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ORIGINAL ARTICLE
Critical Care

Outcomes of Older Patients With Cardiogenic Shock Using the Impella Device
— Insights From the Japanese Registry for Percutaneous Ventricular Assist Device (J-PVAD) —

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Background: Aging has progressed in several regions of the world with more older patients experiencing acute cardiovascular disease. Impella is a percutaneous potent circulatory support device associated with substantial cost and potential device-related complications.

Methods and Results: We analyzed the Japanese nationwide registry, encompassing consecutive patients with cardiogenic shock using Impella. Among 5,718 patients treated between 2020 and 2022, we compared older patients (≥75 years) with younger patients. The primary outcome was the Kaplan-Meier estimated 30-day mortality, and the secondary outcome was Impella-related complications. The median age of the 5,718 patients was 69 (58–77) years, and 1,807 (31.6%) were older, with smaller body mass index, frequent acute coronary syndrome, and infrequent myocarditis. Comorbidities were frequently observed in older patients with a higher ejection fraction and less frequency of extracorporeal membrane oxygenation. Older patients had a higher 30-day mortality than younger patients (38.9% vs. 32.5%; P<0.0001). The 30-day mortality was statistically equivalent among older subsets (75–79 vs. 80–84 vs. ≥85 years). Device-related complications similarly occurred similarly among the older subsets, except for a modest increase in cardiac tamponade and limb ischemia. Older age, body mass index, myocarditis, prior arrhythmia, shock severity, renal and hepatic impairment, and limb ischemia were associated with 30-day mortality.

Conclusions: The selected older patients using Impella exhibited modestly higher 30-day mortality with similar safety profiles. A longer follow up and optimal patient selection are important.

Key Words: Geriatric; Impella; Older; Percutaneous ventricular assist device (PVAD)

The population is aging in regions worldwide. Japan had the highest aging rate (i.e., the proportion of people aged ≥65 years) of 29% in 2023,[1] whereas several countries will reach 20% within the next 20–30 years.[2] Aging is a risk factor for cardiovascular diseases, including heart failure, acute coronary syndrome, acute aortic dissection, and atrial fibrillation; therefore, the number of older patients with emergent cardiovascular disease is predicted to increase.[3,4] Shimokawa et al. reported a steep increase in new-onset heart failure in older patients in the past 50 years.[3] However, older patients often have poor physical function, malnutrition, and multimorbidity. Medical futility, which means futile intervention without a projected outcome, is an ineligible issue.[5] Cardiogenic shock (CS) is the worst cardiac condition with 30–50% mortality in the short term. In the SHOCK (Should we emergently revascularize Occluded Coronaries in cardiogenic shocK) trial demonstrating the effectiveness of percutaneous coronary intervention (PCI) in patients with shock myocardial infarction, PCI could not improve the outcome in older patients who were aged ≥75 years.[6] Among several therapeutic interventions tested in CS, limited interventions proved to be effective.[7] A percutaneous ventricular assist device (PVAD) is a percutaneously inducible and potent mechanical circulatory support (MCS) device. According to the recent positive result of the DanGer SHOCK trial,[8] PVAD can improve the prognosis of patients with CS. The target population of the

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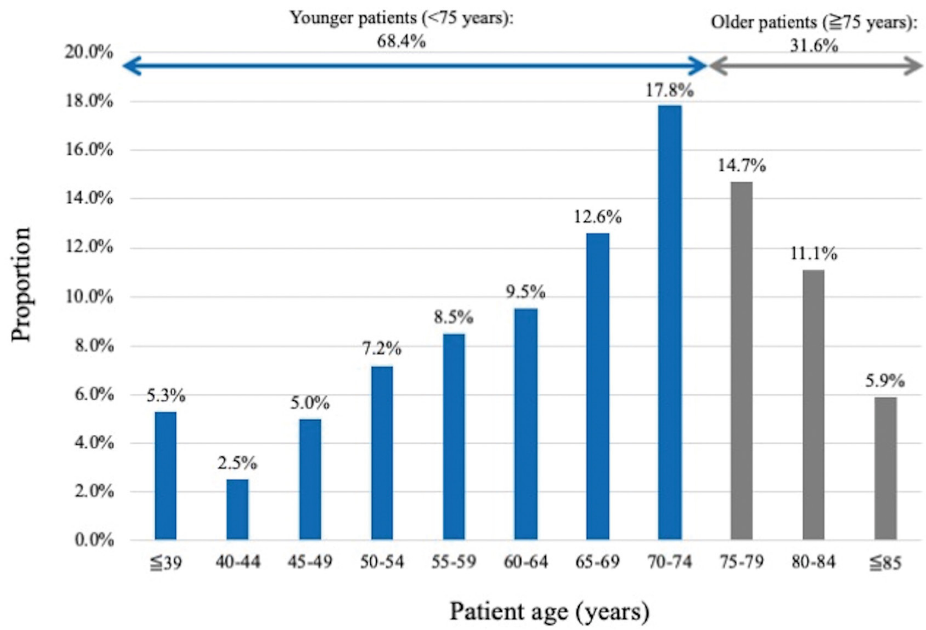

Figure 1. Distribution of patients' age. Among 5,718 patients, 31.6% were older patients (age ≥75 years) using the Impella device between February 2020 and December 2022 in Japan; 75–79 years: 14.7%; 80–84 years: 11.1%; and ≥85 years: 5.9%.

DanGer SHOCK trial had a median age of 67 years. Interventional cardiologists, heart failure physicians, emergency physicians, and intensivists are skeptical of the use of PVAD to favorably treat older patients with CS.[5] We previously reported that being octo-/nonagenarian was independently associated with 1-year mortality after cardiac care unit admission in a high-volume center in Japan.[9] As for cardiopulmonary resuscitation using another advanced MCS, venoarterial extracorporeal membrane oxygenation (ECMO), the Extracorporeal Life Support Organization (ELSO) has suggested an upper limit of age 70 years based on a previous report regarding out-of-hospital cardiac arrest.[10,11] Furthermore, we have limited data on the current status and outcome of PVAD focusing on older patients. This study aimed to investigate the characteristics and outcomes of older patients (age ≥75 years) using PVAD based on the Japanese Registry for Percutaneous Ventricular Assist Device (J-PVAD) data, which encompasses consecutive patients using the Impella (Abiomed, Danvers, MA, USA) device in Japan.

Methods

Study Design

This observational study used data from the nationwide J-PVAD registry (Trial no. UMIN000033603), which registered consecutive patients using the Impella device in Japan. The details of the J-PVAD registry have been reported previously.[12] In Japan, Impella is the only approved PVAD that can be used in a certified institution. Use of the device was approved by the Council for Clinical Use of Ventricular Assist Device-Related Academic Societies, Impella Committee, which comprised 10 relevant academic organizations. One prerequisite for site certification is the registration of consecutive patients using an Impella device. The J-PVAD registry was approved by the Central Institutional Review Board (Osaka University ethics committee; Approval no. 17232) and the Institutional Review Boards of the participating centers. This study was conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology statement and the latest version of the Declaration of Helsinki.

Study Population

Of the 5,721 patients who used the Impella device between February 2020 and December 2022, 5,718 (99.9%) patients were analysed; 3 (0.1%) patients with no clinical data were excluded. The indication for PVAD was drug-refractory heart failure, particularly CS. Impella 2.5 and 5.0 were reimbursed in September 2017, Impella CP in May 2019, and Impella 5.5 in February 2022. The introduction and selection of the device were determined by a local heart team.

Study Outcome

The primary outcome was the Kaplan-Meier estimated 30-day mortality after Impella insertion. The secondary outcomes were PVAD-related complications, including bleeding requiring transfusion, cardiac tamponade, ischemic or hemorrhagic cerebrovascular accident, hemolysis, lower limb ischemia, acute kidney injury, sepsis, and vascular injury requiring intervention (**Supplementary Table 1**). The characteristics and outcomes of older patients (age ≥75 years) were compared with those of younger patients (age <75 years).

Statistical Analysis

The categorical variables were expressed as numbers with percentages, and continuous variables were expressed as average±standard deviation or median (interquartile range) according to the normality of variables. Normality

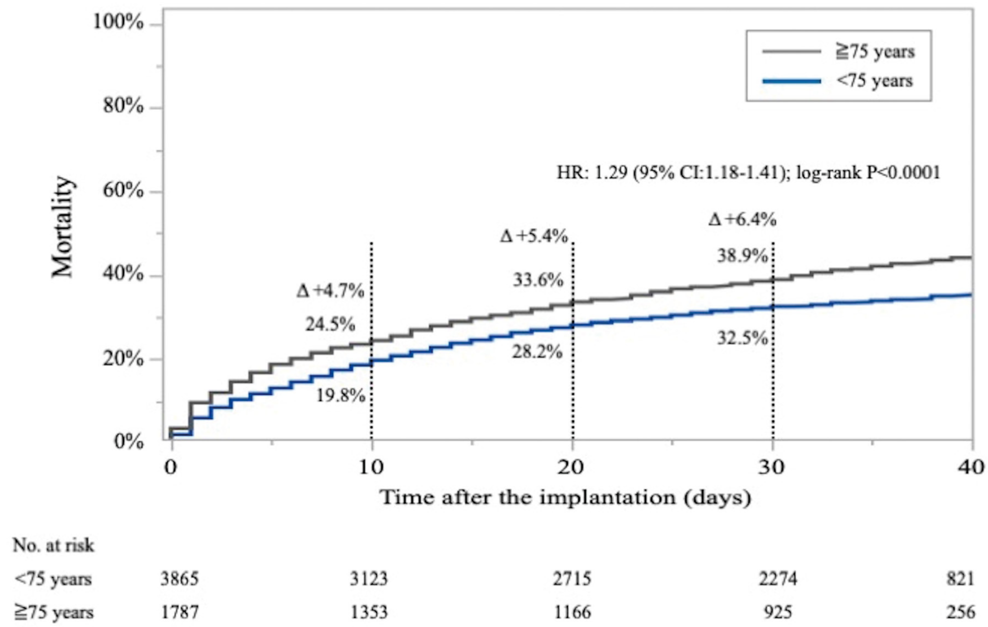

Figure 2. Kaplan-Meier estimated 30-day mortality after Impella insertion in older (age ≥75 years) and younger (age <75 years) patients. The estimated 30-day mortality was 38.9% in the older cohort (age ≥75 years) vs. 32.5% in the younger cohort (age <75 years). CI, confidence interval; HR, hazard ratio.

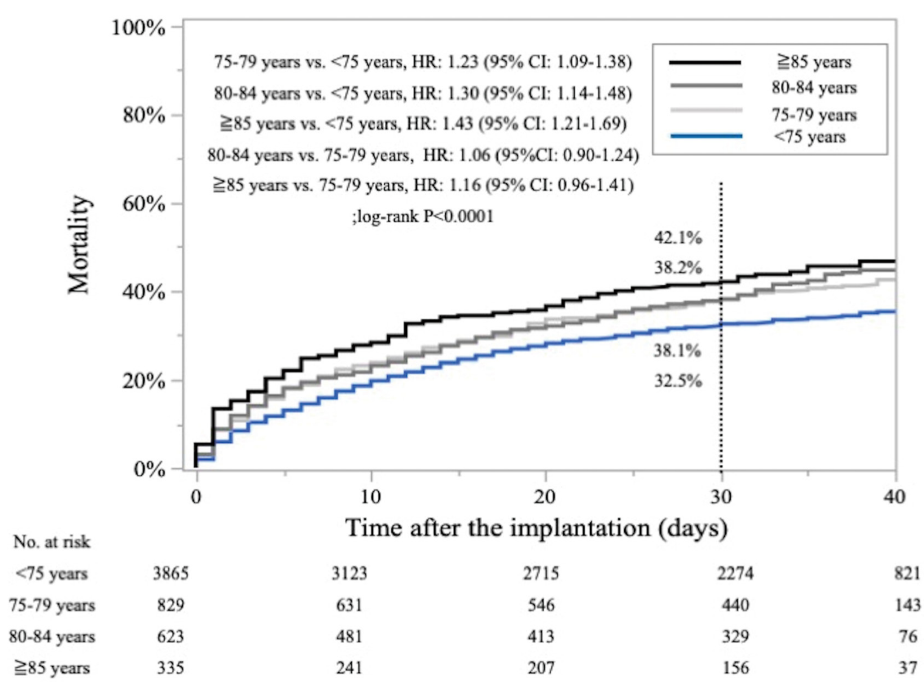

Figure 3. Kaplan-Meier estimated 30-day mortality after Impella insertion in older (age 75–79, 80–84, and ≥85 years) and younger (age <75 years) patients. The estimated 30-day mortality was 38.1%, 38.2%, and 42.1% in patients aged 75–79, 80–84, and ≥85 years, respectively. These rates were higher than those in younger patients (age <75 years), and statistically similar among the respective older groups. CI, confidence interval; HR, hazard ratio.

was assessed using the Anderson-Darling test. To compare the parameters of older patients with younger patients, the χ^2 test or Fisher exact test was used for the categorical variables, and the Student's t-test or Wilcoxon signed-rank test was used for the continuous variables. We analyzed the factors related to 30-day mortality using Cox regression analysis. Multivariate factors were selected based on the results of the univariate analysis, background knowledge, clinical plausibility, and multicollinearity. Statistical significance was defined as a P value <0.05. The statistical software, JMP Pro (ver. 16.0.0; SAS Institute Inc., Cary, NC, USA), was used.

Results

Study Population

The 5,718 participants had a median age of 69 (58–77) years; 1,807 (31.6%) patients were in the older (age ≥75 years) group and 3,911 (68.4%) patients were in the younger (age <75 years) group (**Figure 1**). During the inclusion period, the proportion of patients in the older group was consistent with 376 (30.7%) of 1,225 in 2020, 615 (31.7%) of 1,941 in 2021, and 816 (32.0%) of 2,552 in 2022 (P=0.64). Compared with younger patients, older patients were associated with a lower percentage of males, smaller body mass index, more frequent acute coronary syndrome, and infrequent myocarditis as reasons for admission. The older group had less frequent out-of-hospital cardiac arrest, and more frequent comorbidities including hypertension, dyslipidemia, diabetes, arrhythmia, coronary artery disease, heart failure, valvular heart disease, and cerebral infarction/transient ischemic attacks. Younger patients were hemodynamically unstable based on hemodynamic parameters: lower systolic blood pressure, higher lactate level, and frequent use of a vasopressor/inotrope. Impella CP was used in approximately 90% of both groups, and the use of Impella 5.0/5.5 was more frequent in the younger group. The proportions of non-transfemoral Impella, additional

Table 1. Baseline and Procedural Characteristics

	Younger (n=3,911)	Older (n=1,807)	P value
Baseline characteristics			
Age (years)	62 [53–70]	80 [77–83]	<0.0001*
Male sex	3,155 (80.7)	1,250 (69.2)	<0.0001*
BMI (kg/m²)	23.7 [21.1–26.6]	22.4 [20.0–24.7]	<0.0001*
Cause of admission			<0.0001*
Cardiogenic shock	330 (8.4)	142 (7.9)	
Cardiac arrest	452 (11.6)	77 (4.3)	
Acute coronary syndrome	1,665 (42.6)	1,052 (58.2)	
Myocarditis	363 (9.3)	39 (2.2)	
Heart failure	549 (14.0)	242 (13.4)	
Chronic coronary syndrome	158 (4.0)	100 (5.5)	
Arrhythmia	136 (3.5)	23 (1.3)	
Other	258 (6.6)	132 (7.3)	
OHCA	933 (23.9)	164 (9.9)	<0.0001*
Hypertension	2,022 (51.7)	1,296 (71.7)	<0.0001*
Pulmonary hypertension	155 (4.0)	79 (4.4)	0.10
Dyslipidemia	1,591 (40.7)	867 (48.0)	<0.0001*
Diabetes	1,434 (36.7)	802 (44.4)	<0.0001*
Arrhythmia†	670 (17.1)	315 (17.4)	0.003*
Coronary artery disease	992 (25.4)	615 (34.0)	<0.0001*
Heart failure	1,056 (27.0)	526 (29.1)	0.013*
Cardiomyopathy	337 (8.6)	73 (4.0)	<0.0001*
Valvular heart disease	343 (8.8)	217 (12.0)	<0.0001*
Cerebral infarction/transient ischemic attack	246 (6.3)	215 (11.9)	<0.0001*
SBP (mmHg)	90 [74–110]	93 [76–114]	0.0001*
Ejection fraction (%)	25 [18–34]	30 [23–43]	<0.0001*
Lactate (mmol/L)	4.3 [2.1–9.5]	4.1 [2.1–7.8]	0.005*
LDH (U/L)	404 [262–766]	369 [244–686]	0.0001*
Creatinine (mg/dL)	1.21 [0.93–1.76]	1.25 [0.95–1.88]	0.020*
Total bilirubin (mg/dL)	0.7 [0.5–1.2]	0.8 [0.5–1.1]	0.14
Albumin (g/dL)	3.4 [2.8–3.8]	3.3 [2.9–3.8]	0.27
Creatine kinase (U/L)	214 [100–798]	225 [88–819]	0.13
C-reactive protein (mg/dL)	0.80 [0.12–5.42]	1.12 [0.16–5.52]	0.009*
Vasopressor/inotrope	2,976 (76.1)	1,329 (73.6)	0.037*
Pulmonary artery catheter	2,542 (65.0)	1,072 (59.3)	0.0002*

(**Table 1** continued the next page.)

	Younger (n=3,911)	Older (n=1,807)	P value
Procedural characteristics			
Type of Impella			<0.0001*
Impella 2.5	139 (3.6)	92 (5.1)	
Impella CP	3,512 (89.8)	1,637 (90.6)	
Impella 5.0/5.5	260 (6.7)	78 (4.3)	
Access site			0.023*
Transfemoral	3,609 (92.3)	1,698 (94.0)	
Transsubclavian/transaortic	301 (7.7)	109 (6.05)	
Support duration (h)	113 [49–192]	84 [28–163]	<0.0001*
Additional MCS‡	2,114 (54.1)	793 (43.9)	<0.0001*
ECPELLA	1,738 (44.4)	571 (31.6)	<0.0001*
Procedural complications			
Bleeding	817 (20.9)	398 (22.0)	0.33
Cardiac tamponade	68 (1.8)	63 (3.5)	<0.0001*
Cerebrovascular accident	240 (6.1)	89 (4.9)	0.068
Hemolysis	511 (13.1)	219 (12.1)	0.32
Limb ischemia	136 (3.5)	102 (5.6)	0.0001*
Acute kidney injury	324 (8.3)	159 (8.8)	0.52
Sepsis	199 (5.1)	103 (5.7)	0.34
Vascular injury	48 (1.2)	25 (1.4)	0.24
Interventions during the Impella insertion			
PCI	2,300 (58.8)	1,338 (74.1)	<0.0001*
CABG	335 (8.6)	194 (10.7)	0.009*
Valve surgery	223 (5.7)	102 (5.6)	0.93
Catheter ablation	133 (2.3)	31 (1.7)	0.037*
Follow-up period (days)	32 [14–38]	30 [10–36]	<0.0001*

Unless indicated otherwise, data are presented as n (%) or median [IQR]. *P values are statistically significant. †Including atrial fibrillation, supraventricular tachycardia, atrioventricular block, and ventricular tachycardia/ventricular fibrillation. ‡Including intra-aortic balloon pumping, extracorporeal membrane oxygenation, ventricular assist device, and Impella. BMI, body mass index; CABG, oronary artery bypass grafting; ECPELLA, combination of venoarterial extracorporeal membrane oxygenation and Impella; LDH, lactate dehydrogenase; MCS, mechanical circulatory support; OHCA, out of hospital cardiac arrest; PCI, percutaneous coronary intervention; SBP, systolic blood pressure.

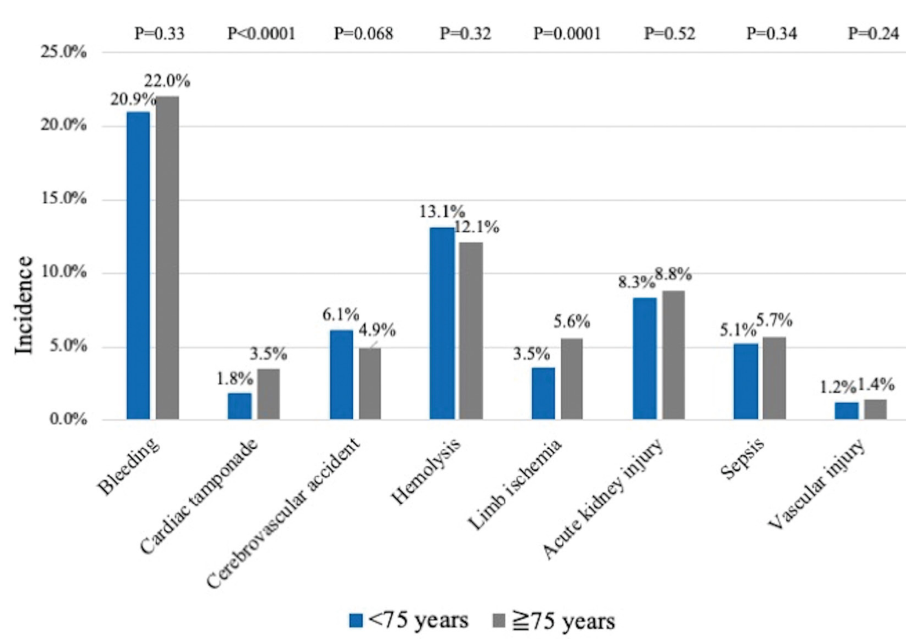

Figure 4. Incidence of Impella-related complications. The rate of Impella-related complications was similar between the older and younger groups, except for modest differences in cardiac tamponade and limb ischemia.

MCS, and Impella combined with ECMO (ECPELLA) were lower in older patients.

30-Day Mortality and Procedural Complications

The 30-day mortality was higher in the older group, and the difference in mortality diverged slightly over time (38.9% vs. 32.5%; log-rank P<0.0001; **Figure 2**). Dividing the older group into 3 age groups (75–79 years, 80–84 years, and ≥85 years), the 30-day mortality of every subset was higher than that of the younger group, whereas there was a numerically modest but statistically non-significant difference among the older subsets (**Figure 3**). The rates of Impella-related complications were similar, except for a modest increase in cardiac tamponade and limb ischemia in the older group (**Table 1**, **Figure 4**). The 30-day mortality and procedural complications are further stratified by ECMO use and the year of Impella insertion (**Supplementary Tables 2**,**3**).

Predictors of 30-Day Mortality

The results of the univariate and multivariate analyses are presented in **Table 2**. Older age, body mass index, myocarditis, prior arrhythmia, ejection fraction, lactate level, creatinine, bilirubin, albumin, ECPELLA, and limb ischemia were associated with 30-day mortality. Age as a continuous variable was an independent predictor of 30-day mortality (hazard ratio per 1 year increase, 1.03; 95% confidence interval 1.02–1.04; P<0.0001).

Discussion

The main findings of the present study are as follows: (1) Of the 5,718 patients using the Impella device for CS between 2020 and 2022 in Japan, there were 1,807 (31.6%) older patients (age ≥75 years). The older group presented with a smaller body mass index, frequent acute coronary syndrome, and infrequent myocarditis. Although comor-

Table 2. Predictors of Mortality After Impella Insertion

	Univariate			Multivariate		
	HR	95% CI	P value	HR	95% CI	P value
Baseline characteristics						
Age ≥75 years	1.29	1.18–1.41	<0.0001*	1.83	1.56–2.16	<0.0001*
Male sex	0.96	0.86–1.06	0.37			
BMI per 1 kg/m² increase	1.05	1.04–1.06	<0.0001*	1.05	1.03–1.06	<0.0001*
Cause of admission						
Cardiogenic shock	Ref.			Ref.		
Cardiac arrest	1.48	1.24–1.76	<0.0001*	1.05	0.71–1.54	0.82
Acute coronary syndrome	0.74	0.64–0.86	<0.0001*	1.08	0.84–1.37	0.56
Myocarditis	0.38	0.30–0.49	<0.0001*	0.43	0.30–0.63	<0.0001*
Heart failure	0.62	0.52–0.74	<0.0001*	0.82	0.62–1.08	0.16
Chronic coronary syndrome	0.45	0.34–0.60	<0.0001*	1.06	0.66–1.71	0.81
Arrhythmia	0.75	0.56–1.01	0.057			
Other	1.04	0.86–1.27	0.68			
OHCA	1.86	1.69–2.05	<0.0001*	1.15	0.89–1.48	0.30
Hypertension	1.20	1.10–1.32	<0.0001*	NA	NA	NA
Pulmonary hypertension	1.00	0.81–1.25	0.97			
Dyslipidemia	0.94	0.86–1.03	0.16			
Diabetes	1.09	1.00–1.19	0.055			
Arrhythmia	1.18	1.06–1.32	0.003*	1.29	1.07–1.55	0.007*
Coronary artery disease	1.10	1.00–1.21	0.055			
Heart failure	1.03	0.93–1.13	0.61			
Cardiomyopathy	1.03	0.93–1.13	0.61			
Valvular heart disease	1.11	0.96–1.27	0.15			
Cerebral infarction/transient ischemic attack	1.14	0.98–1.33	0.079			
SBP per 1 mmHg increase	0.99	0.99–0.99	<0.0001*	NA	NA	NA
Ejection fraction per 1% increase	0.99	0.98–0.99	<0.0001*	0.99	0.99–1.00	0.064
Lactate per 1 mmol/L increase	1.02	1.02–1.03	<0.0001*	1.02	1.01–1.03	0.0005*
LDH per 1 U/L increase	1.00	1.00–1.00	<0.0001*	NA	NA	NA
Creatinine per 1 mg/dL increase	1.08	1.06–1.10	<0.0001*	1.08	1.04–1.11	0.0003*
Total bilirubin per 1 mg/dL increase	1.07	1.05–1.09	<0.0001*	1.06	1.03–1.09	0.0004*
Albumin per 1 g/dL increase	0.70	0.66–0.75	<0.0001*	0.82	0.73–0.93	0.002*
Creatine kinase per 1 U/L increase	1.00	1.00–1.00	<0.0001*	NA	NA	NA
C-reactive protein per 1 mg/dL increase	1.02	1.01–1.02	<0.0001*	1.00	0.99–1.01	0.92
Vasopressor/inotrope	1.79	1.60–2.01	<0.0001*	NA	NA	NA
Pulmonary artery catheter	0.93	0.85–1.02	0.31			

(**Table 2** continued the next page.)

	Univariate			Multivariate		
	HR	95% CI	P value	HR	95% CI	P value
Procedural characteristics						
Type of Impella						
Impella 2.5	0.87	0.70–1.09	0.22			
Impella CP	Ref.					
Impella 5.0/5.5	0.91	0.76–1.08	0.27			
Access site						
Transfemoral	0.98	0.84–1.14	0.80			
Transsubclavian/transaortic	Ref.					
Support duration per 1 h increase	1.00	1.00–1.00	0.60			
Additional MCS	2.23	2.04–2.44	<0.0001*	1.05	0.81–1.37	0.69
ECPELLA	2.43	2.23–2.64	<0.0001*	1.80	1.39–2.34	<0.0001*
Procedural complications						
Bleeding	1.19	1.07–1.41	0.0007*	1.04	0.87–1.24	0.67
Cardiac tamponade	1.78	1.42–2.23	<0.0001*	1.30	0.85–1.99	0.24
Cerebrovascular accident	1.55	1.33–1.80	<0.0001*	1.28	1.00–1.65	0.060
Hemolysis	0.88	0.78–1.01	0.056			
Limb ischemia	1.52	1.28–1.82	<0.0001*	1.49	1.13–1.97	0.007*
Acute kidney injury	1.25	1.09–1.43	<0.0001*	1.09	0.86–1.39	0.47
Sepsis	1.32	1.13–1.56	0.0007*	0.92	0.71–1.20	0.55
Vascular injury	0.74	0.49–1.13	0.16			
Interventions during Impella insertion						
PCI	1.03	0.94–1.12	0.57			
CABG	0.93	0.80–1.07	0.32			
Valve surgery	0.90	0.75–1.09	0.27			
Catheter ablation	0.82	0.61–1.11	0.20			

*P values are statistically significant. CI, confidence interval; HR, hazard ratio; NA, not applicable. Other abbreviations as in Table 1.

bidities were frequent in the older group, the younger patients had more unstable hemodynamics, characterized by lower systolic blood pressure, a higher lactate level, and more frequent use of a vasopressor/inotrope and ECPELLA. (2) The 30-day mortality more frequently occurred in the older group than in the younger group (38.9% vs. 32.5%; P<0.0001). Mortality among the older subsets was statistically equivalent (75–79 vs. 80–84 vs. ≥85 years: 38.1% vs. 38.2% vs. 42.1%). (3) The occurrence of Impella-related complications was similar between the older and younger groups, except for a modest increase in cardiac tamponade and limb ischemia. (4) Age ≥75 years, body mass index, myocarditis, prior arrhythmia, shock severity (i.e., lactate level, use of ECMO), renal and liver impairment, and limb ischemia were associated with 30-day mortality after Impella insertion.

The present study provides novel insights into the management of older patients with CS who may be candidates for PVAD, which addresses a critical gap in the current literature.

Expanding Population of Older Patients With CS

A growing problem in modern intensive or interventional cardiology is management of the expanding number of older patients with CS.[5] In single-center studies researching advanced MCS in Germany and Spain, 18.1% and 27.4% were aged ≥70 years.[13,14] In multicenter studies with myocardial infarction-related CS in Australia and Germany, older patients aged ≥75 years were 29.0% and 32.8%, respectively.[15,16] In the present study, 31.6% of refractory heart failure patients using Impella were aged ≥75 years. Our higher percentage of older patients may be due to differences in the aging rate, healthcare system, life expectancy, culture, and ethics. The ELSO registry, a global ECMO registry, reported that the proportion of older patients (age ≥70 years) using ECMO doubled from 6.6% in 1999–2004 to 14.8% in 2011–2015.[16] We lacked data on what proportion of older patients were selected or not selected for advanced MCS. Because being older is a negative predictor in CS,[16,17] invasive procedures (e.g., catheter intervention and cardiac surgery) and MCS are thought to be introduced for selected patients who are clinically judged to have an expected better survival. For instance, the use of PCI and intra-aortic balloon pumping was less frequent in older patients aged ≥75 years in the SHOCK registry.[18] The lower prevalence of negative predictors (i.e., low ejection fraction, high lactate level, and ECPELLA) in our older patients indicates such selection. The higher but acceptable mortality rate among older patients likely reflects the discretion of the on-site physicians in choosing older patients with more favorable outcomes. Considering the expansion of shock in older patients and limited medical resources, optimal patient selection should become more relevant. The conventional prognostic prediction model adopts age, medical history, and hemodynamic parameters.[19] However, chronological age is not equal to biological age, especially in older patients, and the expected outcome differs between older and younger patients.[5] The addition of a comprehensive geriatric assessment, including parameters such as frailty, multimorbidity, and quality of life, to the conventional risk model can predict the prognosis of older patients more efficiently, leading to better shared decision-making. In the Japanese study including older patients with acute myocardial infarction, the modified Katz index was associated with in-hospital mortality.[20] In the area of structural heart disease intervention, frailty was associated with post-procedural prognosis.[21,22] We need a geriatric index that can be simply and widely measured to effectively predict the prognosis in older patients with CS.

Older Patients and PVAD

Although PVAD is a potent MCS and enables significant left-ventricular unloading than that enabled by intra-aortic balloon pumping, its larger profile and strict anticoagulation are associated with the risk of device-related complications. While PVAD improved 90-day mortality in the DanGer SHOCK trial, several complications, including bleeding, limb ischemia, acute kidney injury and sepsis, frequently occurred in the cohort assigned to PVAD.[8] These complications can impair the prognosis of patients using PVAD. Limb ischemia was associated with a worse prognosis in this study. Older patients commonly have vascular pathologies like vascular stiffness, endothelial dysfunction, and overt peripheral artery disease.[5] They also have a risk of large bore catheter-induced vascular injury, bleeding, and limb ischemia. To lessen vascular and bleeding complications, especially in older patients, preventive strategies should be considered, including echo-guided puncture using a microneedle, optimal management of the catheter insertion site, bicarbonate-based purge solution in those at high risk of bleeding, and tailored antithrombotic peri-PCI.[23,24] To prevent lower limb ischemia during PVAD support, limb perfusion needs to be repetitively assessed with clinical evaluation, Doppler flow, ultrasound, and near-infrared spectroscopy, and protect distal perfusion in case of limb ischemia or high risk of ischemia.[25,26] Because heart transplantation or a durable ventricular assist device is not a realistic option in older patients, an exit strategy should be assumed prior to the introduction of PVAD. Before PVAD is initiated, we must assess the feasibility and recoverability of definitive therapy, including optimal medical therapy, coronary revascularization, catheter ablation, structural heart disease intervention, and cardiac surgery. Within the available limited time due to deteriorating CS, we need to integrate prognostication, the feasibility of MCS, an exit plan, geriatric assessment, and the patient's goal, and share these findings with patients regarding the decision-making process. These steps would be common in catheter interventions, and physicians managing older patients with acute cardiovascular disease should be sophisticated in comprehensive geriatric assessment.[5]

Study Limitations

First, this study was observational and lacked data on patients who were treated medically and conservatively. However, PVAD was safely used in selected older patients, and the 30-day mortality was acceptable compared with younger patients. Second, the J-PVAD registry lacked specific parameters for older age such as the frailty index, physical function, and cognitive function. For better decision-making in older patients, these variables should be added to the dataset of catheter intervention. Third, the follow-up duration of the J-PVAD registry was limited. Owing to the low physical reserve and possible longer recovery periods in older patients, a longer follow-up period is required. Last, we lacked an event committee, which may have led to under-reporting of complications.

Conclusions

From the J-PVAD registry enrolling patients with CS using Impella in Japan between 2020 and 2022, 31.6% were aged ≥75 years. There were several differences in the baseline and procedural characteristics between older and younger patients. While the safety profile of Impella was similar between the 2 groups, the 30-day mortality rate was acceptable but significantly higher in older patients. The number of older patients with CS will increase further in the near future, and a comprehensive patient assessment, including geriatric domains, is needed.

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Disclosures

None declared.

Author Contributions

R.H.: conceptualization, formal analysis, investigation, methodology, writing original draft, reviewing, and editing. M.N.: conceptualization, methodology, supervision, and reviewing. Y.H., M.I.: supervision, and reviewing.

IRB Information

The Central Institutional Review Board (Osaka University ethics committee; Approval no. 17232) and the Institutional Review Boards of the participating centers.

Data Availability

The data underlying this article will be shared on request after approval from the bureau of the J-PVAD registry and relevant ethical committee.

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Supplementary Files

Please find supplementary file(s);
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