Multicenter registry of Impella-assisted high-risk percutaneous coronary interventions and cardiogenic shock in Poland (IMPELLA-PL)

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ABSTRACT

Background: Impella is a percutaneous mechanical circulatory support device for treatment of cardiogenic shock (CS) and high-risk percutaneous coronary interventions (HR-PCIs). IMPELLA-PL is a national retrospective registry of Impella-treated CS and HR-PCI patients in 20 Polish interventional cardiological centers, conducted from January 2014 until December 2021.

Aims: We aimed to determine the efficacy and safety of Impella using real-world data from IMPELLA-PL and compare these with other registries.

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Methods: IMPELLA-PL data were analyzed to determine primary endpoints: in-hospital mortality and rates of mortality and major adverse cardiovascular and cerebrovascular events (MACCE) at 12 months post-discharge.

Results: Of 308 patients, 18% had CS and 82% underwent HR-PCI. In-hospital mortality rates were 76.4% and 8.3% in the CS and HR-PCI groups, respectively. The 12-month mortality rates were 80.0% and 18.2%, and post-discharge MACCE rates were 9.1% and 22.5%, respectively. Any access site bleeding occurred in 30.9% of CS patients and 14.6% of HR-PCI patients, limb ischemia in 12.7% and 2.4%, and hemolysis in 10.9% and 1.6%, respectively.

Conclusions: Impella is safe and effective during HR-PCIs, in accordance with previous registry analyses. The risk profile and mortality in CS patients were higher than in other registries, and the potential benefits of Impella in CS require investigation.

Key words: cardiogenic shock, high risk-percutaneous coronary intervention, Impella, mechanical circulatory support, ST-segment elevation myocardial infarction

INTRODUCTION

The use of mechanical circulatory support (MCS) devices, developed to provide circulatory support in the setting of critical cardiogenic shock (CS) or end-stage heart failure (HF), has expanded to prophylactic short-term support during percutaneous cardiovascular procedures [1]. Joint efforts in biomedical engineering over the last 50 years have led to a shift from intracorporeal surgically-implanted MCS devices to the first extracorporeal percutaneous MCS devices, including the intra-aortic balloon pump (IABP) and percutaneous microaxial blood-pump (Impella) (Abiomed, Danvers, MA, US) [2]. Impella can provide hemodynamic support by continuously pumping blood from the left ventricle into the ascending aorta [3]. According to the European Society of Cardiology (ESC) guidelines, Impella should be considered in CS as bridge-to-recovery, bridge-to-decision, or bridge-to-bridge therapy (class IIa recommendation) [4]. Elective use of Impella during high-risk percutaneous coronary intervention (HR-PCI) procedures, while not clearly endorsed by the ESC [5], is advocated by the American College of Cardiology to prevent hemodynamic deterioration in selected high-risk patients, especially those with multivessel disease (MVD), left main (LM) disease, disease of the last patent conduit, and severe left ventricular dysfunction (class IIb recommendation) [6]. Since data on the superiority of Impella over the IABP are conflicting [7, 8], studies that evaluate the efficacy, safety, and cost-effectiveness of Impella use in real-world settings are urgently needed. Given that large, randomized trials of hemodynamic support in patients with CS and undergoing HR-PCI are challenging to conduct, national and international registries are a crucial source of high-quality data that provide novel insights into the characteristics of patients treated with Impella, supporting the decision-making process. Hitherto, four registries that specifically focus on Impella devices have been conducted: the Impella Italian Registry (IMP-IT) and German Registry in Europe, Japanese Registry for Percutaneous Ventricular Assist Device (J-PVAD) in Asia, and Catheter-Based Ventricular Assist Devices (cVAD) Registry in the US [9–12]. Regarding differences in international clinical practice and the dynamic development of Impella hemodynamic technology, the national, multicenter, investigator-initiated IMPELLA-PL registry was developed to share the knowledge and clinical experiences collected since the implementation of Impella technology in Poland.

The main goal of the IMPELLA-PL registry was to (1) describe clinical characteristics of patients treated with Impella during HR-PCI and CS; (2) evaluate the efficacy and safety of

WHAT'S NEW?

This retrospective study suggests that the percutaneous microaxial blood pump, Impella, is safe and effective in the treatment of high-risk percutaneous coronary intervention (HR-PCI). The PROTECT IV trial aimed to determine the safety and efficacy of Impella use in HR-PCI patients. The risk profile and mortality in cardiogenic shock (CS) patients were higher than in other registries; therefore, it remains challenging to compare our results with previously published data. The potential benefits of Impella in CS should be further investigated.

Impella-assisted treatment according to the prespecified endpoint definitions; and (3) compare the results with other registries.

METHODS

Design

IMPELLA-PL is a national, multicenter, retrospective registry conducted under auspices of the Polish Association of Cardiovascular Interventions [13]. The registry included consecutive treated with Impella for CS and HR-PCI in all Polish interventional cardiac centers which performed at least 3 interventions using Impella. IMPELLA-PL included consecutive patients treated with Impella for CS and HR-PCI. The subgroup of patients undergoing Impella-assisted revascularization included hemodynamically stable patients with severe coronary artery disease undergoing elective or urgent HR-PI after a Heart Team had determined that it was the appropriate therapeutic option. The subgroup of patients treated with Impella due to CS included those with ongoing CS refractory to the optimal medical management and conventional treatment measures, including volume loading and use of pressors and inotropes, with or without an IABP [13].

Clinical characteristics, procedural data, and outcomes for consecutive patients treated with Impella devices from 2014 until December 2021 were collected retrospectively in a password-protected database, with a 12-month follow-up data collected on the basis of in-hospital and ambulatory medical records.

Endpoints

The main efficacy endpoints were (1) in-hospital mortality, (2) 12-month mortality; and (3) 12-month major adverse cardiovascular and cerebrovascular events (MACCEs), including mortality, rehospitalization for HF, acute myocardial infarction (MI), repeat revascularization, stroke, left ventricular assist device (LVAD) implantation, and heart transplantation following hospital discharge. Data on efficacy and safety were collected as well, including cardiosurgical intervention, exacerbation of HF, MI, acute kidney injury (AKI) inflammatory complications, severe bleeding complications (per operator judgment and defined as type ≥3 according to the Bleeding Academic Research Consortium; BARC), and device-related complications. The prespecified endpoint definitions have been published previously [13].

Statistical analysis

Statistical analysis was performed by an independent statistician with IBM SPSS Statistics, version 24.0. Categorical variables were summarized using frequencies and proportions and compared using the χ^2 test. Continuous data were expressed as means (standard deviations) or medians (interquartile ranges) and compared using a t-test or Mann–Whitney U test, depending on distribution. Statistical tests were two-sided, with a significance level of 0.05.

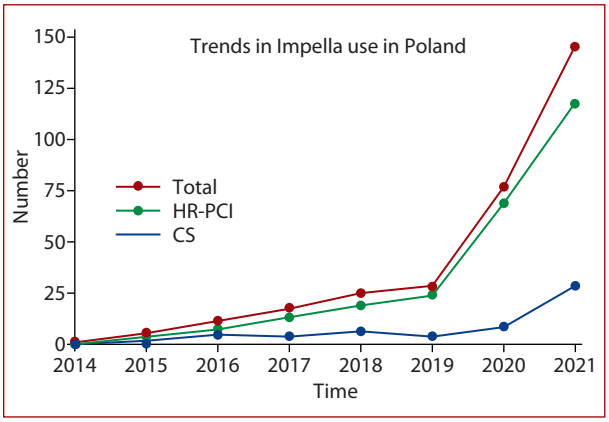

Figure 1. Trends in the use of Impella in Poland during the study period in patients presenting with CS (blue line), undergoing HR-PCI (green line), and total insertions (red line)

Abbreviations: CS, cardiogenic shock; HR-PCI, high-risk percutaneous coronary intervention

RESULTS

Altogether, 308 patients were enrolled in the registry in 20 Polish centers, including 253 (82.1%) who received Impella support for HR-PCI and 55 (17.9%) who received it for CS. Trends in the use of Impella in Poland during the study period in patients presenting with CS (blue line), undergoing HR-PCI (green line), and total insertions (red line) are shown in Figure 1. The study chart diagram is shown in Figure 2. Overall, the use of Impella increased steadily from 2014 to 2019 and exponentially from 2019 to 2021, with 4.6-fold higher Impella use in HR-PCI, compared to CS. Baseline characteristics and angiographic and procedural characteristics of patients treated with Impella for CS and HR-PCI are presented in Table 1 and Table 2, respectively. In-hospital and 12-month outcomes are reported in Table 3.

Impella for cardiogenic shock

In terms of baseline characteristics (Table 1), the median age of patients presenting with CS was 63.0 years, and 76% were male. The main CS etiology was ST-segment elevation myocardial infarction (STEMI), followed by non-ST-segment elevation myocardial infarction (NSTEMI) and myocarditis. Over 30% of patients had a history of prior MI, and over 20%, had a history of prior PCI. Median left ventricular ejection fraction (LVEF) was 22.5%, and the median EuroSCORE II value was 21.8.

Coronary angiography was performed in 90.9% of patients (Table 2). The majority of patients presented with MVD, either with or without LM coronary artery stenosis. The median SYNTAX Score II was 38.5. In terms of procedural characteristics, emergent PCI was done in 83.6% of patients, including the LM coronary artery PCI in 47.3%. All lesions were successfully treated in 63.6%.

All patients were treated with Impella Cardiac Power (CP), except for one case of Impella 5.0 use (Table 2). Impella was inserted before PCI in 52.7% of patients, during PCI in 27.3% of patients and after PCI in 14.5%. It was explanted

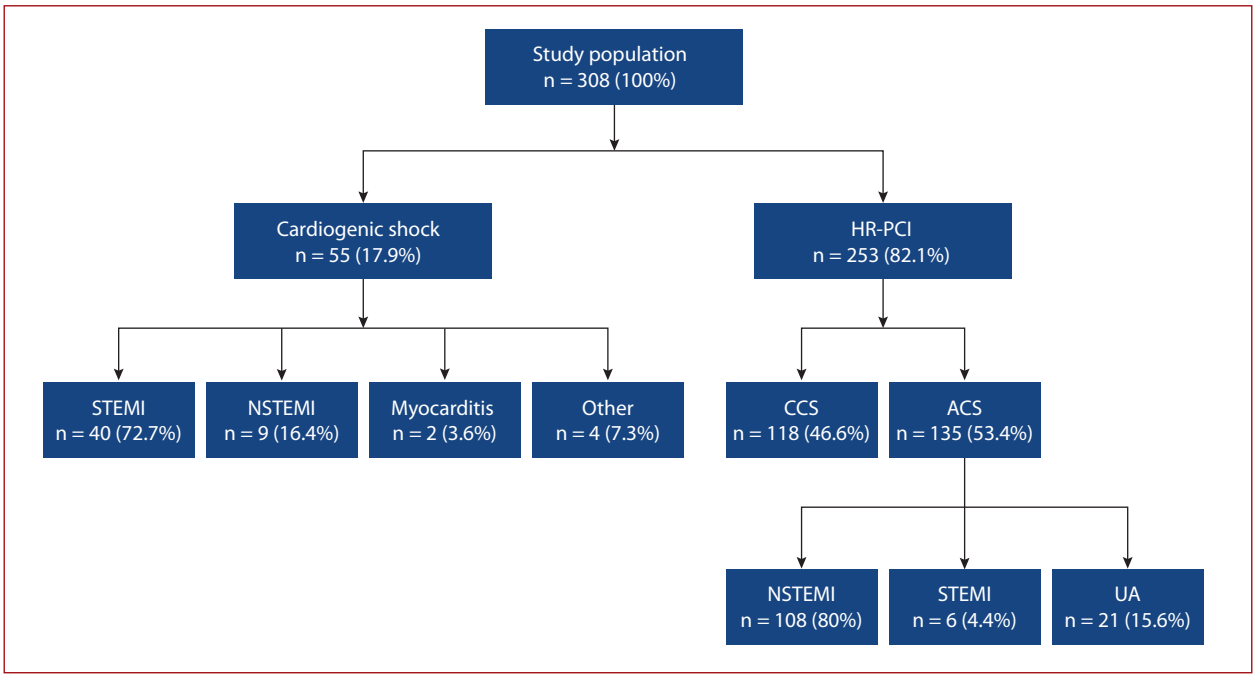

Figure 2. Study flow chart of the IMPELLA-PL registry

Abbreviations: ACS, acute coronary syndrome; CCS, chronic coronary syndrome; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; UA, unstable angina

in the catheterization laboratory in 14.5% of patients. The median insertion time was 20 minutes, and the median duration of support was 45 hours. The most common vascular access sites for Impella were the right and left femoral arteries (Table 2). Single access for simultaneous mechanical support and PCI was used in fewer than 10% of patients.

Regarding other measures of cardiopulmonary support, nearly all patients received catecholamines, most required mechanical ventilation, nearly 30% received levosimendan, 25.5% received an IABP (11 before and 3 after Impella insertion), and 12.7% received extracorporeal membrane oxygenation (ECMO; 3 patients before and 4 after Impella insertion).

The Kaplan-Meier curve showing 12-month survival in the IMPELLA-PL registry is in Figure 3. In-hospital and 12-month outcomes are presented in Table 3. The in-hospital mortality rate was 76.4% (42 patients), and the total 12-month mortality rate was 80.0% (44 patients). Five patients (9.1%) experienced 12 MACCEs during the 12-month follow-up period, including 2 post-discharge deaths, 3 readmissions for HF, 1 MI, 1 stroke, 1 LVAD implantation, and 1 heart transplantation.

Acute kidney injury occurred in over 60% of patients, and 32.7% of them required dialysis. One in three patients experienced bleeding complications according BARC criteria. Device-related complications, including any access site bleeding, limb ischemia, and hemolysis, occurred in 30.9%, 12.7%, and 10.9% of patients, respectively.

Impella to protect HR-PCI

The median age of patients in the HR-PCI group was 70.0 years, and 87.4% were male (Table 1). 53.4% of patients underwent HR-PCI in the setting of chronic coronary syndrome and the remaining in the setting of acute coronary syndrome, mostly NSTEMI. More than 50% of patients had a history of prior MI, nearly 40% a history of previous PCI, and over 10% a history of previous coronary artery bypass grafting. Median LVEF was 26.0%, and the median EuroSCORE II value was 5.1.

In terms of angiographic characteristics (Table 2), over 60% of patients presented with MVD including the LM, followed by MVD except for the LM. Severe calcifications and chronic total occlusions were present in 55.3% and 54.2%, respectively. The median SYNTAX Score II was 43. PCI was performed in nearly all patients, including the LM coronary artery in nearly 69.2% and the left anterior descending artery in nearly 78.3%. All lesions were successfully treated in over 83%. PCI was performed *via* the Impella sheath in about 17.8% of patients.

All patients were treated with Impella CP (Table 2). Impella was inserted before PCI in 81.8%. It was removed directly after PCI in 93.7%. The median insertion time was 25.0 minutes, and the median duration of support was 3.0 hours. The most common vascular access for Impella was the right or left femoral artery (54.5% and 39.9% of patients, respectively). Alternative access was used in 14 patients (approximately 5%). Single access for simultaneous mechanical support and PCI was used in 17.8%.

Table 1. Baseline characteristics

	Cardiogenic shock (n = 55; 17.9)	HR-PCI (n = 253; 82.1)
Age	63.0 (50.0–69.0)	70.0 (64.0–78.0)
Male sex, n (%)	42 (76.4)	221 (87.4)
BMI, kg/m^2	27.7 (24.7–31.1)	27.1 (24.4–30.5)
Clinical presentation		
Acute coronary syndrome, n (%)	49 (89.1)	135 (53.4)
STEMI, n (%)	40 (72.7)	6 (4.4)
NSTEMI, n (%)	9 (16.4)	108 (80)
Unstable angina, n (%)	0 (0.0)	21 (15.6)
Chronic coronary syndrome, n (%)	0 (0.0)	118 (46.6)
Myocarditis, n (%)	2 (3.6)	0 (0.0)
Risk factors		
Hypertension, n (%)	26 (47.3)	199 (78.7)
Dyslipidemia, n (%)	21 (38.2)	198 (78.3)
Diabetes mellitus, n (%)	18 (32.7)	118 (46.6)
Prior MI, n (%)	19 (35.5)	132 (52.2)
Previous PCI, n (%)	13 (23.6)	93 (36.8)
Previous CABG, n (%)	0 (0)	27 (10.7)
Atrial fibrillation, %	10 (18.2)	75 (29.6)
Paroxysmal	8	37
Permanent	1	25
Persistent	1	13
Chronic heart failure, n (%)	53 (96.4)	249 (98.4)
Previous stroke, n (%)	7 (12.7)	24 (9.5)
Previous TIA, n (%)	3 (5.5)	12 (4.7)
Chronic kidney disease, n (%)	18 (32.7)	94 (37.2)
Dialysis, n (%)	1 (1.8)	4 (1.6)
COPD, n (%)	3 (5.5)	28 (11.5)
PAD, n (%)	7 (12.7)	76 (30.0)
EuroSCORE II, median (range)	21.8 (12.4–37.6)	5.1 (2.7–9.4)
Cardiac arrest before admission, n (%)	26 (47.3)	9 (3.6)
VF, n (%)	16 (29.1)	4 (1.6)
VT, n (%)	3 (5.5)	2 (0.8)
PEA, n (%)	4 (7.3)	2 (0.8)
Asystole, n (%)	5 (9.1)	1 (0.4)
ICED, n (%)	3 (5.5)	43 (17.0)
Pacemaker, n (%)	0 (0)	10 (4.0)
ICD, n (%)	3 (5.5)	28 (11.1)
CRT, n (%)	0 (0)	12 (4.7)
Laboratory investigations		
Hemoglobin, g/dl	13.3 (2.4)	13.0 (2.2)
Platelets, x10^9/l	244.9 (88.7)	222.6 (90.9)
Creatinine, mg/dl	1.4 (1.4)	1.4 (0.7)
NT-proBNP, pg/ml	8784 (9357)	7918 (14132)
Troponin, ng/ml	387 (1348)	467 (3636)
pH	7.3 (7.1–7.4)	7.4 (7.4–7.5)
Lactate, mmol/l	7.4 (7.2–7.5)	1.7 (1.3–4.4)
Echocardiographic characteristics		
LVEDD, mm	53.5 (48.0-59.5)	60.0 (53.0-66.3)
LA, mm	44.0 (38.0-45.0)	45.0 (42.0-50.0)
LVEF, %	22.5 (15.0-29.5)	26.0 (20.0-37.0)
RV dysfunction, n (%)	12 (21.8)	45 (17.8)
Mitral regurgitation grade 3 or 4, n (%)	6 (10.9)	43 (17.0)
Tricuspid regurgitation grade 3 or 4, n (%)	7 (12.7)	36 (14.2)
Severe aortic stenosis, n (%)	1 (1.8)	3 (1.2)

Data presented as n (%), means (standard deviations), or medians (interquartile ranges). The t-test or Mann-Whitney U test was used for continuous variables and the χ^2 test for categorical variables

Abbreviations: BMI, body mass index; CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; CRT, cardiac resynchronization therapy; ICED, implantable cardiac electronic devices; ICD, implantable cardioverter-defibrillator; LVEDD, left ventricular end-diastolic diameter; LA, left atrium; LVEF, left ventricular ejection fraction, MI, myocardial infarction; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention; PEA, pulseless electrical activity; RV, right ventricle; TIA, transient ischemic attack; VF, ventricular fibrillation; VT, ventricular tachycardia

Table 2. Angiographic and procedural characteristics

	Cardiogenic shock (n = 55; 17.9)	High-risk PCI (n = 253; 82.1)
Angiographic characteristics, n (%)		
Coronary angiography performed, %	50 (90.9)	253 (100.0)
Number of vessels with significant stenosis	3 (1.0-4.0)	3 (3.0-4.0)
Severe calcifications	15 (27.3)[a]	140 (55.3)
Chronic total occlusions	14 (25.5)[a]	137 (54.2)
In-stent restenosis	3 (5.5)[a]	17 (6.7)
In-stent thrombosis	2 (3.6)[a]	1 (0.4)
Intravascular imaging	11 (20.0)[a]	104 (41.1)
IVUS	11 (20.0)	102 (40.3)
OCT	0 (0)	2 (0.8)
Functional assessment	0 (0)	9 (3.6)
Extent of the disease		
One-vessel	8 (14.5)	1 (0.4)
Multi-vessel (except for LM)	17 (30.9)	61 (24.1)
Multi-vessel (including LM)	21 (38.2)	161 (63.6)
Missing data	30 (11.9)	9 (16.4)
SYNTAX Score II	38.5 (32.3–47.5)	43 (32.4–55.0)
Procedural characteristics, n (%)		
PCI performed	46 (83.6)	251 (99.2)
Rotational atherectomy used	5 (9.1)	77 (30.4)
All lesions successfully treated	35 (63.6)	210 (83.0)
Vessel treated		
LM	26 (47.3)	175 (69.2)
LAD	34 (61.8)	198 (78.3)
Cx	14 (25.5)	140 (55.3)
RCA	11 (20.0)	48 (19.0)
Impella		
Use of Impella CP, n (%)	54 (98.2)	253 (100.0)
Use of Impella 5.0, n (%)	1 (1.8)	0 (0.0)
Timing of Impella placement		
Before PCI, n (%)	29 (52.7)	207 (81.8)
During PCI, n (%)	15 (27.3)	44 (17.4)
After PCI, n (%)	8 (14.5)	0 (0)
Missing data, n (%)	3 (5.5)	2 (3.6)
Explantation in catheterization lab, n (%)	8 (14.5)	237 (93.7)
Time of insertion, min	20.0 (15.0–31.0)	25.0 (15.0–40.0)
Duration of support, h	45.0 (19.0–120.0)	3.0 (2.0–73.0)
Vascular access for Impella		
Right femoral artery, n (%)	32 (58.2)	138 (54.5)
Left femoral artery, n (%)	22 (40.0)	101 (39.9)
Right subclavian artery, n (%)	1 (1.8)	8 (3.2)
Left subclavian artery, n (%)	0 (0)	6 (2.4)
Ultrasound-guided puncture, n (%)	18 (32.7)	70 (27.7)
Surgical access, n (%)	1 (1.8)	38 (15.0)
Single access, n (%)	4 (7.3)	45 (17.8)
Contralateral safety access, n (%)	1 (1.8)	22 (8.7)
Other cardiopulmonary support		
Use of catecholamines, n (%)	54 (98.2)	47 (18.6)
Use of levosimendan, n (%)	15 (27.3)	13 (5.1)
Use of mechanical ventilation, n (%)	44 (80.0)	10 (4.0)
Mechanical ventilation, hours	43.0 (24.0–110.0)	46.0 (7.75–75.0)
Use of ECMO, n (%)	7 (12.7)	6 (2.4)
Use of IABP, n (%)	14 (25.5)	5 (2.0)
Use of other LVAD, n (%)	12 (21.8)	27 (10.7)
Last available LVEF, n (%)	27.7 (12.6)	32.9 (12.4)
In-hospital stay, days	5.5 (2.0–15.0)	11.0 (7.0–18.0)
Intensive care stay, days	3.5 (2.0–9.0)	6.5 (2.3–30.8)

Data presented as n (%) and medians (interquartile ranges)
[a]In 5 of 55 patients with CS coronary angiography was not performed

Abbreviations: Cx, circumflex artery; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; LAD, left anterior descending artery; LM, left main coronary artery; LVAD, left ventricular assist device; LVEF, left ventricular ejection fraction; OCT, optical coherence tomography; PCI, percutaneous coronary intervention; RCA, right coronary artery

Table 3. In-hospital and 12-month outcomes

	Cardiogenic shock (n = 55; 17.9)	High-risk PCI (n = 253; 82.1)
In-hospital outcomes		
Mortality, n (%)	42 (76.4)	21 (8.3)
Need for cardiosurgical intervention, n (%)	4 (7.3)	1 (0.4)
Exacerbation of HF, n (%)	35 (63.6)	12 (4.7)
Acute myocardial infarction, n (%)	5 (9.1)	11 (4.3)
Acute kidney injury, n (%)	34 (61.8)	32 (12.6)
Need for renal replacement therapy, n (%)	18 (32.7)	4 (1.6)
Inflammatory complications, n (%)	22 (40.0)	35 (13.8)
Any bleeding complications, n (%)	25 (45.5)	34 (13.4)
Severe bleeding complications, n (%)	19 (34.5)	16 (6.3)
BARC 3a	6 (10.9)	12 (4.7)
BARC 3b	7 (12.7)	4 (1.6)
BARC 3c	0 (0.0)	0 (0.0)
BARC 5a	4 (7.3)	0 (0.0)
BARC 5b	2 (3.6)	0 (0.0)
RBC transfusion, n (%)	22 (40)	34 (13.4)
Number of RBC units transfused	4.5 (3–6.5)	2 (2.0–2.0)
Device-related complications, n (%)		
Any access site bleeding	17 (30.9)	37 (14.6)
Limb ischemia	7 (12.7)	6 (2.4)
Endovascular intervention	3 (5.5)	8 (3.2)
Surgical intervention	3 (5.5)	8 (3.2)
Hemolysis	6 (10.9)	4 (1.6)
Aortic injury	0 (0.0)	1 (0.4)
12-month outcomes, n (%)		
Mortality after discharge	2 (3.6)	25 (9.9)
Rehospitalization for HF	3 (5.5)	25 (9.9)
MI	1 (1.8)	3 (1.2)
Repeat revascularization	0 (0)	8 (3.2)
PCI	0 (0)	8 (3.2)
CABG	0 (0)	0 (0)
Stroke	1 (1.8)	4 (1.6)
Permanent LVAD implantation	1 (1.8)	1 (0.4)
Heart transplantation	1 (1.8)	3 (1.2)
Number of MACCEs	9 (16.3)	69 (27.3)
Number of patients that experienced MACCEs	5 (9.1)	57 (22.5)
Total mortality	44 (80.0)	46 (18.2)
In patients who received Impella before PCI	23/29 (79.3)	39/207 (18.8)
In patients who received Impella during or after PCI	19/23 (82.6)	5/44 (11.4)

Data are presented as n (%)

Abbreviations: CABG, coronary artery bypass graft; HF, heart failure; LVAD, left ventricular assist device; PCI, percutaneous coronary intervention; RBC, red blood count

Other cardiopulmonary support (Table 2) included catecholamines (18.6%), levosimendan (5.1%), mechanical ventilation (4.0%), ECMO (2.4%; 1 before and 5 after Impella insertion), and an IABP (2.0%; 4 before and 1 after Impella insertion).

The in-hospital mortality rate was 8.3% (21 patients), and the total 12-month mortality rate was 18.2% (46 patients, Figure 3, Table 3). In a group of patients who were discharged from the hospital, 57 experienced 69 MACCEs during the 12-month follow-up, including 25 post-discharge deaths, 25 readmissions for HF, 3 MI, 8 repeated revascularizations, 4 strokes, 1 LVAD implantation, and 3 heart transplantations.

AKI occurred in 12.6% of patients, and about 1% of them required dialysis (Table 3). Severe bleeding complications according to the BARC definition were reported in 16 patients (6.3%). The rate of device-related complications including any access site bleeding, limb ischemia, hemolysis, and aortic injury was 14.6%, 2.4%, 1.6%, and 0.4%, respectively.

DISCUSSION

The main findings of the IMPELLA-PL registry are that (1) the use of Impella devices for CS and HR-PCI has greatly increased since their introduction in Poland, with HR-PCI being the predominant indication, with more than 80% of patients receiving Impella with nearly exclusive use of Impella CP; (2) the baseline risk profile of CS patients was substantially higher than in other registries and associated with high mortality and complication rates; (3) the risk

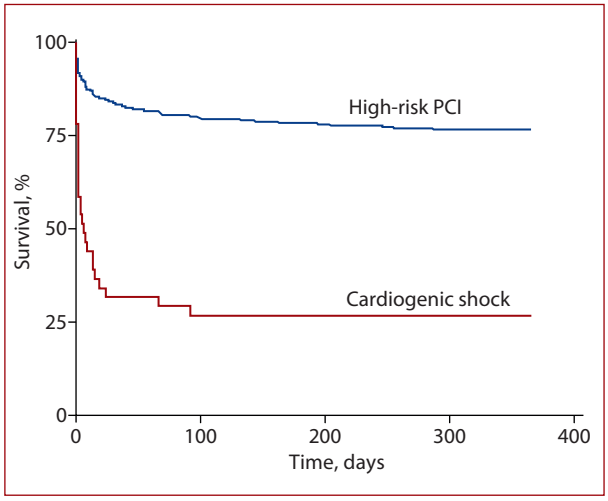

Figure 3. Kaplan-Meier curve showing 12-month survival in the IMPELLA-PL registry

Abbreviations: PCI, percutaneous coronary intervention

profile of HR-PCI patients, their mortality and complications rates were consistent with other registries.

IMPELLA-PL differs from other registries in terms of MCS indications and the Impella model used. First, regarding the indications, HR-PCI constituted over 80% of patients treated with Impella in Poland, whereas over 50% of patients in the Italian registry received Impella due to CS [9]. Other registries published the results for CS and HR-PCI patients separately and from different periods, precluding direct comparisons [9, 11, 12]. Second, in our registry, all CS and HR-PCI patients were treated with Impella CP, except for one CS patient, in whom Impella 5.0 was surgically implanted. In 2008, Impella 2.5 became the first approved Impella model and was the most used device in other registries (60%–96%), although Impella CP was rapidly adopted after its introduction in 2012 [9–12]. The 14 F Impella CP, with an average maximum flow of 3.7 l/min and a peak flow of 4.3 l/min, is designed to offer a higher level of support compared to the 12 F Impella 2.5 [14]. Although there have been no prospective studies comparing both pump models in terms of efficacy and safety, improved prognosis has been reported following the switch from Impella 2.5 to Impella CP in individual patients [15]. Nevertheless, the crude rates of all-cause mortality did not differ according to the type of Impella device used [10]. Still, one should remain cautious when comparing results of different retrospective registries with different endpoint definitions, and prospective studies are needed to research further the development of Impella technology.

Impella in cardiogenic shock

The baseline risk profile of CS patients in our registry was extremely high, with 70% of patients presenting with STEMI, 70% with severe three-vessel disease with or without concomitant left main disease, close to 50% with cardiac arrest before admission; all received catecholamines, 80% required mechanical ventilation, 25% a concomitant IABP and over 10% concomitant ECMO. In other registries, the rate of patients with prior cardiac arrest was lower (23%–24%) [10, 16] and initial ejection fraction was higher [10, 16, 17], suggesting that the baseline risk profile of CS patients in our registry was higher than in other registries. Consequently, the mortality and complication rates were also higher, with AKI, bleeding, and inflammatory complications being the most frequent (Table 4).

Currently, MCS has a class IIa recommendation in the recent ESC guidelines for the treatment of cardiogenic shock, with no preference towards a specific MCS type

Table 4. Comparison of outcomes in patients enrolled in five main registries that specifically focus on Impella devices: Impella in Poland (IMPELLA-PL), Impella Italian (IMP-IT), German Registry, Japanese Registry for Percutaneous Ventricular Assist Device (J-PVAD) in Asia, Catheter-Based Ventricular Assist Devices (cVAD) Registry in the US

Cardiogenic shock				
	IMPELLA-PL n = 55	IMP-IT n = 229	J-PVAD n = 819	cVAD n = 154
Hemolysis, %	10.9	20.5	11.2	10.3
AKI, %	61.8	50.5	–	18.1
Bleeding, %	45.5[a]	15.7	6.1	20.1
Inflammatory, %	40.0	30.5	–	12.9
Neurological, %	1.8	6.6	1.6	1.9
HR-PCI				
	IMPELLA-PL n = 253	IMP-IT n = 177	German Registry n = 154	cVAD n = 637
Hemolysis, %	1.6	0.5	–	0.2
AKI, %	12.6	13.0	–	5.8
Bleeding, %	13.4[a]	5.1	4.5	11.0
Inflammatory, %	13.8	4.1	–	–
Neurological, %	1.6	2.0	0.0	0.0

Definitions of subsequent outcomes may differ between the registries, warranting caution when comparing the outcomes

[a]Any bleeding per investigator judgment

Abbreviations: AKI, acute kidney injury; HR-PCI, high-risk percutaneous coronary intervention

[4]. Initially, it was suggested that Impella may have an advantage over IABPs in patients with MI complicated by CS [18]. Data from systematic reviews and registry-based analyses questioned these assumptions, suggesting no mortality benefit and even adverse effects in patients treated with Impella compared to IABPs [19, 20]. However, the randomized controlled studies included in these meta-analyses had variable definitions of cardiogenic shock, slow enrollment rates, high crossover between the randomization arms, and variable time of Impella treatment initiation. For example, recent analyses showed that the timing of Impella insertion is a key to clinical success, with pre-PCI Impella insertion associated with a substantial survival benefit, compared to insertion during or after PCI [21, 22], especially in women [23]. In our registry, the baseline risk was very high, so Impella was inserted before PCI in about 50% of patients and mostly used to escalate IABP or ECMO therapy, which explains the very unfavorable outcomes [10]. Due to the retrospective design, we did not have complete clinical variables to establish the Society of Cardiovascular Angiography & Interventions (SCAI) Shock Classification. We believe that one of the reasons for high mortality in CS patients was implementation of Impella therapy far too late (as indicated by the median lactate of 7.4 mmol/l) potentially due to initial reimbursement problems with Impella in Poland. We are planning to complete the missing clinical variables and perform a separate analysis in CS patients to better understand the potential reasons for such high mortality. Altogether, further studies are required for heart teams to navigate toward the optimal patient selection and timing of MCS initiation and answer the question of whether the survival benefit of Impella therapy in CS outweighs the risk of complications, compared with the standard of care.

Impella to protect HR-PCI

The prospective multicenter PROTECT I trial (n = 20) demonstrated that Impella 2.5 can be successfully used during HR-PCI [24]. In the intention-to-treat analysis of the randomized controlled PROTECT II trial, patients supported with Impella 2.5 (n = 226) had numerically improved outcomes at 90 days compared to the IABP (n = 226) ($P = 0.147$). In the per-protocol analysis, Impella was associated with fewer MACCEs than the IABP ($P = 0.048$) [25]. Subsequently, analysis of the prospective single-arm PROTECT III trial including HR-PCI patients supported with Impella 2.5 and Impella CP (n = 504) demonstrated more complete revascularization, lower bleeding rate, and improved 90-day clinical outcomes compared to the historic cohort of PROTECT II patients with mean LVEF of 23% [26]. The use of Impella was associated with over 75% lower risk of post-PCI AKI than expected in the current risk models, and lower risk of AKI than the use of veno-arterial ECMO, suggesting that Impella insertion might be a new protective strategy against AKI during HR-PCI [27, 28]. However, a retrospective study including 1680 patients found that HR-PCI was successfully performed in over 98% of patients without MCS support, with a mortality rate of only 1.6% 30 days post-procedure [29]. However, detailed data on the completeness of revascularization as well as long-term outcomes were not provided. In addition, a recent single-center analysis of patients undergoing complex high-risk PCIs performed with either an IABP or Impella showed similar outcomes in terms of MACCE and mortality rates for both devices [30]. Altogether, the optimal selection of patients who truly require MCS during HR-PCI and the selection of the most suitable device remains to be further investigated.

Limitations

Our study has several limitations. First, since this was a registry-based study, it was limited by the completeness of the available medical records and the lack of an independent event adjudication committee. Thus, both baseline characteristics and data on endpoints might be prone to under or overreporting bias despite prespecified definitions. Second, there was no control group of patients treated with IABPs, ECMO, or no MCS, precluding any comparison between Impella and other MCS types. Third, due to the adoption of Impella mostly in the HR-PCI patients in Poland, the absolute number of CS patients included in the registry was low (55 patients over 8 years, ~7 patients per year in the whole country), making the statistical power of the CS subgroup analysis low and not reflecting contemporary medical practice. Altogether, given the observational, retrospective study design, our findings are hypothesis-generating and should be interpreted with caution.

CONCLUSIONS

The use of Impella in CS was low, compared with the use of Impella in HR-PCI, with almost exclusive use of Impella CP. The risk profile and mortality in CS patients were higher than in other registries, and the potential benefits of Impella in CS remain to be further investigated. In contrast, Impella seems safe and effective during HR-PCI, in accordance with the results from previous registries.

Article information

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