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Supplemental Materials.

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SUPPLEMENTAL MATERIALS

Online Supplement for manuscript entitled:

Relationship between the volume and in-hospital mortality in patients with cardiogenic shock receiving mechanical circulatory support

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Supplemental Tables: 1-3
Supplemental Figures and Figure Legends: 1-6

SUPPLEMENTAL TABLES

Supplemental Table 1. Patient characteristics according to the tertile categories in the volume of Impella cohort.

	Tertile 1 (-4.5 cases/year) N=201	Tertile 2 (4.6-9.0 cases/year) N=257	Tertile 3 (9.1- cases/year) N=238	p for trend
Impella, cases/year	3.0 (3.0-4.0)	7.5 (5.7-8.0)	12.0 (10.7-15.0)	<0.001
Age, years	66.0±14.9	65.6±14.4	66.8±13.1	0.92
Age groups, no. (%)				
18-49	26 (12.9)	37 (14.4)	27 (11.3)	0.59
50-59	33 (16.4)	45 (17.5)	38 (16.0)	0.88
60-69	45 (22.4)	60 (23.3)	59 (24.8)	0.55
70-79	62 (30.8)	73 (28.4)	79 (33.2)	0.56
80-	35 (17.4)	42 (16.3)	35 (14.7)	0.44
Male sex, no. (%)	152 (75.6)	197 (76.7)	183 (76.9)	0.76
Body mass index, kg/m^2 *	23.7±4.2	23.6±3.9	23.0±4.3	0.18
Body mass index categories, no. (%)				
<18.5	14 (7.5)	14 (6.3)	25 (12.2)	0.092
>=18.5 and <25.0	117 (62.9)	141 (63.2)	119 (58.0)	0.32
>=25.0 and <30.0	45 (24.2)	55 (24.7)	53 (25.9)	0.70
>=30.0	10 (5.4)	13 (5.8)	8 (3.9)	0.49
Chronic kidney disease, no. (%)	14 (7.0)	23 (8.9)	20 (8.4)	0.60
Diabetes Mellitus, no. (%)	44 (21.9)	53 (20.6)	50 (21.0)	0.83
Cause of CS, no. (%)				
AMI	120 (59.7)	164 (63.8)	188 (79.0)	<0.001
HF	38 (18.9)	28 (10.9)	26 (10.9)	0.017

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Valvular disease	5 (2.5)	8 (3.1)	6 (2.5)	>0.99
FM	27 (13.4)	47 (18.3)	13 (5.5)	0.007
Arrhythmia	11 (5.5)	9 (3.5)	5 (2.1)	0.060
PE	0 (0.0)	1 (0.4)	0 (0.0)	0.95
Procedure, no. (%)				
Cardiopulmonary resuscitation †	32 (15.9)	46 (17.9)	41 (17.2)	0.73
Intubation	160 (79.6)	201 (78.2)	201 (84.5)	0.18
Right heart catheterization	171 (85.1)	229 (89.1)	210 (88.2)	0.34
Renal replacement therapy	24 (11.9)	17 (6.6)	24 (10.1)	0.57
PCI in AMI	109 (90.8)	144 (87.8)	172 (91.5)	0.73
CABG in AMI	5 (4.2)	8 (4.9)	3 (1.6)	0.17
Concomitant use of MCS device, no. (%)				
Impella alone ‡	94 (46.8)	121 (47.1)	108 (45.4)	0.76
ECMO	107 (53.2)	136 (52.9)	130 (54.6)	0.76
Breakdown of Impella device, no. (%)				
Impella 2.5/CP §	177 (88.1)	205 (79.8)	225 (94.5)	0.024
Impella 5.0 §	24 (11.9)	52 (20.2)	13 (5.5)	0.024
Number of hospital beds, no. ‖	730.0 (600.0-934.0)	655.0 (482.0-827.0)	877.0 (604.0-1033.0)	0.088
Number of certificated cardiologists, no.	14.0 (8.0-20.0)	14.0 (9.0-20.0)	17.0 (11.0-19.0)	0.016
Era, no. (%)				
2017	3 (1.5)	10 (3.9)	5 (2.1)	0.75
2018	39 (19.4)	75 (29.2)	51 (21.4)	0.72
2019	159 (79.1)	172 (66.9)	182 (76.5)	0.64

Data excluding missing data are presented as mean±standard deviation, median (interquartile range) or number (percentage).

ECMO cases also overlap in the ECMO cohort.

* Height recorded as less than 50 cm and weight recorded as less than 20 kg or 600 kg were regarded as missing data. There were 82 missing data.

† On or before the date when MCS was introduced.

‡ IABP was used in 79 patients.

§ Patients for whom an artificial vessel was used when initial Impella device was implanted were regarded as using Impella 5.0, and the remaining patients were regarded as using Impella 2.5/CP.

|| Hospital type of all hospitals was a Class A JCS-certified teaching hospital.

AMI indicates acute myocardial infarction; CABG, coronary artery bypass graft; CS, cardiogenic shock; ECMO, extracorporeal membrane oxygenation; FM, fulminant myocarditis; HF, heart failure; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support; PCI, percutaneous coronary intervention and PE, pulmonary embolism.

Supplemental Table 2. Patient characteristics according to the quintile categories in the volume of all MCS cohort.

	Quintile 1 (-8.9 cases/year) N=13,018	Quintile 2 (9.0-15.5 cases/year) N=13,213	Quintile 3 (15.6-23.1 cases/year) N=12,958	Quintile 4 (23.2-32.5 cases/year) N=13,116	Quintile 5 (32.6- cases/year) N=13,532	p for trend
All MCS, cases/year	6.0 (4.1-7.3)	12.0 (10.5-13.9)	19.0 (16.9-20.8)	28.1 (25.0-30.9)	41.6 (38.0-52.0)	<0.001
Age, years *	70.1±12.8	69.2±13.2	68.2±13.4	68.5±13.2	69.1±13.3	<0.001
Age groups, no. (%)						
18-49	1,001 (7.7)	1,172 (8.9)	1,334 (10.3)	1,257 (9.6)	1,234 (9.1)	<0.001
50-59	1,524 (11.7)	1,613 (12.2)	1,749 (13.5)	1,766 (13.5)	1,736 (12.8)	<0.001
60-69	3,165 (24.3)	3,330 (25.2)	3,318 (25.6)	3,368 (25.7)	3,281 (24.2)	0.81
70-79	3,985 (30.6)	3,975 (30.1)	3,739 (28.9)	3,892 (29.7)	4,092 (30.2)	0.38
80-	3,343 (25.7)	3,123 (23.6)	2,817 (21.7)	2,833 (21.6)	3,189 (23.6)	<0.001
Male sex, no. (%)	9,528 (73.2)	9,809 (74.2)	9,756 (75.3)	9,810 (74.8)	9,920 (73.3)	0.55
Body mass index, kg/m^2 †	23.6±3.9	23.7±4.5	23.7±4.0	23.6±4.5	23.6±6.2	0.031
Body mass index categories, no. (%)						
<18.5	830 (7.6)	944 (8.2)	829 (7.3)	935 (8.1)	1,006 (8.4)	0.097
>=18.5 and <25.0	6,574 (60.6)	6,914 (59.9)	6,925 (60.8)	7,003 (60.3)	7,304 (60.7)	0.59
>=25.0 and <30.0	2,791 (25.7)	2,948 (25.5)	2,900 (25.4)	2,942 (25.3)	2,979 (24.8)	0.10
>=30.0	659 (6.1)	737 (6.4)	741 (6.5)	733 (6.3)	738 (6.1)	0.98
Chronic kidney disease, no. (%)	1,111 (8.5)	1,122 (8.5)	1,144 (8.8)	1,186 (9.0)	1,280 (9.5)	0.002
Diabetes Mellitus, no. (%)	3,957 (30.4)	3,876 (29.3)	3,733 (28.8)	3,741 (28.5)	3,934 (29.1)	0.006
Cause of CS, no. (%)						
AMI	10,698 (82.2)	10,343 (78.3)	9,941 (76.7)	9,872 (75.3)	10,094 (74.6)	<0.001
HF	1,294 (9.9)	1,398 (10.6)	1,393 (10.8)	1,405 (10.7)	1,695 (12.5)	<0.001
Valvular disease	192 (1.5)	335 (2.5)	339 (2.6)	393 (3.0)	504 (3.7)	<0.001
FM	308 (2.4)	375 (2.8)	325 (2.5)	334 (2.5)	335 (2.5)	0.85
Arrhythmia	290 (2.2)	526 (4.0)	652 (5.0)	828 (6.3)	650 (4.8)	<0.001
PE	236 (1.8)	236 (1.8)	308 (2.4)	284 (2.2)	254 (1.9)	0.20
Procedure, no. (%)						
Cardiopulmonary resuscitation ‡	2,663 (20.5)	2,637 (20.0)	2,818 (21.7)	2,690 (20.5)	2,314 (17.1)	<0.001

Intubation	7,426 (57.0)	7,816 (59.2)	7,627 (58.9)	8,341 (63.6)	7,353 (54.3)	0.35
Right heart catheterization	4,367 (33.5)	5,285 (40.0)	5,920 (45.7)	6,585 (50.2)	7,196 (53.2)	<0.001
Renal replacement therapy	779 (6.0)	766 (5.8)	853 (6.6)	968 (7.4)	952 (7.0)	<0.001
PCI in AMI	9,573 (89.5)	9,309 (90.0)	8,962 (90.2)	8,849 (89.6)	9,110 (90.3)	0.20
CABG in AMI	371 (3.5)	551 (5.3)	614 (6.2)	598 (6.1)	602 (6.0)	<0.001
Concomitant use of MCS device, no. (%)						
IABP alone	10,503 (80.7)	9,739 (73.7)	9,325 (72.0)	9,203 (70.2)	9,873 (73.0)	<0.001
ECMO	2,484 (19.1)	3,424 (25.9)	3,579 (27.6)	3,858 (29.4)	3,526 (26.1)	<0.001
ECMO alone	649 (5.0)	789 (6.0)	834 (6.4)	859 (6.5)	742 (5.5)	0.019
ECMO+IABP	1,817 (14.0)	2,551 (19.3)	2,689 (20.8)	2,931 (22.3)	2,637 (19.5)	<0.001
ECMO+Impella	18 (0.1)	84 (0.6)	56 (0.4)	68 (0.5)	147 (1.1)	<0.001
Impella	49 (0.4)	134 (1.0)	110 (0.8)	123 (0.9)	280 (2.1)	<0.001
Impella alone §	31 (0.2)	50 (0.4)	54 (0.4)	55 (0.4)	133 (1.0)	<0.001
Breakdown of Impella device, no. (%)						
Impella 2.5/CP ‖	41 (83.7)	108 (80.6)	94 (85.5)	119 (96.7)	245 (87.5)	<0.001
Impella 5.0 ‖	8 (16.3)	26 (19.4)	16 (14.5)	4 (3.3)	35 (12.5)	0.022
Number of hospital beds, no. #	357.0 (288.0-473.0)	437.0 (328.0-600.0)	550.0 (420.0-694.0)	636.0 (511.0-733.0)	606.0 (450.0-819.0)	<0.001
Hospital type. (%) **						
Class A JCS-certified teaching hospitals	11,321 (87.0)	12,276 (92.9)	12,858 (99.2)	13,116 (100.0)	13,532 (100.0)	<0.001
Class B JCS-certified teaching hospitals	1,459 (11.2)	921 (7.0)	86 (0.7)	0 (0.0)	0 (0.0)	<0.001
Others	238 (1.8)	16 (0.1)	14 (0.1)	0 (0.0)	0 (0.0)	<0.001
Number of certificated cardiologists, no. ††	4.0 (3.0-5.0)	5.0 (3.0-8.0)	6.0 (5.0-8.0)	8.0 (5.0-13.0)	9.0 (6.0-14.0)	<0.001
Era, no. (%)						
2012-13	2,568 (19.7)	2,414 (18.3)	3,046 (23.5)	2,772 (21.1)	2,489 (18.4)	0.93
2014-15	3,067 (23.6)	3,122 (23.6)	3,060 (23.6)	3,147 (24.0)	3,306 (24.4)	0.070
2016-17	3,659 (28.1)	3,718 (28.1)	3,383 (26.1)	3,614 (27.6)	3,709 (27.4)	0.11
2018-19	3,724 (28.6)	3,959 (30.0)	3,469 (26.8)	3,583 (27.3)	4,028 (29.8)	<0.001

Data excluding missing data are presented as mean±standard deviation, median (interquartile range) or number (percentage).

* One patient was described as being aged 121 so was regarded as missing data.

† Height recorded as less than 50 cm and weight recorded as less than 20 kg or 600 kg were regarded as missing data. Body mass index was missing in 8,405 cases.

‡ On or before the date when MCS was introduced.

§ IABP was used in 79 patients.

‖ Patients for whom an artificial vessel was used when initial Impella device was implanted were regarded as using Impella 5.0, and the remaining patients were regarded as using Impella 2.5/CP.

The number of beds was missing in 5 cases.

** Class A JCS-certified teaching hospitals need more than 2 JCS board-certified cardiologists and 30 cardiovascular beds, and class B need more than 1 JCS board-certified cardiologist and 15 cardiovascular beds.

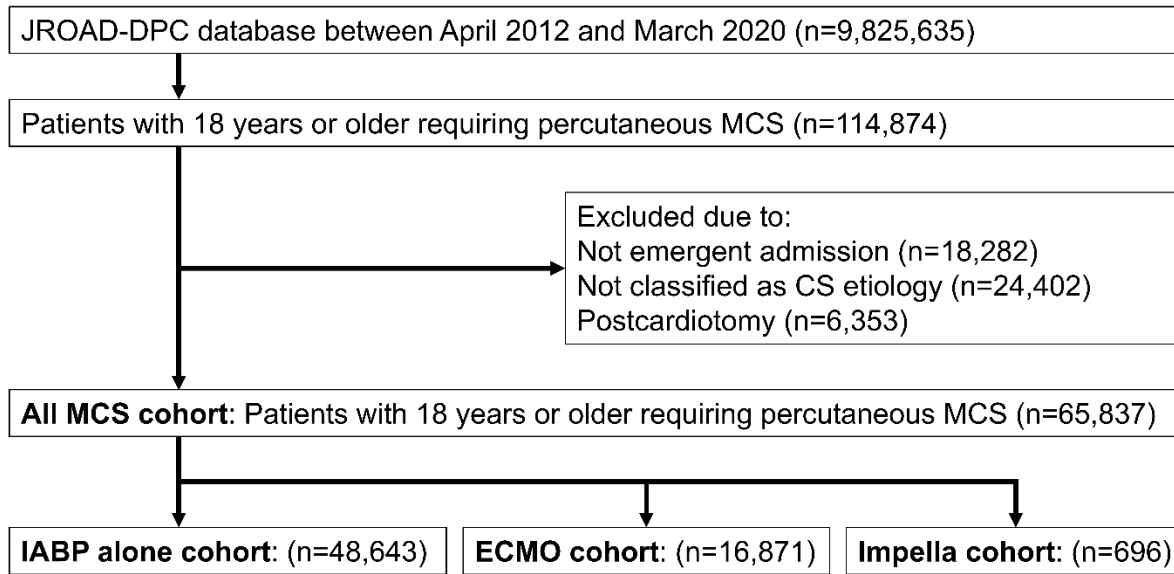†† The number of certificated cardiologists was missing in 67 cases.

AMI indicates acute myocardial infarction; CABG, coronary artery bypass graft; CS, cardiogenic shock; ECMO, extracorporeal membrane oxygenation; FM, fulminant myocarditis; HF, heart failure; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support; PCI, percutaneous coronary intervention and PE, pulmonary embolism.

Supplemental Table 3. Multivariable analysis for in-hospital mortality according to the quintiles, qurtiles or tertiles of short-term MCS volume in the models adjusted for the number of hospital beds and the number of certificated cardiologists.

		IABP alone cohort		ECMO cohort		Impella cohort		All MCS cohort	
		Odds Ratio (95%CI)	P-value	Odds Ratio (95%CI)	P-value	Odds Ratio (95%CI)	P-value	Odds Ratio (95%CI)	P-value
The volume of cases	Quintile 1	Reference		Reference		Reference		Reference	
	Quintile 2	0.83 (0.77, 0.90)	<0.001	0.87 (0.77, 0.98)	0.020	0.87 (0.56, 1.37)	0.555	0.87 (0.81, 0.92)	<0.001
	Quintile 3	0.80 (0.74, 0.87)	<0.001	0.88 (0.78, 0.996)	0.043	0.89 (0.57, 1.41)	0.624	0.78 (0.73, 0.84)	<0.001
	Quintile 4	0.67 (0.61, 0.73)	<0.001	0.85 (0.75, 0.96)	0.010			0.76 (0.70, 0.81)	<0.001
	Quintile 5	0.67 (0.62, 0.74)	<0.001	0.76 (0.68, 0.86)	<0.001			0.73 (0.68, 0.78)	<0.001
Number of hospital beds	Qurtile 1	Reference		Reference		Reference		Reference	
	Qurtile 1	0.95 (0.88, 1.02)	0.141	1.02 (0.91, 1.15)	0.752	2.02 (0.81, 5.08)	0.133	0.99 (0.93, 1.05)	0.673
	Qurtile 1	0.93 (0.86, 1.003)	0.058	0.99 (0.88, 1.11)	0.893	1.18 (0.55, 2.50)	0.672	0.95 (0.90, 1.02)	0.137
	Qurtile 1	1.002 (0.92, 1.09)	0.956	0.89 (0.79, 1.001)	0.051	1.19 (0.59, 2.39)	0.628	0.98 (0.91, 1.05)	0.505
Number of certificated cardiologist	Tertile 1	Reference		Reference		Reference		Reference	
	Tertile 2	0.89 (0.84, 0.95)	<0.001	0.97 (0.88, 1.07)	0.548	2.39 (0.72, 7.93)	0.154	0.93 (0.88, 0.98)	0.005
	Tertile 3	0.86 (0.80, 0.93)	<0.001	0.995 (0.89, 1.11)	0.936	1.92 (0.56, 6.61)	0.303	0.89 (0.83, 0.95)	<0.001

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support.
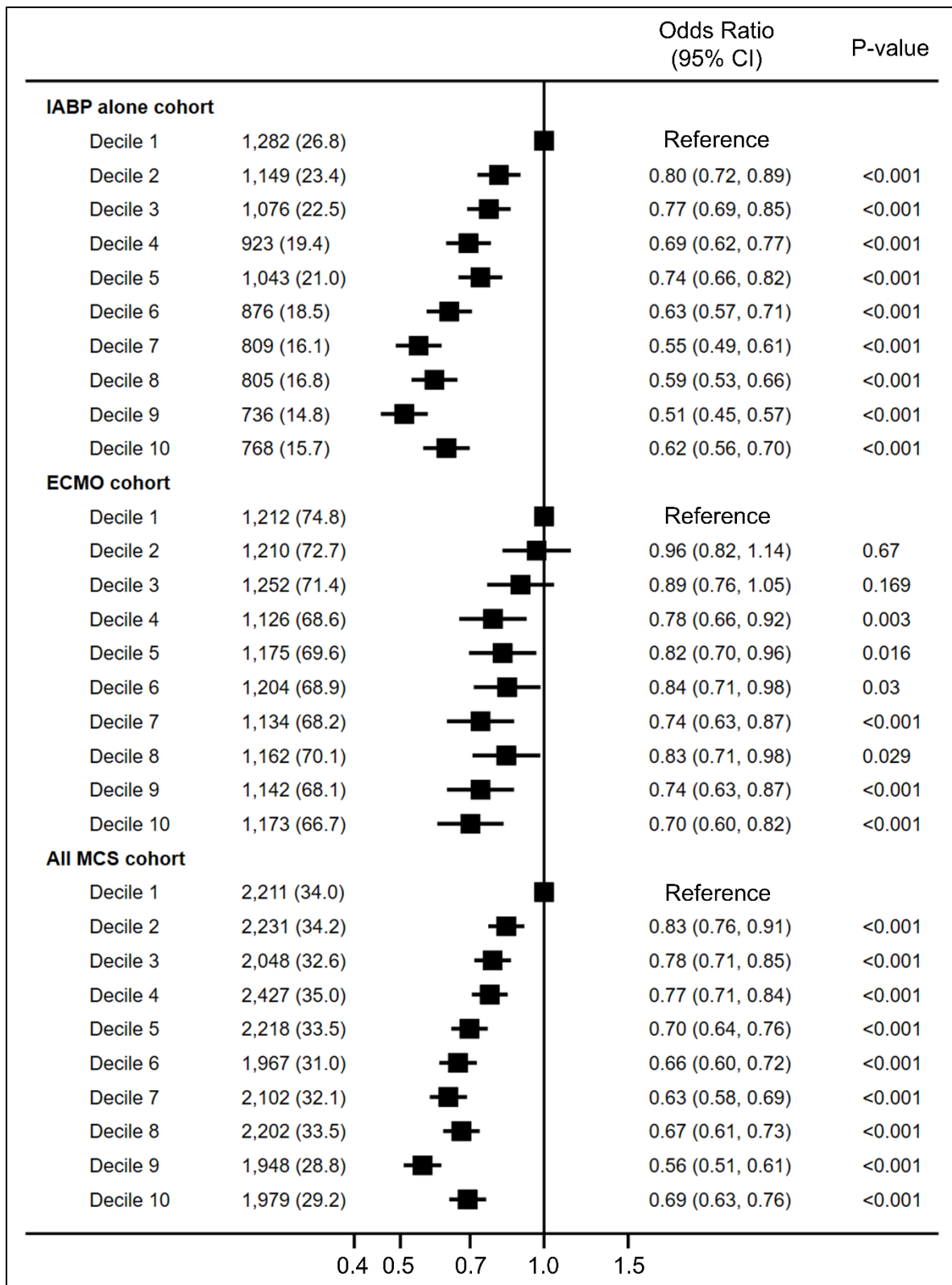
Supplemental Figure 1. Study flow chart

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┌─────────────────────────────────────────────────────────────────────────┐
│ JROAD-DPC database between April 2012 and March 2020 (n=9,825,635)        │
└─────────────────────────────────────────────────────────────────────────┘
                    │
                    ▼
┌─────────────────────────────────────────────────────────────────────────┐
│ Patients with 18 years or older requiring percutaneous MCS (n=114,874)    │
└─────────────────────────────────────────────────────────────────────────┘
                    │                    ┌──────────────────────────────────┐
                    │───────────────────▶│ Excluded due to:                 │
                    │                    │ Not emergent admission (n=18,282)│
                    │                    │ Not classified as CS etiology    │
                    │                    │ (n=24,402)                       │
                    │                    │ Postcardiotomy (n=6,353)         │
                    │                    └──────────────────────────────────┘
                    ▼
┌─────────────────────────────────────────────────────────────────────────┐
│ All MCS cohort: Patients with 18 years or older requiring percutaneous    │
│ MCS (n=65,837)                                                            │
└─────────────────────────────────────────────────────────────────────────┘
        │                       │                        │
        ▼                       ▼                        ▼
┌──────────────────┐  ┌──────────────────┐  ┌──────────────────────┐
│ IABP alone       │  │ ECMO cohort:     │  │ Impella cohort:      │
│ cohort:          │  │ (n=16,871)       │  │ (n=696)              │
│ (n=48,643)       │  │                  │  │                      │
└──────────────────┘  └──────────────────┘  └──────────────────────┘
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ECMO cohort included patients with ECMO alone, ECMO+IABP, and ECMO+Impella. Impella cohort included patient with Impella alone and ECMO+Impella.

CS, cardiogenic shock; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; JROAD-DPC, Japanese Registry of All Cardiac and Vascular Diseases-Diagnosis Procedure Combination; MCS, mechanical circulatory support.

Supplemental Figure 2. In-hospital mortality according to the deciles of short-term MCS volume.

		Odds Ratio (95% CI)	P-value
IABP alone cohort			
Decile 1	1,282 (26.8)	Reference	
Decile 2	1,149 (23.4)	0.80 (0.72, 0.89)	<0.001
Decile 3	1,076 (22.5)	0.77 (0.69, 0.85)	<0.001
Decile 4	923 (19.4)	0.69 (0.62, 0.77)	<0.001
Decile 5	1,043 (21.0)	0.74 (0.66, 0.82)	<0.001
Decile 6	876 (18.5)	0.63 (0.57, 0.71)	<0.001
Decile 7	809 (16.1)	0.55 (0.49, 0.61)	<0.001
Decile 8	805 (16.8)	0.59 (0.53, 0.66)	<0.001
Decile 9	736 (14.8)	0.51 (0.45, 0.57)	<0.001
Decile 10	768 (15.7)	0.62 (0.56, 0.70)	<0.001
ECMO cohort			
Decile 1	1,212 (74.8)	Reference	
Decile 2	1,210 (72.7)	0.96 (0.82, 1.14)	0.67
Decile 3	1,252 (71.4)	0.89 (0.76, 1.05)	0.169
Decile 4	1,126 (68.6)	0.78 (0.66, 0.92)	0.003
Decile 5	1,175 (69.6)	0.82 (0.70, 0.96)	0.016
Decile 6	1,204 (68.9)	0.84 (0.71, 0.98)	0.03
Decile 7	1,134 (68.2)	0.74 (0.63, 0.87)	<0.001
Decile 8	1,162 (70.1)	0.83 (0.71, 0.98)	0.029
Decile 9	1,142 (68.1)	0.74 (0.63, 0.87)	<0.001
Decile 10	1,173 (66.7)	0.70 (0.60, 0.82)	<0.001
All MCS cohort			
Decile 1	2,211 (34.0)	Reference	
Decile 2	2,231 (34.2)	0.83 (0.76, 0.91)	<0.001
Decile 3	2,048 (32.6)	0.78 (0.71, 0.85)	<0.001
Decile 4	2,427 (35.0)	0.77 (0.71, 0.84)	<0.001
Decile 5	2,218 (33.5)	0.70 (0.64, 0.76)	<0.001
Decile 6	1,967 (31.0)	0.66 (0.60, 0.72)	<0.001
Decile 7	2,102 (32.1)	0.63 (0.58, 0.69)	<0.001
Decile 8	2,202 (33.5)	0.67 (0.61, 0.73)	<0.001
Decile 9	1,948 (28.8)	0.56 (0.51, 0.61)	<0.001
Decile 10	1,979 (29.2)	0.69 (0.63, 0.76)	<0.001

Scale: 0.4 0.5 0.7 1.0 1.5

Adjusted odds ratios for in-hospital mortality for each category are presented with the lowest group as a reference.

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support.

Supplemental Figure 3. Continuous relationship between unadjusted ORs for in-hospital mortality and the volume.
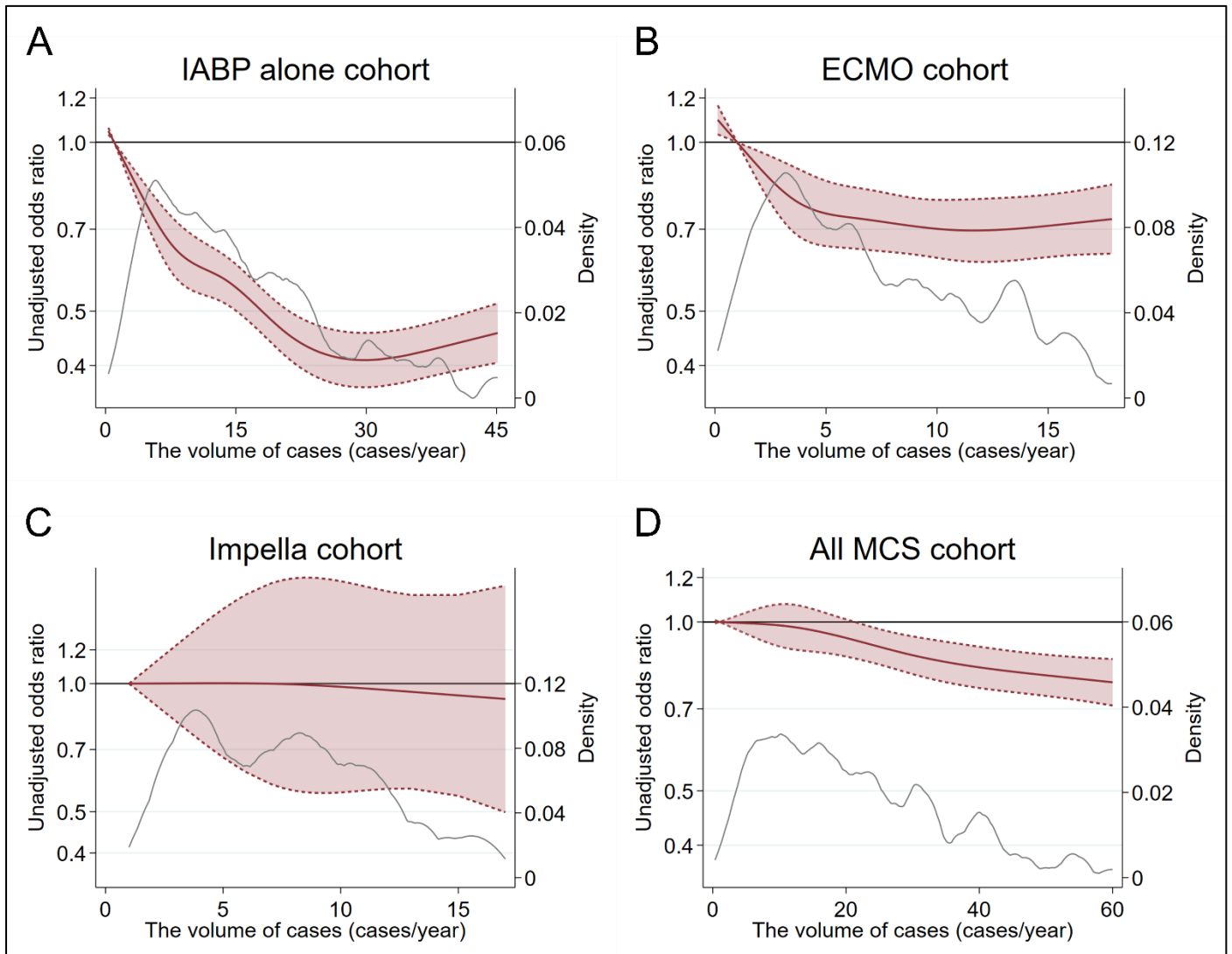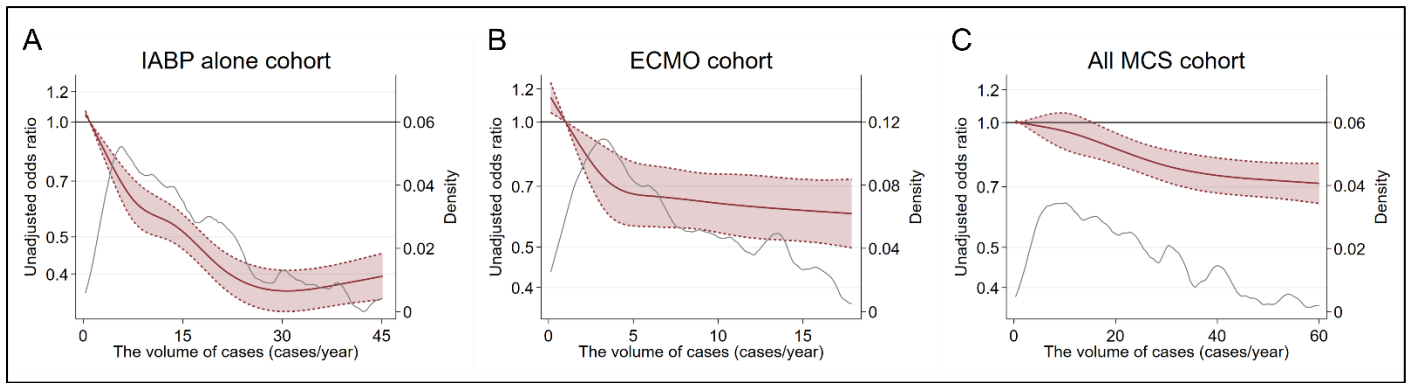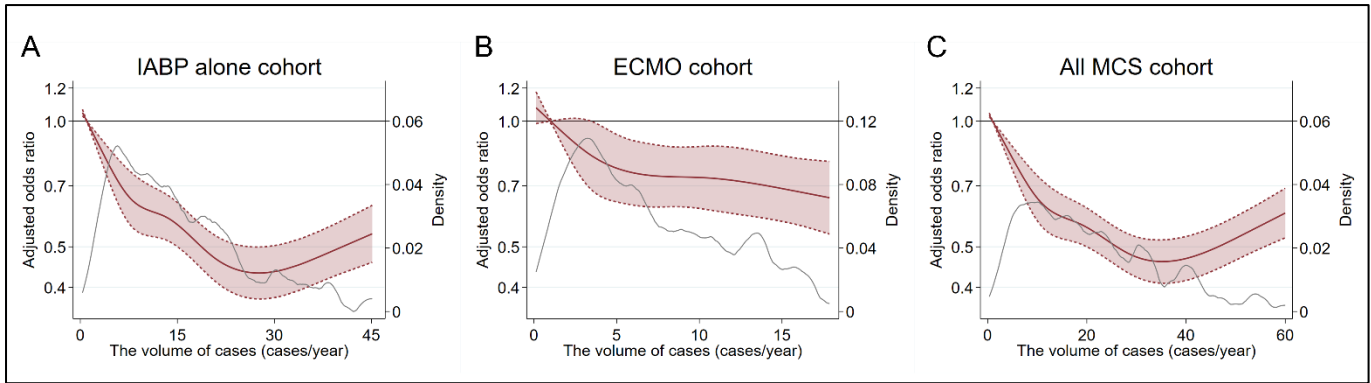

Continuous relationship between unadjusted odds ratio for in-hospital mortality and the volume of cases in the IABP alone cohort (A), ECMO cohort (B), Impella cohort (C), and all MCS cohort (D). A hospital with 1 case/year for each cohort was used as reference. The solid red line illustrates a continuous odds ratio, and the interrupted red lines on either side reveal the 95% confidence interval.
Below 98 percentiles of the volume of cases in each cohort were depicted.
Kernel density estimation was drawn as the black line to express the case volume distribution.
ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support; PE, pulmonary embolism.

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Supplemental Figure 4. Continuous relationship between unadjusted ORs for in-hospital mortality and the volume in patients with AMI.

Continuous relationship between unadjusted odds ratios for in-hospital mortality and the volume of cases in the IABP alone cohort (A), ECMO cohort (B), and all MCS cohort (C). A hospital with 1 case/year for each cohort was used as reference. The solid red line illustrates a continuous odd ratio and the interrupted red lines on either side reveal the 95% confidence interval.

Below 98 percentiles of the volume of cases in each cohort were depicted.

Kernel density estimation was drawn as the black line to express the case volume distribution.

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; and MCS, mechanical circulatory support.

Supplemental Figure 5. Continuous relationship between adjusted ORs for in-hospital mortality and the volume in patients with AMI.

Continuous relationship between adjusted odds ratios for in-hospital mortality and the volume of cases in the IABP alone cohort (A), ECMO cohort (B), and all MCS cohort (C). A hospital with 1 case/year for each cohort was used as reference. The solid red line illustrates a continuous odds ratio and the interrupted red lines on either side reveal the 95% confidence interval.

Below 98 percentiles of the volume of cases in each cohort were depicted.

The model was adjusted for age category, sex, body mass index category, chronic kidney disease, diabetes mellites, cardiopulmonary resuscitation (on or before the date when MCS was introduced), intubation, right heart catheterization, causes of CS (AMI, HF, FM, arrhythmia, or PE), and era (2012-2013, 2014-2015, 2016-2017, 2018-2019).

Kernel density estimation was drawn as the black line to express the case volume distribution.

AMI, acute myocardial infarction; CS, cardiogenic shock; ECMO, extracorporeal membrane oxygenation; FM, fulminant myocarditis; HF, heart failure; IABP, intra-aortic balloon pump; and MCS, mechanical circulatory support and PE, pulmonary embolism.

Supplemental Figure 6. Continuous relationship between in-hospital mortality and the volume in patients with AMI.
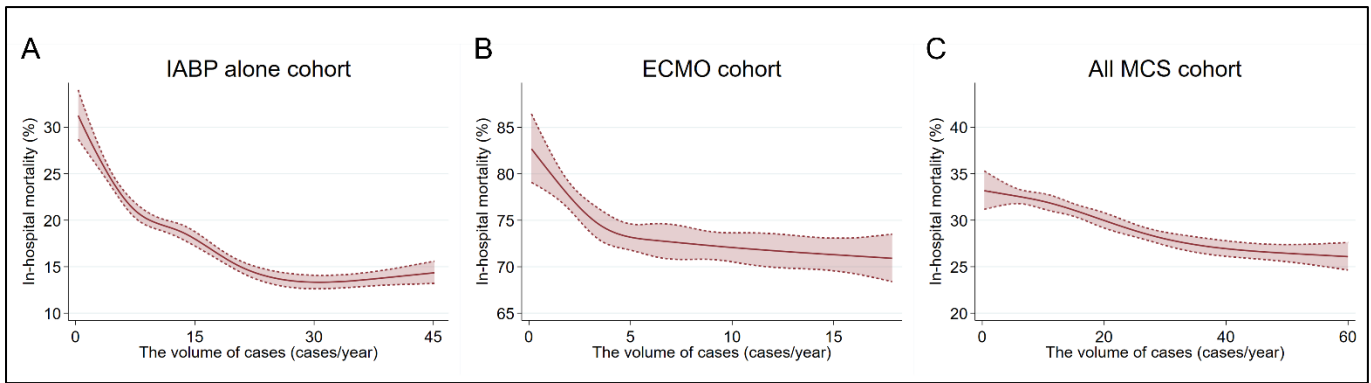
Continuous relationship between in-hospital mortality and the volume of cases in the IABP alone cohort (A), ECMO cohort (B), and all MCS cohort (C). The solid red line illustrates a continuous in-hospital mortality (%) and the interrupted red lines on either side reveal the 95% confidence interval.

Below 98 percentiles of the volume of cases in each cohort were depicted.

ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support.