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Early outcomes of microaxial flow pump (Impella)–supported coronary artery bypass grafting for acute myocardial infarction with cardiogenic shock: national reference estimates from the J-PVAD registry

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Background: Contemporary national data on outcomes of coronary artery bypass grafting (CABG) performed under microaxial flow pump (Impella) support for acute myocardial infarction (AMI) complicated by cardiogenic shock are scarce. We aimed to provide contemporary national reference estimates and, as a *post hoc* exploratory analysis, to describe outcomes according to the setting of Impella insertion.
Methods: From the Japanese Registry for Percutaneous Ventricular Assist Devices (J-PVAD; February 2020 to December 2024), we analyzed 245 patients from 116 centers with AMI-related cardiogenic shock who underwent CABG under Impella support, after excluding ventricular septal perforation repair and unsuccessful insertion. The primary outcome was all-cause mortality within 30 days after Impella implantation; in-hospital mortality and adverse events were secondary. Proportions are reported with Wilson 95% confidence intervals (CIs). Operating-room insertion ($n = 19$) was compared with non-operating-room insertion ($n = 226$) by Firth-penalized logistic regression with propensity score overlap weighting (age, systolic blood pressure, and extracorporeal membrane oxygenation initiated before Impella).
Results: Thirty-day mortality was 20.8% (51/245; 95% CI: 16.2–26.3); in 24 patients discharged alive before day 30, survival to day 30 was assumed from the recorded status. In-hospital mortality was 33.1% (81/245; 95% CI: 27.5–39.2). Adverse events included bleeding (17.6%; 95% CI: 13.3–22.8), renal failure (9.8%), sepsis (9.0%), hemolysis (8.6%), and stroke (6.5%). Thirty-day mortality was 36.8% (7/19) after operating-room insertion and 19.5% (44/226) after non-operating-room insertion (weighted odds ratio 1.63; 95% CI: 0.62–4.16). This estimate had a wide confidence interval, consistent with either a substantially lower or a substantially higher mortality after operating-room insertion, and more than half of the baseline characteristics remained imbalanced after weighting.

Conclusion: These nationwide data provide contemporary reference estimates for Impella-supported CABG in AMI-related cardiogenic shock. The registry records the setting (operating room or elsewhere), but not the intent or clinical timing, of Impella insertion, and the comparative safety of operating-room vs. non-operating-room insertion cannot be determined from these data.

KEYWORDS

30-day mortality, acute myocardial infarction, cardiogenic shock, coronary artery bypass grafting, Impella, mechanical circulatory support, microaxial flow pump, nationwide registry

Introduction

Acute myocardial infarction (AMI) complicated by cardiogenic shock carries in-hospital mortality rates of 40%–50% (1, 2), and a subset of these patients require emergent or urgent coronary artery bypass grafting (CABG) when percutaneous coronary intervention (PCI) is not feasible or when multivessel disease precludes adequate percutaneous revascularization. The perioperative management of these critically ill patients represents one of the most challenging scenarios in contemporary cardiac surgery.

Historically, the intra-aortic balloon pump (IABP) was the standard mechanical circulatory support (MCS) device in this setting; however, the IABP-SHOCK II trial demonstrated no reduction in 30-day or long-term mortality, leading to its guideline downgrading (1, 3). Venoarterial extracorporeal membrane oxygenation (VA-ECMO) provides potent hemodynamic support but increases left ventricular (LV) afterload, potentially exacerbating myocardial injury (4). These limitations have shifted attention toward the Impella percutaneous ventricular assist device, which achieves direct LV unloading and can be deployed before or during cardiac surgery (4, 5). In the DanGer Shock trial, a microaxial flow pump reduced mortality in selected patients with ST-elevation myocardial infarction and cardiogenic shock, at the cost of more bleeding, limb ischemia, and renal replacement therapy (6, 7). The 2025 ACC/AHA guideline accordingly assigns a Class 2a recommendation for selected patients with AMI-related cardiogenic shock, balancing the mortality benefit against these complications (8); neither the trial nor the guideline directly addresses patients undergoing CABG.

Nationwide J-PVAD reports have described the overall experience with Impella in Japan (9) and short-term outcomes of Impella support for AMI-related cardiogenic shock (10, 11), but CABG appeared in these reports only as a covariate, and the surgical population has not been characterized. In the Society of Thoracic Surgeons database, the use of mechanical circulatory support in CABG for AMI-related cardiogenic shock rose from 6.9% to 22.2% between 2012 and 2022, with microaxial flow pumps used in 10.6%, and the authors concluded that the role, timing, and trigger for insertion relative to CABG require further study (12). Other reports are limited to a single-center series of perioperative Impella use in various cardiac operations (13) and a manufacturer-funded registry of Impella 5.5 support for AMI-related cardiogenic shock that was not restricted to patients undergoing CABG (14). Using the J-PVAD registry, our primary aim was to provide contemporary national reference estimates of 30-day and in-hospital outcomes after CABG performed under Impella support for AMI-related cardiogenic shock. As a *post hoc* exploratory analysis, we described outcomes according to the setting of Impella insertion (operating room vs. elsewhere), recognizing that the registry does not record the intent or the clinical circumstances of insertion and that this comparison is constrained by small numbers and confounding.

Methods

Study design and population

This was a retrospective analysis of prospectively collected data from the Japanese Registry for Percutaneous Ventricular Assist Devices (J-PVAD), a nationwide registry that captures all patients receiving Impella support at certified Japanese institutions; its design and enrollment have been described previously (9–11). A total of 12,462 patients were registered between February 2020 and December 2024. The registry has no separate field for cardiogenic shock. In Japan, Impella is approved for drug-refractory acute heart failure such as cardiogenic shock, and every registered patient received the device under this indication; AMI-related cardiogenic shock was therefore defined as Impella use under this indication with an underlying disease of AMI or its mechanical complication, as recorded in the registry field for the underlying disease leading to Impella use. The presence and severity of shock could not be ascertained independently from the data provided. The registry data center applied two criteria to the 12,462 patients and provided the records of all patients who fulfilled both: (1) an underlying disease of AMI or its mechanical complication, and (2) CABG during the index admission, with or without concomitant cardiac procedures ($n = 665$; underlying disease recorded as AMI in 539, as mechanical complication of AMI in 122, and as other in 4, in whom the free-text entry specified subacute myocardial infarction in 1 and post-infarction ventricular septal perforation in 3). The number of patients who fulfilled the first criterion, irrespective of the second, was not available to us. Of the 665 patients, 113 who underwent ventricular septal perforation (VSP) repair were excluded because post-infarction VSP is a distinct mechanical complication with a different pathophysiology and prognosis; VSP repair was identified from the free-text fields for concomitant cardiovascular surgery at both the patient level and

the device level. Twelve further patients in whom Impella (Abiomed, Danvers, MA, USA) insertion was unsuccessful were excluded (in one of the 113 patients with VSP repair, insertion was also unsuccessful). Of the remaining 540 patients, CABG was performed under Impella support in 245, identified from the registry field for the procedures supported by Impella; these patients formed the study cohort. The other 295 patients underwent CABG without recorded Impella support during CABG and were not included, because the registry does not record the date of CABG and the temporal relation between Impella and surgery cannot be established for them. Patients with other mechanical complications and those undergoing other concomitant procedures, including valve surgery, were retained. Patients in whom the same Impella had also supported percutaneous coronary intervention (PCI) were included; the registry records that the device supported both procedures but not their order, because the date of CABG is not recorded. Cohort derivation is shown in Figure 1 and, with the registry field used at each step, in Supplementary Table 4 and Supplementary Methods (Section 1). The final cohort comprised 245 patients from 116 contributing centers (median 1 patient per center; range 1–11); 13 centers contributed patients with operating-room insertion.

The J-PVAD registry is approved by the ethics committee of the representative institution (Osaka University Hospital; approval no. 17232) and by the institutional review boards of all participating centers, with approval renewed upon each protocol revision. The registry protocol specifies that additional analyses may be conducted and published after review by the Impella subcommittee. The research proposal for the present analysis (dated October 15, 2025; approved by the subcommittee on December 1, 2025) specified comparison groups according to the timing of Impella insertion relative to CABG (before, during, and after) and 30-day survival as the primary endpoint. Because the registry does not record the date of CABG, insertion after CABG could not be identified, and the comparison was reduced to the two groups that the registry can define. No statistical analysis plan for the propensity score model, composite endpoints, or E-value was specified in advance, and these analyses are therefore *post hoc* and exploratory. The present study was approved by the ethics committee of Sakakibara Heart Institute (approval no. 18-027)

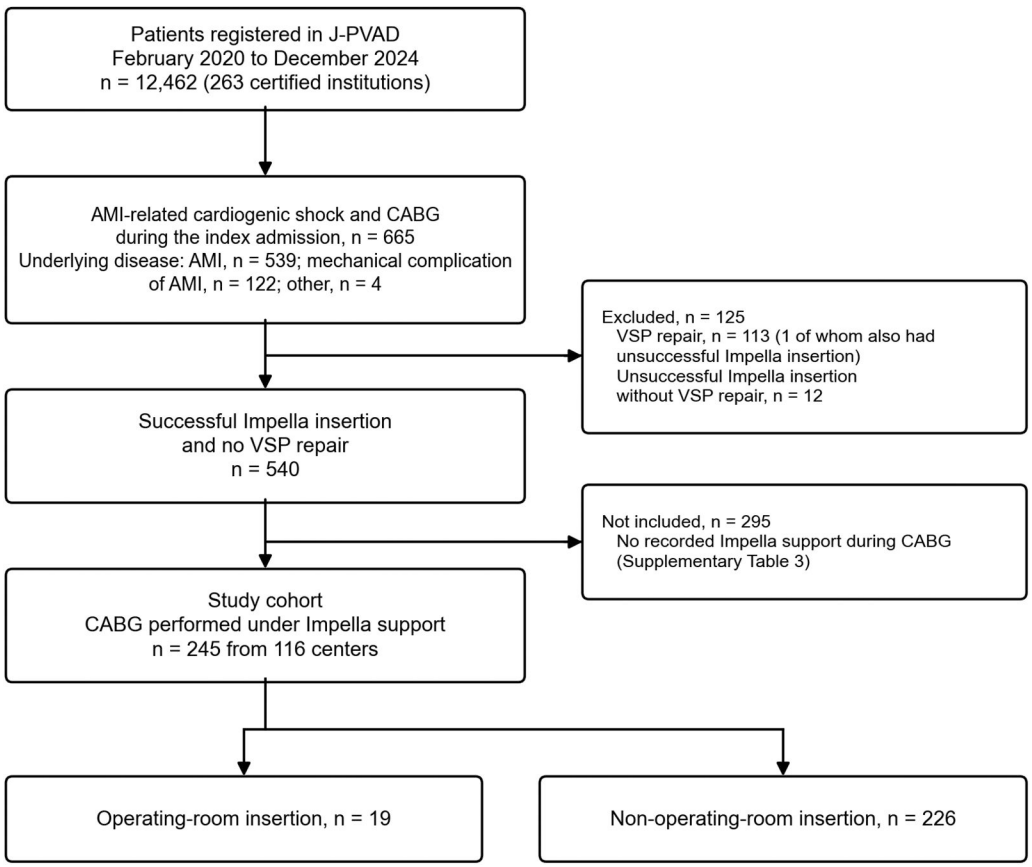


FIGURE 1
Derivation of the study cohort from the J-PVAD registry. AMI-related cardiogenic shock was identified from the registry field for the underlying disease leading to Impella use. The total of 12,462 is the number of registered patients provided by the data center; records in which the first device, the status at device removal, and the 30-day status were all unknown had been removed by the data center, and their number is not available (Supplementary Methods, Section 1). Patients with VSP repair or unsuccessful Impella insertion were excluded first. Patients who underwent CABG without recorded Impella support during CABG were not included; their mortality is shown for reference in Supplementary Table 3. The status at the registry follow-up assessment and at discharge was recorded for all 245 patients; the 30-day status was documented by a date in 221 (see Results). The weighted analysis included 244 (systolic blood pressure missing in 1). AMI, acute myocardial infarction; CABG, coronary artery bypass grafting; J-PVAD, Japanese Registry for Percutaneous Ventricular Assist Devices; VSP, ventricular septal perforation.

and was conducted in accordance with the Declaration of Helsinki and the Japanese Ethical Guidelines for Medical and Biological Research Involving Human Subjects. Patient consent was obtained through an opt-out mechanism at each center. This report follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement.

Data collection

The J-PVAD registry prospectively collects standardized data on all patients receiving Impella support. Variables analyzed in this study included demographic characteristics, comorbidities, pre-implantation status (blood pressure, laboratory data, out-of-hospital cardiac arrest, cardiopulmonary resuscitation, inotrope or vasopressor use), mechanical circulatory support (Impella device type, access site, duration of support, and the use and timing of ECMO and intra-aortic balloon pump relative to Impella), surgical details (timing of Impella support relative to CABG and cardiopulmonary bypass, concomitant procedures), and clinical outcomes. The registry field from which each variable was derived, the coding rules for eligibility, insertion setting, PCI support, and mortality, and the conventions for missing values are documented in a variable definitions document that was made available to the editors and reviewers together with the analysis code; the derivation of the cohort is given in Supplementary Table 4. For fields answered yes or no, blank entries and entries recorded as unknown were treated as missing and were not recoded as absent. Sub-fields that are completed only when a parent entry is present (for example, the timing of ECMO and of intra-aortic balloon pump, and cardiopulmonary resuscitation) were coded as absent when no entry was made; these are identified in the variable definitions document. The following variables are not collected by the registry and could not be reported: SCAI shock stage, number of grafts, cardiopulmonary bypass and cross-clamp times, the date of CABG, and intensive care unit length of stay.

Definitions and endpoints

The exposure was the setting of Impella insertion, that is, the place in the hospital where the device was inserted and not the vascular access site, as recorded in the registry: operating-room insertion ($n = 19$) or non-operating-room insertion ($n = 226$). All 19 operating-room insertions were performed during on-pump CABG, 9 before and 10 after weaning from cardiopulmonary bypass. In the non-operating-room group, Impella was already in place on arrival in the operating room in 201 patients, 24 underwent Impella-supported off-pump CABG, and the timing category was not recorded in 1. The registry does not record whether insertion was planned or prompted by hemodynamic deterioration, the indication for insertion, or the time from shock onset to CABG. The exposure therefore represents a composite of setting, device type, and vascular access site, and cannot be interpreted as a planned vs. rescue strategy.

The primary outcome was all-cause mortality within 30 days after Impella implantation, which corresponds to the primary endpoint of the registry and of the research proposal. The secondary outcome was in-hospital mortality, defined as death before discharge from the index hospitalization irrespective of its timing and ascertained from the registry field for status at discharge. The time origin for all analyses was the date of Impella implantation. Adverse events (bleeding or hematoma, renal failure, sepsis, hemolysis, stroke, limb ischemia, and others) were reported by the treating physicians at each institution, without central adjudication, together with the date of onset; relatedness to the device was also judged by the treating physician. Definitions published by the registry investigators are available for 7 of the 15 categories reported here (11); the other categories, including hemolysis and thrombocytopenia, represent the diagnosis of the treating physician. All reported events were counted, irrespective of whether they were judged to be related to the device and irrespective of seriousness; the definitions and the numbers judged to be device-related are given in Supplementary Table 5 and Supplementary Methods (Section 2). Because the period at risk differs between groups, death competes with non-fatal events, and events in the operating-room group were too few for time-to-event comparison, adverse events are reported descriptively, with their timing, and were not compared between groups.

Vital status was derived from five registry fields: the status (alive or dead) at the registry follow-up assessment, the date of that assessment, the date of death, the status at discharge, and the date of discharge. As described by the registry investigators, vital status is confirmed by the participating institutions through in-hospital follow-up, chart review, or contact by telephone or letter (11). Patients were enrolled until December 31, 2024, and the latest recorded date (a date of death) was May 18, 2025. Death within 30 days after implantation was counted irrespective of whether it occurred before or after discharge. Transfer to another hospital was recorded as discharge from the index hospitalization; it ended the ascertainment of in-hospital mortality but not that of 30-day mortality. The status at the follow-up assessment and at discharge was recorded for all patients, and every recorded death had a date. A blank or unknown entry was never classified as survival: every patient classified as alive at 30 days had either a recorded status of alive at the follow-up assessment or a recorded date of death later than day 30. Because the follow-up assessment could be dated before day 30, we also recorded whether the 30-day status was documented by a date (death within 30 days, or a follow-up assessment, discharge, or death on or after day 30); in patients whose last dated confirmation of survival preceded day 30, survival to day 30 was assumed from the recorded status in the primary analysis and was examined in sensitivity analyses.

Statistical analysis

Statistical analysis was reviewed and verified by a biostatistician and coauthor (Y.O.). Continuous variables are presented as median [interquartile range] and categorical variables as counts and percentages, with group-specific denominators where data were missing. Proportions are reported with Wilson 95% confidence intervals (CIs). Differences between groups are expressed as standardized mean

differences (SMDs). For unadjusted comparisons of mortality, odds ratios were estimated by Firth-penalized logistic regression with profile-likelihood CIs, and risk differences with Newcombe hybrid-score CIs. Missing data were not imputed; the numbers of missing values by group are given in Table 1.

For the *post hoc* exploratory comparison, we used propensity score overlap weighting (average treatment effect in the overlap population) (15). Because the operating-room group ($n = 19$) supports very few parameters, the propensity score was estimated by Firth-penalized logistic regression with three covariates chosen on clinical grounds, not by statistical testing, to represent age, hemodynamic status, and the intensity of circulatory support at the time of implantation: age, pre-implantation systolic blood pressure, and ECMO initiated before Impella; continuous covariates were standardized. ECMO initiated during or after Impella support was not used, because it may lie on the pathway between exposure and outcome. The outcome model was a weighted Firth-penalized logistic regression, and the weighted risk difference was the difference in weighted event proportions.

Ninety-five percent CIs were percentile intervals from 1,000 bootstrap replicates in which patients were resampled and the propensity score was re-estimated in each replicate. All 1,000 replicates yielded estimates. Two-sided *P* values were calculated as twice the smaller proportion of bootstrap estimates lying on either side of the null. Because patients are clustered within centers, the bootstrap was repeated with centers as the resampling unit. Complete-case analysis included 244 patients (19 and 225; systolic blood pressure was missing in 1). Balance was assessed before and after weighting for baseline variables, which were recorded before implantation, and separately for device, procedural, and post-implantation characteristics, together with the distributions of the propensity score and weights and the effective sample size (Supplementary Table 1; Supplementary Figure 1).

Sensitivity analyses used alternative covariate sets: replacing pre-Impella ECMO with the registry field for ECMO use at any time, omitting ECMO, adding creatine kinase, and adding Impella device type (5.0/5.5 vs. CP/2.5). Because creatine kinase was missing in 5 patients, the primary model was also fitted in the patients in whom it was available. Systolic blood pressure was recorded as 0 mmHg in 9 patients, 5 of whom had cardiac arrest, cardiopulmonary resuscitation, or ECMO at the time of implantation; the analysis was repeated without these 9 patients. It was also repeated after excluding patients with mechanical complications, those undergoing off-pump CABG, and those in whom the same Impella had supported PCI (Supplementary Table 2). To examine the ascertainment of the 30-day status, 30-day mortality was re-estimated by the Kaplan–Meier method with censoring at the last dated confirmation of survival (log–log confidence limits), the weighted analysis was repeated after excluding patients in whom survival to day 30 was not documented by a date, and mortality was calculated under the assumption that all of these patients had died. The E-value was calculated after converting the odds ratio to an approximate risk ratio by the square-root transformation, because the outcome was common.

The time course of in-hospital death and discharge alive was described by cumulative incidence functions treating the two events as competing, with Gray's test for between-group comparison. A two-sided $P < 0.05$ was considered statistically significant; no adjustment for multiple comparisons was made, and all between-group comparisons are exploratory. Analyses were performed using R version 4.4.0 (R Foundation for Statistical Computing) with the logistf, cmprsk, and survival packages. The annotated analysis code and the variable definitions document were made available to the editors and reviewers.

Results

Patient characteristics

Of 12,462 patients registered between February 2020 and December 2024, 665 had AMI-related cardiogenic shock and underwent CABG during the index admission. After exclusion of 113 with VSP repair and 12 with unsuccessful insertion, 540 remained; 245 of them, from 116 centers, underwent CABG under Impella support and formed the study cohort (Figure 1). Patient characteristics are summarized in Table 1.

The median age was 72 years [interquartile range 63–77], and 203 patients (82.9%) were male. Hypertension was present in 168 of 230 patients with available data (73.0%), diabetes mellitus in 130 of 230 (56.5%), renal dysfunction in 90 of 228 (39.5%), a history of heart failure in 70 of 229 (30.6%), and prior myocardial infarction in 77 of 230 (33.5%). Twenty-seven of 243 patients (11.1%) had experienced out-of-hospital cardiac arrest. ECMO had been initiated before Impella in 37 patients (15.1%), and ECMO was used at any time in 84 of 244 (34.4%). The same Impella supported both PCI and CABG in 44 patients (18.0%). In 43 of them the device was in place on arrival in the operating room or supported off-pump CABG; in 1 patient, an Impella 5.5 was inserted in the operating room after weaning from cardiopulmonary bypass, and PCI was performed under the same device 2 days later. The first device was an Impella 5.0 or 5.5 in 21 patients (8.6%), and access was femoral in 220 (89.8%). The median duration of Impella support was 109 h [54–168]. Concomitant valve surgery was performed in 35 patients (14.3%; mitral in 29, aortic in 5, and isolated tricuspid in 1). The registered underlying disease was a mechanical complication of myocardial infarction in 13 patients, none of whom underwent VSP repair and 8 of whom underwent mitral surgery; the registry does not record the indication for mitral surgery in the remaining 21.

Nineteen patients (7.8%) underwent operating-room insertion and 226 (92.2%) non-operating-room insertion. The groups differed in several respects, and not uniformly in the direction of greater severity in one group (Table 1). Patients with operating-room insertion more often had a history of heart failure (72.2% vs. 27.0%; SMD: 1.00) and prior myocardial infarction (66.7% vs. 30.7%; SMD: 0.76), had lower left ventricular ejection fraction (median 20% vs. 30%; SMD: −0.82), lower diastolic blood pressure, and lower serum albumin, and more often received inotropes or vasopressors (89.5% vs. 62.7%; SMD: 0.66); conversely, their lactate was lower (median 2.0 vs. 3.9 mmol/L; SMD: −0.55). Device and access also differed markedly: Impella 5.0 or 5.5 was used in 52.6% vs. 4.9% (SMD:

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TABLE 1 Baseline, device, and procedural characteristics by setting of Impella insertion.

Variable	Total (*n* = 245)	Operating-room insertion (*n* = 19)	Non-operating-room insertion (*n* = 226)	SMD
Demographics				
Age, years	72 [63–77]	73 [66–77]	72 [63–77]	+0.10
Male sex	203/245 (82.9%)	17/19 (89.5%)	186/226 (82.3%)	+0.20
Body mass index, kg/m²	23.6 [21.5–26.4] (*n* = 242)	24.2 [22.3–25.1] (*n* = 18)	23.6 [21.4–26.4] (*n* = 224)	+0.06
Comorbidities				
Hypertension	168/230 (73.0%)	14/19 (73.7%)	154/211 (73.0%)	+0.02
Diabetes mellitus	130/230 (56.5%)	8/17 (47.1%)	122/213 (57.3%)	−0.20
Dyslipidemia	125/231 (54.1%)	11/18 (61.1%)	114/213 (53.5%)	+0.15
Renal dysfunction	90/228 (39.5%)	8/17 (47.1%)	82/211 (38.9%)	+0.16
History of heart failure	70/229 (30.6%)	13/18 (72.2%)	57/211 (27.0%)	+1.00
Prior myocardial infarction	77/230 (33.5%)	12/18 (66.7%)	65/212 (30.7%)	+0.76
Prior stroke/TIA	25/231 (10.8%)	3/17 (17.6%)	22/214 (10.3%)	+0.21
Current smoker	78/210 (37.1%)	8/15 (53.3%)	70/195 (35.9%)	+0.35
Clinical presentation				
STEMI	144/231 (62.3%)	11/18 (61.1%)	133/213 (62.4%)	−0.03
Out-of-hospital cardiac arrest	27/243 (11.1%)	3/19 (15.8%)	24/224 (10.7%)	+0.15
Cardiopulmonary resuscitation before arrival	27/245 (11.0%)	3/19 (15.8%)	24/226 (10.6%)	+0.15
NYHA class IV	185/221 (83.7%)	17/19 (89.5%)	168/202 (83.2%)	+0.18
Pre-implantation hemodynamics and support				
Systolic blood pressure, mmHg	100 [80–120] (*n* = 244)	85 [70–108]	100 [80–122] (*n* = 225)	−0.33
Diastolic blood pressure, mmHg	61 [48–78] (*n* = 244)	50 [38–60]	62 [50–78] (*n* = 225)	−0.48
Heart rate, bpm	96 [79–110] (*n* = 244)	98 [83–110]	94 [78–112] (*n* = 225)	0.00
LVEF, %	30 [23–40] (*n* = 157)	20 [17–32] (*n* = 16)	30 [25–40] (*n* = 141)	−0.82
Inotrope or vasopressor use	158/244 (64.8%)	17/19 (89.5%)	141/225 (62.7%)	+0.66
ECMO initiated before Impella	37/245 (15.1%)	6/19 (31.6%)	31/226 (13.7%)	+0.43
IABP before Impella	27/245 (11.0%)	2/19 (10.5%)	25/226 (11.1%)	−0.02
Laboratory data				
Creatine kinase, U/L	284 [138–731] (*n* = 240)	366 [167–1,078] (*n* = 17)	282 [137–699] (*n* = 223)	+0.37
Creatinine, mg/dL	1.2 [1.0–1.7] (*n* = 241)	1.1 [0.9–1.4] (*n* = 17)	1.2 [1.0–1.7] (*n* = 224)	+0.13
Lactate, mmol/L	3.8 [1.9–7.2] (*n* = 185)	2.0 [1.2–5.0] (*n* = 13)	3.9 [2.1–7.4] (*n* = 172)	−0.55
Albumin, g/dL	3.6 [3.1–3.9] (*n* = 227)	3.2 [2.7–3.5] (*n* = 16)	3.6 [3.1–3.9] (*n* = 211)	−0.62
Total bilirubin, mg/dL	0.7 [0.5–1.0] (*n* = 234)	0.7 [0.5–0.9] (*n* = 16)	0.7 [0.6–1.0] (*n* = 218)	+0.06
AST, U/L	61 [33–129] (*n* = 241)	100 [24–315] (*n* = 17)	60 [34–126] (*n* = 224)	−0.02
LDH, U/L	398 [280–644] (*n* = 228)	432 [330–850] (*n* = 17)	396 [273–607] (*n* = 211)	+0.02
CRP, mg/dL	1.1 [0.2–4.6] (*n* = 234)	3.5 [0.8–5.1] (*n* = 17)	1.1 [0.2–4.5] (*n* = 217)	+0.11
Device and support (at or after implantation)				
First device: Impella CP	219/245 (89.4%)	8/19 (42.1%)	211/226 (93.4%)	−1.28
First device: Impella 5.5	15/245 (6.1%)	7/19 (36.8%)	8/226 (3.5%)	+0.89

(*Continued*)

TABLE 1 Continued

Variable	Total (*n* = 245)	Operating-room insertion (*n* = 19)	Non-operating-room insertion (*n* = 226)	SMD
First device: Impella 5.0	6/245 (2.4%)	3/19 (15.8%)	3/226 (1.3%)	+0.52
First device: Impella 2.5	5/245 (2.0%)	1/19 (5.3%)	4/226 (1.8%)	+0.19
First device: Impella 5.0 or 5.5	21/245 (8.6%)	10/19 (52.6%)	11/226 (4.9%)	+1.21
Femoral access	220/245 (89.8%)	9/19 (47.4%)	211/226 (93.4%)	−1.14
Axillary or subclavian access	19/245 (7.8%)	9/19 (47.4%)	10/226 (4.4%)	+1.10
Second Impella device added	33/245 (13.5%)	3/19 (15.8%)	30/226 (13.3%)	+0.07
ECMO at any time	84/244 (34.4%)	9/19 (47.4%)	75/225 (33.3%)	+0.28
PCI supported by the same Impella	44/245 (18.0%)	1/19 (5.3%)	43/226 (19.0%)	−0.43
Duration of support, hours	109 [54–168] (*n* = 244)	184 [121–224]	103 [52–164] (*n* = 225)	+0.63
Surgical details				
Off-pump CABG under Impella support	24/245 (9.8%)	0/19 (0.0%)	24/226 (10.6%)	−0.49
Concomitant valve surgery	35/245 (14.3%)	3/19 (15.8%)	32/226 (14.2%)	+0.05
Other concomitant cardiovascular surgery	23/245 (9.4%)	5/19 (26.3%)	18/226 (8.0%)	+0.49

Values are median [interquartile range] or n/N (%); N is the number of patients with available data in each group. Variables under "Device and support" and 'Surgical details' describe the exposure, the operation, or the course after implantation and were not treated as baseline variables; ECMO at any time includes ECMO initiated before Impella. Systolic blood pressure, diastolic blood pressure, and heart rate were recorded as 0 in 9, 11, and 9 patients, respectively (with cardiac arrest, cardiopulmonary resuscitation, or ECMO at the time of implantation in 5, 6, and 2 of them); these values are shown as recorded. SMD, standardized mean difference (operating-room minus non-operating-room insertion), before weighting.
AST, aspartate aminotransferase; CRP, C-reactive protein; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; LDH, lactate dehydrogenase; LVEF, left ventricular ejection fraction; NYHA, New York Heart Association; STEMI, ST-elevation myocardial infarction; TIA, transient ischemic attack.

TABLE 2 Thirty-day and in-hospital mortality, overall and by setting of Impella insertion.

Outcome	Total (*n* = 245)	Operating-room insertion (*n* = 19)	Non-operating-room insertion (*n* = 226)	Odds ratio (95% CI)	Risk difference, percentage points (95% CI)	*P*
Thirty-day mortality (primary)	51 (20.8%) [16.2–26.3]	7 (36.8%) [19.1–59.0]	44 (19.5%) [14.8–25.1]	2.46 (0.90–6.34)	17.4 (−1.2 to 40.0)	0.078
In-hospital mortality	81 (33.1%) [27.5–39.2]	9 (47.4%) [27.3–68.3]	72 (31.9%) [26.1–38.2]	1.93 (0.75–4.88)	15.5 (−5.5 to 37.2)	0.167

Values are *n* (%) [Wilson 95% confidence interval]. Unadjusted odds ratios (operating-room versus non-operating-room insertion) are from Firth-penalized logistic regression with profile-likelihood confidence intervals, and risk differences have Newcombe hybrid-score confidence intervals. Weighted estimates are given in Supplementary Table 2.
Thirty-day mortality: death from any cause within 30 days after Impella implantation, before or after discharge. In-hospital mortality: death before discharge from the index hospitalization, irrespective of timing. In 24 patients in the non-operating-room group who were discharged alive before day 30, the last dated confirmation of survival preceded day 30; with censoring at that date, the Kaplan–Meier estimate of 30-day mortality was 21.1% [16.5–26.8].
CI, confidence interval.

1.21) and femoral access in 47.4% vs. 93.4%. Of the 19 operating-room insertions, 8 were Impella CP (7 femoral, 1 axillary or subclavian), 7 Impella 5.5 (6 axillary or subclavian, 1 through a side branch of a vascular graft), 3 Impella 5.0 (2 axillary or subclavian, 1 femoral), and 1 Impella 2.5 (femoral); in the non-operating-room group, 211 of 226 first devices (93.4%) were Impella CP, almost all inserted through the femoral artery. A second Impella was added in 3 of 19 (15.8%) and 30 of 226 patients (13.3%), most often an Impella 5.5. The duration of Impella support was longer after operating-room insertion (median 184 vs. 103 h). Left ventricular ejection fraction was missing in 3 of 19 and 85 of 226 patients, and lactate in 6 of 19 and 54 of 226, respectively.

Clinical outcomes

Thirty-day mortality after Impella implantation was 20.8% (51/245; 95% CI: 16.2–26.3), and in-hospital mortality was 33.1% (81/245; 95% CI: 27.5–39.2) (Table 2). Thirty-one in-hospital deaths occurred later than 30 days after implantation (7 later than 90 days), and one patient died within 30 days after having been discharged alive. The 30-day status was documented by a date in 221 patients (90.2%). Of the 56 patients discharged alive before day 30, 32 had a dated confirmation of survival on or after day 30; the remaining 24, all in the non-operating-room group, had a recorded status of alive, with the last dated confirmation between day 16 and day

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TABLE 3 Adverse events during the index hospitalization, overall and by setting of Impella insertion.

Adverse event	Total (n = 245)	Operating-room insertion (n = 19)	Non-operating-room insertion (n = 226)	Day of onset after implantation, median [IQR]
Bleeding or hematoma	43 (17.6%) [13.3–22.8]	1 (5.3%) [0.9–24.6]	42 (18.6%) [14.1–24.2]	1 [0–2]
Renal failure	24 (9.8%) [6.7–14.2]	1 (5.3%) [0.9–24.6]	23 (10.2%) [6.9–14.8]	4 [1–7]
Sepsis	22 (9.0%) [6.0–13.2]	1 (5.3%) [0.9–24.6]	21 (9.3%) [6.2–13.8]	8 [5–22]
Hemolysis	21 (8.6%) [5.7–12.7]	1 (5.3%) [0.9–24.6]	20 (8.8%) [5.8–13.3]	1 [0–2]
Thrombocytopenia	21 (8.6%) [5.7–12.7]	0 (0.0%) [0.0–16.8]	21 (9.3%) [6.2–13.8]	1 [1–3]
Cerebrovascular accident or stroke	16 (6.5%) [4.1–10.3]	3 (15.8%) [5.5–37.6]	13 (5.8%) [3.4–9.6]	7 [5–11]
Respiratory failure	15 (6.1%) [3.7–9.9]	2 (10.5%) [2.9–31.4]	13 (5.8%) [3.4–9.6]	9 [4–21]
Limb ischemia	11 (4.5%) [2.5–7.9]	0 (0.0%) [0.0–16.8]	11 (4.9%) [2.7–8.5]	3 [1–4]
Ventricular fibrillation	10 (4.1%) [2.2–7.3]	0 (0.0%) [0.0–16.8]	10 (4.4%) [2.4–8.0]	6 [4–8]
Insertion site infection	9 (3.7%) [1.9–6.8]	0 (0.0%) [0.0–16.8]	9 (4.0%) [2.1–7.4]	11 [6–20]
Ventricular tachycardia	7 (2.9%) [1.4–5.8]	1 (5.3%) [0.9–24.6]	6 (2.7%) [1.2–5.7]	5 [1–7]
Liver failure	5 (2.0%) [0.9–4.7]	0 (0.0%) [0.0–16.8]	5 (2.2%) [0.9–5.1]	3 [1–8]
Cardiac tamponade	4 (1.6%) [0.6–4.1]	0 (0.0%) [0.0–16.8]	4 (1.8%) [0.7–4.5]	4 [1–6]
Ventricular perforation	3 (1.2%) [0.4–3.5]	0 (0.0%) [0.0–16.8]	3 (1.3%) [0.5–3.8]	22 [11–59]
Vascular injury requiring treatment	3 (1.2%) [0.4–3.5]	0 (0.0%) [0.0–16.8]	3 (1.3%) [0.5–3.8]	10 [8–11]

Values are n (%) [Wilson 95% confidence interval]. The table includes all events reported by the treating physicians in 15 categories of the registry adverse-event form, irrespective of whether they were judged to be related to the device and irrespective of seriousness. The remaining categories (thrombotic complication outside the central nervous system in 6 patients, cardiogenic shock in 4, four other categories in 1 or 2 each, and events entered as "other" in 15) and the numbers judged to be device-related or serious are given in Supplementary Table 5. Events were not centrally adjudicated and could occur at any time during the index hospitalization; published registry definitions exist for 7 of the 15 categories, and the others are diagnoses of the treating physician (Supplementary Table 5). The day of onset is given for all patients with the event and is rounded to whole days. Events are presented descriptively without between-group testing because the period at risk differs between groups and death is a competing event.
IQR, interquartile range.

29 and no recorded death. When these 24 patients were censored at that date, the Kaplan–Meier estimate of 30-day mortality was 21.1% (95% CI: 16.5–26.8). Excluding them, which removes only survivors and therefore overestimates mortality, gave 23.1% (51/221; 95% CI: 18.0–29.1); if all 24 had died, mortality would have been 30.6% (75/245). The most frequent adverse events were bleeding or hematoma (43 patients, 17.6%; 95% CI: 13.3–22.8), renal failure (24, 9.8%; 6.7–14.2), sepsis (22, 9.0%; 6.0–13.2), hemolysis (21, 8.6%; 5.7–12.7), thrombocytopenia (21, 8.6%; 5.7–12.7), and stroke (16, 6.5%; 4.1–10.3) (Table 3). Limb ischemia occurred in 11 patients (4.5%; 2.5–7.9) and insertion site infection in 9 (3.7%; 1.9–6.8). Bleeding and hemolysis occurred early [median day 1 after implantation (interquartile range 0–2) for both], renal failure on day 4 [1–7], and sepsis and stroke later [day 8 [5–22] and day 7 [5–11], respectively].

Thirty-day mortality was 36.8% (7/19; 95% CI: 19.1–59.0) after operating-room insertion and 19.5% (44/226; 14.8–25.1) after non-operating-room insertion (unadjusted odds ratio 2.46, 95% CI: 0.90–6.34; risk difference 17.4 percentage points, 95% CI: −1.2 to 40.0). In-hospital mortality was 47.4% (9/19) and 31.9% (72/226), respectively (odds ratio 1.93, 95% CI: 0.75–4.88; risk difference 15.5 percentage points, 95% CI: −5.5 to 37.2). Adverse events by group, with their day of onset, are shown descriptively in Table 3; with 19 patients in the operating-room group, the upper confidence limit for an event that was not observed is 16.8%.

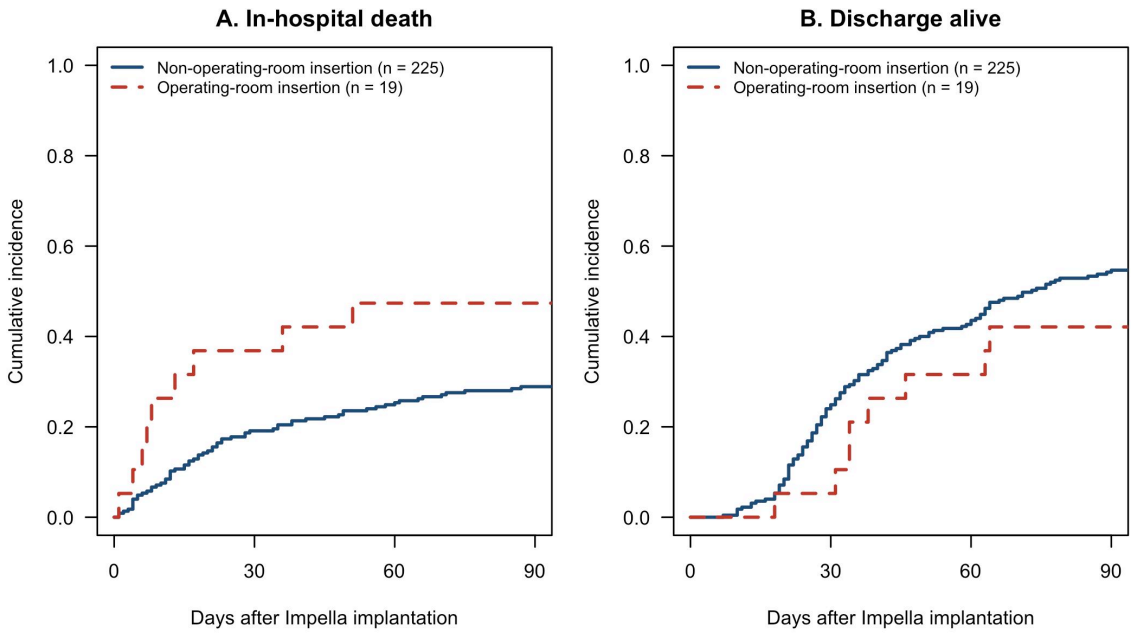
Cumulative incidence of in-hospital death and discharge

Cumulative incidence functions for in-hospital death and discharge alive are shown in Figure 2. At 30, 60, and 90 days after implantation, the cumulative incidence of in-hospital death was 36.8%, 47.4%, and 47.4% after operating-room insertion and 19.1%, 25.3%, and 28.9% after non-operating-room insertion (Gray's test $P = 0.066$); the corresponding cumulative incidence of discharge alive was 5.3%, 31.6%, and 42.1% vs. 24.9%, 43.6%, and 54.7% ($P = 0.437$). One patient with an implausible date of discharge was excluded from this analysis. At 90 days, 2 and 37 patients, respectively, were still hospitalized.

Post hoc exploratory weighted comparison

After overlap weighting, the three covariates in the propensity score model were balanced (absolute SMD ≤ 0.02), but many other baseline variables were not: the absolute SMD exceeded 0.1 for 16 of the 31 baseline variables, including history of heart failure (0.97), prior myocardial infarction (0.71), left ventricular ejection fraction (−0.76), and inotrope or vasopressor use (0.46). Device type and access site, which are components of the exposure, also remained different (Impella 5.0/5.5, 1.23; femoral access, −1.16); other procedural and post-implantation characteristics are shown separately in Supplementary Table 1. Propensity scores ranged from 0.04 to 0.27 in the operating-room group and from 0.03 to 0.32 in the non-operating-room group, and the effective sample sizes were 18.9 and 174.4 (Supplementary Figure 1).

The weighted 30-day mortality was 35.5% vs. 24.7% (odds ratio 1.63, 95% CI: 0.62–4.16; $P = 0.29$; risk difference 10.8 percentage points, 95% CI: −8.8 to 34.5). Resampling centers instead of patients gave a similar interval (0.60–3.69). Across alternative covariate sets the odds ratio ranged from 1.10 (0.31–3.06) when creatine kinase was added to 1.99 (0.72–5.17) when Impella device type was added, and between 1.57 and 1.80 in analyses restricted to subsets of the cohort. The analysis with creatine kinase omitted 5 patients in whom it was missing, including 2 patients with operating-room insertion who died within 30 days; the primary model in the same 239 patients gave an odds ratio of 1.29 (0.39–3.48). The odds ratio was 1.48 (0.56–3.44) when patients without dated documentation of survival to day 30 were excluded (Supplementary Table 2). For in-hospital mortality the weighted odds ratio was 1.43 (0.58–



Number of patients	Day 0	Day 30	Day 60	Day 90
Non-operating-room insertion				
Still hospitalized (at risk)	225	126	70	37
Died in hospital (cumulative)	0	43	57	65
Discharged alive (cumulative)	0	56	98	123
Operating-room insertion				
Still hospitalized (at risk)	19	11	4	2
Died in hospital (cumulative)	0	7	9	9
Discharged alive (cumulative)	0	1	6	8

FIGURE 2
Cumulative incidence of in-hospital death **(A)** and discharge alive **(B)** after Impella implantation, by setting of insertion, treating the two events as competing. The time origin is the date of Impella implantation. The table below the panels shows, for each group, the number of patients still hospitalized (at risk) and the cumulative numbers who had died in hospital or had been discharged alive at 0, 30, 60, and 90 days. One patient with an implausible date of discharge was excluded, and one patient who died after discharge is counted as discharged alive. Gray's test: $P = 0.066$ for death and $P = 0.437$ for discharge.

3.41). The E-value for the point estimate was 1.87, and 1.00 for the confidence limit closest to the null. These estimates have wide confidence intervals and vary with the choice of covariates; the data are consistent with either a substantially lower or a substantially higher mortality after operating-room insertion.

Discussion

Using the nationwide J-PVAD registry, we characterized 245 patients from 116 centers who underwent CABG under Impella support for AMI-related cardiogenic shock. Our contribution is descriptive: 30-day mortality after implantation was 20.8% (95% CI: 16.2–26.3; 21.1% when the 24 patients without dated confirmation of survival to day 30 were censored) and in-hospital mortality was 33.1% (27.5–39.2), with bleeding (17.6%), renal failure (9.8%), and sepsis (9.0%) as the most frequent adverse events. The difference between the two mortality figures shows that more than one third of in-hospital deaths in this population occur later than 30 days after implantation, so that 30-day mortality alone underestimates the hospital course. In a *post hoc* exploratory comparison, mortality was numerically higher after operating-room insertion, but the estimate was imprecise and confounded, and these data cannot determine the comparative safety of the insertion setting.

Reference estimates for impella-supported CABG in AMI-related cardiogenic shock

The present cohort is conditional on having received Impella and on having survived to undergo CABG under Impella support; it is therefore not comparable with unselected populations with AMI-related cardiogenic shock, and no non-Impella comparison group is available in the registry. With this caveat, surgical registries of CABG for AMI-related cardiogenic shock have reported in-hospital mortality of 19.8% in the North Rhine-Westphalia registry (16) and cohort mortality of 39.6% in a population-based Canadian study (17). In the Society of Thoracic Surgeons database (2012–2022; 29,835 patients undergoing CABG within 7 days of AMI with cardiogenic shock), operative mortality was 21.3%, and 23.0% when shock was ongoing at the time of surgery; only 10.6% of these patients received a microaxial flow pump (12). The 30-day mortality of 20.8% and in-hospital mortality of 33.1% in our cohort, in which every patient required Impella support, are of the same order, but the definitions of mortality, the time origin, and the case mix differ, and the figures should not be compared directly. Experimental and early clinical data suggest that ventricular unloading limits infarct size (18–21), but our data do not permit any inference about the effect of Impella support on outcome. ECMO use at any time in 34.4% and out-of-hospital cardiac arrest in 11.1% indicate the severity of illness in this population.

Relation to previous J-PVAD reports. Ikeda et al. and Arai et al. reported short-term outcomes of all patients with AMI-related cardiogenic shock in J-PVAD (10, 11). In the report by Arai et al. (February 2020 to December 2023; $n = 3{,}975$), CABG was one covariate (296 patients, 7.4%), counted irrespective of whether it was performed under Impella support and including patients with mechanical complications. Our cohort is restricted to CABG performed under Impella support, excludes VSP repair, and extends enrollment by one year; patients enrolled up to December 2023 are expected to be included among those of Arai et al., but the surgical population was not analyzed separately there. The present study adds the setting of insertion and its timing relative to cardiopulmonary bypass, device type and access, concomitant procedures, in-hospital mortality beyond 30 days, and the competing course of death and discharge.

The adverse event profile was consistent with published experience with Impella in critically ill and surgical patients (22, 23); in a manufacturer-funded registry of 177 patients supported with Impella 5.5 for AMI-related cardiogenic shock, stroke, hemolysis, acute limb ischemia, and bleeding during support were reported in 4.0%, 9.0%, 4.0%, and 16.4%, with in-hospital survival of 65% (14). Bleeding occurred in 17.6%, mostly within 2 days of implantation, reflecting the tension between the anticoagulation required for the device and surgical hemostasis after CABG. Stroke occurred in 6.5% (95% CI: 4.1–10.3) and hemolysis in 8.6%. Because events were reported by the treating institutions without central adjudication, these estimates should be regarded as national reference estimates under registry definitions rather than as standardized benchmarks.

Setting of Impella insertion: A *post hoc* exploratory comparison

The registry records where the Impella was inserted, but not why or when in the clinical course. Operating-room insertion in this cohort differed from non-operating-room insertion not only in setting but also in device (Impella 5.0/5.5 in half), access (non-femoral in half), and the phase of surgery (before or after weaning from cardiopulmonary bypass); an effect of timing alone cannot be estimated. About half of the operating-room insertions were Impella 5.0 or 5.5 placed through the axillary or subclavian artery, which requires surgical exposure and a vascular graft and provides higher flow for longer support, whereas most of the remainder were percutaneous Impella CP devices inserted through the femoral artery, as in nearly all non-operating-room insertions. The registry does not record why a device was chosen, whether direct aortic insertion was used, or the technical details of insertion; the longer duration of support after operating-room insertion is consistent with the greater use of devices intended for prolonged support. Baseline differences were not uniformly in one direction: left ventricular function was poorer and inotrope use more frequent, whereas lactate was lower, in the operating-room group.

Thirty-day mortality was numerically higher after operating-room insertion, both before (odds ratio 2.46, 95% CI: 0.90–6.34) and after overlap weighting (1.63, 0.62–4.16). The weighted estimate does not remove confounding: only three covariates could be modeled, most other characteristics remained imbalanced, and the estimate varied from 1.10 to 1.99 across covariate sets. The confidence interval is compatible with a substantial increase as well as a reduction in mortality. In addition, the two groups were not observed over comparable periods. Counting from implantation removes the interval between admission and implantation, but patients in the non-

operating-room group also had to survive from implantation to CABG to enter the cohort, whereas implantation and surgery coincided in the operating-room group. We therefore draw no conclusion about comparative safety.

Adverse events were not compared between groups. Patients with non-operating-room insertion were at risk before, during, and after surgery, whereas those with operating-room insertion were at risk only from the time of surgery, and their higher early mortality reduced the opportunity to observe non-fatal events. The lower crude frequency of bleeding after operating-room insertion (1/19 vs. 42/226) should not be interpreted as a protective effect.

Marin-Cuartas et al. reported 30-day mortality of 12.5%, 60.0%, and 28.6% after preoperative, intraoperative, and postoperative Impella implantation in 33 patients undergoing various cardiac operations in a single center, of whom 11 underwent CABG (30-day mortality 45.4%) (13), and Sommer et al. compared simultaneous with delayed implantation of surgically implanted microaxial pumps in 42 patients after CABG (24). Like the present analysis, these studies are small and observational and cannot separate the effect of timing from that of patient selection.

The AATS expert consensus document endorses temporary mechanical circulatory support, including Impella, to facilitate hemodynamic stabilization in patients requiring surgery for AMI-related cardiogenic shock (25). Whether and when Impella should be inserted in relation to CABG cannot be answered by registry data that lack the indication and timing of insertion; prospective studies recording these items are required.

Limitations

First, only 19 patients underwent operating-room insertion; the propensity score model was restricted to three covariates, the comparison has very low power, and its estimates are unstable.

Second, confounding is not controlled: after weighting, 16 of 31 baseline variables remained imbalanced, and device type and access site are inseparable from the exposure. The E-value of 1.87 (1.00 for the confidence limit) indicates that unmeasured or unmodeled confounding of moderate strength could fully explain the point estimate.

Third, cardiogenic shock was defined by the indication under which Impella is approved and registered in Japan, and its presence and severity could not be verified independently from the data provided. The registry records the setting of insertion but not the intent, indication, or clinical timing of insertion, the reason for the choice of device, or the technical details of insertion, and the non-operating-room group includes insertions in the catheterization laboratory, intensive care unit, and emergency department that cannot be distinguished.

Fourth, adverse events were site-reported without central adjudication, and SCAI stage, number of grafts, cardiopulmonary bypass times, and intensive care unit stay are not collected; the date of CABG is not recorded, so that patients in whom Impella was inserted only after CABG could not be identified and the order of PCI and CABG could not be established in patients in whom the same device supported both; left ventricular ejection fraction and lactate were missing in about one third and one quarter of patients.

Fifth, J-PVAD centers are certified institutions experienced in mechanical circulatory support, most centers contributed a single patient, and the cohort is conditional on survival to CABG under Impella support; among 295 patients in the registry who underwent CABG without recorded Impella support during surgery, in whom Impella may have been inserted after CABG, 30-day mortality was 38.0% (Supplementary Table 3); this figure is given for context and is not comparable with that of the study cohort. The estimates therefore apply only to patients operated on under Impella support and may not generalize to other settings. The registry infrastructure is partly funded by the device manufacturer.

Sixth, using implantation as the time origin does not remove selection by survival to CABG. In the non-operating-room group, in which the device was in place before surgery, patients who died between implantation and CABG are not in the cohort, and the interval between implantation and CABG, which the registry does not record, lies within the 30-day window. In the operating-room group, implantation and surgery coincided. The postoperative periods covered by 30-day mortality are therefore not comparable between the groups, and this selection may have lowered the apparent mortality of the non-operating-room group relative to the operating-room group; the same applies to the cumulative incidence curves and to in-hospital mortality, which is likewise conditional on having reached CABG.

Seventh, in 24 patients (9.8%), all in the non-operating-room group, who were discharged alive before day 30, the recorded status was alive but its last dated confirmation was between day 16 and day 29; they were counted as alive at 30 days on the basis of the recorded status. If any of them died before day 30, 30-day mortality is underestimated and, because no such patient was in the operating-room group, the difference between the groups is overestimated. With censoring at the last dated confirmation, the Kaplan–Meier estimate was 21.1%. The estimate after their exclusion (23.1%) removes only survivors from the denominator and overestimates mortality; it is not an upper bound. If all 24 had died, mortality would have been 30.6% (75/245).

Finally, the cohort comprised CABG with or without concomitant cardiac surgery (valve surgery in 14.3%) and included 13 patients with mechanical complications who did not undergo VSP repair; the indication for mitral surgery was not recorded in most patients, and the estimates should be interpreted accordingly.

Conclusion

This nationwide registry analysis provides contemporary national reference estimates for CABG performed under Impella support in AMI-related cardiogenic shock: a 30-day mortality of 20.8% (95% CI: 16.2–26.3; 21.1% with censoring of patients without dated confirmation of survival to day 30) and an in-hospital mortality of 33.1% (27.5–39.2), with bleeding, renal failure, and sepsis as the most frequent adverse events. Mortality was numerically higher after operating-room than after non-operating-room insertion, but the comparison was imprecise and confounded, and the registry does not record the intent or timing of insertion; comparative safety cannot be determined from these data.

Data availability statement

The data analyzed in this study is subject to the following licenses/restrictions: The dataset is owned and governed by the J-PVAD registry, not by the authors. Patients consented via an opt-out mechanism that did not cover open data sharing, and sharing is further restricted by patient-privacy requirements under the Japanese Ethical Guidelines for Medical and Biological Research Involving Human Subjects and by the registry protocol, which requires approval by the registry committee for any use of registry data. Access requests are forwarded by the corresponding author to the J-PVAD registry office. Requests to access these datasets should be directed to Yoshinori Nakahara, ynakaha@shi.heart.or.jp.

Ethics statement

The studies involving humans were approved by Ethics Committee of Sakakibara Heart Institute, Fuchu, Tokyo, Japan (approval no. 18-027). The J-PVAD registry is approved by the Ethics Committee of Osaka University Hospital (approval no. 17232) and by the institutional review boards of all participating centers. The studies were conducted in accordance with the local legislation and institutional requirements. The ethics committee/institutional review board waived the requirement of written informed consent for participation from the participants or the participants' legal guardians/next of kin because this was a retrospective analysis of de-identified data already collected in a nationwide multicenter registry, involving no intervention and posing minimal risk to participants. Obtaining individual written informed consent from all patients across the participating nationwide centers was not practicable. In accordance with the Japanese Ethical Guidelines for Medical and Biological Research Involving Human Subjects and the requirements of the approving ethics committees, the requirement for written informed consent was waived, and patients were instead given the opportunity to decline participation through an opt-out mechanism at each participating center.

Author contributions

YN: Methodology, Conceptualization, Writing – review & editing, Writing – original draft, Formal analysis. TI: Writing – review & editing, Investigation, Data curation. AM: Supervision, Writing – review & editing. YO: Writing – review & editing, Formal analysis, Validation.

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Conflict of interest

The author(s) declared that this work was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Generative AI statement

The author(s) declared that generative AI was used in the creation of this manuscript. Generative AI was used for English language editing and refinement of the manuscript text. The tool used was Claude (model Claude Opus 4.8; Anthropic, San Francisco, CA, USA). DeepL (DeepL SE, Cologne, Germany) was additionally used to translate portions of the text from Japanese into English. All output was reviewed, verified, and edited by the authors.

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Supplementary material

The Supplementary Material for this article can be found online at: https://www.frontiersin.org/articles/10.3389/fcvm.2026.1941963/full#supplementary-material

DATA SHEET 1
Supplementary Tables 1-5, Supplementary Figure 1, and Supplementary Methods.

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