American Heart Journal Plus: Cardiology Research and Practice 12 (2021) 100067

Contents lists available at ScienceDirect

American Heart Journal Plus: Cardiology Research and Practice

journal homepage: www.sciencedirect.com/journal/american-heart-journal-plus-cardiology-research-and-practice

Research paper

Outcomes of Impella compared with intra-aortic balloon pump in ST-elevation myocardial infarction complicated by cardiogenic shock

Samarthkumar Thakkar [a,1], Harsh P. Patel [b,1], Ashish Kumar [c,d], Bryan E-Xin Tan [a], Shilpkumar Arora [e], Smit Patel [f], Rajkumar Doshi [g], Jeremiah P. Depta [h], Ankur Kalra [c,i], Sourbha S. Dani [j], Abhishek Deshmukh [k], Apurva Badheka [l], Robert J. Widmer [m], Mamas A. Mamas [n,o], Charanjit S. Rihal [k], Saket Girotra [p], Sidakpal S. Panaich [p,*]

[a] Department of Internal Medicine, Rochester General Hospital, Rochester, NY, USA
[b] Department of Internal Medicine, Louis A Weiss Memorial Hospital, Chicago, IL, USA
[c] Section of Cardiovascular Research, Heart, Vascular and Thoracic Department, Cleveland Clinic Akron General, Akron, OH, USA
[d] Department of Internal Medicine, Cleveland Clinic Akron General, Akron, OH, USA
[e] Department of Cardiology, Case Western University, Cleveland, OH, USA
[f] Department of Internal Medicine, Vassar Brothers Medical Center, Poughkeepsie, NY, USA
[g] Department of Internal Medicine, University of Nevada Reno School of Medicine, Reno, NV, USA
[h] Sands Constellation Heart Institute, Rochester Regional Health, Rochester, NY, USA
[i] Department of Cardiovascular Medicine, Heart, Vascular and Thoracic Institute, Cleveland Clinic, Cleveland, OH, USA
[j] Department of Cardiology, Lahey Hospital & Medical Center, MA, USA
[k] Department of Cardiovascular Medicine, Mayo Clinic, Rochester, MN, USA
[l] Heart and Vascular Center, The Everett Clinic, Everett, WA, USA
[m] Department of Cardiovascular Medicine, Baylor Scott & White Health, Temple, TX, USA
[n] Keele Cardiovascular Research Group, Institute of Applied Clinical Science, Keele University, Stoke-on-Trent, UK
[o] Keele Cardiovascular Research Group, Institute of Primary Care and Health Sciences, Keele University, Stoke-on-Trent, UK
[p] Department of Cardiology, University of Iowa Carver College of Medicine, IA, USA

ARTICLE INFO

Keywords:
Impella
IABP
STEMI
Cardiogenic shock
Mortality

ABSTRACT

Background: Despite limited randomized trial data demonstrating clinical efficacy, the utilization of Impella in ST-elevation myocardial infarction (STEMI) patients complicated with cardiogenic shock (CS) has increased over time.

Methods: We identified 75,769 hospitalizations with STEMI complicated by CS between October 2015 and December 2018 using International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes. From this cohort, hospitalizations were stratified according to IABP or Impella placement. The primary outcome was all-cause in-hospital mortality. Secondary outcomes were divided into efficacy, safety, and device-related complications. Propensity-score matching was used to account for differences in the baseline characteristics between the groups. Logistic regression was performed to get the odds ratio and confidence intervals.

Results: Among 75,769 admissions with STEMI and CS, hospitalizations with <18 years old, both IABP and Impella placement, and who underwent ECMO and/or LVAD implantation were excluded. After the exclusion, out of 72,791 admissions, 25,260 (34.70%) hospitalizations received IABP, and 7825 (10.75%) received Impella support. After propensity score-matched analysis, 7345 hospitalizations were included in each group. All-cause in-hospital mortality was higher in the hospitalizations requiring Impella support as compared to IABP (42.10% vs. 31.54%, adjusted OR 1.71; 95% confidence interval (CI) 1.60–1.84, $P < 0.0001$). Impella was associated with a higher risk of in-hospital complications and hospitalization cost compared with IABP.

Conclusion: Impella compared with IABP in STEMI patients with CS was associated with higher in-hospital mortality and other adverse clinical and procedural outcomes.

* Corresponding author at: University of Iowa Hospitals & Clinics, 200 Hawkins Dr, Iowa City, IA 52242, USA.
E-mail address: drspanaich@gmail.com (S.S. Panaich).
[1] Thakkar and Patel contributed equally to this manuscript as co-first authors.

https://doi.org/10.1016/j.ahjo.2021.100067
Received 7 June 2021; Received in revised form 21 October 2021; Accepted 27 October 2021
Available online 19 November 2021

1. Introduction

Despite advances in treatment, cardiogenic shock (CS) remains the foremost cause of in-hospital mortality among patients presenting with acute myocardial infarction (AMI), with a mortality rate of approximately 50% [1]. Studies have reported the incidence of CS complicating AMI, ranging from 4% to 14% [1–3]. Furthermore, patients with ST-elevation myocardial infarction (STEMI) are more likely to develop CS than non-ST-elevation myocardial infarction (NSTEMI) [1].

While immediate revascularization in AMI patients with CS is life-saving, controversy remains regarding the role of mechanical circulatory support (MCS) devices in such patients. Data from randomized controlled trials have not found a consistent benefit of routine use of temporary MCS devices in AMI patients. The routine use of intra-aortic balloon pump (IABP) did not reduce mortality in patients with AMI and CS treated with immediate revascularization [4]. Although Impella has been shown to improve hemodynamic parameters such as blood pressure and cardiac output, the IMPRESS trial and other retrospective analyses comparing IABP vs. Impella in STEMI patients complicated by severe CS did not show a significant difference in 30-day mortality [5,6]. Recent reports from National Cardiovascular Data Registry and Premier Healthcare Database have suggested higher mortality and risk of complications with Impella compared with IABP [7,8]. In contrast, recent reports from National Cardiogenic Shock Initiative (NCSI) have suggested improvement in survival rates in acute MI and CS patients with Impella [9]. Despite limited data exhibiting improvements in clinical outcomes relative to IABP, the trend in the utilization of Impella devices has increased over time in CS [10–12]. Hence; we sought to demonstrate the comprehensive nationwide data on the overall outcomes associated with the use of Impella versus IABP specifically in STEMI complicated by CS hospitalizations, using the most recent National Inpatient Sample (NIS) database.

2. Methods

2.1. Data sources

We used the National Inpatient Sample (NIS) database between October 2015 and December 2018 for the present analysis. The NIS is the largest publicly available all-payer inpatient care database in the United States. Unweighted, it contains data from more than 7 million hospital stays each year, and weighted, it estimates more than 35 million hospitalizations nationally. The NIS is maintained by the Healthcare Cost and Utilization Project (HCUP) through a Federal-State-Industry partnership sponsored by the Agency for Healthcare Research and Quality (AHRQ) [13]. Its large sample size is ideal for developing national and regional estimates and enables analyses of rare conditions, uncommon treatments, and special populations. Since the NIS uses de-identified hospital discharges as samples with prior ethical committee approval, no additional ethical committee approval was required for the present analysis. The NIS contains information regarding patient demographics, primary and secondary diagnosis at discharge, hospital characteristics, payment source, total charge, discharge status, length of stay and severity, and comorbidity measures. The Reporting of studies Conducted using Observational Routinely-collected health Data (RECORD) Statement – a checklist of items is provided as Supplementary Table 1.

2.2. Study cohort

We identified hospitalizations with STEMI complicated by CS, with either IABP or Impella implanted, between October 2015 and December 2018 using appropriate International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes (Supplementary Tables 2 and 3). We excluded the hospitalizations with <18 years old, who received both Impella and IABP, as well as underwent extracorporeal membrane oxygenation (ECMO) and/or left ventricular assist device (LVAD) placement (Fig. 1). The primary outcome was all-cause in-hospital mortality. The secondary outcomes were classified as efficacy, safety, and device-related complications endpoint as well as hospitalization cost. To obtain the cost of hospitalization, hospital charges were multiplied with the cost-to-charge ratios for each hospital for a given year and indexing to the year 2018 to adjust for inflation [14]. We also performed the subgroup analysis looking at the outcomes in hospitalizations who underwent PCI only as well as who did not have any intervention in terms of CABG or PCI (medically managed only).

2.3. Statistical analysis

We compared hospitalizations for age, gender, comorbidities, use of vasopressor support, and outcomes between patients who received IABP vs. Impella during the hospitalization. The Elixhauser Comorbidity Index was used to identify comorbid disorders.

Categorical variables are presented as numbers and percentages and compared using the Chi-square test. Numerical variables are presented as the median and interquartile range (IQR) and were compared using the Wilcoxon test. The P value of <0.05 was set as a level of significance. Discharge weights provided by the HCUP were applied to generate the national estimates as recommended [15]. Next, we examined whether the use of IABP, compared with Impella, was associated with a lower risk of our study endpoints. Since patients who receive IABP may differ from patients who receive Impella, we used a matched propensity score analysis to account for confounding. The propensity score was estimated using a non-parsimonious logistic regression model where the outcome was a receipt of IABP or Impella. The model included comorbidities and the use of vasopressors as variables and estimated the probability of receiving Impella for a given patient. We created matched cohorts using propensity score matching to balance the differences in comorbidities between the two groups. After logistic regression, propensity matching was performed using a one-to-one scheme without replacement using the nearest neighbor matching and a caliper width of 0.05 on the probability scale. We followed the methodology for analysis recommended by the NIS-HCUP as described in previous studies and included in Supplementary Table 4 [10,16]. All statistical analysis was performed with SAS 9.4 (SAS Institute, Inc., Cary, North Carolina).

3. Results

Among 75,769 STEMI hospitalizations complicated by CS, age < 18 (N = 15), hospitalizations who had both IABP and Impella placement (N = 1519), as well as who underwent ECMO and/or LVAD implantation (N = 1444) were excluded. In the final analysis, out of 72,791 admissions, 25,260 (34.70%) hospitalizations received IABP, and 7825 (10.75%) received Impella support (Fig. 1). Table 1 demonstrates baseline characteristics between IABP and Impella groups. The mean age was 65.9 years in the IABP cohort and 64.4 years in the Impella cohort. Males were less likely to receive IABP compared with Impella (70.51% vs. 75.08%, P value <0.0001). Hospitalizations which received IABP had a higher prevalence of major co-morbidities, including hypertension (39.37% vs. 30.46%, P value <0.0001), hyperlipidemia (54.39% vs. 47.64%, P value <0.0001), hypothyroidism (6.95% vs. 5.56%, P value <0.0001), and prior CABG (17.38% vs. 6.19%, P value <0.0001). In contrast, hospitalizations with Impella had a higher prevalence of electrolyte imbalance (48.67% vs. 55.04%, P value <0.0001), coagulopathy (16.45% vs. 20.31%, P value <0.0001), anemia (12.75% vs. 15.07%, P value <0.0001), peripheral vascular disease (7.88% vs. 11.30%, P value <0.0001), and prior percutaneous coronary intervention (75.42% vs. 82.89%, P value <0.0001). After the propensity-score matched analysis, each group had 7345 hospitalizations (Table 2). After propensity score matching, we did not notice any significant difference between the groups except gender difference and males remained significantly high in the Impella group. Absolute standardized difference

between variables before and after matching has been depicted in Fig. 2.

After propensity score-matched analysis, higher all-cause in-hospital mortality was observed in the Impella study cohort compared with IABP (42.10% vs. 31.54%; OR 1.71; 95% confidence interval (CI) 1.60–1.84, P value <0.0001) (Fig. 3, Tables 3 and 4). *Efficacy outcomes* including metabolic complications such as rate of acute kidney injury (AKI) (52.96% vs. 46.43%, OR 1.31, CI 1.22–1.40, P value <0.0001) and AKI requiring dialysis (7.42% vs. 4.90%, OR 1.56, CI 1.35–1.81, P value <0.0001) were significantly higher in Impella group compared with IABP. *Safety outcomes* including neurological complications such as ischemic stroke (3.88% vs. 2.45%, OR 1.34, CI 1.33–1.35, P value <0.0001) and hemorrhagic stroke (1.43% vs. 0.88%, OR 1.59, CI 1.16–2.18, P value 0.003) were significantly higher in Impella group compared with IABP. Hematological complications including rate of major bleeding (16.88% vs. 11.10%, OR 1.74, CI 1.58–1.92, P value <0.0001), GI bleeding (8.10% vs. 5.99%; OR 1.42, CI 1.25–1.62, P value <0.0001) and blood transfusion (12.93% vs. 6.74%; OR 2.27, CI 2.01–2.56, P value <0.0001) were also more in the Impella group compared with the IABP group. Furthermore, patients in the Impella cohort had higher rates of acquired hemolytic anemia than IABP (1.29% vs. 0.07%, OR: 20.49, CI 8.28–50.73, P value <0.0001). *Device-related complications* including device-related infection (0.48% vs. 0.07%, OR 7.58, CI 2.94–19.50, P value <0.0001), access site hemorrhage (1.70% vs. 0.41%, OR 4.64, CI 3.10–6.94, P value <0.0001) and hematoma (1.36% vs. 0.48%, OR 2.72, CI 1.84–4.02, P value <0.0001) were significantly higher in Impella group compared with IABP. Finally, total hospital charges 60,196 (43,636–84,239) vs. 36,073 (25,105–56,074) (P value <0.0001) were significantly higher in hospitalizations undergoing Impella placement compared with IABP. Outcomes in the PCI-only group and medically managed group have been described in Supplementary Tables 5, 6, 7, and 8.

4. Discussion

The present study compared in-hospital outcomes of MCS using IABP versus Impella in STEMI complicated by CS using the most recent national database. The main findings of our study are: (a) Impella was used in younger hospitalizations that were more likely to be male in

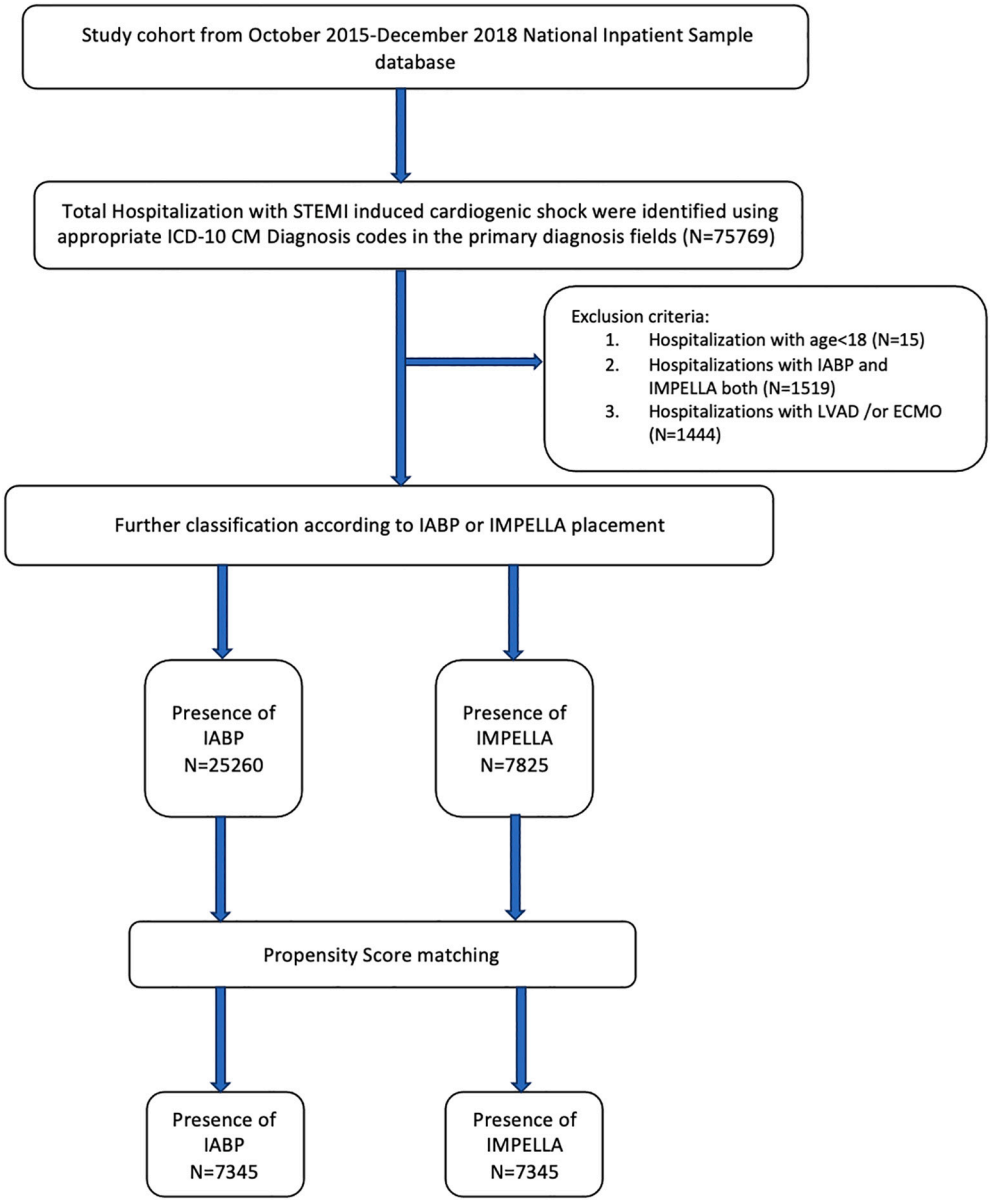

Fig. 1. Flow chart for participant inclusion.

Table 1
Baseline characteristics of hospitalizations with IABP compared with IMPELLA placements.

N = 72,791	IABP N = 25,260	Impella N = 7825	P value	SD
Mean age (SD)	65.9 ± 11.92	64.42 ± 11.74	<0.0001	13.0
Gender			<0.0001	10.0
Male	70.51%	75.08%		
Female	29.49%	24.92%		
Comorbidities				
Obesity	12.59%	12.52%	0.86	0.00
OSA	4.99%	4.73%	0.34	1.00
HTN	39.37%	30.46%	<0.0001	19.0
HLD	54.39%	47.64%	<0.0001	14.0
Family H/o CAD	9.22%	7.85%	0.0002	5.00
DM	13.56%	12.84%	0.10	2.00
Hypothyroidism	6.95%	5.56%	<0.0001	6.00
CHF	1.66%	1.47%	0.23	2.00
COPD	13.42%	13.86%	0.32	1.00
CKD	15.14%	15.01%	0.76	0.00
Pulmonary HTN	0.06%	0.06%	0.88	0.00
Smoking (tobacco use disorder)	26.23%	24.52%	0.002	4.00
Alcohol use	3.54%	3.77%	0.35	1.00
Drug abuse	2.30%	2.11%	0.32	1.00
Valvular heart disease	0.12%	0.13%	0.84	0.00
Electrolyte imbalance	48.67%	55.04%	<0.0001	13.0
Coagulopathy	16.45%	20.31%	<0.0001	10.0
Anemia	12.75%	15.07%	<0.0001	7.00
PVD	7.88%	11.30%	<0.0001	12.0
PCI	75.42%	82.89%	<0.0001	18.0
CABG	17.38%	6.19%	<0.0001	35.0
Use of vasopressors	10.67%	12.90%	<0.0001	7.00

Abbreviations: OSA = obstructive sleep apnea, HTN = hypertension, HLD = hyperlipidemia, CAD = coronary artery disease, DM = diabetes mellitus, CHF = congestive heart failure, COPD = chronic obstructive pulmonary disease, CKD = chronic kidney disease, PVD = peripheral vascular disease, PCI = percutaneous coronary intervention, CABG = coronary artery bypass graft.

Table 2
Baseline characteristics of hospitalizations with IABP compared with IMPELLA placements (Propensity Score Matched).

	IABP N = 7345	IMPELLA N = 7345	P value	SD
Mean age (SD)	64.78 ± 12.38	64.53 ± 11.70	0.57	*
Gender			<0.0001	*
Male	71.00%	74.86%		
Female	29.00%	25.14%		
Comorbidities				
Obesity	10.69%	11.32%	0.19	0.7
OSA	4.49%	4.70%	0.55	1.3
HTN	30.16%	30.63%	0.53	1.0
HLD	47.17%	48.20%	0.21	2.0
FH CAD	7.49%	8.24%	0.09	2.6
DM	12.05%	12.87%	0.13	2.4
Hypothyroidism	5.45%	5.92%	0.21	1.9
CHF	1.43%	1.50%	0.73	0.5
COPD	13.41%	13.89%	0.40	1.3
CKD	14.23%	15.25%	0.08	2.8
Pulmonary HTN	0.14%	0.07%	0.19	2.6
Smoking (tobacco use disorder)	23.89%	24.85%	0.17	2.1
Alcohol use	3.54%	3.88%	0.27	1.7
Drug abuse	2.38%	2.04%	0.16	2.3
Valvular heart disease	0.07%	0.14%	0.19	1.8
Electrolyte imbalance	54.32%	54.59%	0.74	0.5
Coagulopathy	20.35%	19.67%	0.30	1.7
Anemia	13.75%	14.84%	0.06	3.1
PVD	11.03%	11.10%	0.89	0.2
PCI	83.46%	83.05%	0.50	1.0
CABG	6.19%	6.13%	0.86	0.2
Use of vasopressors	13.27%	12.93%	0.54	1.05

Abbreviations: OSA = obstructive sleep apnea, HTN = hypertension, HLD = hyperlipidemia, CAD = coronary artery disease, DM = diabetes mellitus, CHF = congestive heart failure, COPD = chronic obstructive pulmonary disease, CKD = chronic kidney disease, PVD = peripheral vascular disease, PCI = percutaneous coronary intervention, CABG = coronary artery bypass graft.

comparison to IABP (b) The use of IABP was 3.2 times more common than Impella in STEMI hospitalizations complicated by CS. (c) Impella was associated with higher in-hospital mortality, AKI and AKI requiring dialysis (d) Impella was associated with a higher incidence of ischemic and hemorrhagic stroke, gastrointestinal bleeding, blood transfusion, and acquired hemolytic anemia compared with IABP. (e) The device-related complications were also higher with Impella as compared with IABP. (f) Hospitalizations in the Impella cohort were associated with significantly higher total hospital charges compared with IABP.

Previous clinical trials and observational studies have failed to show a significant improvement in mortality in patients with acute myocardial infarction complicated by CS who received IABP versus Impella [5,6,17–19]. The major limitation was each of these randomized controlled trials (RCTs) enrolled a limited number of patients. Additionally, as noted many times in the past, it is exceptionally difficult to start an RCT in an emergency setting like STEMI CS. Basir et al. and colleagues from the Detroit Cardiogenic shock initiative revealed mortality rates as low as 28% in patients who received Impella [20], compared to 42% in the present analysis, which can be explained by the Impella use by the organized and standardized shock team approach which incorporates hemodynamics and real time multidisciplinary discussions as part of an algorithm, strict exclusion criteria including several conditions that are independently associated with increased in-hospital mortality (i.e. unwitnessed arrest) designed for early response to MI and shock. However, it is not always the case in the real world, especially in small centers with limited pLVAD experience. Another plausible explanation for higher mortality in our study is that we only included patients with STEMI, compared to the study by Basir et al., which had both STEMI (71%) and NSTEMI (29%). Moreover, the 30-day mortality analysis of 237 patients from the IABP-SHOCK II trial revealed all-cause mortality in the Impella arm to be 48.5% which is even higher than our study [6]. A 2018 meta-analysis of five randomized controlled trials and one observational study comparing IABP and percutaneous ventricular assist devices (Impella & TandemHeart) included a total of 674 patients and found no significant differences with regards to 30-day or long-term mortality [21]. In a propensity-matched analysis utilizing the Premier Healthcare Database (2004–2016), an all-payer database representing approximately 20% of all acute care hospitalizations in the U.S., Amin et al. reported that Impella use was associated with a higher risk of in-hospital mortality compared with IABP in patients who underwent percutaneous coronary intervention requiring MCS [7]. Similar to the findings by Amin et al., the use of Impella was associated with worse all-cause in-hospital mortality compared with IABP in STEMI patients complicated by CS in our analysis as well.

The use of IABP was associated with a lower incidence of AKI compared with Impella, likely due to the diastolic augmentation of renal perfusion by IABP, thereby reducing rates of pre-renal AKI. This could also explain the higher mortality with Impella than IABP, similar to that seen with radial vs. femoral access in STEMI [22]. Another factor could be a higher volume of contrast exposure with Impella placement increasing the risk of contrast-induced nephropathy and AKI [23]. A higher incidence of hemolytic anemia due to mechanical hemolysis seen in the Impella cohort could also potentially account for AKI rates which were also observed in the previous studies [19,24,25]. Cerebrovascular accidents, including ischemic stroke, are rare with IABP since the balloon is positioned distal to the left subclavian artery, except if it is accidentally placed or migrates proximally [26]. Impella placement, on the other hand, inevitably requires crossing the aortic arch and the aortic valve, which could potentially account for the higher rates of embolic stroke seen with Impella in our study. Adequate anticoagulation

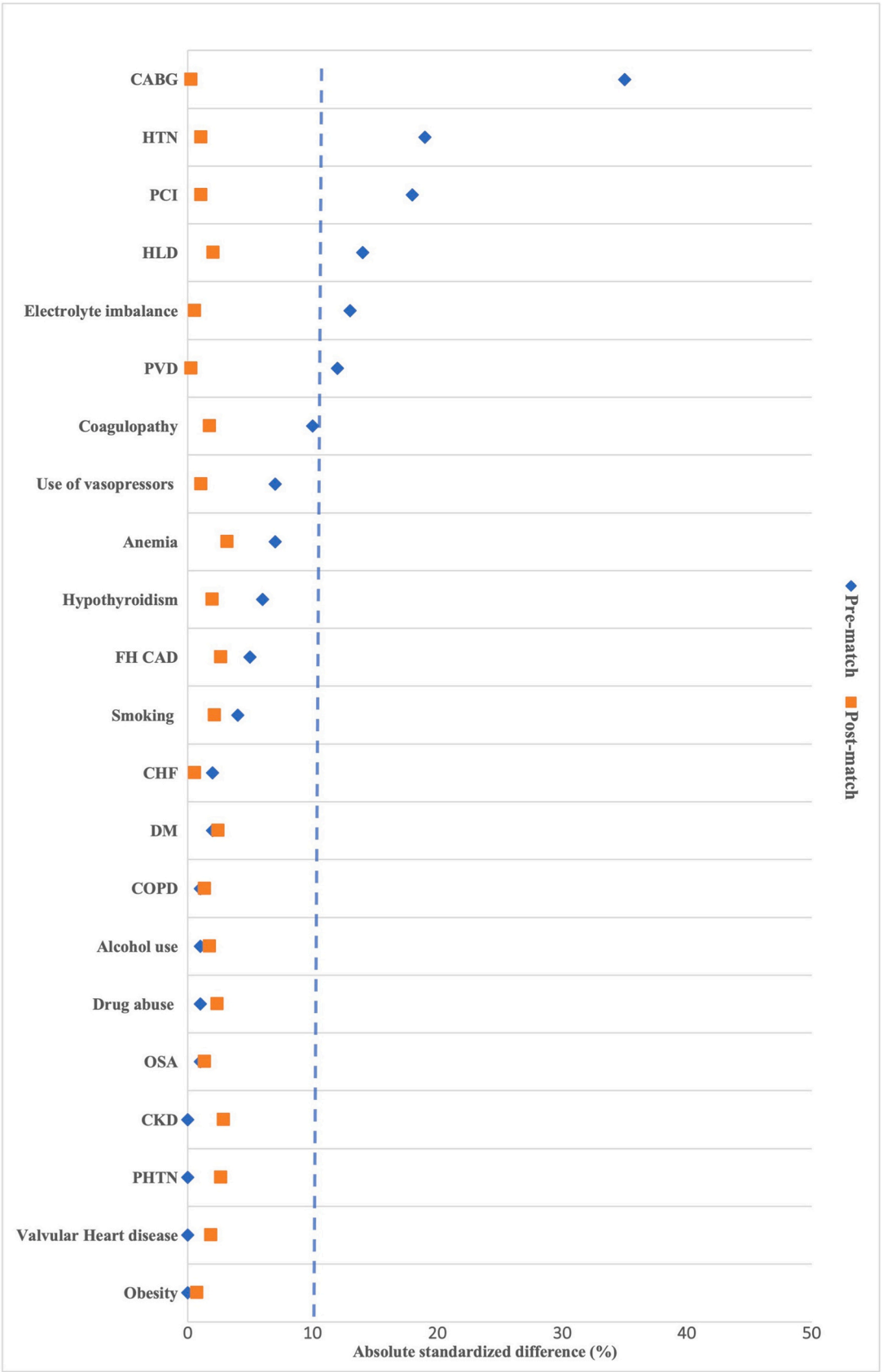

Fig. 2. Love plot representing the absolute standardized difference between variables before and after matching. OSA = obstructive sleep apnea, HTN = hypertension, HLD = hyperlipidemia, CAD = coronary artery disease, DM = diabetes mellitus, CHF = congestive heart failure, COPD = chronic obstructive pulmonary disease, CKD = chronic kidney disease, PVD = peripheral vascular disease, PCI = percutaneous coronary intervention, CABG = coronary artery bypass graft.

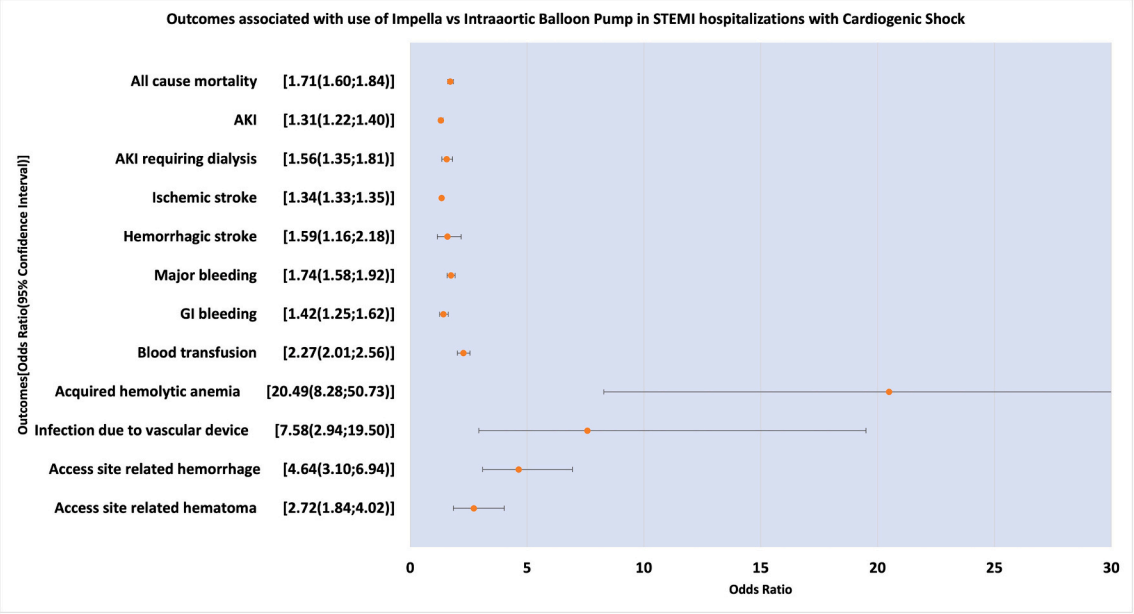

Fig. 3. Forest plot for in-hospital outcomes post propensity score matching. AKI = acute kidney injury, GI = gastro-intestinal.

Table 3
Outcomes of hospitalizations with IABP compared with IMPELLA placements (Propensity Score Matched).

Outcomes	IABP N = 7345	Impella N = 7345	P value
Efficacy endpoints			
All cause in hospital mortality	31.54%	42.10%	<0.0001
AKI	46.43%	52.96%	<0.0001
AKI requiring dialysis	4.90%	7.42%	<0.0001
Safety endpoints			
Ischemic stroke	2.45%	3.88%	<0.0001
Hemorrhagic stroke	0.88%	1.43%	0.002
Major bleeding (hemorrhage)	11.10%	16.88%	<0.0001
GI bleeding	5.99%	8.10%	<0.0001
Blood transfusion	6.74%	12.93%	<0.0001
Acquired hemolytic anemia	0.07%	1.29%	<0.0001
Device related complications			
Infection due to vascular device	0.07%	0.48%	0.0001
Access site related Hemorrhage	0.41%	1.70%	<0.0001
Access site related Hematoma	0.48%	1.36%	<0.0001
Hospital charges (median) ($)	36,073 (25,105–56,074)	60,196 (43,636–84,239)	<0.0001

Abbreviations: AKI = acute kidney injury.

Table 4
Odds ratio for outcomes of hospitalizations with IMPELLA compared with IABP placements (Propensity Score Matched).

Outcomes	Odds ratio	LL	UL	P value
Efficacy endpoints				
All cause in hospital mortality	1.71	1.60	1.84	<0.0001
AKI	1.31	1.22	1.40	<0.0001
AKI requiring dialysis	1.56	1.35	1.81	<0.0001
Safety endpoints				
Ischemic stroke	1.34	1.33	1.35	<0.0001
Hemorrhagic stroke	1.59	1.16	2.18	0.003
Major bleeding	1.74	1.58	1.92	<0.0001
GI bleeding	1.42	1.25	1.62	<0.0001
Blood transfusion	2.27	2.01	2.56	<0.0001
Acquired hemolytic anemia	20.49	8.28	50.73	<0.0001
Device related complications				
Infection due to vascular device	7.58	2.94	19.50	<0.0001
Access site related Hemorrhage	4.64	3.10	6.94	<0.0001
Access site related Hematoma	2.72	1.84	4.02	<0.0001

Abbreviations: AKI = acute kidney injury.

is a must with Impella to maintain the patency of the purge pathway in the event blood enters the motor, which is not the case with IABP where anticoagulation can be omitted as suggested in previous studies [27,28]. This, along with a higher rate of vascular complications, could partly explain the higher rate of bleeding complications along with the higher incidence of blood transfusion with Impella in our study, similar to the retrospective analysis by Amin et al. [7].

Access site-related hematoma/hemorrhage was more common with Impella use. This finding is intuitive as Impella requires a bigger access catheter size compared with IABP. The total hospital charges that were higher with the Impella group can be related to the higher cost of the Impella device and higher complication rates than IABP, as seen in this study [29]. Amin et al. also found higher incremental hospitalization costs associated with Impella use in their analysis [7].

The present analysis has several limitations. The NIS database is an administrative database and hence subject to under-coding, over-coding, or erroneous coding. However, since coding is the means of obtaining reimbursement, the error in coding for procedures like IABP and Impella implantation is less likely. While the ICD-10 PCS code only provides codes for percutaneous left ventricular assist device (pLVAD) placement, of which Impella forms the majority, the effect of other pLVAD cannot be excluded from the present analysis. However, these coding strategies have been utilized in prior studies and hence are validated. Second, we couldn't assess the severity of CS and thus the acuteness of the clinical picture due to the inherent limitation of the database, which can have a significant effect on the selection of the device and in-hospital outcomes. Along with CS severity, the NIS cannot assess the timing of Impella placement since the earlier placement of Impella has been linked with better outcomes [30]. Third, long-term outcomes in the two cohorts were not evaluated, which can substantially influence the choice of the MCS. Recent reports from registries like

the NCSI have reported significant improvements in survival rates in AMI CS patients when best practices like early initiation of MCS, following CS protocols, and large bore access care are followed. Whether the lack of such best practices and operator experience across multiple centers in the nation resulted in worse outcomes in Impella cohort cannot be addressed in a retrospective study. Fourth, there could be selection bias as this is not a randomized controlled trial, and the selection of the MCS devices may have been done at the operator's discretion. However, the use of Impella is expanding nationally, and our results do not support that this has been accompanied by improvement in outcomes. Standardization of CS protocols besides demonstration of benefit in randomized control trials is vital to improve outcomes in CS patients. The strengths of our analysis include using previously validated ICD-10 codes to identify conditions and propensity-score-matched analysis to reduce the effect of confounders.

In conclusion, the present analysis reported that in hospitalizations with STEMI complicated by CS, Impella compared with IABP was associated with higher in-hospital mortality, morbidity, and procedural-related outcomes. To further evaluate this, large-scale randomized studies are warranted to determine the effect of the Impella in this acutely sick population. Until then, the best approach would be to use team-based approaches to evaluate as much information as possible to help guide device selection on an individual patient basis, taking into account center and operator experience.

Funding

No funding was provided or utilized for this study.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ahjo.2021.100067.

References

[1] B. Redfors, O. Angerås, T. Råmunddal, C. Dworeck, I. Haraldsson, D. Ioanes, P. Petursson, B. Libungan, J. Odenstedt, J. Stewart, E. Lodin, M. Wahlin, P. Albertsson, G. Matejka, E. Omerovic, 17-year trends in incidence and prognosis of cardiogenic shock in patients with acute myocardial infarction in western Sweden, Int. J. Cardiol. 185 (2015) 256–262, https://doi.org/10.1016/j.ijcard.2015.03.106.

[2] R.V. Jeger, D. Radovanovic, P.R. Hunziker, M.E. Pfisterer, J.-C. Stauffer, P. Erne, P. Urban, Ten-year trends in the incidence and treatment of cardiogenic shock, Ann. Intern. Med. 149 (2008) 618–626, https://doi.org/10.7326/0003-4819-149-9-200811040-00005.

[3] K. Dhaval, K. Sahil, M. Marjan, A.W. S., P. Chandrasekar, S. Sachin, J. Diwakar, G. William, A. Ali, F.W. H., F.G. C., Trends in Incidence, Management, and Outcomes of Cardiogenic Shock Complicating ST-Elevation Myocardial Infarction in the United States, J. Am. Heart Assoc. 3 (2020), e000590, https://doi.org/10.1161/JAHA.113.000590.

[4] H. Thiele, U. Zeymer, F.-J. Neumann, M. Ferenc, H.-G. Olbrich, J. Hausleiter, G. Richardt, M. Hennersdorf, K. Empen, G. Fuernau, S. Desch, I. Eitel, R. Hambrecht, J. Fuhrmann, M. Böhm, H. Ebelt, S. Schneider, G. Schuler, K. Werdan, Intraaortic balloon support for myocardial infarction with cardiogenic shock, N. Engl. J. Med. 367 (2012) 1287–1296, https://doi.org/10.1056/NEJMoa1208410.

[5] D.M. Ouweneel, E. Eriksen, K.D. Sjauw, I.M. van Dongen, A. Hirsch, E.J.S. Packer, M.M. Vis, J.J. Wykrzykowska, K.T. Koch, J. Baan, R.J. de Winter, J.J. Piek, W. K. Lagrand, B.A.J.M. de Mol, J.G.P. Tijssen, J.P.S. Henriques, Percutaneous mechanical circulatory support versus intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction, J. Am. Coll. Cardiol. 69 (2017) 278–287, https://doi.org/10.1016/j.jacc.2016.10.022.

[6] S. Benedikt, I. Karim, L. Tobias, W. Nikos, S. Jan-Malte, P. Federico, P. Marina, S. Carsten, L. Alexander, L. Ulf, W. Ralf, H. Patrick, P. Matthias, E. Dennis, T. Raphael, N. Peter, S. Tim, A. Peter, E. Klaus, H.J. P.S., B.M. C., F.S. B., S. Jan-Thorben, M.J. Eifer, P. Nilesh, H. Jonathan, M. Philip, B.M. W., M.-W. Sven, S. P. Christian, O. Taoufik, Z. Uwe, S. Steffen, B. Stefan, T. Holger, S. Andreas, W. Dirk, Impella support for acute myocardial infarction complicated by cardiogenic shock, Circulation 139 (2019) 1249–1258, https://doi.org/10.1161/CIRCULATIONAHA.118.036614.

[7] A.P. Amin, J.A. Spertus, J.P. Curtis, N. Desai, F.A. Masoudi, R.G. Bach, C. McNeely, F. Al-Badarin, J.A. House, H. Kulkarni, S.V. Rao, The evolving landscape of impella use in the United States among patients undergoing percutaneous coronary intervention with mechanical circulatory support, Circulation 141 (2020) 273–284, https://doi.org/10.1161/CIRCULATIONAHA.119.044007.

[8] S.S. Dhruva, J.S. Ross, B.J. Mortazavi, N.C. Hurley, H.M. Krumholz, J.P. Curtis, A. Berkowitz, F.A. Masoudi, J.C. Messenger, C.S. Parzynski, C. Ngufor, S. Girotra, A.P. Amin, N.D. Shah, N.R. Desai, Association of use of an intravascular microaxial left ventricular assist device vs intra-aortic balloon pump with in-hospital mortality and major bleeding among patients with acute myocardial infarction complicated by cardiogenic shock, JAMA 323 (2020) 734–745, https://doi.org/10.1001/jama.2020.0254.

[9] I.D. Hanson, T. Tagami, R. Mando, A. Kara Balla, S.R. Dixon, S. Timmis, S. Almany, S.S. Naidu, D. Baran, A. Lemor, S. Gorgis, W. O'Neill, M.B. Basir, N.C. S. Investigators, SCAI shock classification in acute myocardial infarction: insights from the National Cardiogenic Shock Initiative, Catheter. Cardiovasc. Interv. 96 (2020) 1137–1142, https://doi.org/10.1002/ccd.29139.

[10] R. Khera, P. Cram, X. Lu, A. Vyas, A. Gerke, G.E. Rosenthal, P.A. Horwitz, S. Girotra, Trends in the use of percutaneous ventricular assist devices: analysis of national inpatient sample data, 2007 through 2012, JAMA Intern. Med. 175 (2015) 941–950, https://doi.org/10.1001/jamainternmed.2014.7856.

[11] A. Sandhu, L.A. McCoy, S.I. Negi, I. Hameed, P. Atri, S.J. Al'Aref, J. Curtis, E. McNulty, H.V. Anderson, A. Shroff, M. Menegus, R.V. Swaminathan, H. Gurm, J. Messenger, T. Wang, S.M. Bradley, Use of mechanical circulatory support in patients undergoing percutaneous coronary intervention insights from the national cardiovascular data registry, Circulation 132 (2015) 1243–1251, https://doi.org/10.1161/CIRCULATIONAHA.114.014451.

[12] M. Shah, S. Patnaik, B. Patel, P. Ram, L. Garg, M. Agarwal, S. Agrawal, S. Arora, N. Patel, J. Wald, U.P. Jorde, Trends in mechanical circulatory support use and hospital mortality among patients with acute myocardial infarction and non-infarction related cardiogenic shock in the United States, Clin. Res. Cardiol. 107 (2018) 287–303, https://doi.org/10.1007/s00392-017-1182-2.

[13] HCUP-US NIS Overview, (n.d.). https://www.hcup-us.ahrq.gov/nisoverview.jsp (accessed March 19, 2021).

[14] CPI Inflation Calculator, (n.d.). https://www.bls.gov/data/inflation_calculator.htm (accessed March 19, 2021).

[15] R. Khera, S. Angraal, T. Couch, J.W. Welsh, B.K. Nallamothu, S. Girotra, P.S. Chan, H.M. Krumholz, Adherence to methodological standards in research using the National Inpatient Sample, JAMA 318 (2017) 2011–2018, https://doi.org/10.1001/jama.2017.17653.

[16] S. Thakkar, H.P. Patel, M. Chowdhury, K. Patel, A. Kumar, S. Arora, S. Zahid, M. Goel, K. Barssoum, V. Jain, O.F. AbouEzzeddine, C.V. DeSimone, B. Baibhav, M. Rao, A. Deshmukh, Impact of arrhythmias on hospitalizations in patients with cardiac amyloidosis, Am. J. Cardiol. (2021), https://doi.org/10.1016/j.amjcard.2020.12.024.

[17] S. Manzo-Silberman, J. Fichet, A. Mathonnet, O. Varenne, S. Ricome, A. Chaib, B. Zuber, C. Spaulding, A. Cariou, Percutaneous left ventricular assistance in post cardiac arrest shock: comparison of intra aortic blood pump and IMPELLA recover LP2.5, Resuscitation 84 (2013) 609–615, https://doi.org/10.1016/j.resuscitation.2012.10.001.

[18] B. Alushi, A. Douedari, G. Froehlig, W. Knie, T.H. Wurster, D.M. Leistner, B.-E. Staehli, H.-C. Mochmann, B. Pieske, U. Landmesser, F. Krackhardt, C. Skurk, Impella versus IABP in acute myocardial infarction complicated by cardiogenic shock, Open Heart 6 (2019), e000987, https://doi.org/10.1136/openhrt-2018-000987.

[19] M. Seyfarth, D. Sibbing, I. Bauer, G. Fröhlich, L. Bott-Flügel, R. Byrne, J. Dirschinger, A. Kastrati, A. Schömig, A randomized clinical trial to evaluate the safety and efficacy of a percutaneous left ventricular assist device versus intra-aortic balloon pumping for treatment of cardiogenic shock caused by myocardial infarction, J. Am. Coll. Cardiol. 52 (2008) 1584–1588, https://doi.org/10.1016/j.jacc.2008.05.065.

[20] M.B. Basir, T.L. Schreiber, C.L. Grines, S.R. Dixon, J.W. Moses, B.S. Maini, A. K. Khandelwal, E.M. Ohman, W.W. O'Neill, Effect of early initiation of mechanical circulatory support on survival in cardiogenic shock, Am. J. Cardiol. 119 (2017) 845–851, https://doi.org/10.1016/J.AMJCARD.2016.11.037.

[21] S.A. Rios, C.A. Bravo, M. Weinreich, W. Olmedo, P. Villablanca, M.A. Villela, H. Ramakrishna, S. Hirji, O.A. Robles, P. Mahato, C. Gluud, D.L. Bhatt, U.P. Jorde, Meta-analysis and trial sequential analysis comparing percutaneous ventricular assist devices versus intra-aortic balloon pump during high-risk percutaneous coronary intervention or cardiogenic shock, Am. J. Cardiol. 122 (2018) 1330–1338, https://doi.org/10.1016/j.amjcard.2018.07.011.

[22] J. Silvain, L.S. Nguyen, V. Spagnoli, M. Kerneis, P. Guedeney, N. Vignolles, K. Cosker, O. Barthelemy, C.Le Feuvre, G. Helft, J.-P. Collet, G. Montalescot, Contrast-induced acute kidney injury and mortality in ST elevation myocardial infarction treated with primary percutaneous coronary intervention, Heart 104 (2018) 767–772, https://doi.org/10.1136/heartjnl-2017-311975.

[23] W.W. O'Neill, N.S. Kleiman, J. Moses, J.P.S. Henriques, S. Dixon, J. Massaro, I. Palacios, B. Maini, S. Mulukutla, V. Džavík, J. Popma, P.S. Douglas, M. Ohman, A prospective, randomized clinical trial of hemodynamic support with impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention: the PROTECT II study, Circulation 126 (2012) 1717–1727, https://doi.org/10.1161/CIRCULATIONAHA.112.098194.

[24] C.E. Kummerfeldt, A. Toma, A.O. Badheka, I. Azzam, D. Andrews, C. Alfonso, S. V. Chaparro, Severe hemolytic anemia and acute kidney injury after percutaneous continuous-flow ventricular assistance, Circ. Heart Fail. 4 (2011), https://doi.org/10.1161/CIRCHEARTFAILURE.111.964023.

[25] M. Sibbald, V. Džavík, Severe hemolysis associated with use of the impella LP 2.5 mechanical assist device, Catheter. Cardiovasc. Interv. 80 (2012) 840–844, https://doi.org/10.1002/ccd.24280.

[26] Intraaortic balloon pump counterpulsation - UpToDate, (n.d.). https://www.uptodate.com/contents/intraaortic-balloon-pump-counterpulsation (accessed December 24, 2020).

[27] L. Succar, E.M. Sulaica, K.R. Donahue, M.A. Wanat, Management of Anticoagulation with Impella® percutaneous ventricular assist devices and review of new literature, J. Thromb. Thrombolysis 48 (2019) 284–291, https://doi.org/10.1007/s11239-019-01837-6.

[28] P.H. Pucher, I.G. Cummings, A.R. Shipolini, D.J. McCormack, Is heparin needed for patients with an intra-aortic balloon pump? Interact. Cardiovasc. Thorac. Surg. 15 (2012) 136–139, https://doi.org/10.1093/icvts/ivs017.

[29] S.M. Fernando, D. Qureshi, P. Tanuseputro, R. Talarico, B. Hibbert, R. Mathew, B. Rochwerg, E.P. Belley-Côté, E. Fan, A. Combes, D. Brodie, M. Schmidt, T. Simard, P. Di Santo, K. Kyeremanteng, Long-term mortality and costs following use of Impella® for mechanical circulatory support: a population-based cohort study, Can. J. Anesth. 67 (2020) 1728–1737, https://doi.org/10.1007/s12630-020-01755-9.

[30] M.P. Flaherty, A.R. Khan, W.W. O'Neill, Early initiation of impella in acute myocardial infarction complicated by cardiogenic shock improves survival: a meta-analysis, JACC Cardiovasc. Interv. 10 (2017) 1805–1806, https://doi.org/10.1016/j.jcin.2017.06.027.