations, including STEMI and cardiac arrest, consistent with preferential selection of ECMO for the most hemodynamically compromised patients. Sex differences across treatment groups were also notable: 70.6% of ECMO-treated patients were male compared with 58.4% of those receiving medical therapy alone, a pattern consistent with prior reports of differential MCS use by sex in cardiogenic shock.[22] Prior studies suggest that women with MI-CS tend to be older and have more comorbidities, features that may discourage ECMO use.[22] Women are also more likely to present at a more advanced stage of cardiogenic shock, potentially because of delays in recognition and triage, which may paradoxically result in less aggressive device escalation.[22] Ultimately, the presence of important differences

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Table 3. Mortality Outcomes Stratified by Methodology: Crude Observed Event Rates, Inverse Probability Treatment Weighting, G-Formula, and Grace Period Approach

	ECMO (n=723)	Impella (n=2597)	IABP (n=6042)	Medical Therapy (n=14 296)	ECMO – Impella Difference [95% CI]	ECMO – IABP Difference [95% CI]	ECMO – Medical Therapy Difference [95% CI]
Observed event rates							
All-cause mortality at 30 d	67.9% (491/723)	58.5% (1518/2597)	35.6% (2149/6042)	44.7% (6386/14296)	9.5% [5.6%, 13.4%]	32.3% [28.7%, 36.0%]	23.2% [19.7%, 26.7%]
IPTW							
All-cause mortality at 30 d	68.6% [64.1%, 73.6%]	57.4% [55.0%, 59.9%]	36.2% [35.0%, 37.5%]	43.7% [43.0%, 44.6%]	11.1% [5.8%, 16.7%]	32.4% [27.8%, 37.6%]	24.8% [20.2%, 30.0%]
G-Formula							
All-cause mortality at 30 d	70.2% [64.9%, 74.8%]	55.9% [53.6%, 58.3%]	36.4% [35.2%, 37.7%]	43.5% [42.8%, 44.4%]	14.3% [8.5%, 19.0%]	33.8% [28.4%, 38.4%]	26.7% [21.2%, 31.1%]
Grace period							
All-cause mortality at 30 d	53.6% [45.1%, 64.4%]	53.5% [45.0%, 63.5%]	39.3% [35.2%, 42.3%]	37.9% [35.9%, 38.8%]	0.1% [–0.1%, 2.5%]	14.3% [6.4%, 24.8%]	15.6% [8.1%, 26.9%]

ECMO indicates extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; and IPTW, inverse probability of treatment weighting.

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in measured baseline characteristics across treatment groups raises concern that unmeasured differences in cardiogenic shock severity and clinician intent at the time of device selection may limit valid comparison between therapies, particularly for analytic approaches that rely on measured covariates to adjust for confounding. Even within each treatment group, substantial heterogeneity in patient characteristics and shock severity likely exists, further complicating the interpretation of outcome differences across therapies. For example, the medical therapy cohort was the oldest group, yet had lower rates of several cardiovascular comorbidities compared with the Impella and IABP groups, likely reflecting a combination of factors driving the decision to manage MI-CS without device support. Some patients managed with medical therapy alone may have presented with less hemodynamically severe shock, and thus not have had a medical need for MCS support. Others may have been older with greater frailty, leading clinicians to defer MCS in favor of a less invasive approach. This breadth of patient characteristics across and within treatment groups highlights the need to fully characterize disease severity and the drivers of clinical decision-making in order to make valid comparisons in observational analyses of MI-CS.

In our study, the crude 30-day mortality rate in patients with MI-CS treated with ECMO was higher than that of patients treated with alternative therapies. A prior analysis of National Inpatient Sample claims-based data in a younger cohort of CS patients treated with ECMO (mean age 58 years) than the cohort in our study found a 58% in-hospital mortality rate.[23] Our cohort likely had a higher mortality rate because of the older age of patients and higher rates of comorbidities. Because 30-day mortality was so high among patients treated with ECMO, the composite endpoint of all-cause mortality and all-cause rehospitalization added limited incremental information in this group, as few patients survived to be re-hospitalized. By contrast, in the lower-mortality IABP and medical therapy groups, the composite endpoint captured a meaningful additional burden of rehospitalization among survivors, with approximately 10 percentage point differences between the mortality-alone and composite rates in each group in the unadjusted analysis.

Using observational data to address device safety and effectiveness questions is often challenged by a variety of biases.[24–26] A key component of interpreting observational comparative effectiveness research is critically evaluating whether biases that threaten the causal interpretation of the findings are present and whether the assumptions required for valid causal inference are met. In contrast to randomized clinical trials, comparative observational data are often characterized by imbalanced measured baseline covariates. In our study, despite propensity-score based weighting, there remained significant baseline imbalances in clinical characteristics, which could have been related to model misspecification or insurmountable differences between the patient populations receiving each device. The IPTW and the G-formula regression resulted in a similar magnitude of association to the crude observed event rates. Given that patients who received ECMO were younger and had fewer comorbidities compared with other treatment groups, it would be expected that comorbidity adjustment would result in widening of the gap in outcomes

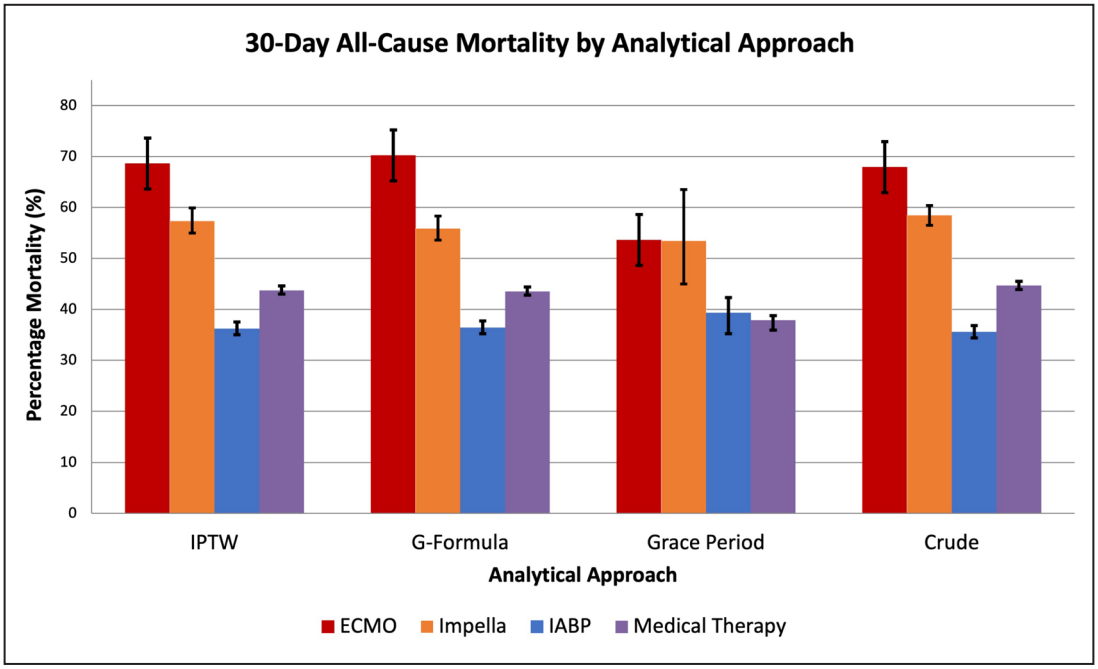


Figure 2. Thirty-day mortality rates stratified by causal inference techniques.
Differences in the unadjusted and adjusted all-cause mortality rates for patients receiving ECMO vs Impella vs IABP vs medical management for the treatment of MI-CS. The adjusted all-cause mortality rates were estimated using inverse probability of treatment weighting (IPTW), G-formula methods, and grace period study design methods. ECMO indicates extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; and IPTW, inverse probability of treatment weighting.

between ECMO and alternative therapies. The lack of change in the event rates with comorbidity adjustment through IPTW and G-formula regression suggests the possible presence of a persistent bias, such as unmeasured confounding (possibly attributable to the lack of shock severity captured in Medicare claims data) or immortal time bias. It is likely that our models are unable to fully account for differences between treatment groups, such as the higher acuity and more advanced shock stage that are likely to characterize patients selected for ECMO. Similarly, although the grace period analysis is designed to address immortal time bias, the Medicare claims data set does not capture adequate time-varying clinical parameters (such as worsening shock severity) that predict ECMO initiation, limiting the validity of this approach in our setting. Therefore, although it is possible that ECMO is associated with higher mortality in older Medicare beneficiaries than in the younger populations enrolled in clinical trials, the assumptions required for valid causal inference are not met in this analysis, and the adjusted estimates should not be interpreted as causal effect estimates.

While large national claims data sets may not capture sufficient granularity, cardiogenic shock specific registries, such as the cardiogenic shock working group (CSWG) and the American Heart Association (AHA) cardiogenic shock registry, may contain more detailed data for comparative effectiveness research. Combining these purpose-built registries with carefully selected causal inference methodologies may accelerate much needed data generation in cardiogenic shock care.[27] This combination can inform the design of future clinical trials as investigators can emulate target trials and extend causal inferences from completed randomized trials to under-studied patient cohorts, such as women, older patients, and minorities who are often under-represented in randomized trials.[4,13,28–33] To date, there have been relatively few adequately powered randomized clinical trials including patients with cardiogenic shock attributable to the ethical and logistical challenges of enrolling critically ill patients.[9,34] Therefore, it is important that rigorous observational research synergizes with randomized trials to drive evidence generation in cardiogenic shock.

There are several strengths of our analysis and some important limitations. First, although we employed a variety of causal inference techniques to address various biases that limit the validity of our analysis, there remains concern for unmeasured confounding. MI-CS is a heterogeneous disease state with a broad spectrum of severity and a highly dynamic physiological state. Many pertinent clinical factors that capture cardiogenic shock severity such as lactate, pH, dose of vasoactive medications, and Glasgow coma scale are not captured in

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an administrative data set like Medicare.[35,36] Additionally, there may be measurement error in the capture of some patient factors because of the use of Medicare administrative claims data that was not designed for research purposes. For example, intubation status may be undercoded, as events occurring before hospital arrival or not assigned a discrete billing code may not be reflected in the data. Utilization of pulmonary artery catheters is likely also undercaptured because of inconsistent coding in cases with intensive care unit line placement. Similarly, we were only able to include select outcomes (eg, death or rehospitalization) as endpoints for our study because many important clinical outcomes, such as bleeding and vascular complications, are not well captured in Medicare administrative claims. Second, we were specifically interested in exploring ECMO utilization and outcomes in older adults, but this MCS modality is less frequently employed in older adults which may have limited our sample size. A third limitation is that we were unable to assign time zero as the time of cardiogenic shock onset because of limitations in the Medicare claims data set. Estimates from the SHOCK trial and registry suggest that the median time from symptoms to cardiogenic shock onset in MI-CS is 5–6 hours.[37] For patients with delayed shock onset, the inclusion of the pre-shock interval in the risk window from hospital admission introduces a source of bias that our analytic framework does not fully address. Finally, we lack information on the clinician's intent at the time of MCS implantation, making it difficult to interpret the outcomes associated with multiple MCS device use based on claims data. For example, an Impella may have been placed initially as a venting strategy for subsequent ECMO, or ECMO may have been deployed in response to inadequate support from an Impella.

In conclusion, we found that ECMO was infrequently used for MI-CS management in a contemporary older cohort (1.1%), although utilization has increased and the percentage of hospitals using ECMO for MI-CS has also grown. When utilized, ECMO was often used in conjunction with either IABP or Impella. The observed 30-day mortality for patients treated with ECMO was high, exceeding 68%. Despite the use of complementary causal inference approaches, the lack of data granularity on the severity of cardiogenic shock precludes the use of a claims data set for comparative effectiveness evaluations in MI-CS. Further research, including the use of registries that collect granular MI-CS data, is needed to better define the safety and effectiveness of ECMO use in MI-CS.

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Supplemental Material

Data S1
Tables S1–S6
Figures S1–S2

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