Hemodynamic support by Impella in cardiogenic shock patients: Results from J-PVAD registry

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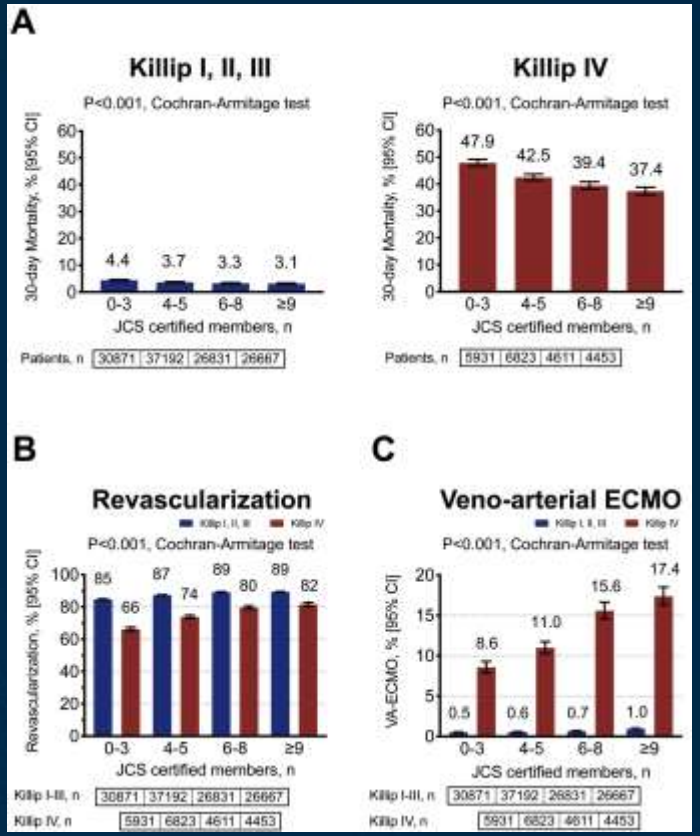
Disclosure

- Consultation Fee: Abiomed

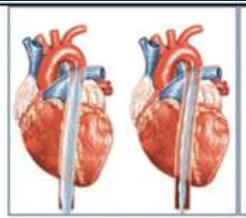
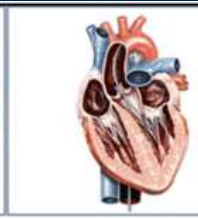
Cardiogenic shock
The next frontier



Regardless of the size of the institution, the number of certified cardiologists, Killip IV MI is still associated with significantly worse clinical outcomes, even with use of VA ECMO.

Circ J 2021; 85: 1797 – 1805

MCS
Hemodynamic effects

	IABP	IMPELLA	TANDEMHEART	VA-ECMO
Cardiac Flow	0.3-0.5 L/ min	1-5L/ min (Impella 2.5, Impella CP, Impella 5)	2.5-5 L/ min	3-7 L-min
Mechanism	Aorta	LV → AO	LA → AO	RA → AO
Maximum implant days	Weeks	7 days	14 days	Weeks
Sheath size	7-8 Fr	13-14 Fr Impella 5.0 - 21 Fr	15-17 Fr Arterial 21 Fr Venous	14-16 Fr Arterial 18-21 Fr Venous
Femoral Artery Size	>4 mm	Impella 2.5 & CP - 5-5.5 mm Impella 5 - 8 mm	8 mm	8 mm
Cardiac synchrony or stable rhythm	Yes	No	No	No
Afterload	↓	↓	↑	↑↑↑
MAP	↑	↑↑	↑↑	↑↑
Cardiac Flow	↑	↑↑	↑↑	↑↑
Cardiac Power	↑	↑↑	↑↑	↑↑
LVEDP	↓	↓↓	↓↓	↔
PCWP	↓	↓↓	↓↓	↔
LV Preload	---	↓↓	↓↓	↓
Coronary Perfusion	↑	↑	---	---
Myocardial oxygen demand	↓	↓↓	↔↓	↔

J Am Coll Cardiol Intv 2016;9:871–83

Impella Heart Pump in Japan

2012 2013 2014 2015 2016 2017 2018 2019 2020 2021 2022 2023

510K Approval

PMA High-risk PCI

PMA CGS

Sep PMDA Regulatory Approval

Jul Appropriate Use Guidance Issued by Impella Committee

Oct First Case in Japan

As of Jan > 7,500 pts treated by Impella

Approved indication:

Drug-resistant acute heart failure such as cardiogenic shock

Impella Site Qualification & Initiation Process in Japan

1 Qualification Application

2 Document Review

3 On-site Inspection
When needed

4 Facility Qualification
Issuance of facility qualification certification

5a Preparation of Registry
- IRB, EDC setup etc

J-PVAD Registry

5b Training Program
- e-Learning
- On-site training

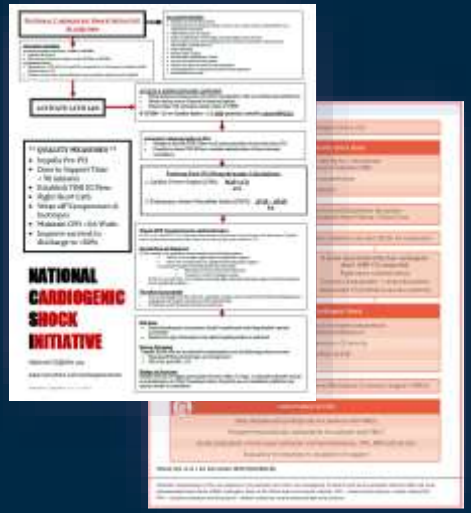
6 Start clinical use of Impella

The Council for Clinical Use of Ventricular Assist Device Related Academic Societies, IMPELLA committee
補助人工心臓治療関連学会協議会 インペラ部会
https://j-pvad.jp

Best Practice Implementation in Japan

Prospective, FDA-audited, multi-center study
cVAD study

Investigator-led prospective studies
NCSI, Inova,…



Impella Best Practice

- Early identification of CGS & use of Impella
- Pre-PCI Impella initiation
- Use of PAC and hemodynamic-guided decision making
- Minimizing inotropes/vasopressor use

Impella best practice in pts with CGS is introduced in training program and adopted

J-PVAD registry

Journal of Artificial Organs (2023) 26:17–23
https://doi.org/10.1007/s10047-022-01328-1

ORIGINAL ARTICLE

Artificial Heart (Clinical)

Three-year experience of catheter-based micro-axial left ventricular assist device, Impella, in Japanese patients: the first interim analysis of Japan registry for percutaneous ventricular assist device (J-PVAD)

Koichi Toda[1] · Junya Ako[2] · Atsushi Hirayama[3] · Koichiro Kinugawa[4] · Yoshio Kobayashi[5] · Minoru Ono[6] · Takashi Nishimura[7] · Naoki Sato[8] · Takahiro Shindo[9] · Morimasa Takayama[10] · Satoshi Yasukochi[11] · Akira Shiose[12] · Yoshiki Sawa[1] · J.-PVAD registry study investigators

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Impella Experience in Japan – Indication

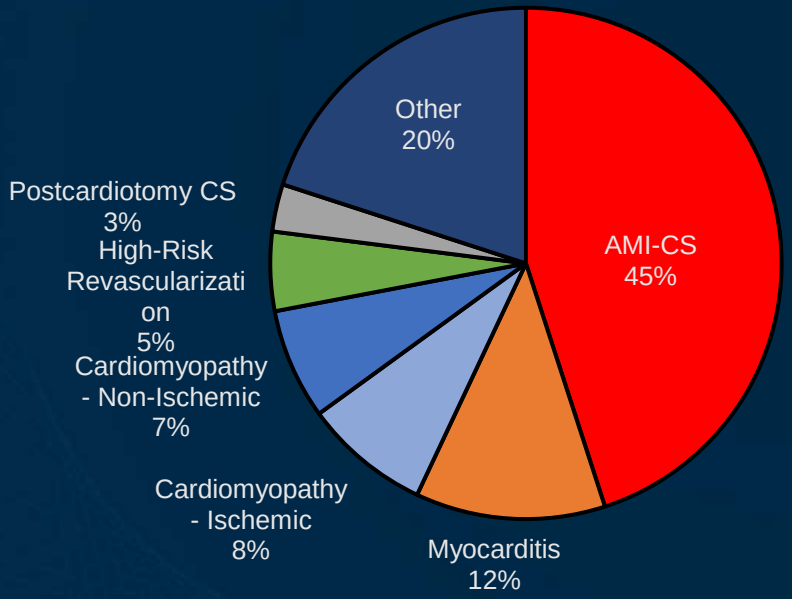
J-PVAD Registry

Multi-Center, Prospective clinical registry led by Impella Committee

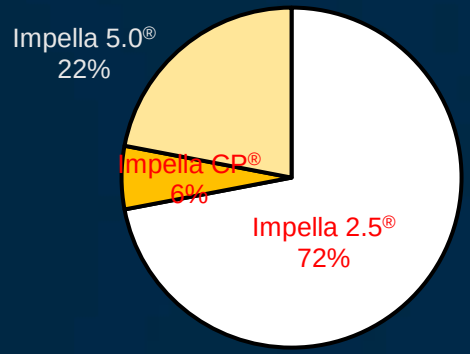
Three-year interim analysis[1]
Enrollment period: Oct 2017 – Jan 2020

N = 823

Indications



Device Distribution



Note: Impella CP became available in Oct 2019

Duration of Support

By device, days

Impella 2.5 – 4.32 ± 3.95
Impella CP – 5.96 ± 4.79
Impella 5.0 – 13.09 ± 13.95

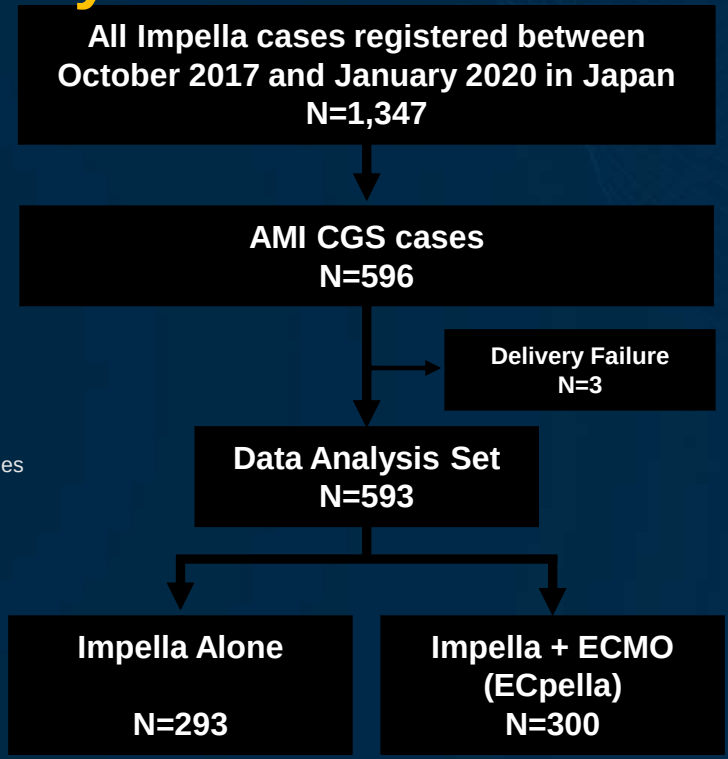
By indication, days

AMI-CS – 5.9 ± 4.7
Myocarditis – 10.8 ± 6.7

J Artifical Organs 2023:26;17-23

Japanese Registry for Percutaneous VAD (J-PVAD) AMI-CGS subanalysis

- Investigator-led, observational, multicenter study of ALL Impella use in Japan conducted by the Japan Impella Committee, comprised of 10 societies*
- 593 consecutive patients with AMI CGS supported by Impella at 109 hospitals between October 2017 and January 2020



* Japan Impella Committee of The Council for Clinical Use of Ventricular Assist Device Related Academic Societies

- The Japanese Circulation Society (JCS)
- Japanese Association of Cardiovascular Intervention and Therapeutics (CVIT)
- Japanese College of Cardiology (JCC)
- The Japanese Heart Failure Society (JHFS)
- Japanese Society for Artificial Organs (JSAO)
- The Japanese Society of Intensive Care Medicine (JSICM)
- Japanese Society of Pediatric Cardiology & Cardiac Surgery (JSPCCS)
- The Japanese Association for Thoracic Surgery (JATS)
- The Japanese Society for Cardiovascular Surgery (JSCVS)
- Japanese Society of Percutaneous Cardiopulmonary Support / Extracorporeal Membrane Oxygenation (PCPS/ECMO)

Ikeda Y, Ako J, et al. Circ J. 2023 Apr 25;87(5):588-597.

J-PVAD AMI CGS: Patient Characteristics

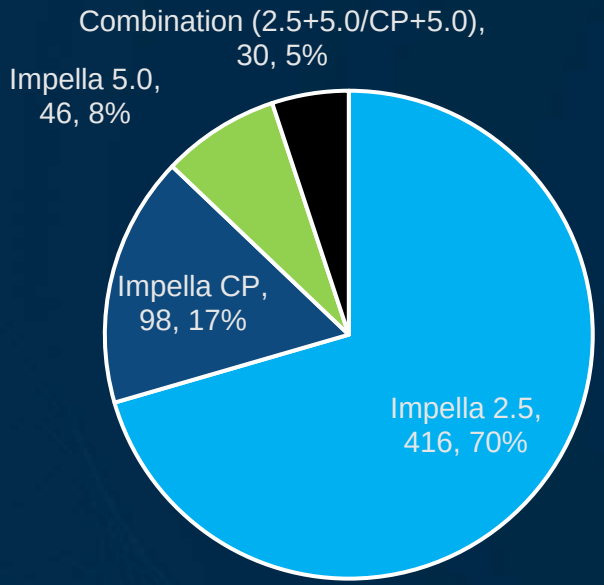
	All Cases (n=593)	Impella Alone (n=293)	ECpella (n=300)	NCSI ** (n=267)
Age (years), median [IQR]	70 [61–77]	72 [65–78]	68 [59–75]*	63.7
Male, %	79.1	75.8	82.3	77%
Semi-coma/coma/deep coma (Jpn Coma Scale ≥100), %	49.7	28.7	70.3*	-
Out-of-Hospital Cardiac Arrest, %	24.1	15.7	32.3*	19%
In-Hospital Cardiac Arrest prior to Impella support, %	30.5	14.3	46.3*	30%
Mechanical Ventilation prior to Impella Support, %	57.9	49.5	63.4*	-
≥2 Vasoactive & Inotropic Drug use, %	38.1	32.9	42.6*	20%
Shock diagnosis–to–Impella Support <6 hours, %	80.7	82.9	78.5	-
Comorbidities, %				
Diabetes Mellitus	40.1	39.3	41.0	40%
Hypertension	68.2	71.6	64.5	10%
LVEF <30%, %	44.5	27.6	63.9*	-
Systolic Arterial Pressure <90 mmHg, %	39.7	39.6	39.9	(Pre-MCS SBP 94.7)
Lactate ≥2.0 mmol/L, %	84.2	76.4	91.8*	
Lactate ≥4.0 mmol/L, %	62.5	47.9	76.6*	(Pre-MCS Lac 5.4)
eGFR <60 mL/min/1.73m^2, %	72.1	67.4	77.0*	(Pre-MCS Cre 1.7)
Brain Natriuretic Peptide ≥200 pg/mL, %	45.0	51.9	37.8*	-
CK-MB ≥50 IU/L, %	39.1	34.5	43.9*	-
Cardiac Troponin I ≥50 ng/L, %	29.0	26.4	31.5	-

Ikeda Y, Ako J, et al. Circ J. 2023 Apr 25;87(5):588-597.

* p<0.05 vs. Impella alone
** Adapted from Basir et al. CCI. 2022 Feb;99(3):650-657

Device Type and Support Duration

Device Type



Note: Impella CP became available in Oct 2019

Support Duration by Device

Median (Min. – Max.), days

	All Cases (n=593)	Impella Alone (n=293)	ECpella (n=300)
Impella 2.5	3.1 (0.0 – 20.9) n=416	2.3 (0.1 – 20.2) n=220	4.6 (0.0 – 20.9)* n=196
Impella CP	4.0 (0.1 – 17.9) n=98	3.2 (0.2 – 17.9) n=44	4.8 (0.1 – 17.8) n=54
Impella 5.0	7.7 (0.0 – 63.6) n=46	5.8 (0.0 – 19.9) n=21	8.8 (0.1 – 63.6) n=25
Impella 2.5+5.0	15.8 (1.3 – 47.0) n=27	13.9 (1.3 – 47.0) n=6	15.8 (3.9 – 46.3) n=21
Impella CP+5.0	22.8 (19.7 – 29.8) n=3	19.7 n=1	22.8, 29.8 n=2

* $p<0.05$ vs. Impella alone

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Patient, Coronary and Procedural Characteristics Patients with AMI CS underwent PCI (N=335)

	All Cases (n=335)	Impella Alone (n=203)	ECpella (n=132)	**NCSI * (n=267)**
STEMI, % (in all ACS patients)	83.5	82.7	84.2	79%
LMT, %	37.0	33.5	42.4	-
Multivessel disease, %	73.7	72.9	75.0	64%
SYNTAX Score, median [IQR]	23.5 [15.0 – 32.2]	23.0 [15.0 – 32.0]	24.8 [15.0 – 32.4]	-
Impella Support Prior to PCI, %	65.7	66.0	65.2	70%

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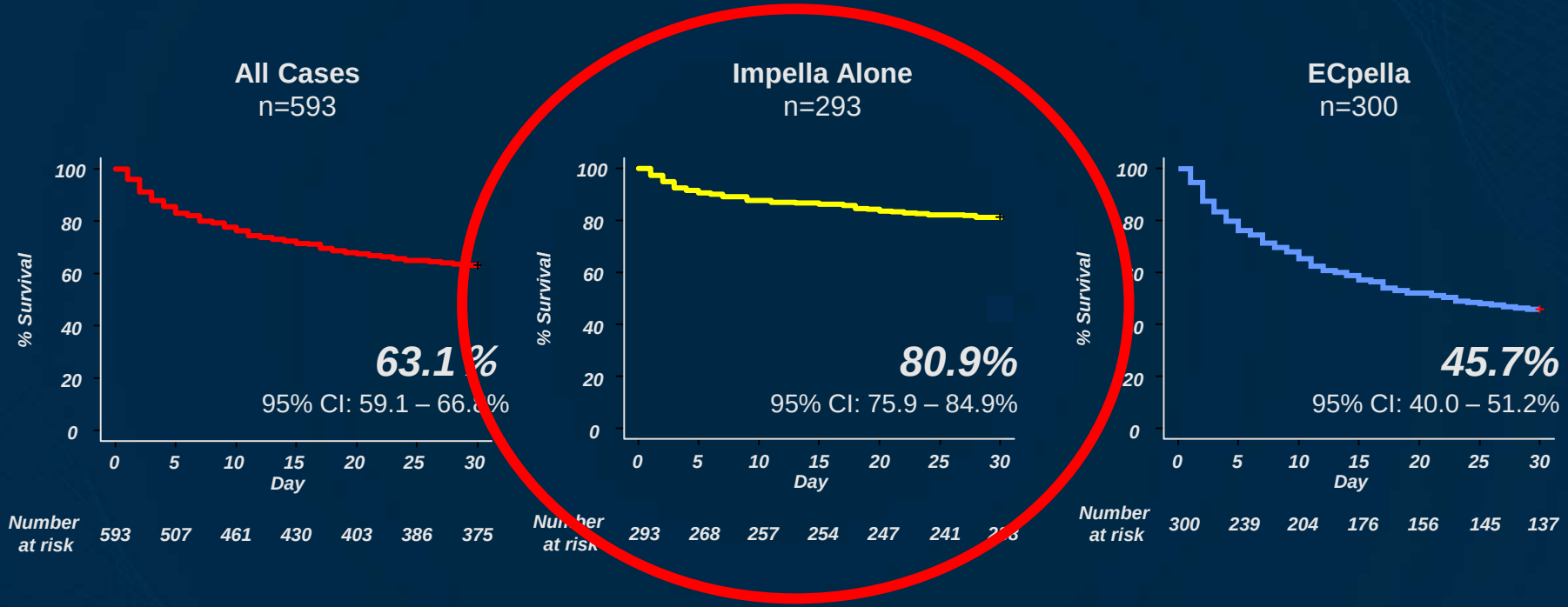
* Adapted from Basir et al. CCI. 2022 Feb;99(3):650-657.

30-Day Survival



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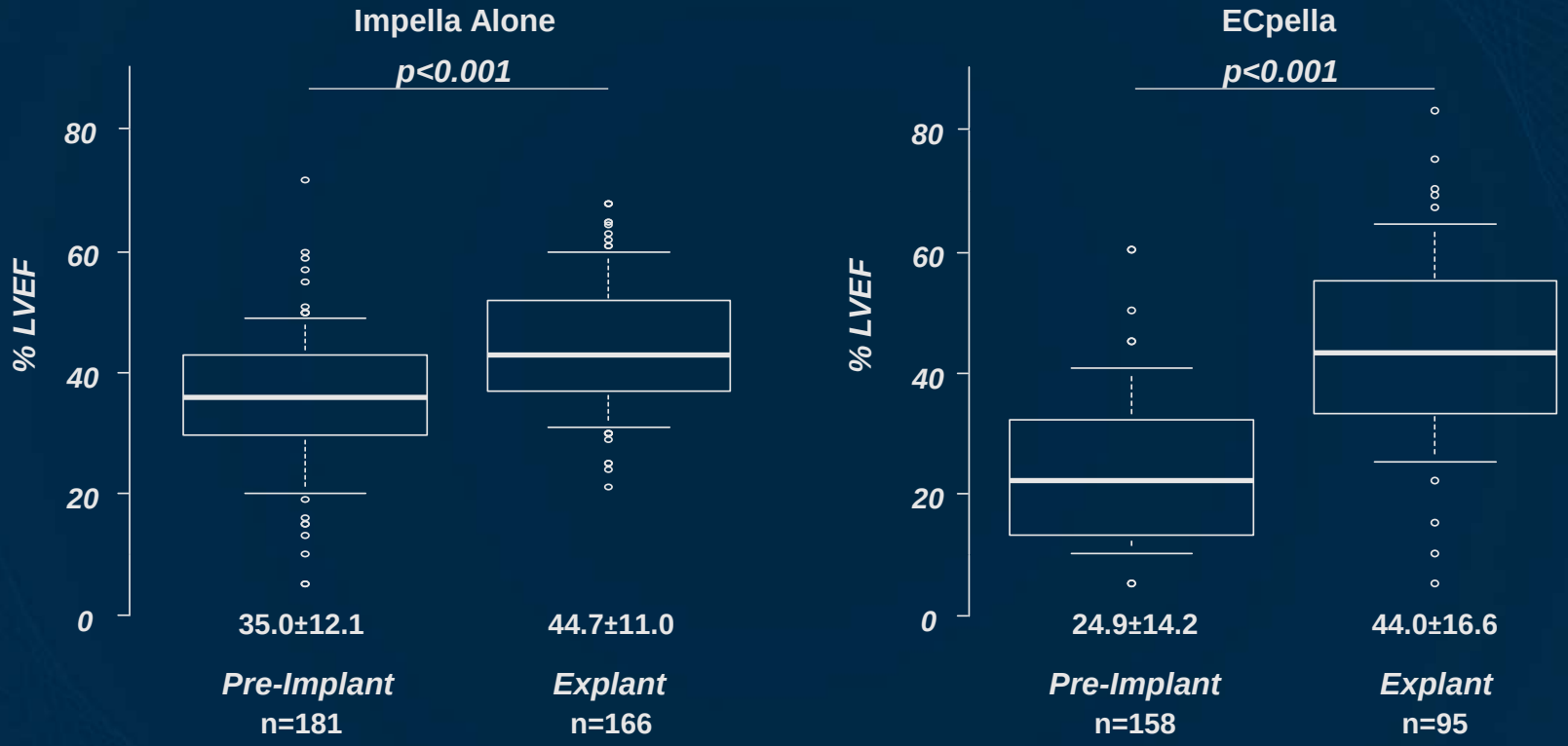
Change in LVEF between Pre-Impella and Explant



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Major Adverse Events

	All Cases (n=593)	Impella Alone (n=293)	ECpella (n=300)
Hemolysis, %	10.8	13.0	8.7
Hemorrhage/Hematoma, %	7.6	5.8	9.3
Peripheral Ischemia, %	4.4	4.1	4.7
Stroke, %	1.3	1.0	2.0
Thrombosis, %	0.7	1.0	0.3

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Cox-Proportional Hazards for Incidence of 30-day Mortality

(Univariable Analysis)

	Impella Alone		ECpella	
	HR(95% CI)	p-value	HR(95% CI)	p-value
Age ≥75 years	**1.878 (1.141 – 3.089)**	**0.013**	**1.842 (1.344 – 2.524)**	**<0.001**
Shock diagnosis-to-Impella <6 hours	**0.499 (0.292 – 0.850)**	**0.011**	0.906 (0.630 – 1.302)	0.593
Systolic Arterial Pressure <90 mmHg	**1.810 (1.071 – 3.060)**	**0.027**	1.028 (0.730 – 1.447)	0.875
Lactate ≥2 mmol/L	**4.322 (1.328 – 14.07)**	**0.015**	2.265 (0.920 – 5.577)	0.076
CK-MB ≥50 ng/mL	**1.938 (1.130 – 3.324)**	**0.016**	1.082 (0.765 – 1.530)	0.657
eGFR <60 mL/min/1.73m^2	**3.391 (1.599 – 7.194)**	**0.001**	**1.823 (1.186 – 2.804)**	**0.007**

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J-P VAD registry
AMI CGS subanalysis

- Favorable 30-day survival with acceptable safety profiles were demonstrated.
  - 30-day survival – Impella alone group: **80.9%**, ECpella group: **45.7%**
  - Change in LVEF between Pre-Impella and Explant – Impella alone group: **35.0% to 44.7%**, ECpella group: **24.9% to 44.0%**
  - Major adverse events – Hemolysis: **10.8%**, Hemorrhage/Hematoma: **7.6%**, and peripheral ischemia: **4.4%**, Stroke: **1.3%**

- Following best practices widely adapted in previous initiatives,
  - **Early identification of CS & use of Impella** – Impella support within 6 hours from shock diagnosis was achieved in **80.7%** of all AMICS patients
  - **Pre-PCI Impella initiation** – Impella was initiated prior to PCI in **65.7%** of patients with AMICS underwent PCI
  - **Hemodynamic-guided decision-making** – Serial and quantitative hemodynamic assessment using multimodality including RHC and ECHO was applied to guide therapy and identify needs for escalation of therapy (LV-/RV-/BiV-support, hemodynamic support, respiratory support).
    - ECpella was initiated in **50.6%** of all AMICS patients