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ORIGINAL ARTICLE
Interventional cardiology and cardiac surgery

Mechanical circulatory support devices for elective percutaneous coronary interventions: novel insights from the Japanese nationwide J-PCI registry

Takashi Muramatsu [1,*], Taku Inohara[2], Shun Kohsaka [2], Kyohei Yamaji [3], Hideki Ishii[4], Toshiro Shinke[5], Takuo Toriya[1], Yu Yoshiki[6], Yukio Ozaki[6], Hirohiko Ando[7], Tetsuya Amano[7], Masato Nakamura [8], Yuji Ikari [9] and on behalf of the Japanese Association of Cardiovascular Intervention and Therapeutics

[1]Department of Cardiology, Cardiovascular Center, Fujita Health University Hospital, Toyoake, Japan; [2]Department of Cardiology, Keio University School of Medicine, Tokyo, Japan; [3]Department of Cardiovascular Medicine, Kyoto University, Kyoto, Japan; [4]Department of Cardiovascular Medicine, Gunma University Graduate School of Medicine, Maebashi, Japan; [5]Department of Cardiology, Showa University School of Medicine, Tokyo, Japan; [6]Department of Cardiology, Fujita Health University Okazaki Medical Center, Okazaki, Japan; [7]Department of Cardiology, Aichi Medical University, Nagakute, Japan; [8]Division of Cardiovascular Medicine, Toho University Ohashi Medical Center, Tokyo, Japan; and [9]Department of Cardiology, Tokai University School of Medicine, Isehara, Japan

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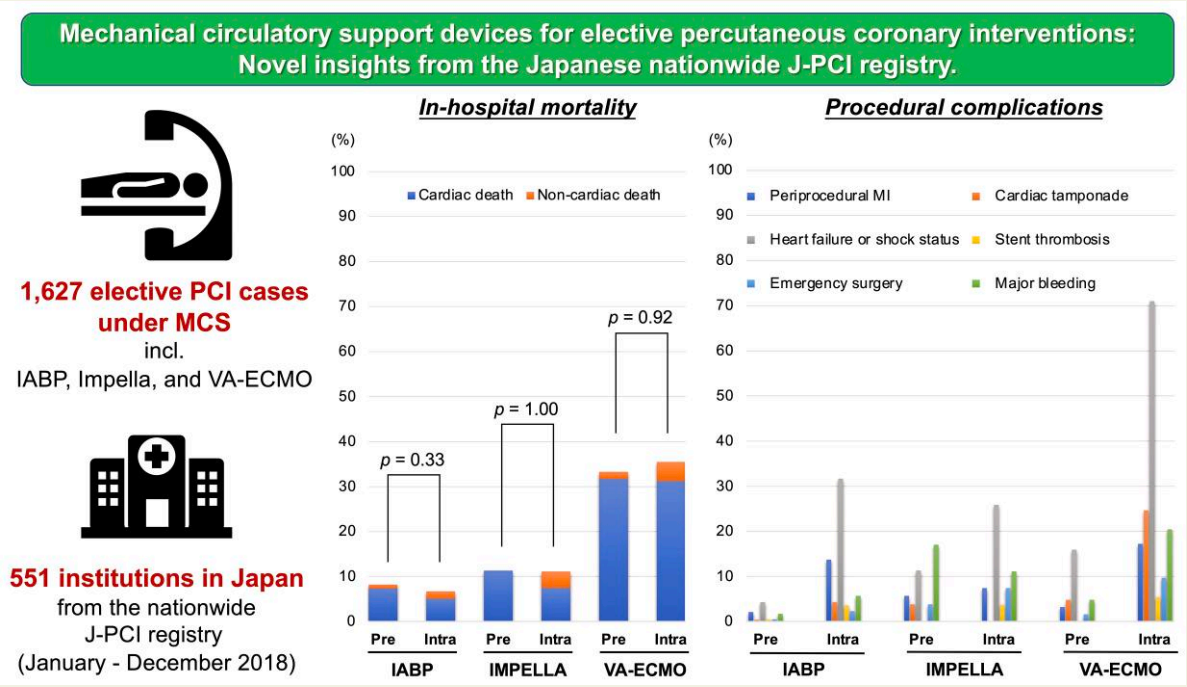
Aims We examined in-hospital outcomes of patients that required mechanical circulatory support (MCS), such as intra-aortic balloon pumping (IABP), Impella®, or veno-arterial extracorporeal membrane oxygenation (VA-ECMO), for elective percutaneous coronary interventions (PCIs).

Methods and results The J-PCI is a prospective Japanese nationwide multicentre registry sponsored by the Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT) and designed to collect clinical variables and in-hospital outcome data on consecutive patients undergoing PCI. Of the 253 228 patients registered between January 2018 and December 2018, 1627 patients (0.6%) undergoing elective PCI under MCS at 551 sites were analyzed. The mean age of the patients was 74 years, and 25.2% of the patients were females. Multivessel disease and left main disease were observed in 59.0% and 19.7% of the patients, respectively. Majority of patients were treated with IABP alone (86.2%), followed by IABP plus VA-ECMO (6.0%) and Impella alone (3.9%). In-hospital mortality was reported in 134 patients (8.2%). Cardiac death was more common than non-cardiac death (6.8% vs. 1.5%). About 34.6% of the patients receiving VA-ECMO died during hospitalization, whereas 7.2% and 5.3% of patients receiving Impella and IABP died, respectively ($P < 0.01$). The proportion of patients with VA-ECMO or Impella who had major bleeding requiring blood transfusion was higher than that of patients with IABP (14.1% vs. 13.0% vs. 2.8%).

Conclusion In the setting of elective PCI, in-hospital mortality of patients requiring MCS was considerably high. VA-ECMO or Impella was associated with a higher risk of major bleeding than IABP.

* Corresponding author. Tel: +81 562 93 2312, Fax: +81 562 93 2315, Email: takam@fujita-hu.ac.jp

Graphical Abstract



Keywords Coronary artery disease • Percutaneous coronary intervention • Mechanical circulatory support • Heart failure • Cardiogenic shock • Complication

Introduction

Mechanical circulatory support (MCS) devices are often used for patients presenting with deteriorated or unstable hemodynamic conditions during percutaneous coronary interventions (PCIs). Percutaneously insertable MCS devices, including intra-aortic balloon pumping (IABP) (counter-pulsation), percutaneous ventricular assist device (PVAD), and veno-arterial extracorporeal membrane oxygenation (VA-ECMO), are currently available in the clinical setting.[1]

Considering relatively stable haemodynamic conditions, elective PCI for chronic coronary syndrome is less likely to require MCS than emergent or urgent PCI for acute coronary syndrome. Nevertheless, the number of complex PCIs, such as multivessel disease, left main disease, chronic total occlusion (CTO), or severely calcified lesions, has been steadily increased over years.[2,3] Patients with such complex lesions are more likely to have co-morbidities, such as low left ventricular ejection fraction (LVEF), diabetes mellitus, and chronic kidney disease, which are associated with poor clinical outcomes after PCI. The multicentre registry in the United States reported that elective MCS was used in 4% and urgent MCS was used only in 1% of patients undergoing CTO-PCI.[4] Given a substantially limited number of cases with MCS for elective PCI, the clinical consequences have not been systematically investigated.

This study was designed to examine the demographic characteristics and in-hospital clinical outcomes of patients having MCS in the setting of elective PCI using a nationwide PCI registry database in Japan.

Methods

Data source and verification

The Japanese Percutaneous Coronary Intervention (J-PCI) registry is a nationwide registry sponsored by the Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT). The outline of the J-PCI registry was described elsewhere.[5] Briefly, the registry database covers more than 200,000 cases annually in ~900 institutions representing more than 90% of PCI centres in Japan. Data were collected through the National Clinical Database website using an electronic data capture system. Participating sites are randomly selected for annual audits by the members of the CVIT registry subcommittee. The study protocol of the J-PCI registry was approved by a third party ethics committee at the Osaka University (i.e. central institutional review board) as well as the local institutional review board at the Fujita Health University (identifier: HM21-066) and complied with the principles contained within the Declaration of Helsinki. Written informed consent was waived because of the retrospective and observational nature of the study.

Study population

All subjects registered in the J-PCI database between January 2018 and December 2018 ($n = 253\,228$) were included in this study. The exclusion criteria were as follows: patients <20 years or >100 years of age ($n = 63$), those undergoing emergent PCI defined as the procedure not scheduled until the day before ($n = 72\,823$), and those having unknown myocardial infarction (MI) ($n = 161$). Note that there were no missing data regarding

age, sex, or in-hospital outcome. Moreover, cases without MCS use (n = 178 175), those with MCS other than IABP, Impella® (ABIOMED, Danvers, MA), or VA-ECMO (n = 184), or those with postprocedural MCS use (n = 195) were also excluded from the current analysis.

We compared the demographic characteristics and clinical outcome measures among the types of MCS (i.e. IABP, Impella, and VA-ECMO). Given the presence of patients having these devices overlapped (n = 113), we categorized the groups according to the following hierarchy: VA-ECMO outweighs Impella, and Impella outweighs IABP.

Definitions of variables

The definitions of variables were summarized elsewhere.[5] Briefly, in-hospital mortality was defined as all-cause mortality during hospitalization or within 30 days of admission with subclassification into cardiac or non-cardiac.[6] Heart failure was defined as symptoms of heart failure within 24 h before the PCI procedure, including dyspnoea on mild activity, orthopnoea, body fluid retention, moist rales, neck vein distention, and pulmonary oedema, which were equivalent to congestive heart failure of the New York Heart Association functional classification Class IV. Cardiogenic shock was defined as a sustained episode of systolic blood pressure of <80 mmHg, cardiac index of <1.8 L/min/m^2 determined to be secondary to cardiac dysfunction, and/or the requirement for a parenteral inotropic or vasopressor agent or MCS to maintain blood pressure and cardiac index above the specified levels. Chronic kidney disease in this registry was defined as the presence of proteinuria, serum creatinine of ≥1.3 mg/dL, or estimated glomerular filtration rate of ≤60 mL/min/1.73 m^2, according to the guidelines from the Japanese Society of Nephrology (https://cdn.jsn.or.jp/guideline/pdf/CKDguide2012.pdf). Preoperative and intraoperative MCS use was defined when the MCS was introduced before entry and exit from the catheterization laboratory, respectively.

Clinical outcome measures

The primary endpoint was in-hospital mortality and the secondary outcome was procedural complications, including periprocedural MI, cardiac tamponade, heart failure or shock status, definite stent thrombosis according to the Academic Research Consortium definition,[7] emergency surgery, and major bleeding requiring blood transfusion. The J-PCI registry collects data on in-hospital mortality and the aforementioned complications separately from each patient, which allowed us to avoid double counting events.

Statistical analysis

Continuous variables are presented as means (standard deviations). Categorical variables are presented as numbers (percentages) and were compared using the χ^2 test or Fisher's exact test. Differences with P-values of <0.05 were considered statistically significant. Statistical analyses were performed using R (version 3.6.1; R Foundation for Statistical Computing, Vienna, Austria).

Results

Demographics

In this analysis, 1627 cases undergoing elective PCI under MCS at 551 sites were included (*Figure 1*). The mean age of the included patients was 74 years, and among them, 25.2% were females. Histories of PCI, MI, and congestive heart failure were observed in 52.7, 36.8, and 40.3% of the patients, respectively. Multivessel disease and left main coronary artery disease were observed in 59.0 and 19.7%, respectively. Vascular access via the radial artery for PCI was made in 49.3% of the patients, and drug-eluting stents (DESs) and rotational atherectomy were used in 86.2 and 19.4% of the patients, respectively (*Table 1*).

Distributions of the MCS are shown in *Figure 2*. Majority of patients were treated with IABP alone (n = 1402; 86.2%), followed by IABP plus VA-ECMO (n = 97; 6.0%) and Impella alone (n = 64; 3.9%). In the comparison among the MCS (i.e. IABP, Impella, and VA-ECMO), the IABP group had the highest proportion of current smokers and had the highest haemoglobin level (29.3% and 12.1 g/dL, respectively), whereas the Impella group had the highest proportion of patients with diabetes mellitus, left main disease, and DES use (66.7, 26.1, and 91.3%, respectively).

In-hospital clinical outcomes

The in-hospital clinical outcomes are shown in the *Table 2*. In-hospital death was reported in 134 patients (8.2%) in which cardiac death was more common than non-cardiac death (6.8% vs. 1.5%). Moreover, 34.6% of the patients having VA-ECMO died predominantly due to cardiac causes during their hospitalization and had the highest proportion of procedural complications, such as cardiac tamponade, heart failure or shock status, and emergent surgery (16.7, 48.7, and 6.4%, respectively). Major bleeding requiring blood transfusion was more frequently observed in the VA-ECMO or the Impella group than in the IABP group (14.1 and 13.0% vs. 2.8%, respectively). Thrombolysis in myocardial infarction (TIMI) flow Grade 3 at the end of the procedure was achieved in 96.4, 95.7, and 91.0% of the patients in the IABP, Impella, and VA-ECMO groups, respectively (P = 0.01).

Timing of mechanical circulatory support initiation

The variables were compared between preoperative (n = 873) and intraoperative (n = 754) MCS use (*Table 3*). The prevalence of prior PCI, prior MI, current smoking, chronic kidney disease, and congestive heart failure was significantly higher in the preoperative group than that in the intraoperative group. The prevalence of multivessel disease and left main disease was significantly higher in the preoperative group than that in the intraoperative group. The proportion of DES usage was comparable between the two groups, whereas that of rotational atherectomy was higher in the intraoperative group than that in the preoperative group (21.9% vs. 17.3%; p = 0.02). In-hospital mortality was comparable between the preoperative and intraoperative groups (8.7% vs. 7.7%; p = 0.52). The incidence of procedural complications and major bleeding was significantly higher in the intraoperative group than that in the preoperative group (43.8% vs. 9.7% and 6.5% vs. 2.4%; P < 0.01, respectively) (*Table 4*). Heart failure or cardiogenic shock accounted for the highest proportion of procedural complications in both groups.

Discussion

To the best of our knowledge, this is the first and largest-scale study addressing in-hospital clinical outcomes in patients undergoing elective PCI who required the MCS. Our main findings are summarized as follows: (i) haemodynamic support by IABP, Impella, or VA-ECMO

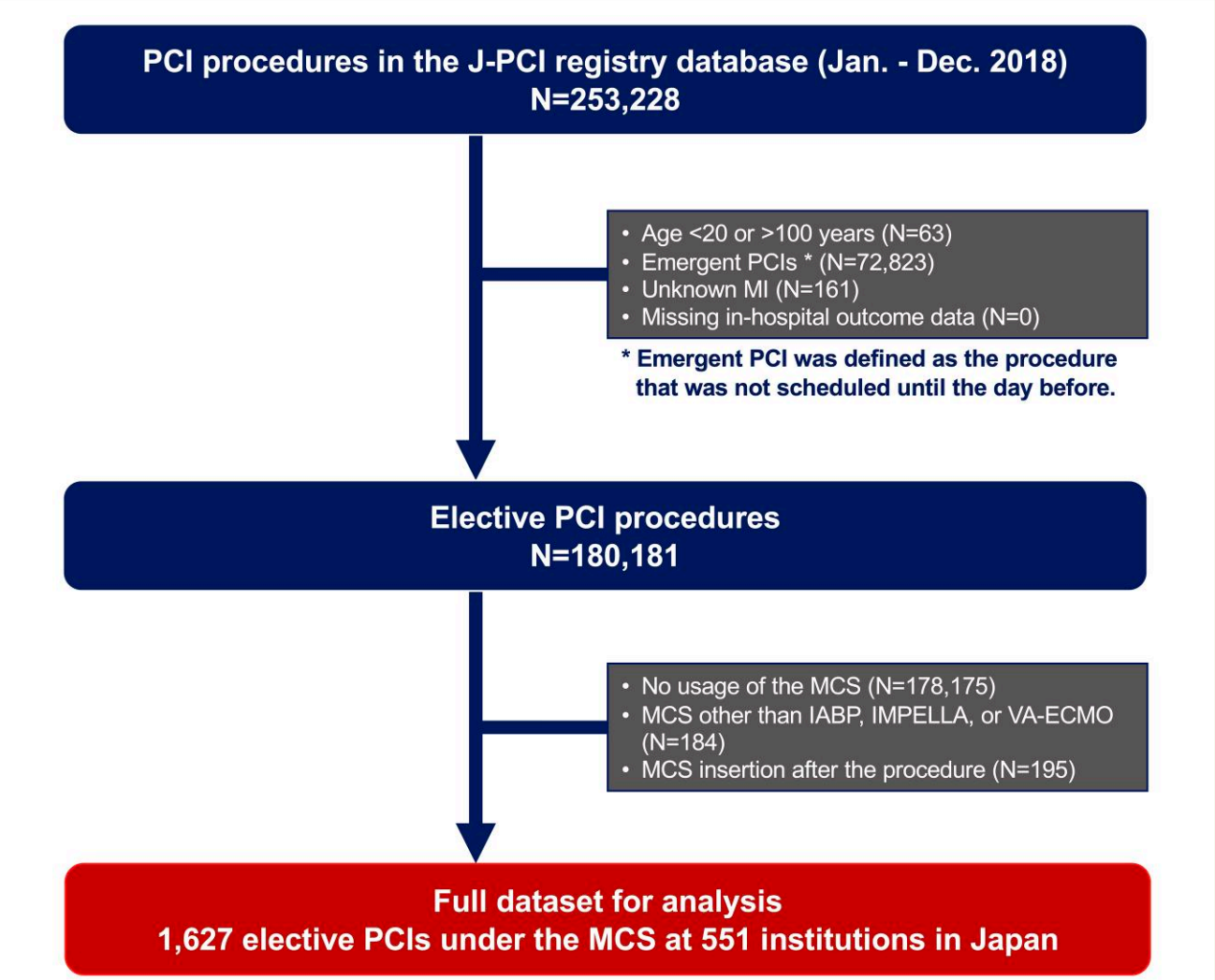


Figure 1 Study flow diagram.

was introduced in 0.9% of all cases undergoing elective PCI in Japan, and among them; (ii) the in-hospital mortality rate was 8.7%, mainly due to cardiac death; (iii) the use of VA-ECMO was associated with a higher incidence of in-hospital death, cardiac tamponade, heart failure or shock status, and emergency surgery; and (iv) major bleeding complications were more frequently observed in patients with Impella or VA-ECMO than in those with IABP.

In this study, majority of patients (86%) had received IABP rather than Impella or VA-ECMO. Although there is growing uncertainty about the efficacy of IABP, specifically in patients with acute MI presenting with cardiogenic shock,[8] our data highlighted that IABP remained the most common MCS device for elective PCI cases in Japan. A much higher usage of IABP might be attributable to wider penetration into hospitals and an easier profile to use than the Impella or VA-ECMO. The Impella was approved by the Japanese Pharmaceuticals and Medical Device Agency (PMDA) in September 2016. Clinical indication for the use of the Impella in Japan has been refractory heart failure or cardiogenic shock, and this device can be used only in hospitals certified by the Japan VAD council, Impella committee (https://j-pvad.jp). Therefore, clinical indications or distributions of the Impella among MCS devices may vary in the future.

The overall in-hospital mortality rate in this study was 8.2%. This was not negligible because previous studies in Japan reported that the in-hospital mortality of chronic coronary syndrome patients undergoing PCI ranged 0.1–0.4%.[6,9] Specifically in patients with VA-ECMO, the in-hospital mortality was overwhelmingly higher (34.6%) than those with IABP or the Impella. Given that the mortality rate did not differ between the preoperative and intraoperative use of VA-ECMO (33.3% vs. 35.5%; $P = 0.92$), more severe haemodynamic conditions necessitating the VA-ECMO in addition to a lower rate of achieving TIMI flow Grade 3 rather than IABP or the Impella might contribute to worse clinical outcomes.

Mechanical circulatory support is considered for elective PCI mostly in the following clinical scenarios: (i) preoperative use for patients presenting with congestive heart failure or cardiogenic shock before PCI, (ii) prophylactic use for patients perceived to have a high risk of haemodynamic instability during PCI, or (iii) intraoperative use

Table 1 Baseline characteristics of the patients

Variables	All N = 1627	IABP N = 1402	IMPELLA N = 69	VA-ECMO N = 156	P-value among MCS
Patient characteristics					
Age, mean (SD)	73.6 (10.5)	73.6 (10.5)	73.3 (9.6)	73.3 (11.3)	0.88
Female, *n* (%)	414 (25.4)	353 (25.2)	17 (24.6)	44 (28.2)	0.70
Prior PCI, *n* (%)	857 (52.7)	736 (52.7)	36 (52.2)	85 (54.5)	0.91
Prior CABG, *n* (%)	93 (5.7)	75 (5.4)	5 (7.5)	13 (8.3)	0.26
Prior myocardial infarction, *n* (%)	599 (36.8)	508 (36.7)	28 (41.8)	63 (40.4)	0.49
Diabetes mellitus, *n* (%)	834 (51.3)	708 (50.5)	46 (66.7)	80 (51.3)	0.03
Hypertension, *n* (%)	1244 (76.5)	1071 (76.4)	54 (78.3)	119 (76.3)	0.94
Dyslipidemia, *n* (%)	1057 (65.0)	912 (65.0)	46 (66.7)	99 (63.5)	0.88
Current smoker, *n* (%)	461 (28.3)	411 (29.3)	19 (27.5)	31 (19.9)	0.045
Chronic kidney disease, *n* (%)	555 (34.1)	464 (33.1)	28 (40.6)	63 (40.4)	0.10
Haemodialysis, *n* (%)	154 (9.5)	127 (9.1)	9 (13.0)	18 (11.5)	0.35
Chronic obstructive pulmonary disease, *n* (%)	71 (4.4)	56 (4.0)	6 (8.7)	9 (5.8)	0.12
Peripheral artery disease, *n* (%)	158 (9.7)	134 (9.6)	10 (14.5)	14 (9.0)	0.38
History of congestive heart failure	656 (40.3)	557 (40.1)	35 (51.5)	64 (41.0)	0.17
Laboratory data					
Haemoglobin, g/dL, mean (SD)	12.0 (2.1)	12.1 (2.1)	11.7 (2.3)	11.7 (2.1)	0.04
Creatinine, mg/dL, mean (SD)	1.6 (2.0)	1.6 (2.0)	1.7 (1.8)	1.7 (2.1)	0.83
Nunmber of diseased vessels, n (%)					
1. Vessel disease	627 (38.5)	541 (38.6)	19 (27.5)	67 (42.9)	0.09
2. Vessel disease	530 (32.6)	457 (32.6)	25 (36.2)	48 (30.8)	0.72
3. Vessel disease	430 (26.4)	372 (26.5)	21 (30.4)	37 (23.7)	0.56
Left main disease	321 (19.7)	283 (20.2)	18 (26.1)	20 (12.8)	0.04
Target lesions, n (%)					
Right coronary artery	476 (29.3)	404 (28.8)	23 (33.3)	49 (31.4)	0.60
Left main coronary artery or left anterior descending	1169 (71.9)	1001 (71.4)	54 (78.3)	114 (73.1)	0.44
Left circumflex artery	531 (32.6)	453 (32.3)	27 (39.1)	51 (32.7)	0.50
Bypass graft	5 (0.3)	3 (0.2)	0 (0.0)	2 (1.3)	0.07
PCI vascular access, n (%)					0.08
Radial artery	802 (49.3)	696 (49.6)	30 (43.5)	76 (48.7)	
Femoral artery	741 (45.5)	640 (45.6)	36 (52.2)	65 (41.7)	
Others	84 (5.2)	66 (4.7)	3 (4.3)	15 (9.6)	
Treatment, n (%)					
Drug-eluting stents	1402 (86.2)	1215 (86.7)	63 (91.3)	124 (79.5)	0.02
Bare metal stents	18 (1.1)	12 (0.9)	1 (1.4)	5 (3.2)	0.03
Rotational atherectomy	316 (19.4)	269 (19.2)	20 (29.0)	27 (17.3)	0.10
Drug-coated balloon	223 (13.7)	196 (14.0)	10 (14.5)	17 (10.9)	0.56

in cases with hemodynamic collapse due to procedural complications. In Japan, however, the prophylactic use of MCS is not officially reimbursed. Thus, most cases with MCS were supposed to be at the first or last conditions in the present analysis. Briguori *et al.*[10] introduced a potential benefit of the prophylactic use of IABP against intraprocedural use to prevent major adverse events in 133 consecutive elective PCI cases with low LVEF. The randomized PROTECT II trial demonstrated that the mid-term clinical outcomes favoured the Impella 2.5 over IABP for hemodynamic support during elective high-risk PCI.[11] A recent PVAD (i.e. Impella® 2.5/CP) study based on the global cVAD registry and the PROTECT III study demonstrated that in-hospital mortality was significantly higher in the bailout use group (49.1%) than that in the prophylactic use group (4.3%).[12] In this study, in-hospital mortality in patients having intraoperative MCS was unexpectedly low (7.7%), and it was comparable to those having preoperative MCS (8.7%). Possible explanations for this finding are the differences in clinical presentation (i.e. only elective PCI cases), MCS types (i.e. dominant IABP), and patient or lesion complexity in the nature of all-comer fashion of the J-PCI registry. Regardless of the type of MCS, the severity of patient or lesion characteristics (e.g. prior MI, congestive heart failure, or 3 vessel disease) were generally higher in the preoperative group than in the intraoperative group (see Supplementary material online, *Table S1*). Conversely, procedural complications were more frequently

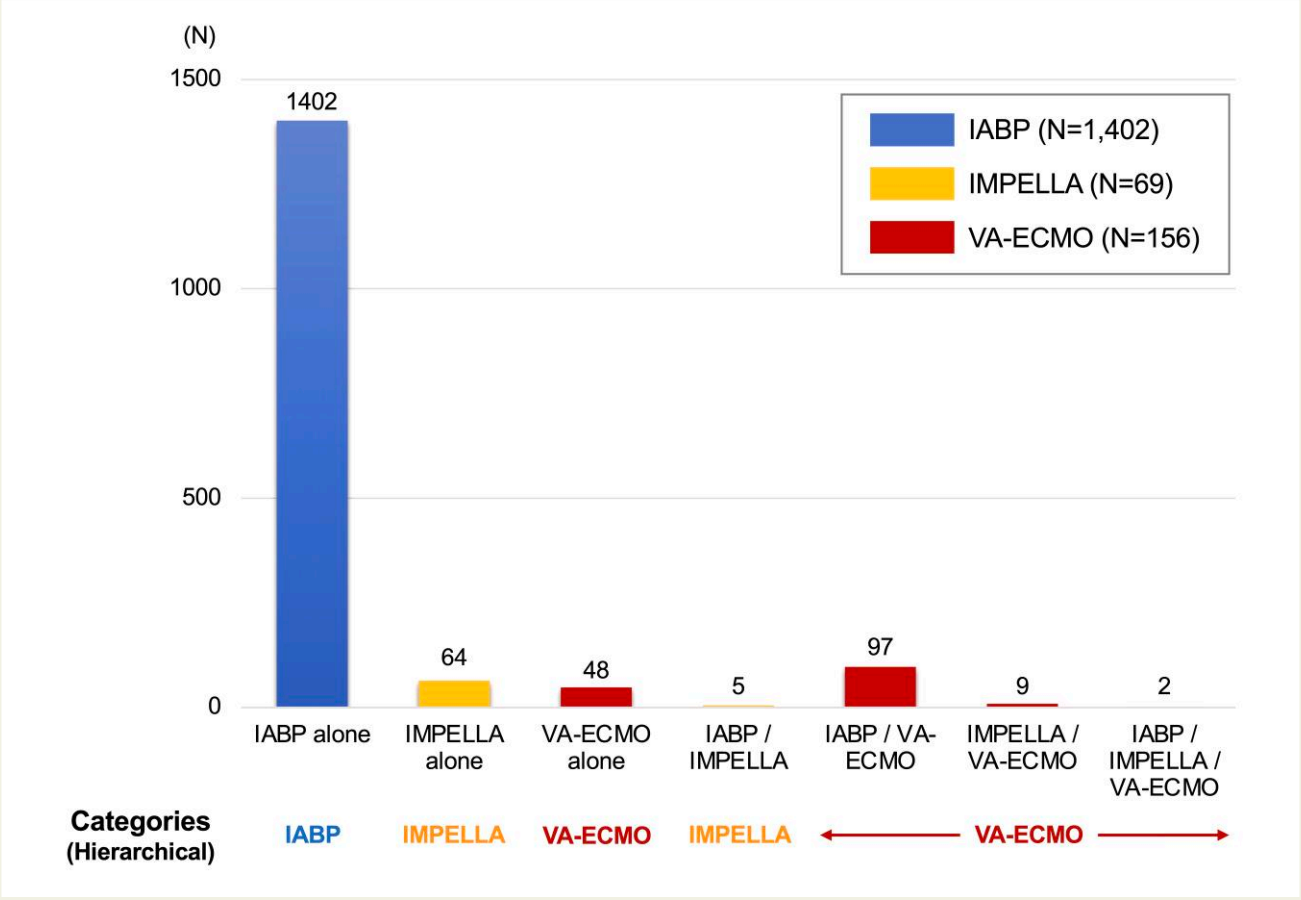


Figure 2 MCS types for elective PCI. IABP, intra-aortic balloon pumping (counter-pulsation); VA-ECMO, veno-arterial extracorporeal membrane oxygenation.

observed in the intraoperative group than in the preoperative group (see Supplementary material online, *Table S2* and *Figure S1*). Note that 35.5% of patients requiring intraoperative VA-ECMO died presumably due to procedural complications resulting in catastrophic hemodynamic conditions. The in-hospital mortality rate was comparable with that reported in previous studies in Western countries investigating the patients with cardiogenic shock undergoing PCI.[13,14] A clinical advantage of the prophylactic use of the Impella over IABP for high-risk PCI in patients with reduced LVEF will be elucidated in the randomized PROTECT IV trial (ClinicalTrials.gov identifier: NCT04763200).

Bleeding is the most common complication after PCI and is associated with an increased risk of in-hospital mortality, with an estimated 12.1% of deaths related to bleeding complications.[15] Bleeding complications can be either vascular access-related or non-vascular access-related (i.e. spontaneous bleeding). A study has reported that spontaneous bleeding conveyed a comparable risk of mortality to that of MI after PCI.[16] Our data revealed that the incidence of major bleeding was significantly higher in the intraoperative group than that in the preoperative group (6.5% vs. 2.4%). More interestingly, the incidence of major bleeding requiring blood transfusion was comparable between vascular access-related (2.2%) and non-vascular access-related (2.3%). For each origin of bleeding complications, the Impella or VA-ECMO was associated with a higher risk of bleeding than IABP. The former was presumably due to the bore size of arterial cannulation, whereas the latter might be associated with antithrombotic therapies after PCI or organ damages due to peripheral perfusion abnormalities. Indeed, the incidence of non-vascular access-related bleeding nearly doubled that of vascular access-related bleeding in patients having VA-ECMO (10.3% vs. 5.1%, respectively). Thus, we may have to pay more attention to the risk of spontaneous bleeding rather than the vascular access site when introducing VA-ECMO.

Our data have the strengths in investigating a nationwide all-comer registry data with a huge sample size and complete in-hospital mortality data, however, several limitations warrant considerations. First, generalizing our data in other countries may be challenging because there are substantial differences in race, indications for the MCS devices, PCI strategies, and many other clinical variables. For instance, intracoronary imaging techniques have been widely and frequently used in Japan,[17] and the rate of surgical turndown for unprotected left main or multivessel coronary artery diseases has been reported to be lower in Japan than that in the United States.[18,19] Second, our definition of cardiogenic shock was based on the historical studies such as the SHOCK trial,[20] but the lack of uniformity of the criteria for defining cardiogenic shock should be reminded. In addition, detailed data on neither LVEF nor hemodynamic status (e.g. urine output, cool extremity, lactate level, or periprocedural cardiac arrest)

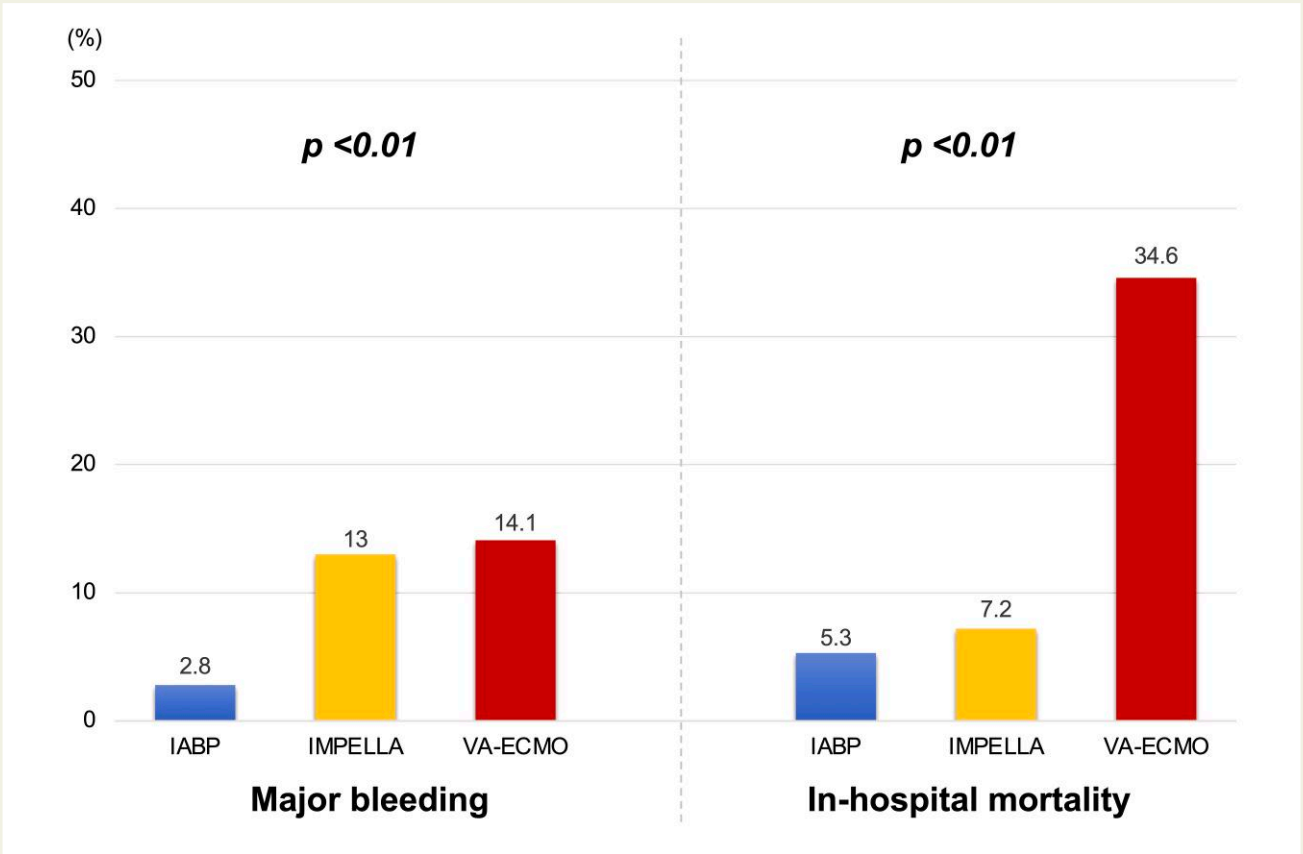


Figure 3 Incidence of major bleeding requiring blood transfusion and in-hospital mortality among MCS devices. IABP, intra-aortic balloon pumping (counter-pulsation); VA-ECMO, veno-arterial extracorporeal membrane oxygenation.

Table 2 **In-hospital outcomes**

Outcomes	All *N* = 1627	IABP *N* = 1402	IMPELLA *N* = 69	VA-ECMO *N* = 156	*P*-value among MCS
In-hospital mortality, *n* (%)	134 (8.2)	75 (5.3)	5 (7.2)	54 (34.6)	<0.01
Cause of death, *n* (%)					0.01
Cardiac death	110 (6.8)	57 (4.1)	4 (5.8)	49 (31.4)	
Non-cardiac death	24 (1.5)	18 (1.3)	1 (1.4)	5 (3.2)	
Procedural complications, *n* (%)	415 (25.5)	309 (22.0)	19 (27.5)	87 (55.8)	<0.01
Periprocedural MI	121 (7.4)	100 (7.1)	3 (4.3)	18 (11.5)	0.08
Cardiac tamponade	45 (2.8)	18 (1.3)	1 (1.4)	26 (16.7)	<0.01
Heart failure or shock status	280 (17.2)	195 (13.9)	9 (13.0)	76 (48.7)	<0.01
Stent thrombosis	30 (1.8)	25 (1.8)	0 (0.0)	5 (3.2)	0.23
Emergency surgery	24 (1.5)	12 (0.9)	2 (2.9)	10 (6.4)	<0.01
Major bleeding requiring blood transfusion	70 (4.3)	39 (2.8)	9 (13.0)	22 (14.1)	<0.01
Vascular access-related	35 (2.2)	22 (1.6)	5 (7.2)	8 (5.1)	<0.01
Non-vascular access-related	37 (2.3)	17 (1.2)	4 (5.8)	16 (10.3)	<0.01
Others	34 (2.1)	29 (9.1)	1 (5.3)	4 (4.5)	0.34
TIMI flow Grade 3 achieved at the end of procedure	1560 (95.9)	1352 (96.4)	66 (95.7)	142 (91.0)	0.01

were available in our data set. Third, specific reasons for MCS use in each patient were unknown as the decision was left to the discretion of each institution. Fourth, this analysis was based on the data at the beginning of the clinical use of the Impella in Japan; therefore, future studies may provide different results since a learning effect was identified to reduce the risk of major adverse events, specifically for this new device.[21] Finally, the causality between MCS use and in-hospital death cannot be inferred in this study.

Table 3 Baseline characteristics of patients with preoperative and intraoperative use of MCS

Variables	Preoperative MCS use N = 873	Intraoperative MCS use N = 754	*P*-value
Patient characteristics			
Age, mean (SD)	73.31 (11.01)	73.91 (9.94)	0.25
Female, *n* (%)	191 (21.9)	223 (29.6)	<0.01
Prior PCI, *n* (%)	495 (56.8)	362 (48.2)	0.01
Prior CABG, *n* (%)	50 (5.7)	43 (5.7)	1.00
Prior myocardial infarction, *n* (%)	393 (45.8)	206 (27.5)	<0.01
Diabetes mellitus, *n* (%)	452 (51.8)	382 (50.7)	0.69
Hypertension, *n* (%)	658 (75.4)	586 (77.7)	0.29
Dyslipidemia, *n* (%)	554 (63.5)	503 (66.7)	0.19
Current smoking, *n* (%)	266 (30.5)	195 (25.9)	0.045
Chronic kidney disease, *n* (%)	331 (37.9)	224 (29.7)	<0.01
Haemodialysis, *n* (%)	77 (8.8)	77 (10.2)	0.38
Chronic obstructive pulmonary disease, *n* (%)	35 (4.0)	36 (4.8)	0.53
Peripheral artery disease, *n* (%)	86 (9.9)	72 (9.5)	0.90
History of congestive heart failure	400 (46.1)	256 (34.3)	<0.01
Laboratory data			
Haemoglobin, g/dL, mean (SD)	11.71 (2.14)	12.38 (2.05)	<0.01
Creatinine, mg/dL, mean (SD)	1.62 (1.84)	1.67 (2.20)	0.59
Number of diseased vessels, n (%)			
1. Vessel disease	292 (33.4)	335 (44.4)	<0.01
2. Vessel disease	299 (34.2)	231 (30.6)	0.13
3. Vessel disease	265 (30.4)	165 (21.9)	<0.01
Left main disease	194 (22.2)	127 (16.8)	0.01
Target lesions, n (%)			
Right coronary artery	262 (30.0)	214 (28.4)	0.51
Left main coronary artery or left anterior desending	630 (72.2)	539 (71.5)	0.80
Left circumflex artery	293 (33.6)	238 (31.6)	0.42
Bypass graft	3 (0.3)	2 (0.3)	1.00
PCI vascular access, n (%)			0.048
Radial artery	408 (46.7)	394 (52.3)	
Femoral artery	413 (47.3)	328 (43.5)	
Others	52 (6.0)	32 (4.2)	
Treatment, n (%)			
Drug-eluting stents	764 (87.5)	638 (84.6)	0.11
Bare metal stents	5 (0.6)	13 (1.7)	0.048
Rotational atherectomy	151 (17.3)	165 (21.9)	0.02
Drug-coated balloon	116 (13.3)	107 (14.2)	0.65

Table 4 In-hospital clinical outcomes between the patients with preoperative and intraoperative MCS use

Outcomes	Preoperative MCS use *N* = 873	Intraoperative MCS use *N* = 754	*P*-value
In-hospital mortality, *n* (%)	76 (8.7)	58 (7.7)	0.52
Cause of death, *n* (%)			<0.01
Cardiac death	67 (7.7)	43 (5.7)	
Non-cardiac death	9 (1.0)	15 (2.0)	
Procedural complications, *n* (%)	85 (9.7)	330 (43.8)	<0.01
Periprocedural MI	21 (2.4)	100 (13.3)	<0.01

Continued

Table 4 ***Continued***

Outcomes	Preoperative MCS use *N* = 873	Intraoperative MCS use *N* = 754	*P*-value
Cardiac tamponade	7 (0.8)	38 (5.0)	<0.01
Heart failure or shock status	40 (4.6)	240 (31.8)	<0.01
Stent thrombosis	4 (0.5)	26 (3.4)	<0.01
Emergency surgery	6 (0.7)	18 (2.4)	0.01
Major bleeding requiring blood transfusion	21 (2.4)	49 (6.5)	<0.01
Vascular access-related	12 (1.4)	23 (3.1)	0.03
Non-vascular access-related	10 (1.1)	27 (3.6)	<0.01
Others	11 (12.1)	23 (6.9)	0.16
TIMI flow Grade 3 at the end of procedure	851 (97.5)	709 (94.0)	<0.01

Conclusions

In the Japanese nationwide registry data, in-hospital mortality of patients requiring MCS was considerably high even in the setting of elective PCI. VA-ECMO was associated with a higher incidence of procedural complications, and major bleeding was more frequently observed in patients with the Impella or VA-ECMO than in patients with IABP. Optimal selection and use of MCS devices need be further clarified.

Lead author biography

Dr. Takashi Muramatsu is an interventional cardiologist and currently associate professor of Cardiology at the Fujita Health University, Japan. He received his MD degree in 2000 and PhD in 2011 from the Nagoya University, Japan. He also earned another PhD in 2015 under the supervision of Professor Patrick Serruys at the Erasmus University Rotterdam, the Netherlands. His clinical and research interest has focused on coronary interventions including bioresorbable scaffolds and intracoronary imaging as well as structural heart disease interventions recently. He has been a Fellow of the European Society of Cardiology (FESC) since 2014.

Data availability

The data underlying this article were provided by the CVIT by permission. Data will be shared on request to the corresponding author with permission of the CVIT.

Supplementary material

Supplementary material is available at *European Heart Journal Open* online.

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