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Gender-based outcomes of impeller pumps percutaneous ventricular assist devices

Mohammed Osman, MD¹, Moinuddin Syed, MD¹, Yasir Abdul Ghaffar, MD¹, Brijesh Patel, DO¹, Ashraf Abugroun, MD², Babikir Kheiri, MD, MSc³, Akram Kawsara, MD¹, Madhavi Kadiyala, MD¹, Sudarshan Balla, MD¹, Ramesh Daggubati, MD¹

¹Division of Cardiology, West Virginia University School of Medicine, Morgantown, West Virginia

²Department of Internal medicine, Medical College of Wisconsin, Milwaukee, Wisconsin

³Knight Cardiovascular Institute, Oregon Health and Science University, Portland, Oregon

Abstract

Background: There is paucity of data focusing on females' outcomes after the use of impeller pumps percutaneous ventricular assist devices (IPVADs).

Methods: Patients who received IPVADs during the period of October 1st, 2015-December 31, 2017, were identified from the United States National Readmission Database. A 1:1 propensity score matching was used to compare the outcomes between females and males.

Results: A total of 19,278 (Female = 5,456; Male = 13,822) patients were included in the current analysis. After propensity score matching and among all-comers who were treated with IPVADs, females had higher in-hospital major adverse events (MAEs) (38 vs. 32.6%, $p < .01$), mortality (31 vs. 28%, $p < .01$), vascular complications (3.3 vs. 2.1%, $p < .01$), major bleeding (7.8 vs. 4.8%, $p < .01$), nonhome discharges (21.6 vs. 16.3%; $p < .01$), and longer length of stay (7 days [IQR 2–12] vs. 6 days [IQR 2–12], $p = .02$) with higher 30-day readmission rate compared to males (20.5 vs. 16.4%, $p < .01$). Furthermore, among patients who received the IPVADs for high-risk percutaneous coronary intervention (HRPCI), females continued to have worse MAEs, which was driven by high rates of major bleeding. However, among patients who received IPVADs for cardiogenic shock (CS) the outcomes of females and males were comparable.

Conclusions: Among all-comers who received IPVADs, females suffered higher morbidity and mortality compared to males. Higher morbidity driven mainly by higher rates of major bleeding was seen among females who received IPVADs for the hemodynamic support during HRPCI and comparable outcomes were observed when the IPVADs were used for CS.

Keywords

30-day readmission; cardiogenic shock; gender disparity; high-risk percutaneous coronary intervention; in-hospital outcomes; percutaneous ventricular assist devices

Correspondence: Ramesh Daggubati MD, WVU Heart and Vascular Institute, West Virginia University, 1 Medical Center Drive, Box 8003, Morgantown, WV 26506. ramesh.daggubati@hsc.wvu.edu, Twitter: @RameshDaggubati. Moinuddin Syed and Yasir Abdul Ghaffar contributed equally to this work

SUPPORTING INFORMATION

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

1 | INTRODUCTION

Impeller pumps percutaneous ventricular assist devices (IPVADs) have gained increasing popularity in the last decade and became an essential component of the cardiovascular therapeutic armamentarium.¹ The American College of Cardiology/American Heart Association/Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) Guideline for Percutaneous Coronary Intervention (PCI) recommends consideration of the use of percutaneous left ventricular assist devices as an adjunct to high-risk-PCI (HRPCI) (Class IIb) and for the hemodynamic support during cardiogenic shock (CS) in the context of ST-elevation myocardial infarction (Class Ib).^{1,2}

Among the currently available IPVADs, the Impella (Abiomed, Danvers, Massachusetts) family of devices are transvalvular microaxial pumps that can be rapidly deployed in the catheterization laboratory and provide direct left ventricular unloading with forward blood flow of up to 5 L/min.¹ The safety and feasibility of a strategy of early upfront use of IPVADs before PCI in patients with CS secondary to acute myocardial infarction (AMI) has recently been demonstrated.^{3,4} Moreover, earlier studies have supported an improvement in the hemodynamic profile, reduced rates of acute kidney injury and trend toward better 90-day clinical endpoints with the use of IPVADs compared to the intra-aortic balloon pump when the IPVADs are used as an adjunct to HRPCI.^{5,6} Although there is a wealth of registry data on the outcomes of IPVADs in the contemporary practice, there is paucity of data focusing on females outcomes.⁷ Females are under-presented in all the trials which assessed the safety and efficacy of IPVADs.^{8,9} Hence, in the current study, we used the National Readmission Database (NRD) to compare the outcomes between females and males in patients who were treated with IPVADs.

2 | METHODS

2.1 | Study data

The study was derived from the NRD, from October 1, 2015 to December 31, 2017. The NRD is part of Healthcare Cost and Utilization Project (HCUP) databases and is sponsored by the Agency for Healthcare Research and Quality (AHRQ).¹⁰ In its most recent release, the NRD reported data collected from 28 states, accounting for 60% of the total U.S. population and 58.2% of all U.S. hospitalizations.¹⁰ Unweighted, each year of the NRD provide data on about 17 million discharges and weighted it estimates more than 36 million discharges. The Institutional Review Board exempted the study because it utilizes publicly de-identified data.

2.2 | Study population

Adult patients (> 18 years) who received IPVADs between October 1, 2015 and December 31, 2017 were identified in the NRD using the International Classification of Disease 10th Procedure codes (PCS) 5A0221D and 5A0211D which are used to code for the use of impeller heart pumps. For the in-hospital outcomes, we excluded the following patients: (a) patients who are younger than 18 years, (b) patients who were transferred to a different hospital on the same day of admission, (b) patients with missing mortality or

gender data, (c) patients who were treated concomitantly with intra-aortic balloon pump or extra-corporal membrane oxygenation. Furthermore, to calculate the 30-day readmission rates we excluded: (a) patients who died during the index admission, (b) patients who were discharged in the month of December, this was done because the NRD provides data on an annual basis and consequently, patients who are discharged in December will not have 30-day follow-up.

2.3 | Study endpoints

The primary endpoint of this study was in-hospital major adverse events (MAEs) (a composite of in-hospital mortality, vascular complications, and major bleeding). The secondary endpoints were, in-hospital mortality, vascular complications, major bleeding (defined as post-procedural bleeding requiring blood transfusion), severe disability surrogates (nonhome discharge and need for mechanical ventilation), resources utilization surrogates (length of stay and cost of hospitalization) and 30-day readmission rate.

2.4 | Statistical analysis

All variables are expressed as weighted national estimates. This was done following the survey analysis method by incorporating the (DISWT) variable as a weight variable, (HOSP_NRD) as a clustering variable and accounting for the different strata in the design of the NRD using the (NRD_STRATUM) as recommended in the AHRQ methods series.¹¹ Categorical variables were expressed as count (percentage) and compared using Scott-Rao Chi-square test. Continuous variables were expressed as median (interquartile range) and compared using the Wilcoxon rank-sum test.

Moreover, a propensity score-matching (PSM) model was calculated using a multivariate logistic regression to derive two matched groups for comparative outcomes analysis (Females vs. Males). We included the discharge weight provided by the HCUP in the propensity score analysis to minimize the differences between the matched cohorts. A nearest neighbor 1:1 variable ratio, parallel, balanced propensity-matching model was applied using a caliper width of 0.01. In addition, we performed several sensitivity analyses as follow: (1) sensitivity analysis by reporting the outcomes among patients in whom the indication for IPVADs was CS. (2) sensitivity analysis by reporting the outcomes in patients who received IPVADs for HRPCI. The HRPCI cohort was isolated by identifying patients who received PCI during the index admission and excluding any patients who had the diagnosis of CS or AMI.

For cost calculation, we used the cost-to-charge ratio files provided by the HCUP to convert the hospital charges to more accurate hospital costs. A p -value of $<.05$ was considered statistically significant. For calculation of the readmission rates, we followed the methods recommended by the HCUP.¹⁰ All statistical analyses were performed using the statistical package for social science (SPSS) version 26 (IBM Corp) and R, version 3.5 for propensity matching.

3 | RESULTS

A total of 19,278 (Female = 5,456; Male = 13,822) patients qualified to be included in the current analysis (Figure 1). Comparing females to males, female patients were older (70 years [IQR 62–79] vs. 68 years [IQR 59–76], $p < .01$), had higher prevalence of hypertension (79.5 vs. 75.7%, $p < .01$), obesity (19.2 vs. 15%, $p < .01$), chronic lung disease (24.2 vs. 21.9; $p < .01$), coagulopathy (20 vs. 17.3%, $p < .01$) and chronic anemia (27.7 vs. 20.4%, $p < .01$). On the other hand, female patients had lower prevalence of chronic kidney disease (28.9 vs. 31.5%, $p = .01$), atrial fibrillation (24.4 vs. 28.5%, $p < .01$) and smoking (12.9 vs. 17.7%, $p < .01$). Detailed baseline characteristics of the two groups are shown in (Table 1).

Before PSM, among all-comers, comparing females to males, females had higher rates of in-hospital MAEs (38 vs. 31.9%, $p < .01$), in-hospital mortality (31 vs. 27.6%, $p < .01$), vascular complications (3.3 vs. 2.2%; $p < .01$), and major bleeding (7.8 vs. 4.3%, $p < .01$). Moreover, females had higher nonhome discharges (21.7 vs. 16%; $p < .01$) compared to males (Table 2). Length of stay was longer in the female group compared to the male group (7 days [IQR 2–12] vs. 6 days [IQR 2–12], $p < .01$). After discharge from the hospital and among survival of index hospitalization, females had higher 30-day readmission rate compared to males (20.5 vs. 16.6%, $p < .01$).

After PSM, two pairs of well-matched female and male groups were compared (Female = 5,385, Male = 5,373) (Table 2). After PSM, standardized mean differences were reduced to $< 10\%$ for all variables indicating an adequate balanced population (Figure 2). Females continued to show higher rates of MAEs (38 vs. 32.6%, $p < .01$), in-hospital mortality (31 vs. 28%, $p < .01$), vascular complications (3.3 vs. 2.1%, $p < .01$) and major bleeding (7.8 vs. 4.8%, $p < .01$). Moreover, females continued to have higher rate of nonhome discharges (21.6 vs. 16.3%; $p < .01$) (Table 2). The length of stay continued to be longer in the female group (7 days [IQR 2–12] vs. 6 days [IQR 2–12], $p = .02$). There was no difference in term of hospitalization costs for females versus males (59,071\$ [IQR 42,908–84,075] vs. 58,789\$ [IQR 41,990–84,354]; $p = .63$). Females continued to show higher 30-day readmission rate compared to males (20.5 vs. 16.4%, $p < .01$).

In the sensitivity analysis, by only including patients who received impella for HRPCI, females continued to show higher rates of MAEs (13.2 vs. 8.7%, $p < .01$), major bleeding (5.5 vs. 2.1%, $p < .01$), nonhome discharge (19.9 vs. 12.6%, $p < .01$), longer length of stay (6 days [IQR 3–11] vs. 5 days [IQR 2–9], $p < .01$), and higher cost of hospitalization (55,010\$ [IQR 41,604–73,011] vs. 52,653\$ [IQR 39,327–69,854]; $p < .01$). Similar in-hospital mortality (6.7 vs. 5.5% $p = .11$) was observed (Table 3).

In the sensitivity analysis, by including only patients with the diagnosis of CS, comparing females to males, females had similar MAEs (56.7 vs. 53.7%, $p = .12$), major bleeding (9.3 vs. 7.3%, $p = .09$) and in-hospital mortality (50.1 vs. 48%, $p = .29$). Female patients with CS had lower cost of hospitalization compared to males (64,274\$ [IQR 44,553–93,886] vs. 67,994\$ [IQR 46,956–101,288]; $p = .02$) (Table 4) and (Figure 3).

4 | DISCUSSION

In the current study, evaluating the outcomes of patients who were treated with IPVADs from a nationally representative database, significant gender-based differences were observed. First, among all patients who received IPVADs irrespective of the indication (HRPCI or CS), females had higher rates of in-hospital MAEs, including mortality, vascular complications, and major bleeding, these differences persisted after PSM. Second, female patients also had a higher 30-day all-cause readmission rate compared to male patients. Third, among patients who received IPVADs for HRPCI, females continued to have higher risk of MAEs, which was driven mainly by higher rates of major bleeding. Fourth, among patients who received IPVADs for CS, females and males had comparable outcomes.

The adoption of shock protocols relying on hemodynamic guided early IPVADs placement in patients with CS has shown promising results in the early reports from National Cardiogenic Shock Initiative.⁴ The early use of IPVADs is a central part of the current shock protocols; this has led to a significant uptrend in the use of IPVADs in recent years.^{12,13} The current analysis is the largest to date to shed some light on the outcomes of IPVADs among females. Our analysis showing higher hospital mortality, vascular complications, and bleeding complications among all-comers females receiving IPVADs is consistent with previous literature showing that females undergoing invasive procedures have a significantly higher risk of vascular complications and bleeding than males.^{14,15} Even the use of intra-aortic balloon pump (IABP) which typically uses a smaller sheath compared to IPVADs has been associated with a higher risk of serious vascular complications among females.¹⁶ Females often have smaller iliofemoral vessels compared to males, this difference persists even after adjusting for height, weight, and other comorbidities known to affect vascular anatomy, this could potentially account for the higher risk of complications among females.¹⁷ As the innovation in device technology continues, a newer version of IPVADs is currently under investigation under the name Impella-ECP (Expandable Cardiac Power). The new device will be able to be introduced with a small nine French sheath, which expands to 15 French in the descending aorta eliminating the need for a larger diameter for vascular access. Though yet to be studied, this can lead to a decrease in vascular and bleeding complications especially among females, which are often access site related. A downtrend in access site complications has been noted with other large-bore sheath access procedures like transcatheter aortic valve replacement, in part due to the decrease in sheath size.¹⁸

Interestingly, while females' outcomes were comparable to the matched male cohort when IPVADs were used in CS, we observed worse outcomes among females with the use of IPVADs as an adjunct for HRPCI. The worse MAEs in females were mainly driven by higher rates of major bleeding compared to males. Bleeding has been the Achilles heel of IPVADs use. Bleeding arises as a complication not only due to the procedure and due to the use of large sheath size but also secondary to post-procedure bleeding risk due to the need for anticoagulation. This reiterates the value of risk stratification to guide optimum patient selection and proper planning for the procedure. A recent report from the PROTECT III trial on HRPCI, showed that when IPVADs were used as bailout strategy without prior planning, in-hospital mortality was significantly higher compared to a planned prophylactic

approach (41.9 vs. 4.3%; $p < .01$). Moreover, more females were treated with the bailout strategy, which may explain the worse outcomes among females compared to males in the HRPCI cohort.¹⁹ Further studies should focus on the underlying mechanisms behind the discrepancies in the outcomes between males and females.

5 | STUDY LIMITATIONS

The current study has several limitations that need to be acknowledged. First, the NRD is an administrative data, which comes with uncertainty pertaining to some diagnoses as we rely on the appropriate capture of ICD 10 codes. Second, the NRD does not provide data on medications such as antiplatelets and anticoagulants and hence we could not adjust for these in the current analysis. Third, the NRD only identify readmissions to the same original state and hence we could not identify patients who were readmitted to out of state hospitals. Fourth, any management that could have been done in the outpatient settings would not be captured by the NRD since the database only captures in-patient admissions.

6 | CONCLUSIONS

Among all-comers who received IPVADs, females had higher rates of in-hospital MAEs, including mortality, vascular complications and bleeding complications with a higher 30-day readmission rate. In addition, higher morbidity derived mainly by higher rates of major bleeding was seen among females who received IPVADs for the hemodynamic support during HRPCI and comparable outcomes were observed when the IPVADs was used for cardiogenic shock. Further studies targeting gender discrepancies in the outcomes are warranted.

ACKNOWLEDGEMENTS

All figures were created at <https://biorender.com/>.

Abbreviations:

AHRQ	agency for healthcare research and quality
CS	cardiogenic shock
HRPCI	high-risk percutaneous coronary intervention
IPVADs	impellor pumps percutaneous ventricular assist devices
NRD	national readmission database

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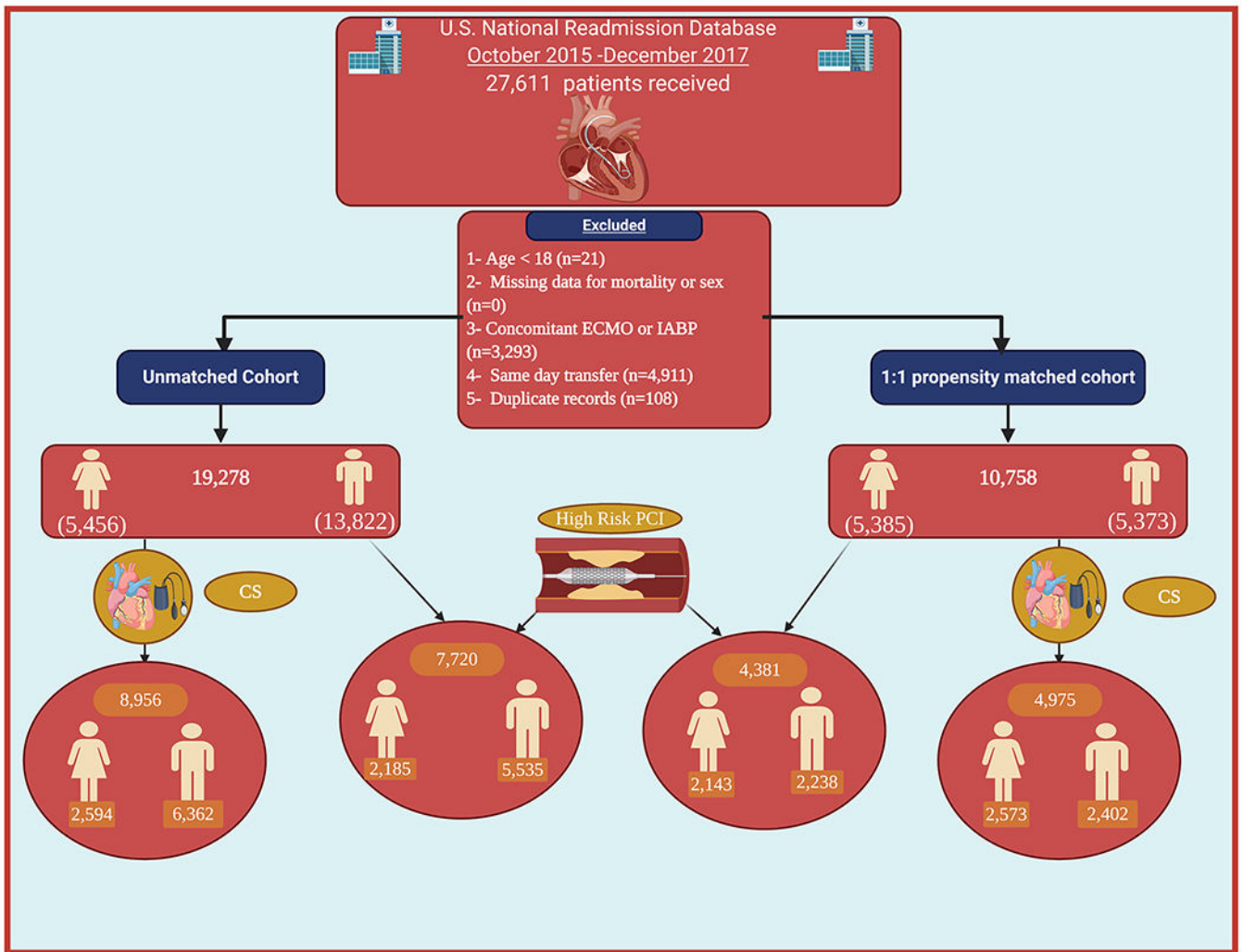


FIGURE 1. Flow chart of the study. CS, cardiogenic shock; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; PCI, percutaneous coronary intervention

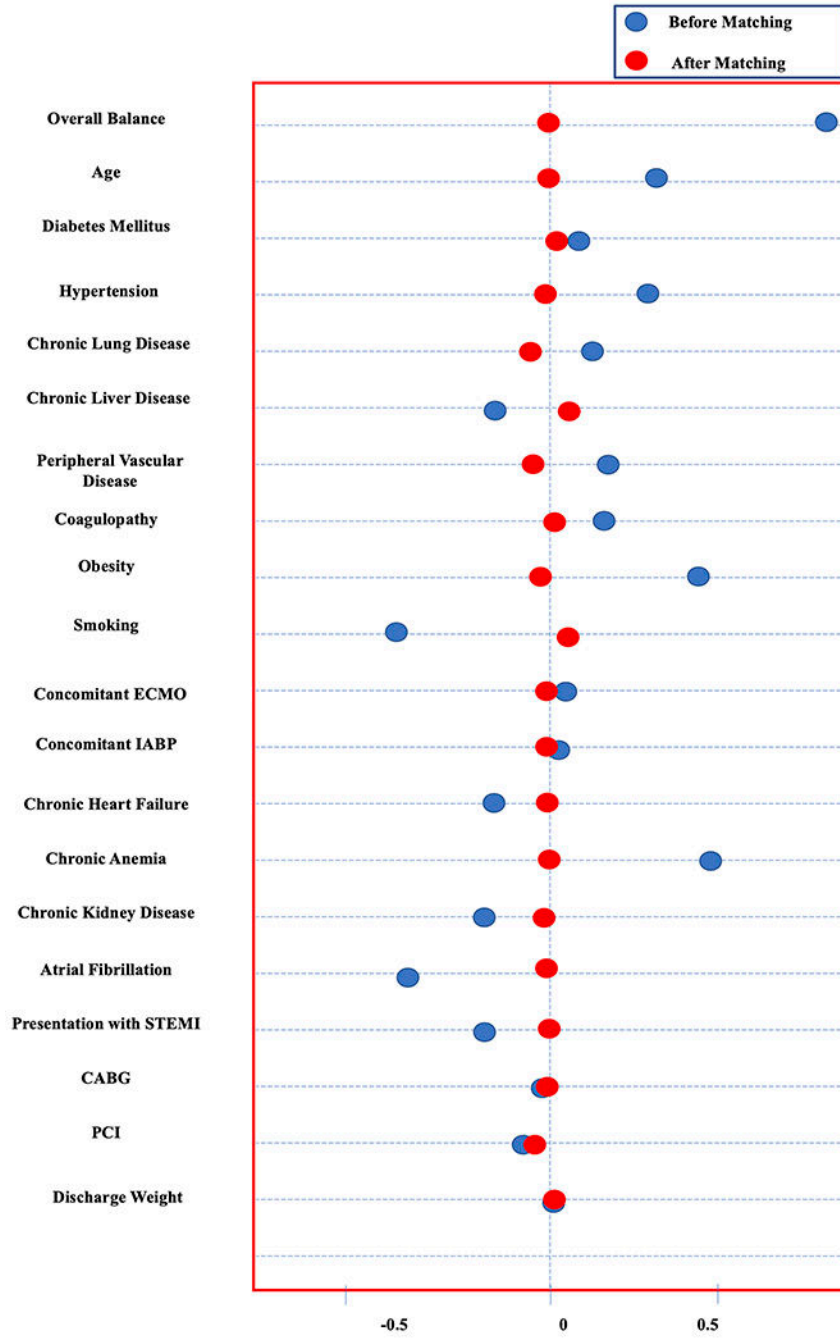


FIGURE 2. Dot plot showing the balance before and after propensity score matching. CABG, coronary artery bypass grafting; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction

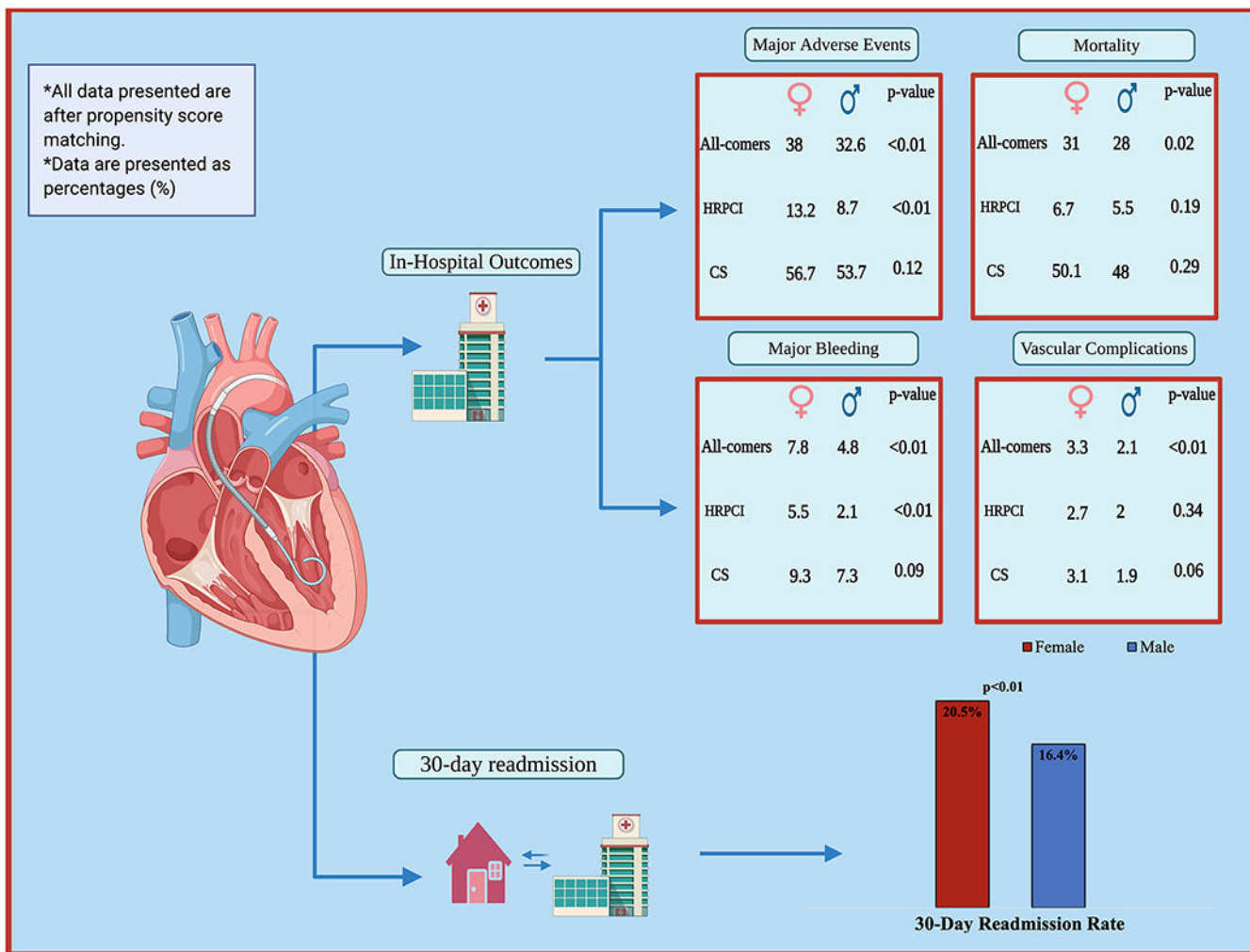


FIGURE 3. Summary of the main findings from the study. CS, cardiogenic shock; HRPCI, high-risk percutaneous coronary intervention

TABLE 1
 Baseline characteristics of the patients included in the analysis before and after propensity score matching

Variables (%)	Unmatched cohorts			Matched cohorts			p-value	Total (n = 10,758)	p-value
	Female (n = 5,456) 70 (62-79)	Male (n = 13,822) 68 (59-76)	Total (n = 19,278) 69 (60-77)	Female (n = 5,385) 70 (62-79)	Male (n = 5,373) 70 (61-78)	Total (n = 10,758) 70 (62-78)			
Age, median (25th-75th IQR)	70 (62-79)	68 (59-76)	69 (60-77)	70 (62-79)	70 (61-78)	70 (62-78)	<.01	70 (62-78)	.12
Diabetes mellitus	44.8	43.2	43.6	44.8	45.1	44.9	.15	44.9	.80
Hypertension	79.5	75.7	76.7	79.3	78.8	79	<.01	79	.59
Peripheral vascular disease	201	18.8	19.2	19.9	20.2	20.1	.17	20.1	.77
Chronic anemia	27.7	20.4	22.4	27.1	26.7	26.9	<.01	26.9	.78
Chronic heart failure	68	70.1	69.5	68.2	67.8	68	.057	68	.77
Chronic kidney disease	28.9	31.5	30.7	28.9	30.9	29.9	.01	29.9	.09
Chronic liver disease	3.1	3.2	3.1	3.1	2.7	2.9	.81	2.9	.36
Chronic lung disease	24.2	21.9	22.5	24	23.9	23.9	.03	23.9	.96
Atrial fibrillation	24.4	28.5	27.3	24.6	24.2	24.4	<.01	24.4	.73
Smoking	12.9	17.7	16.3	12.9	13.7	13.3	<.01	13.3	.42
Coagulopathy	20	17.3	18	19.8	18.7	19.2	<.01	19.2	.29
Obesity	19.2	15	16.2	18.7	20.4	19.6	<.01	19.6	.14
STEMI	26.8	27.9	27.6	27	26.4	26.7	.33	26.7	.64
Percutaneous coronary intervention (PCI)	75.4	74.5	74.7	75.3	74.9	75.1	.38	75.1	.73
Multivessel PCI	38.5	38.8	38.7	38.5	40.2	39.4	.76	39.4	.18
Drug eluting stent	66.5	65.2	65.6	66.6	65.7	66.1	.24	66.1	.49
Bare metal stent	6.3	6.7	6.6	6.1	5.9	6	.46	6	.79

Variables (%)	Unmatched cohorts			Matched cohorts			p-value	p-value
	Female (n = 5,456)	Male (n = 13,822)	Total (n = 19,278)	Female (n = 5,385)	Male (n = 5,373)	Total (n = 10,758)		
Coronary artery bypass grafting	5.4	6.4	6.1	5.4	5.9	5.7	.07	.44
Hospital bed size								
Small	8.7	8.8	8.8	8.7	10.2	9.4	.11	.09
Medium	26.6	24.5	25.1	26.6	24.9	25.7		
Large	64.7	66.7	66.1	64.7	64.9	64.8		

Abbreviations: IQR, interquartile range; STEMI; ST-segment elevation myocardial infarction.

In-hospital outcomes of the patients included in the analysis before and after the propensity score matching

TABLE 2

Variables no. (%)	Unmatched cohorts			Matched cohorts			p-value	Total (n = 10,758)	p-value
	Female (n = 5,456)	Male (n = 13,822)	Total (n = 19,278)	Female (n = 5,385)	Male (n = 5,373)	Total (n = 10,758)			
In-hospital outcomes									
Major adverse events	38	31.9	33.6	<.01	38	32.6	35.3	<.01	
Death	31	27.6	28.6	<.01	31	28	29.5	.02	
Vascular complications	3.3	2.2	2.5	<.01	3.3	2.1	2.7	<.01	
Major bleeding	7.8	4.3	5.3	<.01	7.8	4.8	6.3	<.01	
Severe disability surrogates									
Nonhome discharge	21.7	16	17.6	<.01	21.6	16.3	18.9	<.01	
Mechanical ventilation	35.3	33.3	33.8	.06	35.4	32.4	33.9	.02	
Resources utilization									
Length of hospitalization	7	6	6	<.01	7	6	6	.02	
Median days (25th–75th IQR)	2-12	2-12	2-12	–	2-12	2-12	2-12	–	
Cost of hospitalization	59,090	58,997	59,024	.91	59,071	58,789	58,963	.63	
Median \$ (25th–75th IQR)	(42,898–84,043)	(42,462–84,932)	(42,574–84,533)	–	(42,908–84,075)	(41,990–84,354)	(42,492–84,224)	–	

Abbreviation: IQR, interquartile range.

TABLE 3

Sensitivity analysis including patients who received Impella for high-risk percutaneous coronary intervention

Variables no. (%)	Unmatched cohorts			Matched cohorts			p-value	Total (n = 4,381)	p-value
	Female (n = 2,185)	Male (n = 5,535)	Total (n = 7,720)	Female (n = 2,143)	Male (n = 2,238)	Total (n = 4,381)			
In-hospital outcomes									
Major adverse events	13.2	7.9	9.4	13.2	8.7	10.9	<.01	10.9	<.01
Death	6.7	4.6	5.2	6.7	5.5	6.1	.01	6.1	.19
Vascular complications	2.7	2.3	2.4	2.7	2	2.3	.50	2.3	.34
Major bleeding	5.6	2.1	3.1	5.5	2.1	3.8	<.01	3.8	<.01
Severe disability surrogates									
Nonhome discharge	20.1	11.5	13.9	19.9	12.6	16.1	<.01	16.1	<.01
Mechanical ventilation	7.6	6.9	7.1	7.6	7	7.3	.50	7.3	.62
Resources utilization									
Length of hospitalization	6	5	5	6	5	5	<.01	5	<.01
Median days (25th–75th IQR)	3–11	2–9	2–9	3–11	2–9	2–10	–	2–10	–
Cost of hospitalization	55,036	52,000	52,692	55,010	52,653	53,743	<.01	53,743	.01
Median \$ (25th–75th IQR)	(41,571–73,092)	(39,209–68,369)	(39,726–69,801)	(41,604–73,011)	(39,327–69,854)	(40,427–71,540)	–	(40,427–71,540)	–

Abbreviation: IQR, interquartile range.

TABLE 4
Sensitivity analysis including only patients with diagnoses of cardiogenic shock

Variables no. (%)	Unmatched cohorts			Matched cohorts			p-value	p-value
	Female (n = 2,594)	Male (n = 6,362)	Total (n = 8,956)	Female (n = 2,573)	Male (n = 2,402)	Total (n = 4,975)		
In-hospital outcomes								
Major adverse events	56.8	52	53.4	56.7	53.7	55.2	<.01	.12
Death	50.2	47.1	48	50.1	48	49.1	.07	.29
Vascular complications	3.1	1.7	2.1	3.1	1.9	2.5	.02	.06
Major bleeding	9.2	6.2	7.1	9.3	7.3	8.3	<.01	.09
Severe disability surrogates								
Nonhome discharge	22.2	19.7	20.4	22.4	19.7	21.1	.20	.08
Mechanical ventilation	58.1	57.3	57.5	58.1	55.8	57	.95	.26
Resources utilization								
Length of hospitalization	7	7	7	8	8	7	<.01	.047
Median days (25th-75th IQR)	2-14	3-14	2-14	2-15	3-16	2-14	-	-
Cost of hospitalization	64,208	67,960	66,743	64,274	67,994	65,722	<.01	.02
Median \$ (25th-75th IQR)	(44,521-93,928)	(47,484-101,747)	(46,696-99,538)	(44,553-93,886)	(46,956-101,288)	(45,769-97,147)	-	-

Abbreviation: IQR, interquartile range.