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ORIGINAL STUDIES

EDITORIAL COMMENT: Expert Article Analysis for:
Mechanical circulatory support in high-risk percutaneous coronary intervention: IIb or not IIb?

Outcomes of nonemergent percutaneous coronary intervention requiring mechanical circulatory support in patients without cardiogenic shock

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Abstract

Background: The utilization of mechanical circulatory support (MCS) for percutaneous coronary intervention (PCI) using percutaneous ventricular assist device (PVAD) or intra-aortic balloon pump (IABP) has been increasing. We sought to evaluate the outcome of coronary intervention using PVAD compared with IABP in noncardiogenic shock and nonacute myocardial infarction patients.

Method: Using the National Inpatient Sampling (NIS) database from 2005 to 2014, we identified patients who underwent PCI using ICD 9 codes. Patients with cardiogenic shock, acute coronary syndrome, or acute myocardial infarction were excluded. Patient was stratified based on the MCS used, either to PVAD or IABP. Univariate and multivariate logistic regression were performed to study PCI outcome using PVAD compared with IABP.

Results: Out of 21,848 patients who underwent PCI requiring MCS, 17,270 (79.0%) patients received IABP and 4,578 (21%) patients received PVAD. PVAD patients were older (69 vs. 67, $p < .001$), were less likely to be women (23.3% vs. 33.3%, $p < .001$), and

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had higher rates of hypertension, diabetes, hyperlipidemia prior PCI, prior coronary artery bypass graft surgery, anemia, chronic lung disease, liver disease, renal failure, and peripheral vascular disease compared with IABP group ($p \leq .007$). Using Multivariate logistic regression, PVAD patients had lower in-hospital mortality (6.1% vs. 8.8%, adjusted odds ratio [aOR] 0.62; 95% CI 0.51, 0.77, $p < .001$), vascular complications (4.3% vs. 7.5%, aOR 0.78; 95% CI 0.62, 0.99, $p = .046$), cardiac complications (5.6% vs. 14.5%, aOR 0.29; 95% CI 0.24, 0.36, $p < .001$), and respiratory complications (3.8% vs. 9.8%, aOR 0.37; 95% CI 0.28, 0.48, $p < .001$) compared with patients who received IABP.

Conclusion: Despite higher comorbidities, nonemergent PCI procedures using PVAD were associated with lower mortality compared with IABP.

KEYWORDS

coronary interventions, high-risk intervention, mechanical circulatory support

1 | INTRODUCTION

Percutaneous mechanical circulatory support (MCS) devices are often used during percutaneous coronary intervention (PCI) to maintain systemic perfusion. Patients with multiple comorbidities and complex multi-vessel coronary artery disease are increasingly referred for HRPCI.[1] Complex high-risk indicated patients or what is referred to as (CHIP), are defined by the presence of one of the following: unprotected left main, last patent coronary conduit, a vessel supplying a large myocardial territory with severely depressed ejection fraction (EF), patient who need high risk coronary interventional technique to achieve revascularization, or a vessel supplying a large territory in the setting of cardiogenic shock.[2] During PCI, a transient interruption of blood flow to target vessels occurs, leading to a myocardial function deterioration, which in turn, results in hemodynamic compromise that can affect procedural outcome.[3] Providing hemodynamic support for this patient population using a number of available devices may reduce such peri-procedural hemodynamic compromise.[4–7] Indeed, recent studies and contemporary registries showed increased utilization of MCS for PCI with improved long-term outcomes.[8,9] The current guidelines also provide Class IIb for elective insertion of an appropriate hemodynamic support device in carefully selected patients.[10] Despite the lack of clear evidence, the utilization of PVAD has increased substantially. Given the limited information in comparative studies, we sought to provide further insights into the trend of MCS use for patients undergoing PCI using large hospitalization database and to compare the utilization and outcomes in patients who had PCIs performed with IABP versus PVAD.

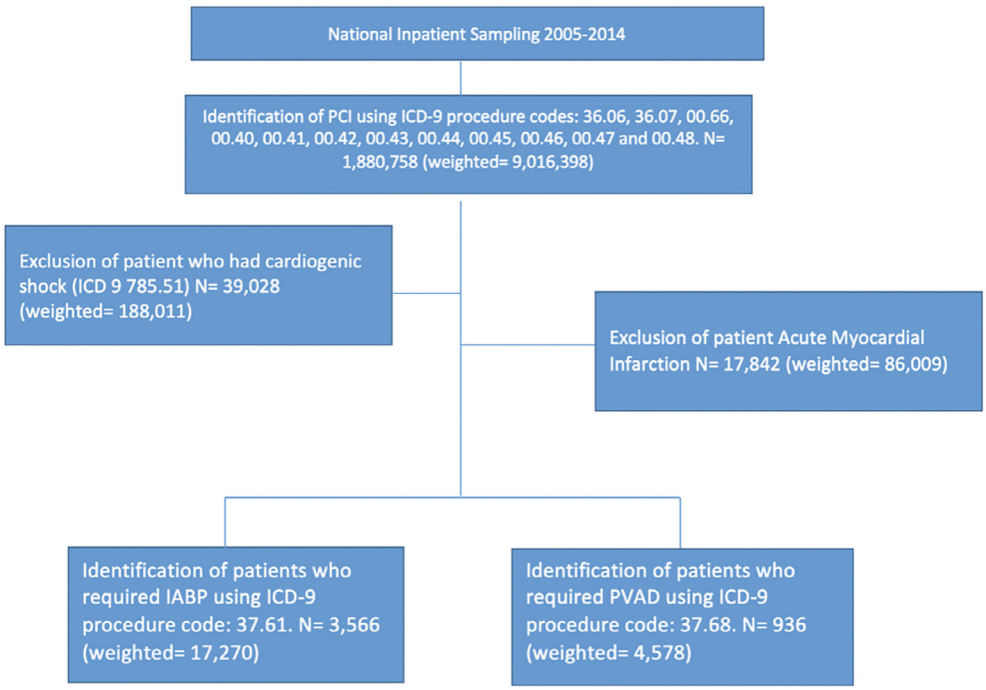

FIGURE 1 Identification of study population using national inpatient sampling database. IABP, intra-aortic balloon pump; PCI, percutaneous coronary intervention; PVAD, percutaneous ventricular assist device [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Baseline characteristics in patients undergoing percutaneous coronary intervention requiring hemodynamic support

Variable	PVAD group	IABP group	*p* value
Age (years)	69.28 ± 11.73	67.40 ± 11.68	<.001
Sex			
Female (%)	23.3	33.3	<.001
Race (%)			<.001
White	72.4	77.3	
Black	7.8	10.2	
Hispanic	7.6	8.0	
Asian or Pacific islander	3.5	2.8	
Native American	0.5	0.7	
Other	5.4	3.8	
Elective hospitalization (%)	45.8	38.7	<.001
Primary expected payer (%)			<.001
Medicare	68.8	61.8	
Medicaid	7.0	6.4	
Private insurance	20.4	26.5	
Self-pay	1.6	3.1	
No charge	0.0	0.1	
Other	2.3	2.1	
Median household income (%)			<.001
0–25 percentile	32.2	26.1	
26–50 percentile	25.8	25.7	
51–75 percentile	22.4	24.0	
76–100 percentile	19.6	24.2	
Bed size (%)			.093
Small	8.1	7.1	
Medium	20.6	20.8	
Large	71.3	72.1	
Location/teaching status (%)			<.001
Rural	7.3	2.6	
Urban nonteaching	34.3	26.1	
Urban teaching	58.4	71.2	
Hospital region (%)			<.001
Northeast	20.8	19.0	
Midwest	23.8	23.6	
South	35.2	34.5	
West	20.2	22.9	
Number of vessels operated on (%)			<.001
One vessel	40.9	66.7	
Two vessels	36.4	24.7	
Three vessels	17.6	6.6	
Four or more vessels	5.0	2.0	
Number of stents inserted during PCI (%)			<.001
One stent	34.4	42.0	
Two stents	31.4	31.9	
Three stents	18.8	15.0	
Four or more stents	15.5	11.2	
Comorbidities			
Hypertension (%)	73.3	67.8	<.001
Diabetes mellitus, uncomplicated (%)	35.9	29.8	<.001
Diabetes mellitus, complicated (%)	8.1	5.7	<.001
Dyslipidemia (%)	57.3	56.4	.259
Atrial fibrillation (%)	18.5	13.8	.097
CAD (%)	74.6	75.5	.233
Prior PCI (%)	15.6	14.0	.007
Prior CABG (%)	9.1	7.5	<.001
Prior stroke/TIA (%)	7.1	3.4	<.001
Carotid disease (%)	5.1	5.4	.378
Smoking (%)	10.1	12.5	<.001
Acquired immune deficiency (%)	0.4	0.2	.002
Alcohol abuse (%)	1.7	2.1	.094
Deficiency anemia (%)	18.4	16.3	.001
Rheumatoid arthritis/collagen vascular disease (%)	2.4	2.1	.214
Chronic blood loss anemia (%)	1.0	1.1	.669
Congestive heart failure (%)	1.9	2.5	.020
Chronic pulmonary disease (%)	21.6	21.2	.476
Depression (%)	5.8	6.0	.600
Coagulopathy (%)	5.7	9.6	<.001
Drug abuse (%)	1.2	1.1	.626
Hypothyroidism (%)	9.5	9.9	.414
Liver disease (%)	2.3	1.2	<.001
Lymphoma (%)	0.6	0.8	.338
Fluid and electrolytes disturbances (%)	17.0	19.1	.001
Metastatic cancer (%)	0.5	0.3	.074
Solid tumor without metastasis (%)	0.8	1.7	<.001
Other neurological disorders (%)	2.9	4.3	<.001
Obesity (%)	12.4	11.7	.255
Paralysis (%)	1.5	1.4	.509
Psychosis (%)	1.1	1.9	<.001
Renal failure (%)	28.0	17.7	<.001

(Continues)

TABLE 1 (Continued)

Variable	PVAD group	IABP group	*p* value
Peripheral vascular disease (%)	24.0	17.3	<.001
Pulmonary circulation disorders (%)	0.3	0.5	.143
Peptic ulcer disease excluding bleeding (%)	0.0	0.0	.207
Valvular disease (%)	0.6	1.0	.039
Weight loss	2.8	3.2	.102

Note: Values are expressed as mean ± *SD* for continuous variables or percentages for categorical variables.
Abbreviations: CABG, coronary artery bypass grafting; CAD, coronary artery disease; IABP, intra-aortic balloon pump; PCI, percutaneous coronary intervention; PVAD, percutaneous ventricular assist device; TIA, transient ischemic attack.

2 | METHODS

2.1 | Study population

The National Inpatient Sample (NIS) is a publicly available and identified database of hospital discharges in the United States, containing data from approximately 8 million hospital stays that were selected using a complex probability sampling design, and the weighting scheme recommended by the Agency for Healthcare Research and Quality which is intended to represent all discharges from nonfederal hospitals.[11] Each record includes one primary diagnosis and up to 14 secondary diagnoses from the years 2005 to 2008, 24 secondary diagnosis codes between 2009 and 2013, and 29 secondary diagnosis codes in 2014. We obtained NIS data from 2005 to 2014 and used the International Classification of Disease, Ninth Edition, Clinical Modification (ICD-9-CM) codes to identify all patients aged ≥18 who underwent PCI. PCI was identified using the ICD-9-CM procedure codes 36.06, 36.07, 00.66, 00.40, 00.41, 00.42, 00.43, 00.44, 00.45, 00.46, 00.47, and 00.48. We excluded patients with cardiogenic shock who were identified using ICD-9-CM diagnosis code 785.51 as well as excluding acute myocardial infection patients using clinical classification codes provided by the Agency for Healthcare Research and Quality. Patients with PVAD and IABP were identified using the ICD-9-CM procedure code 37.68 and 37.61, respectively (Figure 1).

2.2 | Patient and hospital characteristics

Data were retrieved retrospectively. Baseline patient-level characteristics included demographics (age, sex, race, primary expected payer, median household income for patient's zip code), urgency of the procedure (elective vs. nonelective), all of the Elixhauser comorbidities and other relevant comorbidities (smoking, hyperlipidemia, coronary artery disease (CAD), Prior percutaneous coronary intervention (PCI), prior coronary artery bypass grafting (CABG), prior stroke/transient ischemic attack (TIA), atrial fibrillation, carotid artery disease). Hospital-level characteristics were census region, bed size, and teaching status. Using the Clinical Classification Software codes provided by the Healthcare Cost and Utilization Project and the Elixhauser Comorbidity Index comorbidities were appointed via ICD-9 codes. A list of ICD-9-CM codes and Clinical Classification Software codes used to identify comorbidities is included in Supporting Information Table S1.

2.3 | Outcome measures

The primary outcome of interest was in-hospital mortality. In-hospital complications included bleeding requiring transfusion, major vascular complications (injury to blood vessel, accidental puncture, injury to retroperitoneum, other vascular complications, or any vascular complications requiring surgery), cardiac complications (latrogenic cardiac complications, hemopericardium, cardiac tamponade, pericardiocentesis), respiratory complications (postoperative acute pneumothorax, postoperative pulmonary edema, pulmonary collapse, prolonged mechanical ventilation >96 hours, tracheostomy), postprocedural stroke and acute kidney injury (AKI). Length of stay (LOS) and discharge to an outside facility were also included in the secondary outcomes. A list of ICD-9-CM diagnosis codes used to identify in-hospital outcomes is included in Supporting Information Table S1.

2.4 | Statistical analysis

Continuous variables were expressed as weighted mean values ± standard deviation (normal distribution) or median with interquartile range (non-normal distribution), and categorical variables were expressed as percentages. Independent t-tests were used for the comparison of continuous variables measurements, while chi-square test for categorical variables. Weighted values of patient level observations were generated to produce a nationally representative estimate of the entire US population of hospitalized patients. Univariate and multivariate logistic regression analysis were used to compare in-hospital mortality and complications between both groups. The regression model was adjusted for demographics (age, race and gender), patients' insurance, socioeconomic status, calendar year, hospital characteristics, procedure urgency (elective vs. nonelective), number of vessels operated on, number of stents inserted, and all comorbidities listed in Table 1. Adjusted odds ratios (aORs) and 95% confidence intervals (CIs) were used to report the results of regression models. Linear regression models were used to assess the LOS. Log transformation of LOS was done to adjust for positively skewed data.

To further explore the validity of our findings, we performed propensity score-matching analysis between PVAD and IABP groups. All patients in both groups were matched for baseline characteristics, hospital characteristics, patients' socioeconomic status and insurance and procedure characteristics in 1:3 propensity score matching analysis, using nearest neighbor method. For the trend analysis, Cochrane–Armitage test was used to

determine the presence of a linear trend between PVAD and IABP utilization over the studied calendar years. *p* value of less than .05 was considered statistically significant. SPSS version 25 software (IBM Corp, Armonk, NY) was used for all statistical analyses.

3 | RESULTS

3.1 | Baseline characteristics

A total of 21,848 patients underwent PCI from 2005 to 2014 using MCS. Out of 21,848 patients, 17,270 (79.0%) received IABP and 4,578 (21%) received PVAD. Baseline characteristics for both groups are summarized in Table 1. Compared with patients who received IABP (mean age 67.4 ± 11.7 years), patients with PVAD were older (mean age 69.3 ± 11.7 years), less likely to be women or African American ($p < .001$ for all). The prevalence of complicated and uncomplicated diabetes, hypertension, prior stroke/TIA, prior PCI, prior CABG, liver disease, renal failure, valvular disease, peripheral vascular disease, acquired immune deficiency, and deficiency anemia was higher among patients who received PVAD. Smoking, congestive heart failure, coagulopathy, fluid and electrolyte disturbances, solid tumors, other neurological disorders, and psychosis were more prevalent in IABP patients ($p \leq .007$ for all).

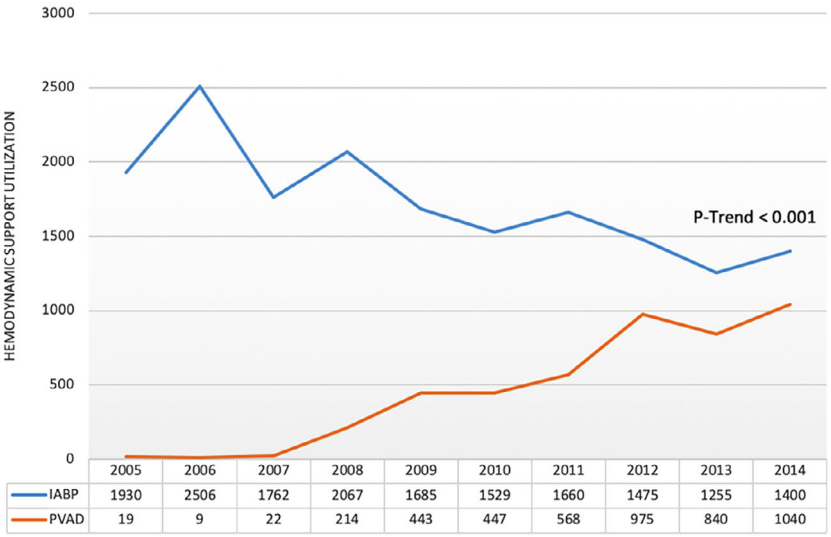

FIGURE 2 Utilization trend of hemodynamic support in patients who underwent percutaneous coronary interventions. IABP, intra-aortic balloon pump; PVAD, percutaneous coronary intervention [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 2 Multivariate logistic regression for the outcome of percutaneous coronary intervention in patients requiring PVAD compared patients requiring IABP

Outcome	PVAD	IABP	UOR (95% CI) PVAD (when compared with IABP)	aOR (95% CI) PVAD (when compared with IABP)	Unadjusted *p* value	Adjusted *p* value
Overall (*n*)	4,578	17,270				
In-hospital mortality (%)	6.1	8.8	0.675 (0.592–0.770)	0.629 (0.513–0.771)	<.001	<.001
Length of stay (IQR)	4 days (2–8 days)	5 days (3–10 days)				<.001
Hemorrhage requiring transfusion (%)	2.7	2.8	0.956 (0.781–1.169)	1.083 (0.817–1.435)	.659	.581
Vascular complications (%)	4.3	7.5	0.558 (0.479–0.650)	0.787 (0.622–0.996)	<.001	.046
Cardiac complications (%)	5.6	14.5	0.351 (0.308–0.401)	0.299 (0.247–0.362)	<.001	<.001
Respiratory complications (%)	3.8	9.8	0.361 (0.308–0.424)	0.375 (0.288–0.488)	<.001	<.001
Postprocedural stroke (%)	5.7	3.0	1.936 (1.662–2.255)	0.656 (0.391–1.099)	<.001	.109
AKI (%)	15.1	14.1	1.086 (0.991–1.190)	0.914 (0.793–1.053)	.077	.215
Discharge to facility (%)	10.7	14.9	0.686 (0.619–0.760)	1.003 (0.863–1.166)	<.001	.972

Note: Unadjusted odds ratios are displayed given low event rate.
Abbreviations: AKI, acute kidney injury; aOR, adjusted odds ratio; IABP, intra-aortic balloon pump; IQR, interquartile range; PVAD, percutaneous ventricular assist device; UOR, unadjusted odds ratio.

PVAD patients had more patients undergoing interventions in 2 vessels (36.4% vs. 24.7%), 3 vessels (17.6% vs. 6.6%) and 4 or more vessels compared with IABP patients (5.0% vs. 2.0%; $p < .001$ for all). Additionally, the PVAD group had more patients with 3 stents insertion during the procedure (18.8% vs. 15.0%) and 4 or more stents (15.5% vs. 11.2%) compared with the IABP group ($p < .001$ for all). Patients with PVAD were less likely to have private insurance, and more likely have median household income in the lowest quartile, compared with IABP patients ($p < .001$). Elective admissions were more frequent in patients who received PVAD ($p < .001$).

Using the Cochrane–Armitage method, we found a statistically significant linear uptrend in the utilization of PVAD from 19 (1.0%) to 1,040 (42.6%) cases between the years 2005 and 2014; whereas the linear trend for the utilization of IABP was down trending from 1,930 (99.0%) to 1,400 (57.4%) cases between 2005 and 2014 (P-Trend < 0.001, for all; Figure 2).

3.2 | In-hospital outcomes

In-hospital mortality was significantly lower in patients who received PVAD compared with patients who received IABP (6.1% vs. 8.8%, $p < .001$). After adjusting for patients' demographics, procedure urgency, comorbidities, insurance and socioeconomic status using multivariate regression mode, PVAD patients remained at lower risk of in-hospital mortality (adjusted OR: 0.62 [95% CI: 0.51–0.77]; Table 2). Risk-adjusted linear regression for LOS demonstrated a statistically significant shorter LOS in the PVAD group (median LOS = 4 days; Interquartile range [IQR] (2–8)) when compared with those with IABP (median LOS = 5 days; [IQR] (3–10); $p < .001$).

Patients with PVAD had lower incidence of vascular complications (4.3% vs. 7.5%, $p = .046$), cardiac complications (5.6% vs. 14.5%, $p < .001$) and respiratory complications (3.8% vs. 9.8%, $p < .001$), but higher incidence of postprocedural stroke (5.7% vs. 3.0%, $p < .001$; Figure 3). After multivariate risk adjustment, the risk of vascular complications (adjusted OR: 0.78 [95% CI: 0.62–0.99]), cardiac complications (adjusted OR: 0.29 [95% CI: 0.24–0.36]), and respiratory complications (adjusted OR: 0.37 [95% CI: 0.28–0.48]) remained significantly lower in PVAD group; whereas postprocedural stroke showed no statistically significant difference between the PVAD group and IABP group (adjusted OR: 0.65 [95% CI: 0.39–1.09]). Furthermore, no statistically significant difference was found between PVAD patients and IABP patients in terms of bleeding requiring transfusion, discharge to an outside facility and AKI (2.7% vs. 2.8%, $p = .581$), (10.7% vs. 14.9%, $p = .972$), (15.1% vs. 14.1%, $p = .215$), respectively. The two groups continue to have no statistically significant difference in terms of bleeding requiring transfusion or AKI even with multivariate risk adjustment (adjusted OR: 1.08 [95% CI: 0.81–1.43] and 0.91 [95% CI: 0.79–1.05], respectively; Table 2).

3.3 | Propensity-score matching and in-hospital outcomes

Baseline characteristics of the propensity matched IABP and PVAD groups are shown in Table 3. Patients who received PVAD had lower in-hospital mortality (3.5% vs. 6.4, OR: 0.53, 95% CI:

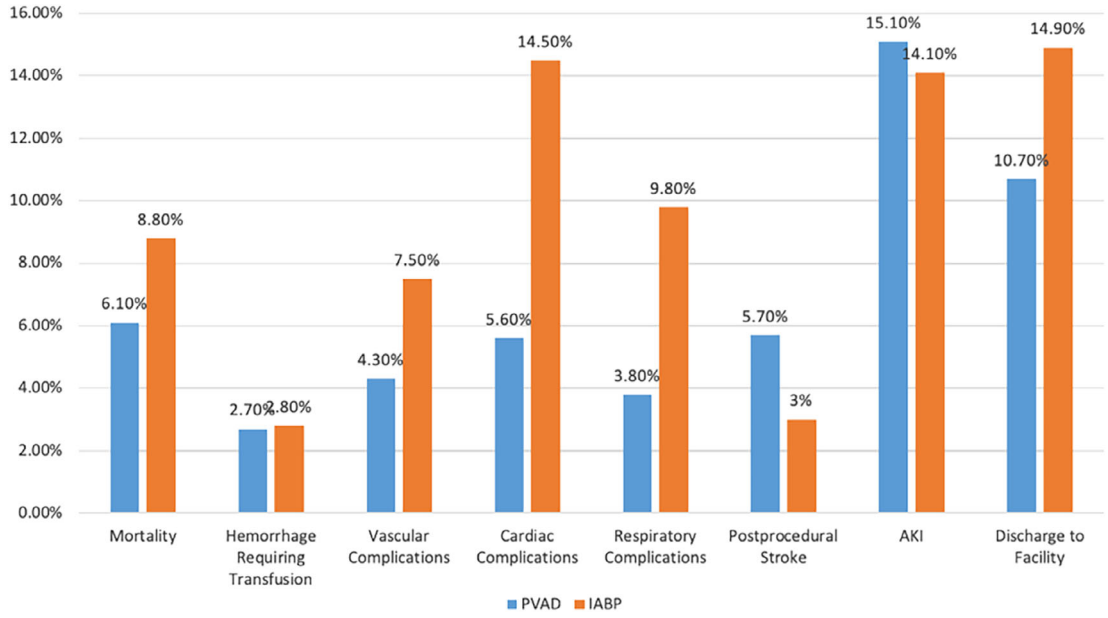

FIGURE 3 Incidence of death and adverse cardiovascular outcomes after percutaneous coronary interventions in PVAD patient versus IABP patients. IABP, intra-aortic balloon pump; PVAD, percutaneous coronary intervention; AKI, acute kidney injury [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 3 Propensity score matching baseline characteristics between PVAD and IABP groups in patients undergoing percutaneous coronary intervention requiring hemodynamic support

Variable	PVAD group	IABP group	*p* value
Age (years)	69.30 ± 11.89	68.63 ± 11.39	.230
Sex			
Female (%)	23.2	26.2	.146
Race (%)			.251
White	72.2	75.7	
Black	9.5	6.4	
Hispanic	8.5	8.7	
Asian or Pacific islander	3.5	3.4	
Native American	0.5	0.6	
Other	5.8	5.3	
Elective hospitalization (%)	49.4	43.8	.022
Primary expected payer (%)			.010
Medicare	70.3	65.3	
Medicaid	6.8	6.3	
Private insurance	19.5	25.1	
Self-pay	1.3	2.2	
No charge	0.0	0.2	
Other	2.3	1.0	
Median household income (%)			.276
0–25 percentile	29.7	26.0	
26–50 percentile	25.2	25.2	
51–75 percentile	22.8	23.5	
76–100 percentile	22.2	25.2	
Bed size (%)			.718
Small	9.2	8.3	
Medium	21.7	20.9	
Large	69.1	70.8	
Location/teaching status (%)			.026
Rural	2.7	4.1	
Urban nonteaching	27.0	31.5	
Urban teaching	70.3	64.3	
Hospital region (%)			.559
Northeast	21.4	22.3	
Midwest	23.6	22.0	
South	32.3	30.6	
West	22.7	25.1	
Number of vessels operated on (%)			<.001
One vessel	41.6	52.4	
Two vessels	37.6	34.4	
Three vessels	15.9	10.2	
Four or more vessels	4.8	3.1	
Number of stents inserted during PCI (%)			.156
One stent	34.4	39.4	
Two stents	33.1	32.1	
Three stents	18.5	16.3	
Four or more stents	14.0	12.2	
Comorbidities			
Hypertension (%)	76.8	73.5	.111
Diabetes mellitus, uncomplicated (%)	36.7	34.7	.392
Diabetes mellitus, complicated (%)	7.4	6.4	.398
Dyslipidemia (%)	60.1	60.3	.951
Atrial fibrillation (%)	18.3	17.6	.712
CAD (%)	74.4	73.8	.783
Prior PCI (%)	16.6	16.8	.897
Prior CABG (%)	10.0	9.5	.750
Prior stroke (%)	6.8	4.8	.070
Carotid disease (%)	5.1	4.4	.498
Smoking (%)	11.9	11.2	.651
Acquired immune deficiency (%)	0.3	0.2	.712
Alcohol abuse (%)	2.3	2.1	.884
Deficiency anemia (%)	19.1	18.1	.584
Rheumatoid arthritis/collagen vascular disease (%)	2.7	2.4	.639
Chronic blood loss anemia (%)	0.5	0.4	.721
Congestive heart failure (%)	1.8	2.4	.392
Chronic pulmonary disease (%)	22.7	21.7	.632
Depression (%)	5.9	6.3	.772
Coagulopathy (%)	5.6	5.6	.979
Drug abuse (%)	1.0	1.2	.612
Hypothyroidism (%)	9.6	10.3	.668
Liver disease (%)	2.4	1.6	.225
Lymphoma (%)	0.5	0.6	.721
Fluid and electrolytes disturbances (%)	16.6	17.0	.799
Metastatic cancer (%)	0.6	0.3	.283
Solid tumor without metastasis (%)	1.0	1.1	.825
Other neurological disorders (%)	2.7	3.6	.319
Obesity (%)	13.3	12.6	.638

(Continues)

(Continues)

TABLE 3 (Continued)

Variable	PVAD group	IABP group	*p* value
Paralysis (%)	1.9	1.2	.174
Psychosis (%)	1.1	1.2	.848
Renal failure (%)	29.3	23.5	.006
PVD (%)	22.8	20.9	.344
Pulmonary circulation disorders (%)	0.5	0.5	.947
Peptic ulcer disease excluding bleeding (%)	0.0	0.0	NA
Valvular disease (%)	0.6	0.7	.906
Weight loss	2.1	2.6	.491

Note: Values are expressed as mean ± *SD* for continuous variables or percentages for categorical variables.
Abbreviations: CABG, coronary artery bypass grafting; CAD, coronary artery disease; IABP, intra-aortic balloon pump; PCI, percutaneous coronary intervention; PVAD, percutaneous ventricular assist device; TIA, transient ischemic attack.

0.33–0.87, p = .012), vascular complications (3.4% vs. 6.0%, OR: 0.54, 95% CI: 0.33–0.89, p = .017), cardiac complications (3.4% vs. 12.2%, OR: 0.25,95% CI: 0.15–0.40, p < .001), and respiratory complications (2.6% vs. 6.1%, OR: 0.40, 95% CI: 0.23–0.69, p = .001; Table 4). There were no differences in the rates of post-procedural stroke between the PVAD and IABP group (5.0% vs. 3.7%, p = .120). Standardized differences of covariates between IABP and PVAD groups before and after matching are shown in Supporting Information Figure S1.

4 | DISCUSSION

The main findings of this study are: (a) The utilization of PVAD for PCI without cardiogenic shock has been increased over time while IABP use has decreased. (b) Patients who received PVAD as MCS device for percutaneous coronary intervention had lower in-hospital mortality compared with those who received IABP. (c) The incidence of vascular complications, cardiac complications and respiratory complications was lower also in patients who received PVAD compared with IABP. (d) Length of stay of patients in the PVAD group was shorter compared with patients in the IABP group.

As the techniques utilized in PCI procedures evolve, the number of high-risk patients referred for PCI has increased as well. Patients who are referred to the catheterization laboratory for HRPCI pose a challenge to the interventionalist due to patient's comorbidities which drives worse outcome. Indeed, HRPCI often have severely calcified complex lesions and multi-vessel coronary artery disease, low creatinine clearance, and severe peripheral arterial disease.[12] The rationale for PVAD for HRPCI is for left ventricular (LV) support during periods of transient hypotension during long coronary balloon inflations and maintaining coronary perfusion throughout the procedure.[13,14] Although guidelines have recommended the use of MCS devices during HRPCI as a class IIb indication,[2] experts have called for further studies to guide the use of these devices.[13]

Multiple studies have been conducted to explore the efficacy of hemodynamic support using IABP during HRPCI with inconsistent results. Reports are mixed in the literature with some reporting favorable outcomes using IABP during PCI without significant difference in mortality.[14–16] Other studies have shown no difference in the outcomes or even a potential harm in IABP use in high-risk PCI.[17–19] Available data from the PROTECT II trial, which explored the outcome of HRPCI in patients using the Impella 2.5 as the PVAD compared with IABP demonstrating no difference in the 30-day major adverse events between both studied groups.[8] However, there was a trend for better outcomes in the Impella 2.5 group at 90 days and significant improvement in the per-protocol group.[8]

Although the PROTECT II trial showed no significant difference in in-hospital mortality between the Impella 2.5 and the IABP group,[8] our study demonstrates that PVAD use was associated with a 36% statistically significant decreased in-hospital mortality compared with the IABP after adjusting for potential cofounders. Furthermore, even after applying propensity score matching, in-hospital mortality was lower in the PVAD group.

This study has several limitations. NIS is a large, nationally representative database that has been validated multiple times for accuracy. Nevertheless, as with all studies that use routinely collected electronic healthcare data, there are several limitations to our study. Given the retrospective design, the possibility of unmeasured confounders is present due to lack of randomization. Given the high number of outcomes, we adjusted for all potential covariates available in the database and used propensity score matching as a sensitivity analysis to correct for differences in baseline characteristics between groups. ICD-9-CM codes identified patients who underwent PCI did not account for coronary artery lesion location or complexity, which could have confounded the outcome analysis. Furthermore, frailty is not captured in the NIS dataset and may confound our analysis through selection bias, as frail patients are more likely to receive IABP rather than PVAD, and frailty associated with worse PCI outcomes which may confound interpretation of data. Further, given the nature of this database, we were not able to obtain information regarding whether successful re-vascularization post-PCI was achieved or not. In addition, data regarding the conditions the procedures were performed under, such as the amount of contrast used, were not available. Furthermore, acuity of the device was obtainable using the NIS database which may have confounded the mortality and vascular complications outcome of this study. We did not have information around hemodynamic parameters during the course of the procedure, vasopressor use or hemodynamic compromise which may provide additional information around efficacy. Finally, outcome analysis was limited to in-hospital outcomes as long-term outcomes and complications after discharge were not recorded.

TABLE 4 Propensity score matching outcomes between PVAD and IABP groups in patients undergoing percutaneous coronary intervention requiring hemodynamic support

Outcome	PVAD	IABP	OR (95% CI) PVAD (when compared with IABP)	*p* value
Overall (*n*)	622	1,304		
In-hospital mortality (%)	3.5	6.4	0.539 (0.334–0.872)	.012
Hemorrhage requiring transfusion (%)	2.6	2.4	1.084 (0.588–1.997)	.795
Vascular complications (%)	3.4	6.0	0.549 (0.336–0.898)	.017
Cardiac complications (%)	3.4	12.2	0.252 (0.158–0.401)	<.001
Respiratory complications (%)	2.6	6.1	0.404 (0.234–0.697)	.001
Postprocedural stroke (%)	5.5	3.8	1.481 (0.946–2.319)	.086
AKI (%)	13.5	14.7	0.904 (0.475–1.192)	.475
Discharge to facility (%)	10.9	11.2	0.974 (0.718–1.321)	.863

Abbreviations: AKI, acute kidney injury; IABP, intra-aortic balloon pump; PVAD, percutaneous ventricular assist device; UOR, unadjusted odds ratio.

5 | CONCLUSION

The utilization rate of PVAD has been increasing over the course of recent years in patients undergoing PCI compared to IABP. Based on this NIS sample analysis, patients who received PVAD had lower in-hospital mortality and better resource utilization compared with patients who received IABP. This real-world data analysis sheds much light into the improved acute outcomes of patients when a PVAD is utilized.

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SUPPORTING INFORMATION

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

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