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

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

**Short title:** Impella-assisted high risk-PCI and cardogenic shock in IMPELLA-PL

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**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 aims to resolve the safety and efficacy of Impella use in HR-PCI patients. The risk profile and mortality in cardogenic 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 remain to be further investigated.

**ABSTRACT**

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

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

**Methods:** IMPELLA-PL data was analysed to determine primary endpoints: in-hospital mortality and rates of mortality and major adverse cardiovascular and cerebrovascular events (MACCE) 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 CS and HR-PCI groups, respectively. The 12-month mortality rates were 80.0% and 8.3%, and post-discharge MACCE rates were 22.5% and 9.1%, respectively. Access site bleeding occurred in 30.9% of CS patients and 14.6% of HR-PCI patients, limb ischaemia in 12.7% and 2.4%, and haemolysis in 10.9% and 1.6%, respectively.

**Conclusions:** Impella is safe and effective during HR-PCI, 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:** High risk-percutaneous coronary intervention, cardiogenic shock, Impella, ST-segment elevation myocardial infarction, mechanical circulatory support

## INTRODUCTION

Mechanical circulatory support (MCS) devices, developed to provide circulatory support in the setting of critical cardiogenic shock (CS) or end-stage heart failure (HF), have 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 CS implanted MCS devices to the development of 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, is able to provide haemodynamic 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 (class IIa recommendation) [4]. Elective use of Impella during high-risk percutaneous coronary intervention (HR-PCI) procedures, while not clearly granted 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 ventricle dysfunction (class IIb recommendation) [6]. Since data regarding the superiority of Impella over 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, randomised 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 which specifically focus on Impella devices have been conducted: the Impella Italian Registry (IMP-IT),the German Registry in Europe, the Japanese Registry for Percutaneous Ventricular Assist Device (J-PVAD) in Asia and the Catheter-Based Ventricular Assist Devices (cVAD) Registry in the US [9–12]. Regarding the differences in international clinical practice and the dynamic development of Impella hemodynamic technology, the national, multicentre, investigator-initiated IMPELLA-PL registry was developed to share the knowledge and clinical experiences collected since the implementation of the 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 Impella-assisted treatment according to the prespecified endpoint definitions; and (3) compare the results with other registries.

## METHODS

### Design

IMPELLA-PL is a national, multicentre, retrospective registry conducted in 20 Polish interventional cardiology centres under the patronage of the Polish Association of Cardiovascular Interventions [13]. IMPELLA-PL included consecutive patients treated with Impella for CS and HR-PCI. The subgroup of patients undergoing Impella-assisted revascularisation included hemodynamically stable patients with severe coronary artery disease undergoing elective or urgent HR-PCI, 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 optimal medical management and conventional treatment measures, including volume loading and use of pressors and inotropes, with or without IABP [13].

Clinical characteristics, procedural data and outcomes of consecutive patients treated with Impella device since 2014 until December 2021 were collected retrospectively in a password-protected database, with a 12-month follow-up collected based on 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 (MACCE) including mortality, rehospitalisation for HF, acute myocardial infarction (MI), repeat revascularisation, stroke, left ventricular assist device (LVAD) implantation and heart transplantation following hospital discharge. Data regarding 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 judgement and defined as type ≥3 according to Bleeding Academic Research Consortium; BARC) and device-related complications. The prespecified endpoint definitions have previously been published [13].

### Statistical analysis

Statistical analysis was performed by an independent statistician with IBM SPSS Statistics, version 24.0. Categorical variables were summarised using frequencies and proportions and compared using the $\chi^2$ test. Continuous data were expressed as mean (standard deviation) or median (interquartile range) and compared using a t-test or U-Mann-Whitney test, depending on the distribution. Statistical tests were two-sided, with a significance level of 0.05.

## RESULTS

Altogether, 308 patients were enrolled in the registry in 20 Polish centres, 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 (black line) are shown in Figure 1. The study flow diagram is shown in the Figure 2. Overall, the use of the 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%,a history of prior PCI. The median left ventricular ejection fraction (LVEF) was 22.5% and the median EuroSCORE II value was 21.8.

Coronary angiography was performed in over 90% 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 over 80% of patients, including the LM coronary artery in over 47%. 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 most often inserted before PCI (more than 50% of patients), followed by implantation during PCI (~30%) and after PCI (~15%). It was explanted in the catheterization laboratory in 15% of patients. The median insertion time was 20 minutes and the median duration of support was 45 hours. The most common vascular access for Impella were right and left femoral artery (Table 2). Single-access for simultaneous mechanical support and PCI was used in less than 10% of patients.

Regarding other measures of cardiopulmonary support, nearly all patients received catecholamines, most required mechanical ventilation, nearly 30% received levosimendan, more than 25% received IABP (11 before and 3 after Impella insertion) and more than 10% received extracorporeal membrane oxygenation (ECMO; 3 patients before and 4 after Impella insertion).

Kaplan-Meier curve showing 12-month survival in the IMPELLA-PL registry is showed in Figure 3. In-hospital and 12-month outcomes are presented in Table 3. 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 12-month observation period, including 2 post-discharge deaths, 3 rehospitalizations for HF, 1 MI, 1 stroke, 1 LVAD implantation and 1 heart transplantation.

Acute kidney injury occurred in over 60% of patients and most of them required dialysis. One in three patients experienced bleeding complications according to BARC. Device-related complications including any access site bleeding, limb ischaemia and haemolysis occurred in 30.9%, 12.7%, 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). About 50% of patients underwent HR-PCI in the setting of chronic coronary syndrome and the remaining 50% 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 CABG. The 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 LM, followed by MVD except for LM. Severe calcifications and chronic total occlusion were present in over 50% of patients. The median Syntax Score II was 43. PCI was performed in nearly all patients, including LM coronary artery in nearly 70% and left anterior descending artery, nearly 80%. All lesions were successfully treated in over 80%. PCI was performed via the Impella sheath in about 20% of patients.

All except for one patient were treated with Impella CP. In one patient, Impella 5.0 was implanted (Table 2). Impella was inserted before PCI in over 80% and during PCI in the remaining patients. It was removed directly after PCI in over 90%. 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 and left femoral arteries (about 50% and 40% of patients, respectively). Alternative access was used in 14 patients (>5%). Single-access for simultaneous mechanical support and PCI was used in more than 15%.

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 IABP (2.0%; 4 before and 1 after Impella insertion).

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). Fifty-seven patients (22.5%) experienced 69 MACCEs during the 12-month observation period, including 25 post-discharge deaths, 25 rehospitalizations for HF, 3 MI, 8 repeated revascularisations, 4 strokes, 1 LVAD implantation and 3 heart transplantations.

AKI occurred in over 10% 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 ischaemia, haemolysis 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 profile of HR-PCI patients, their mortality and complications rate were consistent with other registries. IMPELLA-PL differs from other registries in terms of the indications for MCS and the Impella model used. First, regarding the indication, HR-PCI constituted over 80% of patients in Poland treated with Impella, whereas over 50% of patients in the Italian registry received Impella due to CS [9]. Other registries published the results of CS and HR-PCI patients separately and from different time 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 are no prospective studies comparing both pump models in terms of efficacy and safety, improved prognoses have 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 navigate further development of the 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 prior to admission, all receiving catecholamines, 80% requiring mechanical ventilation, 25% with concomitant IABP and over 10% with concomitant ECMO. In other registries, the rate of patients with prior cardiac arrest was lower (23%–24%) [10, 16] and the 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 recent ESC guidelines for the treatment of cardiogenic shock, with no preference towards a specific MCS type [4]. Initially, it was suggested that Impella may have an advantage over IABP in patients with MI complicated by CS [18]. Data from systematic reviews and registry-based analyses questioned these results, suggesting no mortality benefit and even adverse effects in patients treated with Impella compared to IABP [19, 20]. However, the randomised controlled studies included in these meta-analyses had variable definitions of cardiogenic shock, slow enrollment rates, high crossover between the randomisation 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 being associated with a substantial survival benefit, compared to insertion during or after the PCI [21, 22], especially in women [23]. In our registry, the baseline risk was very high, Impella was inserted prior to PCI in about 50% of patients and mostly used to escalate the 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 the high mortality in CS patients was the implementation of Impella therapy far too late (as indicated by the median lactate of 7.4 mmol/l), potentially due to the 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 of 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 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 IABP (n = 226) ($P$ = 0.147). In the per protocol analysis, Impella was associated with fewer MACCE than 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 a mean LVEF of 23% [26]. The use of Impella

was associated with over 75% lower risk of post-PCI AKI than expected from 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 regarding the completeness of revascularization as well as long-term outcomes were not provided. In addition, recent single-center analysis of patients undergoing complex high-risk PCIs performed with either IABP or Impella showed similar outcomes in terms of MACE and mortality rate 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 history and the lack of an independent event adjudication committee. Thus, both baseline characteristics and data regarding end-points might be prone to under or overreporting bias, despite prespecified definitions. Second, there was no control group of patients treated with IABP, 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.

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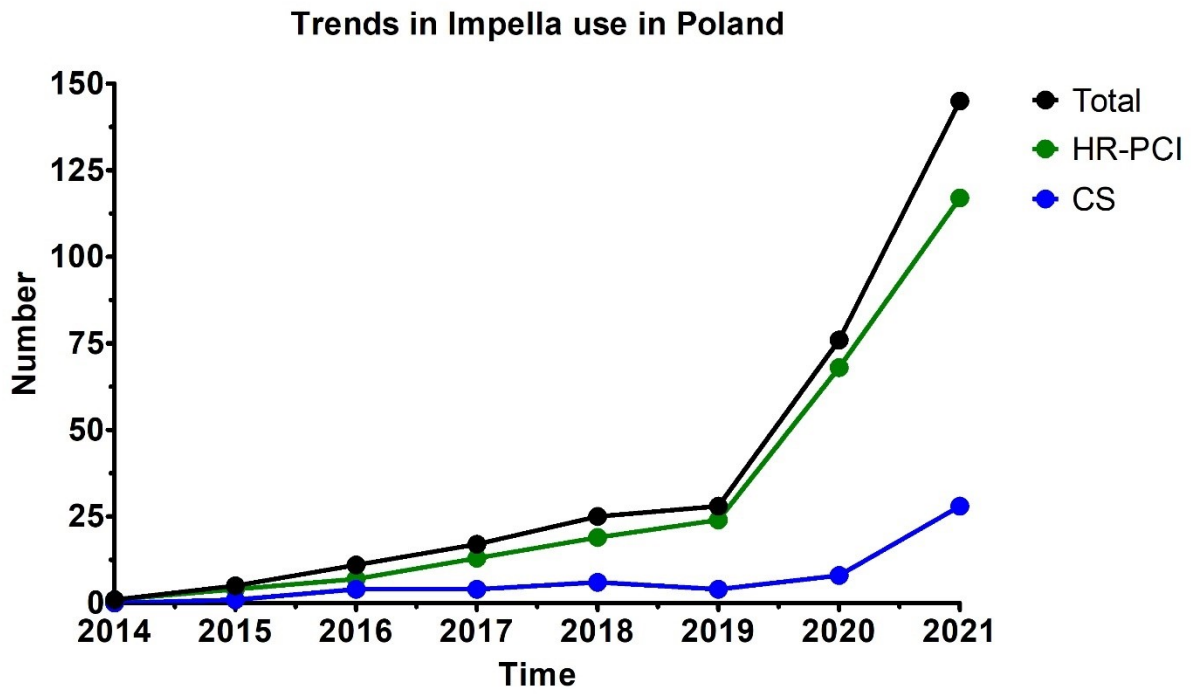


**Figure 1.** Trends in the use of Impella in Poland during the study period in patients presenting with CS (blue line), undergoing HR-PCI (green line), and total insertions (black line)
Abbreviations: CS, cardiogenic shock; HR-PCI, high-risk percutaneous coronary intervention

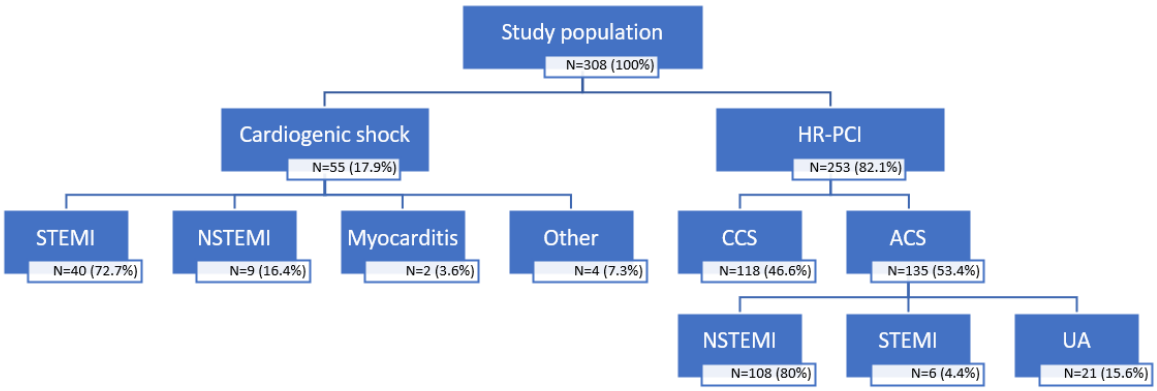


**Figure 2**. Study flow diagram of the IMPELLA-PL registry
Abbreviations: ACS, acute coronary syndrome; CCS, chronic coronary syndrome; NSTEMI, non-ST-segment elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; UA, unstable angina

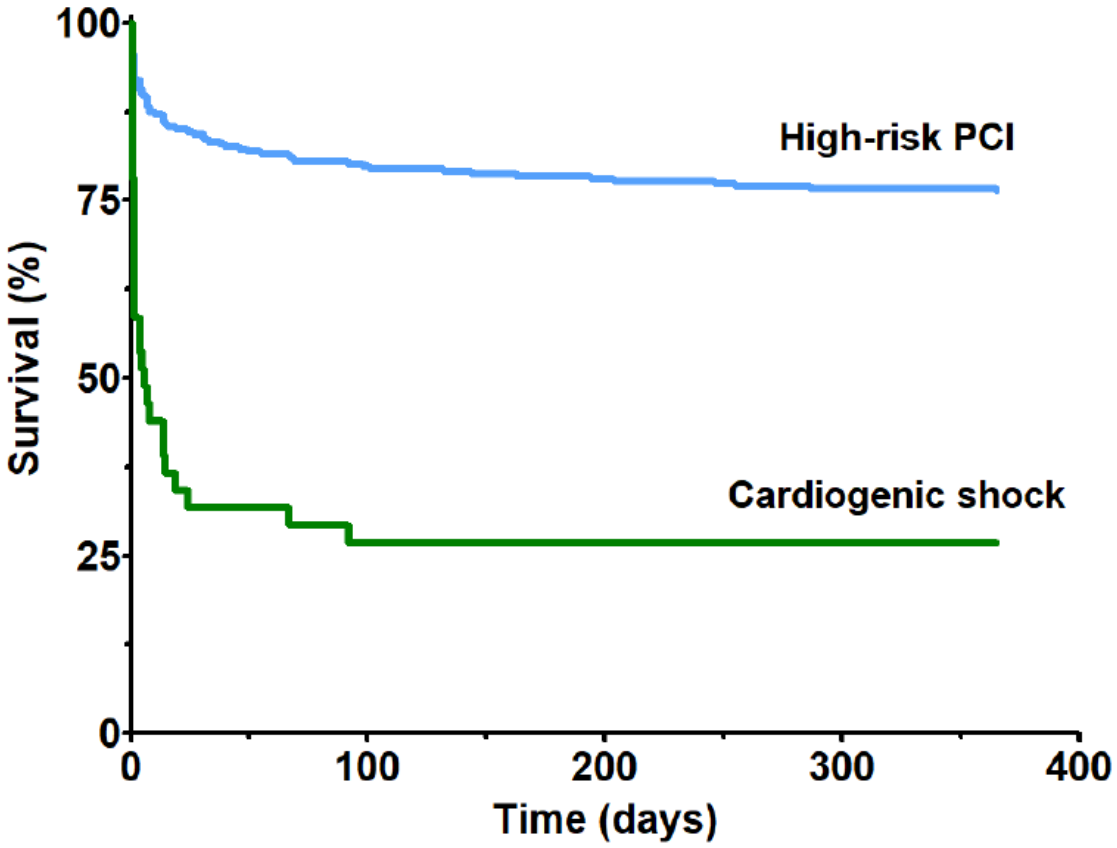


**Figure 3.** Kaplan-Meier curve showing 12-month survival in the IMPELLA-PL registry

Abbreviations: PCI, percutaneous coronary intervention

**Tables**

**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 gender, % | 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 | 49 (89.1) | 135 (53.4) |
| STEMI, % | 40 (72.7) | 6 (4.4) |
| NSTEMI, % | 9 (16.4) | 108 (80) |
| Unstable angina | 0 (0.0) | 21 (15.6) |
| Chronic coronary syndrome | 0 (0.0) | 118 (46.6) |
| Myocarditis, % | 2 (3.6) | 0 (0.0) |
| Risk factors | | |
| Hypertension, % | 26 (47.3) | 199 (78.7) |
| Dyslipidemia, % | 21 (38.2) | 198 (78.3) |
| Diabetes mellitus, % | 18 (32.7) | 118 (46.6) |
| Prior MI, % | 19 (35.5) | 132 (52.2) |
| Previous PCI, % | 13 (23.6) | 93 (36.8) |
| Previous CABG, % | 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, % | 53 (96.4) | 249 (98.4) |
| Previous stroke, % | 7 (12.7) | 24 (9.5) |
| Previous TIA, % | 3 (5.5) | 12 (4.7) |
| Chronic kidney disease, % | 18 (32.7) | 94 (37.2) |
| Dialysis, % | 1 (1.8) | 4 (1.6) |
| COPD, % | 3 (5.5) | 28 (11.5) |
| PAD, % | 7 (12.7) | 76 (30.0) |

| | | |
|---|---|---|
| EuroScore II, median (range) | 21.8 (12.4-37.6) | 5.1 (2.7-9.4) |
| Cardiac arrest prior to admission, % | 26 (47.3) | 9 (3.6) |
| VF, % | 16 (29.1) | 4 (1.6) |
| VT, % | 3 (5.5) | 2 (0.8) |
| PEA, % | 4 (7.3) | 2 (0.8) |
| Asystole, % | 5 (9.1) | 1 (0.4) |
| ICED, % | 3 (5.5) | 43 (17.0) |
| Pacemaker, % | 0 (0) | 10 (4.0) |
| ICD, % | 3 (5.5 ) | 28 (11.1) |
| CRT, % | 0 (0) | 12 (4.7) |
| Laboratory values | | |
| 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 | 53.5 (48.0-59.5) | 60.0 (53.0-66.3) |
| LA | 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, % | 12 (21.8) | 45 (17.8) |
| Mitral regurgitation grade 3 or 4, % | 6 (10.9) | 43 (17.0) |
| Tricuspid regurgitation grade 3 or 4, % | 7 (12.7) | 36 (14.2) |
| Severe aortic stenosis, % | 1 (1.8) | 3 (1.2) |

Data presented as n (%), mean (standard deviation) or median (interquartile range). T-test or U-Mann-Whitney test was used for continuous variables and chi-square test for categorical variables. 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 ventricle ejection fraction, MI, myocardial infarction; PAD, peripheral arterial disease; PCI, percutaneous coronary

intervention; PEA, pulseless electrical activity; RV, right ventricle; TIA, transient ischaemic 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, % | | |
| 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)* | 140 (55.3) |
| Chronic total occlusions | 14 (25.5)* | 137 (54.2) |
| In-stent restenosis | 3 (5.5)* | 17 (6.7) |
| In-stent thrombosis | 2 (3.6)* | 1 (0.4) |
| Intravascular imaging | 11 (20.0)* | 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, % | | |
| 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, % | 54 (98.2) | 253 (100.0) |

| | | |
|---|---|---|
| Use of Impella 5.0, % | 1 (1.8) | 0 (0.0) |
| Timing of Impella placement | | |
| Before PCI, % | 29 (52.7) | 207 (81.8) |
| During PCI, % | 15 (27.3) | 44 (17.4) |
| After PCI, % | 8 (14.5) | 0 (0) |
| Missing data, % | 3 (5.5) | 2 (3.6) |
| Explantation in catheterization lab, % | 8 (14.5) | 237 (93.7) |
| Time of insertion (minutes) | 20.0 (15.0-31.0) | 25.0 (15.0-40.0) |
| Duration of support (hours) | 45.0 (19.0-120.0) | 3.0 (2.0-73.0) |
| Vascular access for Impella | | |
| Right femoral artery, % | 32 (58.2) | 138 (54.5) |
| Left femoral artery, % | 22 (40.0) | 101 (39.9) |
| Right subclavian artery, % | 1 (1.8) | 8 (3.2) |
| Left subclavian artery, % | 0 (0) | 6 (2.4) |
| Ultrasound-guided puncture, % | 18 (32.7) | 70 (27.7) |
| Surgical access, % | 1 (1.8) | 38 (15.0) |
| Single access, % | 4 (7.3) | 45 (17.8) |
| Contralateral safety access, % | 1 (1.8) | 22 (8.7) |
| Other cardiopulmonary support | | |
| Use of catecholamines, % | 54 (98.2) | 47 (18.6) |
| Use of levosimendan, % | 15 (27.3) | 13 (5.1) |
| Use of mechanical ventilation, % | 44 (80.0) | 10 (4.0) |
| Mechanical ventilation, hours | 43.0 (24.0-110.0) | 46.0 (7.75-75.0) |
| Use of ECMO, % | 7 (12.7) | 6 (2.4) |
| Use of IABP, % | 14 (25.5) | 5 (2.0) |
| Use of other LVAD, % | 12 (21.8) | 27 (10.7) |
| Last available LVEF, % | 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 median (interquartile range).

* in 5 out of 55 patients with CS coronary angiography was not performed

Abbreviations: PCI: percutaneous coronary intervention; IVUS: intravascular ultrasound; OCT: optical coherence tomography; LM: left main coronary artery; LAD: left anterior

descending artery; Cx: circumflex artery; RCA: right coronary artery; ECMO: extracorporeal membrane oxygenation; IABP: intra-aortic balloon pump; LVAD: left ventricle assist device; LVEF: left ventricle ejection fraction

Table 2. In-hospital and 12-month outcomes.

| | Cardiogenic shock (N = 55; 17.9) | High-risk PCI (N = 253; 82.1) |
|---|---|---|
| In-hospital outcomes | | |
| Mortality, % | 42 (76.4) | 21 (8.3) |
| Need for cardiosurgical intervention, % | 4 (7.3) | 1 (0.4) |
| Exacerbation of HF, % | 35 (63.6) | 12 (4.7) |
| Acute myocardial infarction, % | 5 (9.1) | 11 (4.3) |
| Acute kidney injury, % | 34 (61.8) | 32 (12.6) |
| Need for renal replacement therapy, % | 18 (32.7) | 4 (1.6) |
| Inflammatory complications, % | 22 (40.0) | 35 (13.8) |
| Any bleeding complications, % | 25 (45.5) | 34 (13.4) |
| Severe bleeding complications, % | 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, % | 22 (40) | 34 (13.4) |
| Number of RBC units transfused | 4.5 (3-6.5) | 2 (2.0-2.0) |
| Device-related complications, % | | |
| 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) |
| Haemolysis | 6 (10.9) | 4 (1.6) |
| Aortic injury | 0 (0.0) | 1 (0.4) |
| 12-month outcomes, % | | |
| Mortality after discharge | 2 (3.6) | 25 (9.9) |
| Rehospitalisation for HF | 3 (5.5) | 25 (9.9) |
| MI | 1 (1.8) | 3 (1.2) |
| Repeat revascularisation | 0 (0) | 8 (3.2) |

| | | |
|---|---|---|
| PCI | 0 (0) | 8 (3.2) |
| CABG | 0 (0) | 0 (0) |
| Stroke | 1 (1.8) | 4 (1.6) |
| Permament 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) |
| Impella insertion before PCI | 23/29 (79.3%) | 39/207 (18.8%) |
| Impella insertion during or after PCI | 19/23 (82.6%) | 5/44 (11.4%) |

Data are presented as n (%). Abbreviations: PCI: percutaneous coronary intervention; RBC: red blood count; HF: heart failure; CABG: coronary artery bypass graft; LVAD: left ventricle assist device

Table 4. Comparison of outcomes in patients enrolled in the five main registries which 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 | IMP-IT | J-PVAD | cVAD |
| | n = 55 | n = 229 | n = 819 | n = 154 |
| Haemolysis, % | 10.9 | 20.5 | 11.2 | 10.3 |
| AKI, % | 61.8 | 50.5 | - | 18.1 |
| Bleeding, % | 45.5 | 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 | IMP-IT | German Registry | cVAD |
| | n = 253 | n = 177 | n = 154 | n = 637 |
| Haemolysis, % | 1.6 | 0.5 | - | 0.2 |
| AKI, % | 12.6 | 13.0 | - | 5.8 |
| Bleeding, % | 13.4 | 5.1 | 4.5 | 11.0 |
| Inflammatory, % | 13.8 | 4.1 | - | - |
| Neurological, % | 1.6 | 2.0 | 0.0 | 0.0 |

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