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Rates and impact of vascular complications in mechanical circulatory support

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Abstract

Background: Mechanical circulatory support (MCS) devices are increasingly used for hemodynamic support in cardiogenic shock or high-risk percutaneous coronary interventions. Vascular complications remain a major source of morbidity and mortality despite technological advances with percutaneous techniques. Little is known about the rates and predictors of vascular complications with large-bore access MCS in the contemporary era.

Methods: The study cohort was derived from National Inpatient Sample using data from 2015 to 2019 for cardiac hospitalizations with the use of: intra-aortic balloon pump (IABP) Impella, and/or extracorporeal membrane oxygenation (ECMO). The rates of vascular complications and in-hospital outcomes were analyzed using multivariable logistic regression.

Results: Of 221,700 hospitalizations with MCS use, the majority had only IABP (68%). The rates of vascular complications were greatest with ECMO (15.8%) when compared with IABP (3.0%) and Impella (5.6%). Among patients with vascular complications, in-hospital mortality was higher with ECMO (56.3%) when compared with IABP (26.2%) and Impella (33.8%). Peripheral arterial disease (PAD) was the strongest predictor of vascular complications, with 10 times higher odds when present (adjusted odds ratio [aOR] 10.96, $p < 0.001$). In risk-adjusted models, when compared with IABP, the use of Impella (aOR: 1.73, $p < 0.001$), ECMO (aOR: 5.35, $p < 0.001$), or a combination of MCS devices (aOR: 3.47, $p < 0.001$) was associated with higher odds of vascular complications.

Conclusions: In contemporary practice, the use of MCS is associated with significant vascular complications and in-hospital mortality. Predictors of vascular complications include larger arteriotomy size, female gender, and peripheral arterial disease. Vascular access management remains essential to prevent major complications.

KEYWORDS
large-bore access, mechanical circulatory support, vascular complications

1 | INTRODUCTION

Percutaneous mechanical circulatory support (MCS) devices are being increasingly used for hemodynamic support in patients with cardiogenic shock and electively in high-risk coronary interventions.[1] Although multiple studies have shown the feasibility and safety of mechanical circulatory support devices,[2–6] vascular complications remain a challenging problem and a source of substantial morbidity. Recent advances in access site management using micropuncture needles, reperfusion sheathes, and vascular closure devices, along with better operator technique, have allowed more complex patients to be considered candidates to receive MCS devices in the contemporary era. Multiple studies have investigated complications and outcomes of percutaneous interventions using large-bore access,[7,8] however there is still limited data about vascular complications with the use of MCS devices. In this study, we sought to evaluate the rates of vascular complications associated with the use of MCS, along with the predictors of these complications and in-hospital mortality using a large national database.

2 | METHODS

2.1 | Data source

The study cohort was derived from MCS using data from 2015 to 2019. The National Inpatient Sample (NIS) is a publicly available database of all-payer hospital inpatient stays developed by the Agency for Healthcare Research and Quality as part of the Healthcare Cost and Utilization Project. The NIS contains all-payer data on a random sample of hospital inpatient stays from states participating in the Healthcare Cost and Utilization Project within the US National estimates were obtained using sampling weights provided. A detailed explanation of all the variables in the NIS is available online (https://www.hcup-us.ahrq.gov/db/nation/nis/nisdde.jsp). This study was deemed exempt by the Institutional Review Board as the NIS is a publicly available database that contains deidentified patient information.

2.2 | Study cohort

Our study sample was comprised of hospital cardiac admissions (acute myocardial infarction, acute heart failure, valvular heart disease, cardiac arrest, ventricular arrhythmias, and cardiomyopathy) in which any of the following procedures were performed: intra-aortic balloon pump (IABP), Impella, and/or extracorporeal membrane oxygenation (ECMO). The study population was identified using the International Classification of Diseases, Tenth Edition, Procedure Coding System (ICD-10-PCS) codes for IABP (5A02210), Impella ® (5A0221D), and ECMO (5A15223, 5A1522F, 5A1522G, 5A15A2F, and 5A15A2G). We divided the study sample into four groups: IABP, Impella, ECMO, and those that required more than one type of MCS during the hospital stay (IABP + ECMO, IABP + Impella, Impella + ECMO, or all three devices; and not necessarily used at the same time). We were unable to accurately identify those undergoing Tandem Heart® placement using ICD10 codes, therefore, this device is not included in the study sample. NIS does not identify individual patients; therefore, we refer to our sample as a number of hospitalizations or procedures, nonetheless, patient characteristics are reported in the database and can be used to describe comorbidities, age, gender, and race.

2.3 | Patient and hospital characteristics

Baseline patient characteristics, such as age, gender, race, and relevant comorbidities were obtained from the NIS data. The severity of comorbid conditions was defined using a validated Deyo modification of the Charlson Comorbidity Index (CCI).[9,10] Other characteristics such as teaching status of the hospital, hospital bed size, hospital region, median household income, and insurance status were also included.

2.4 | Study outcomes

Clinical outcomes were identified from ICD-10 diagnostic or procedural codes. The primary outcome was the rate of vascular complications and the procedure(s) required to treat it, either angioplasty, open vessel repair, fasciotomy, and/or limb amputation. For the purpose of this study, we included the following vascular complications: injury to a blood vessel, noncoronary artery dissection, acquired arteriovenous fistula, acute limb thrombosis, and hemorrhage and/or hematoma following circulatory system procedure. Secondary outcomes included clinical outcomes (such as in-hospital mortality, acute kidney injury requiring dialysis, acute ischemic or hemorrhagic stroke, blood transfusion, and total hospital costs) and procedural outcomes (such as percutaneous coronary intervention [PCI], coronary artery bypass graft [CABG] surgery, right heart catheterization, mechanical ventilation, palliative care consultation, permanent left ventricular assist device [LVAD] implantation, and heart transplantation). Table S1 contains the ICD-10 codes used for each study variable.

2.5 | Statistical analysis

Descriptive statistics are presented as frequencies with percentages for categorical variables, and medians with interquartile ranges for continuous variables. Univariate comparisons were performed using Pearson chi-square tests for categorical variables and Wilcoxon rank-sum tests for continuous variables. Multivariable logistic and linear regression was used to adjust for potential confounders when analyzing clinical outcomes and hospital costs; we included the following variables in the model: age, gender, race, comorbidities (listed in

TABLE 1 Baseline patient and hospital characteristics

	Overall	IABP	Impella	ECMO	>1 MCS
Number	221,700	150,805	50,605	7525	12,765
Age (median [IQR])	67 (58–75)	67 (58–74)	69 (60–77)	62 (51–70)	64 (55–72)
Female	29.4%	28.1%	33.4%	29.1%	29.5%
Race/ethnicity					
White	72.6%	72.9%	73.2%	68.8%	69.1%
Black	9.6%	9.4%	9.5%	13.4%	11.3%
Hispanic	9.2%	9.3%	9.4%	7.9%	9.1%
Other	8.5%	8.4%	7.9%	10.0%	10.5%
Hypertension	77.8%	78.6%	79.3%	64.3%	70.2%
Diabetes mellitus	42.5%	42.3%	46.0%	30.2%	37.1%
Heart failure	61.5%	57.1%	69.8%	71.1%	74.3%
Systolic heart failure	48.7%	44.8%	57.0%	53.2%	60.1%
Peripheral artery disease	14.3%	13.0%	17.4%	16.9%	15.2%
Dyslipidemia	59.4%	61.5%	60.0%	37.7%	45.1%
Prior myocardial infarction	28.7%	32.5%	21.7%	18.8%	17.6%
Prior PCI	13.6%	13.3%	15.6%	11.2%	10.7%
Prior CABG	6.0%	5.2%	9.2%	5.9%	4.2%
Obesity	18.8%	19.5%	17.5%	15.9%	17.7%
Smoker	3.6%	3.6%	2.9%	3.2%	3.6%
COPD	20.2%	20.5%	21.0%	15.6%	15.7%
End-stage renal disease	4.7%	3.9%	6.8%	5.7%	5.2%
Atrial fibrillation	30.0%	31.1%	26.5%	31.9%	29.3%
Charlson Comorbidity Index					
0	2.4%	2.5%	1.9%	4.0%	1.5%
1	15.0%	16.2%	11.6%	19.0%	12.5%
2	23.7%	24.2%	21.8%	23.9%	24.6%
≥3	58.9%	57.1%	64.7%	53.2%	61.3%
Hospital characteristics					
Teaching hospital	79.0%	77.0%	79.5%	95.4%	90.2%
Hospital Bed Size					
Small	11.9%	12.2%	13.3%	4.7%	6.6%
Medium	26.3%	27.4%	26.7%	11.6%	19.5%
Large	61.8%	60.3%	60.0%	83.8%	73.9%
Hospital Region					
Northeast	17.6%	17.9%	14.4%	24.4%	23.5%
Midwest	23.7%	24.7%	20.5%	24.6%	24.0%
South	39.8%	38.8%	44.5%	36.2%	34.9%
West	18.9%	18.7%	20.7%	14.9%	17.6%
Other characteristics					
Elective admission	16.6%	15.2%	20.0%	24.2%	14.8%

(Continues)

TABLE 1 (Continued)

	Overall	IABP	Impella	ECMO	>1 MCS
Median household income					
0–25th percentile	28.6%	28.0%	31.8%	25.2%	25.1%
26th–50th percentile	26.8%	26.9%	27.2%	26.2%	24.1%
51st–75th percentile	24.7%	24.8%	23.6%	26.2%	26.3%
76th–100th percentile	20.0%	20.3%	17.4%	22.3%	24.5%
Primary Payer					
Medicare	56.0%	55.1%	62.4%	44.9%	47.2%
Medicaid	9.9%	10.2%	8.6%	13.2%	10.7%
Private Insurance	26.5%	26.9%	22.0%	34.8%	3439.0%
Self-pay/other	7.6%	7.8%	7.0%	7.2%	7.8%

Abbreviations: CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; IQR, interquartile range; MCS, mechanical circulatory support; PCI, percutaneous coronary intervention.

Table 1), CCI, hospital bed size, hospital teaching status, PCI, CABG, and LVAD implantation. Multivariable logistic regression was used to analyze predictors for vascular complications and in-hospital mortality. Statistical analysis was performed with STATA 14, and a p value less than 0.05 was considered significant for all the analyses.

3 | RESULTS

From 2015 to 2019, we identified 221,700 cardiac hospitalizations with cardiovascular procedures requiring MCS; IABP was the most common form of MCS among the study sample (68.0%), followed by Impella® (22.8%), and then ECMO (3.4%); 5.8% of hospitalizations used more than 1 type of MCS). The ECMO cohort had the youngest patients (median age 62 years old) and with a lower frequency of comorbidities, except for heart failure. Among those requiring more than 1 MCS, 45.9% had IABP and Impella, 30.0% had IABP and ECMO, 18.5% had Impella and ECMO, and 5.6% had all three devices during their hospitalization (Table S2). Table 1 shows a complete description of baseline patient and hospitalization characteristics. In-hospital mortality was highest in the ECMO cohort (53.4%) and lowest in the IABP cohort (21.5%). Those with vascular complications had significantly higher rates of mortality when compared with those without vascular complications, except for the ECMO cohort ($p = 0.26$). The rates of acute kidney injury requiring dialysis, acute ischemic or hemorrhagic stroke, and blood transfusions were higher in those who underwent ECMO. Table 2 shows the clinical outcomes among the study cohorts. The rates of PCI were higher in the Impella cohort (77.3%), and those with IABP had higher rates of CABG (42.7%). Permanent LVAD implantation and heart transplantation were higher in the ECMO cohort. Table 3 shows the procedural outcomes among the study cohorts.

3.1 | Vascular complications and treatment required

Among those who underwent only IABP, 3.0% had vascular complications; in the presence of vascular complications, in-hospital mortality was 26.2%, and 9.1% required either angioplasty or vessel repair. In those with Impella use, 5.6% had vascular complications, and their mortality when vascular complication was present was 33.8%, and 18.2% required angioplasty or vessel repair (Figure S1). The hospitalizations with ECMO use had a 15.8% rate of vascular complications, and their mortality (among those with vascular complications) was 56.3%. Finally, those requiring more than one MCS device had a 10.7% rate of vascular complications. Figure 4 shows the trend of vascular complications for each cohort during the study period.

3.2 | Correlates of vascular complications

Based on multivariable logistic regression, peripheral arterial disease (PAD) was the strongest predictor of vascular complications, with 10 times higher odds when PAD was present (aOR 10.96, $p < 0.001$). Female gender, systolic heart failure, atrial fibrillation, and vasopressor use were also predictors of vascular complications (Figure 1). When compared with IABP, the use of Impella (aOR: 1.73, $p < 0.001$), ECMO (aOR: 5.4, $p < 0.001$), or a combination of MCS (aOR: 3.4, $p < 0.001$) was associated with higher odds of vascular complications.

3.3 | In-hospital mortality

The overall hospital mortality was 21.5%, with higher rates in those with ECMO (53.4%, aOR: 4.64, $p < 0.001$), Impella (24.8%, aOR 1.40, $p < 0.001$), and combination of MCS (47.6%, aOR: 4.28, $p < 0.001$),

TABLE 2 Secondary outcomes

Clinical outcomes	Overall	IABP	Impella	ECMO	>1 MCS
In-hospital mortality	21.5%	16.6%	24.8%	53.4%	47.6%
With vascular complications	35.9%	26.2%	33.8%	56.3%	54.0%
Without vascular complications	20.9%	16.3%	24.3%	52.9%	46.8%
p value*	<0.001	<0.001	<0.001	0.26	0.04
Acute kidney injury requiring hemodialysis	2.2%	1.9%	1.9%	7.2%	4.3%
With vascular complications	4.4%	4.2%	2.0%	7.1%	7.7%
Without vascular complications	2.1%	1.9%	1.9%	7.3%	3.9%
p value#	<0.001	0.007	0.98	0.89	0.03
Acute ischemic or hemorrhagic stroke	2.3%	1.8%	2.1%	6.4%	5.3%
With vascular complications	5.0%	3.3%	4.4%	9.2%	8.5%
Without vascular complications	2.1%	1.8%	2.0%	5.8%	5.0%
p value#	<0.001	0.047	<0.001	0.058	0.227
Blood transfusion	14.8%	14.5%	12.8%	22.7%	21.8%
With vascular complications	24.7%	27.1%	23.5%	18.1%	25.0%
Without vascular complications	14.4%	14.2%	12.1%	23.6%	21.4%
p value#	<0.001	<0.001	<0.001	0.007	0.663

Abbreviations: CABG, coronary artery bypass graft; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; MCS, mechanical circulatory support; PCI, percutaneous coronary intervention.

*Adjusted for age, gender, comorbidities, PCI, CABG, acute stroke, hemodialysis, and LVAD implant.

#Adjusted for age, gender, comorbidities, PCI, CABG, and LVAD implant.

TABLE 3 Procedural outcomes

Procedural outcomes	Overall (%)	IABP (%)	Impella (%)	ECMO (%)	>1 MCS (%)
Percutaneous coronary intervention	46.7	37.9	77.3	15.6	48.0
Coronary artery bypass graft	32.7	42.7	6.8	19.9	24.3
Right heart catheterization	13.3	12.0	13.2	18.2	25.2
Mechanical ventilation	8.4	7.7	10.2	8.7	10.3
Palliative care consultation	8.5	6.5	9.2	23.7	19.8
Permanent LVAD Implantation	2.3	2.0	1.3	7.6	6.1
Heart transplant	1.2	1.0	0.4	5.1	3.4

Abbreviations: ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; MCS, mechanical circulatory support.

when compared with the IABP cohort (16.6%). Vascular complications were associated with higher odds of mortality (aOR: 1.62 $p < 0.001$). Other predictors of mortality were age more than 65 years old, female gender, diabetes, end-stage renal disease (ESRD), vasopressor use, teaching hospital, mechanical ventilation, acute stroke. Lower odds of mortality were seen in those that underwent PCI, CABG, LVAD implant and had open vessel repair (Figure 2).

3.4 | Hospital costs

Overall, the total hospital costs were significantly higher in those patients that had vascular complications when compared with those without ($103,159 vs. $63955, $p < 0.001$). Similarly, total hospital costs based on the procedure type were higher in those with vascular complications. Figure 3 shows a complete analysis of costs by the type of procedure based on the presence or absence of vascular

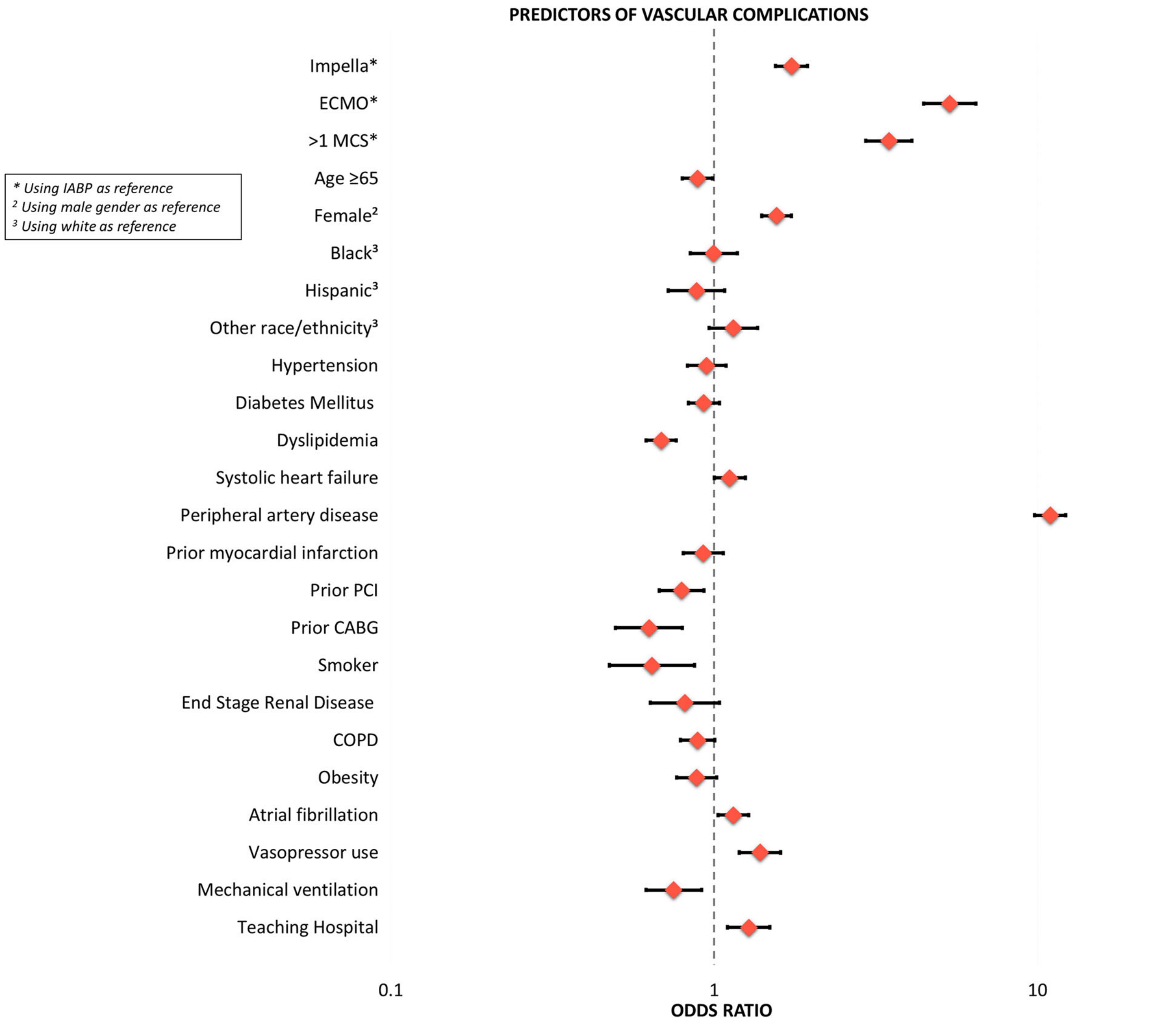

FIGURE 1 Predictors of vascular complications in MCS. Predictors of vascular complications included peripheral arterial disease, female gender, systolic heart failure, atrial fibrillation, and vasopressor use. CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support; PCI, percutaneous coronary intervention [Color figure can be viewed at wileyonlinelibrary.com]

complications, adjusted for baseline characteristics and in-hospital procedures.

4 | DISCUSSION

Using a large, real-world sample, we made several interesting observations among MCS procedures in the United States. First, the frequency of vascular complications varies between the type of MCS, from 3% to 15%. Second, the odds of mortality were significantly higher in patients with vascular complications. Third, predictors of vascular complications include female gender, systolic heart failure, peripheral arterial disease, and vasopressor use. Third, age > 65 years old, female gender, diabetes, ESRD, vasopressor use, admission to a teaching hospital, mechanical ventilation, acute stroke, and vascular complications were predictors of in-hospital mortality. Fourth, hospital costs are significantly higher in patients with vascular complications, irrespective of type of MCS.

Vascular complications from percutaneous interventions are associated with a significant increase in peri-procedural morbidity and mortality.[11–13] Percutaneous options are increasingly sought for the treatment of cardiogenic shock, complex coronary artery disease, and valvular heart disease; however, these therapies frequently require large-bore access and can be harmful. In our current study, the presence of vascular complications ranged from 3% to 15%, however, among those patients with vascular complications, their mortality was significantly higher when compared with those without.

Over the past decade, the use of MCS has increased significantly, with ongoing efforts to help identify which patients benefit from these devices.[14–18] Management of vascular access remains an issue when using these devices. Prior studies have reported vascular complications similar to our findings, around 4% for IABP, 6%–8% for

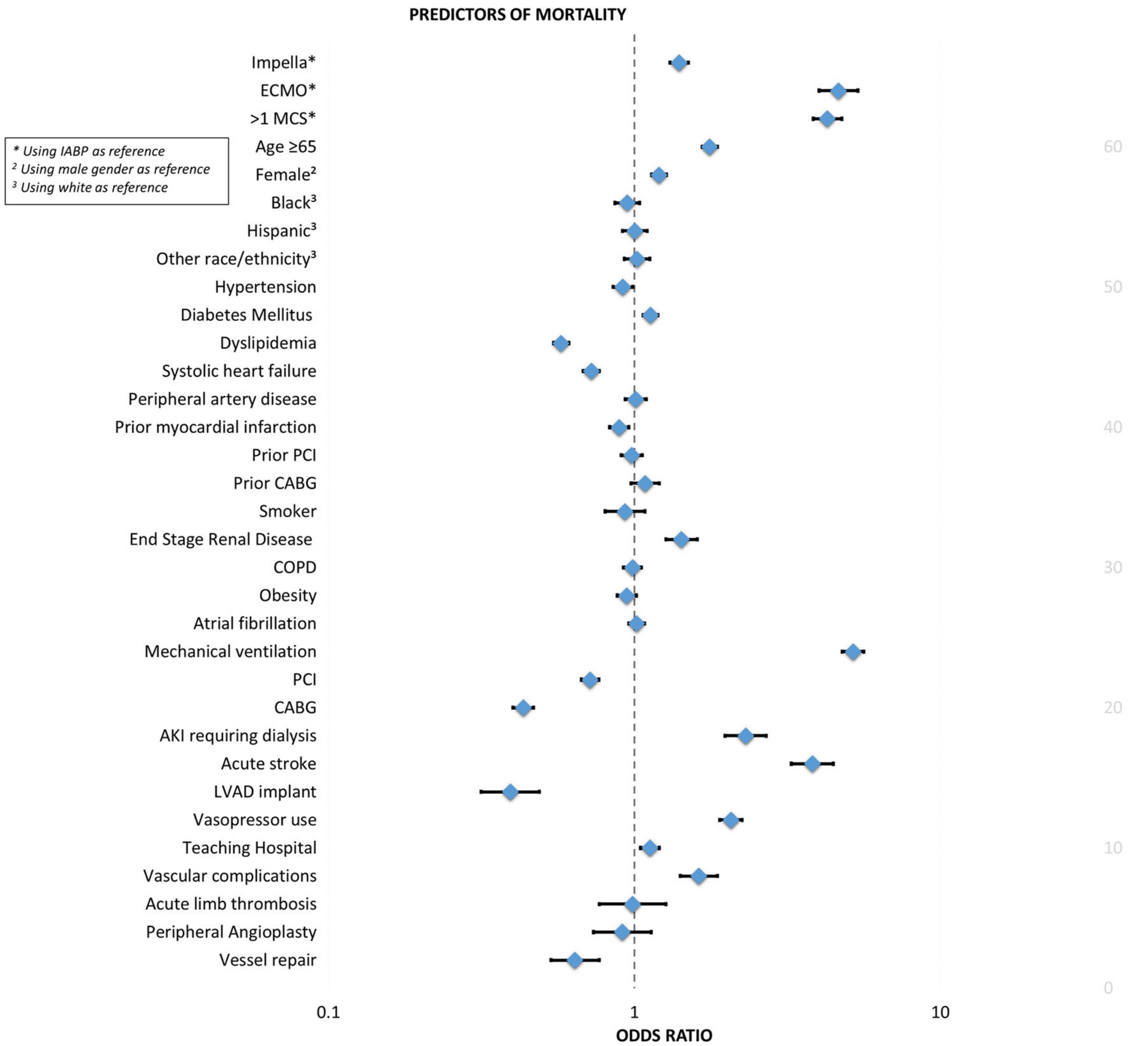

FIGURE 2 Predictors of in-hospital mortality in MCS. In-hospital mortality was higher in patients with vascular complications, those who underwent Impella, ECMO or more than 1 MCS (in comparison with IABP), age more than 65 years old, female gender, diabetes, ESRD, vasopressor use, teaching hospital, mechanical ventilation, and acute stroke. CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; ECMO, extracorporeal membrane oxygenation; ESRD, end-stage renal disease; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support; PCI, percutaneous coronary intervention [Color figure can be viewed at wileyonlinelibrary.com]

Impella, and 12%–15% for ECMO.[6,19] The impact of vascular complications is seen by the significant increase in mortality and hospitalization costs.

Female gender was a strong predictor for developing vascular complications across all forms MCS use (odds ratio 1.56, $p < 0.001$). Multiple previous studies have shown the female gender to be an independent risk factor for developing vascular complications with large-bore access.[20,21] The mechanism of this increased risk is complex and includes variations in hemostasis, inappropriate anticoagulant pharmacological dosing, as well smaller caliber vasculature in women which may contribute to increased risk of vascular trauma and subsequent bleeding or limb ischemia.[22,23] Additionally, other studies have shown the female gender to be associated with arteriotomy closure device failure which may contribute to this increased risk of bleeding.[24,25]

Insertion of large-bore access can lead to significant perfusion compromise depending on vascular caliber and access size. Therefore, reperfusion sheaths have been utilized successfully to ensure adequate perfusion to the limb distally.[26] Alternatively, transcaval access has been used to bypass small iliac arteries or significant occlusive disease in the lower extremity vasculature and deliver large-bore access MCS devices successfully.[27]

The high periprocedural risk of morbidity and mortality mediated by vascular complications can be mitigated by percutaneous management options which are associated with improved outcomes.[28] However, the prevention of vascular complications remains indispensable. This can be done by utilizing MCS devices for the shortest duration, early detection of vascular complications, and appropriate patient and device selection before MCS insertion.[29]

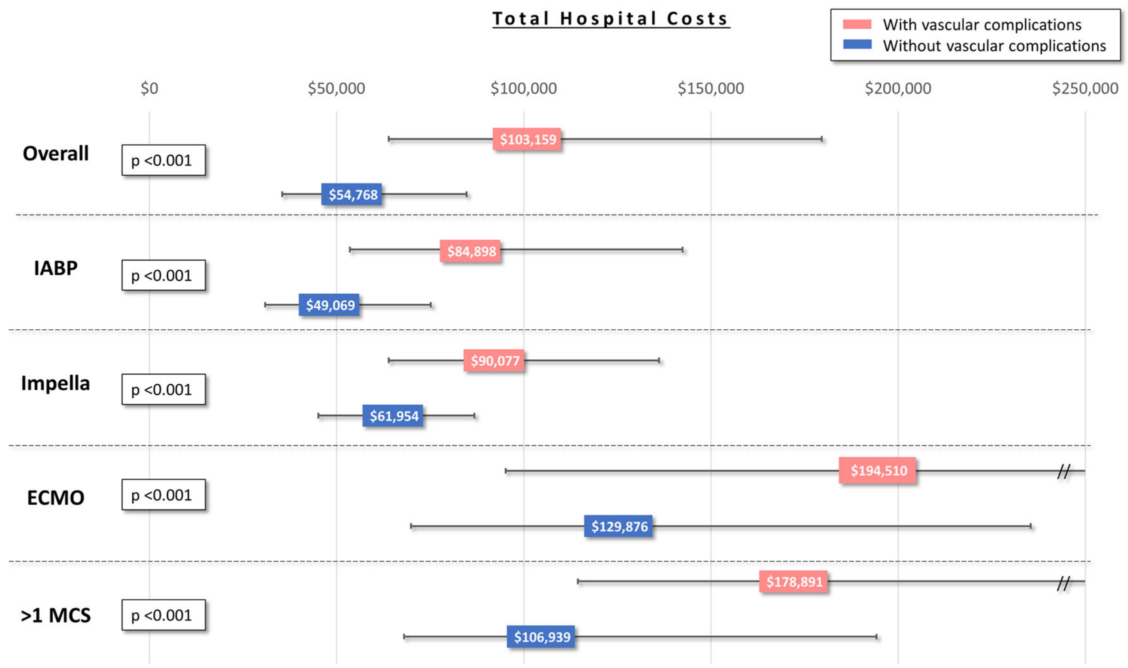

FIGURE 3 Median hospital costs based on the presence or absence of vascular complications. The total hospital costs were significantly higher in those patients that had vascular complications when compared with those without, regardless of the type of MCS used. ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support [Color figure can be viewed at wileyonlinelibrary.com]

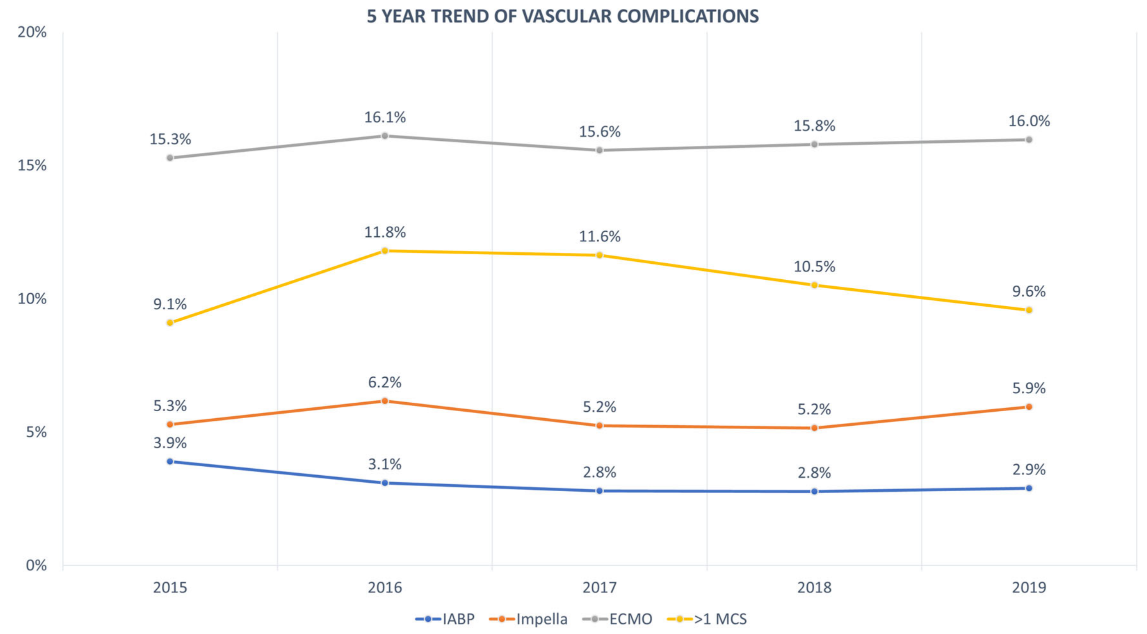

FIGURE 4 Trend of vascular complications during the study period. The rates of vascular complications have remained similar during the study period. ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support [Color figure can be viewed at wileyonlinelibrary.com]

5 | LIMITATIONS

The NIS data is based on ICD- 10 codes, and like any administrative database, there is a possibility of a coding error. The NIS database also does not contain specific information on the indication for the MCS or decision-making regarding the choice of MCS. Lack of information regarding laboratory results, medications, hemodynamic state, and imaging findings renders a more comprehensive analysis infeasible with this database. Despite these limitations, our results provide real-world data on the rates and outcomes of vascular complications in patients undergoing large-bore access MCS procedures in the United States.

6 | CONCLUSION

Vascular complications are associated with higher odds of in-hospital mortality and higher resource utilization after MCS. Predictors of vascular complications include larger arteriotomy size, female gender, systolic heart failure, peripheral arterial disease, and use of vasopressors. These findings emphasize the importance of meticulous vascular access management for any large-bore access procedure to minimize complications and their attendant costs.

CONFLICTS OF INTEREST

Dr. Cohen has received research grants from Edwards Lifesciences, Medtronic, Boston Scientific, Abbott, Philips; and consulting income from Edwards Lifesciences, Medtronic, Boston Scientific, Abbott. Dr. Tehrani is part of the advisory board for Abbott and has received research grant support from Boston Scientific and Inari Medical. Dr. Alqarqaz has the following disclosures: Abiomed. Dr. O'Neill has the following disclosures: Abiomed and Abbott. Dr. Basir has the following disclosures: Abbott Vascular, Abiomed, Chiesi, Cardiovascular Systems, and Zoll. The rest of the authors have nothing to disclose.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from Healthcare Cost and Utilization Project. Restrictions apply to the availability of these data, which were used under license for this study. Data are available at https://www.hcup-us.ahrq.gov/databases.jsp.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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