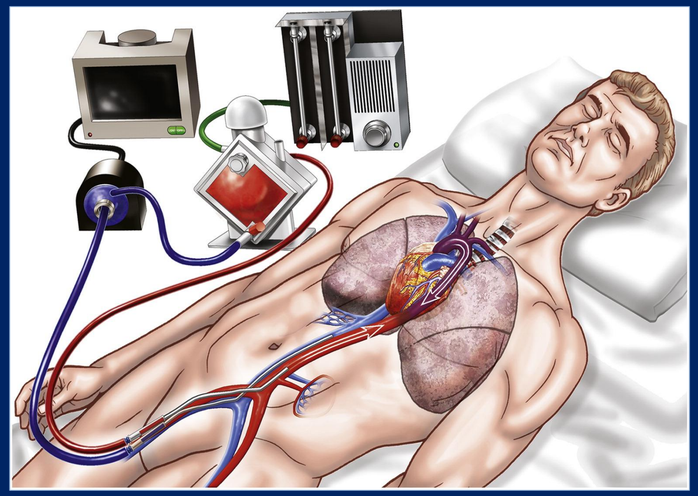
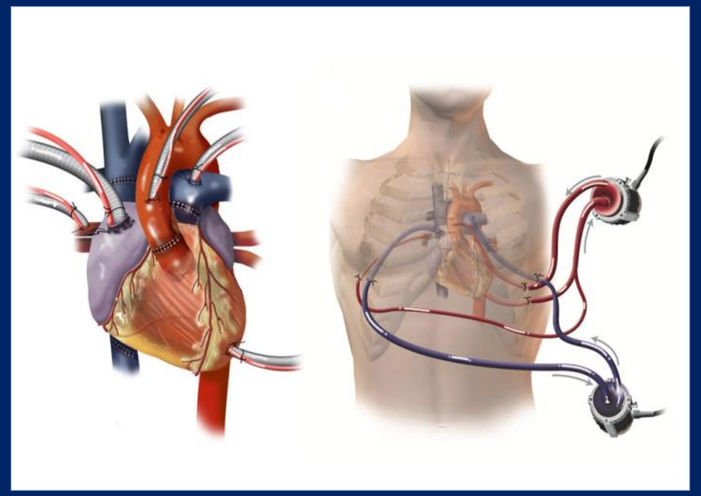
What Is The Best Device for Post Cardiotomy Short-Term Support? ECMO versus CentriMag versus Impella





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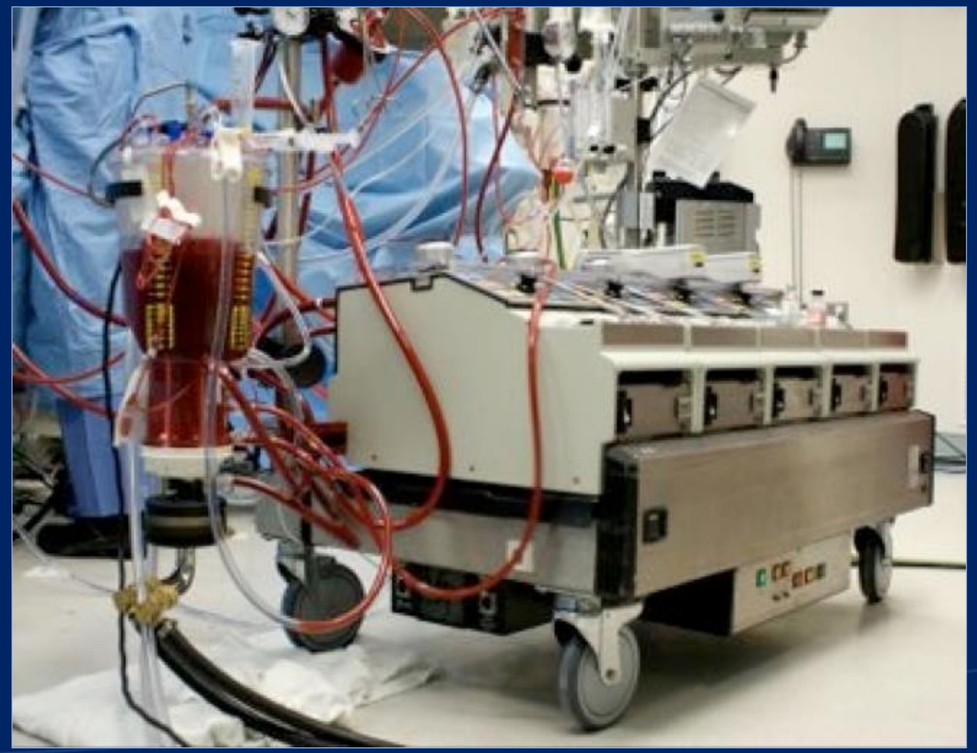
Knowledge and Compassion **Focused on You**

No conflicts of Interest

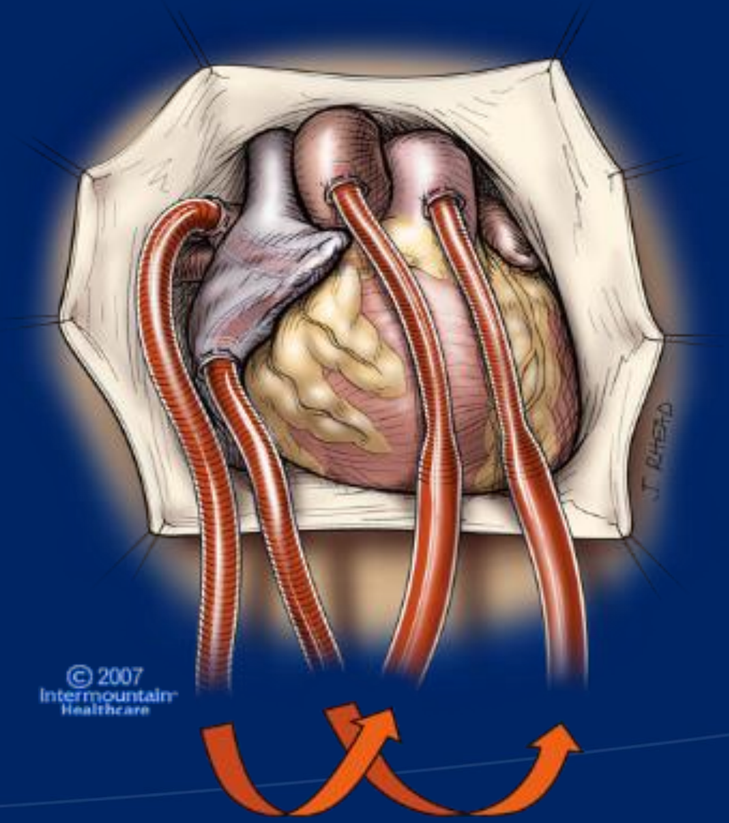
Post Cardiotomy Shock (PCS)

- Incidence 2-6 %
- 0.5-1.5 % refractory to inotropes and IABP
- ECMO, temporary LVADs, Impella
- Historically poor outcomes
- No randomized trials
- What can we do better?



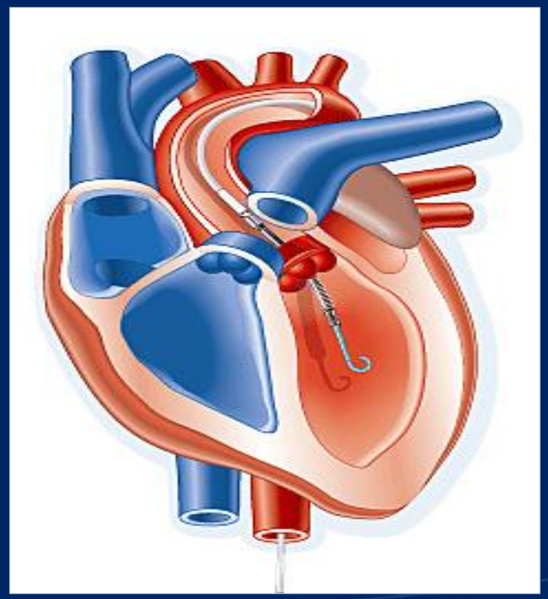
Ideal Support Device in PCS

- Easy and rapid implementation
- Provide robust hemodynamic support
- Provide biventricular and pulmonary support
- Safe to operate with low or no anticoagulation
- Allow ventricular recovery
- Easy to replace and explant
- Cost effective

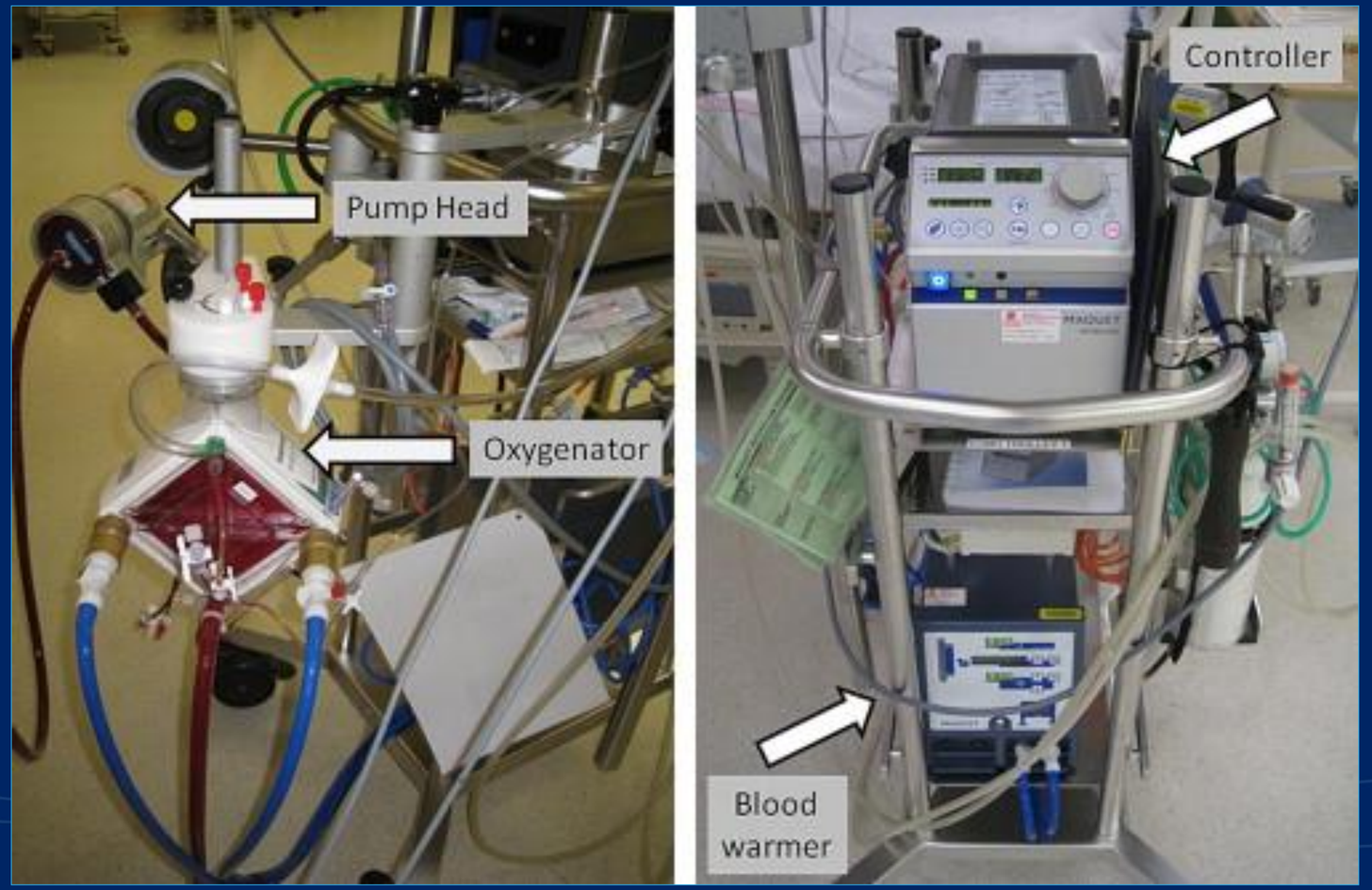


Device Selection

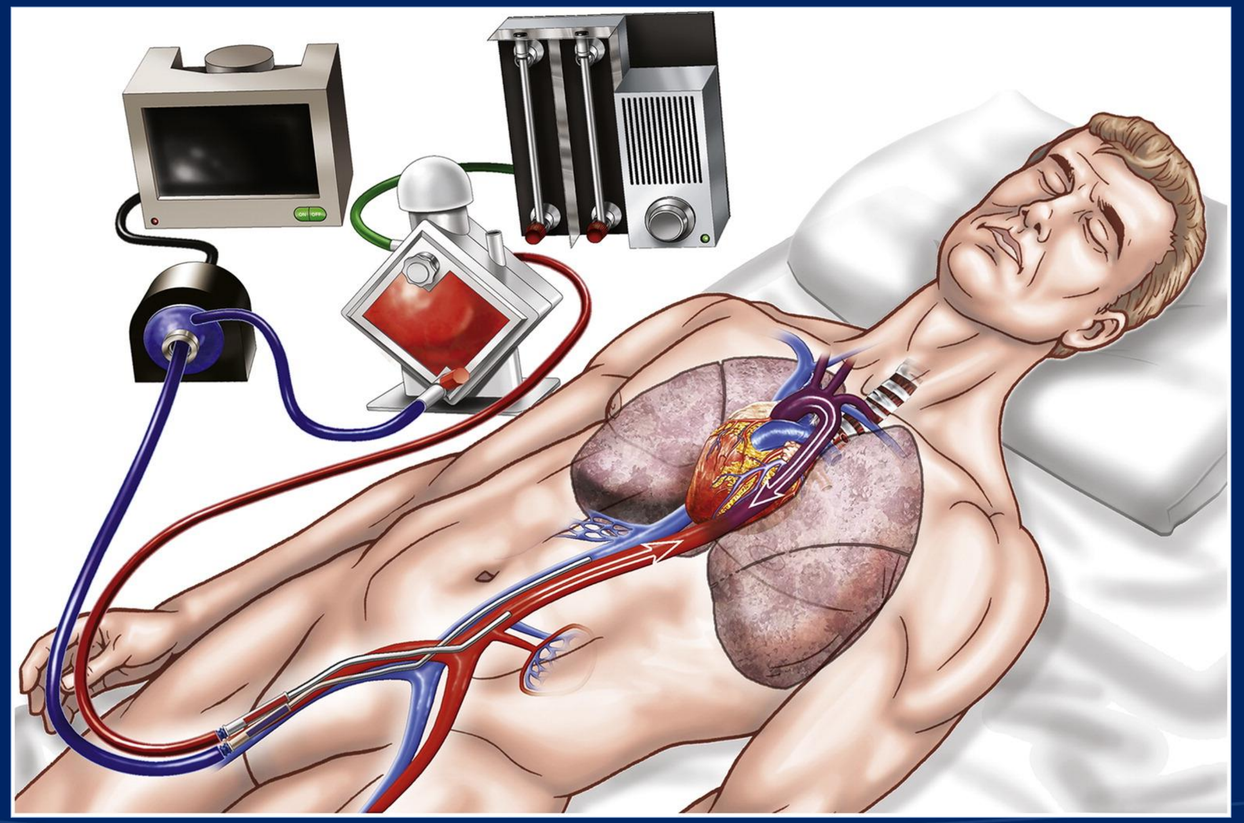
- Etiology and severity of cardiogenic shock
- LV vs. RV or biventricular dysfunction
- Pulmonary edema and hypoxemia?
- Technology available at your institution
- Devices:
  - VA ECMO
  - CentriMag
  - Impella



VA ECMO



VA ECMO



Abrams et al, J Am Coll Cardiol, 2014

ECMO Advantages

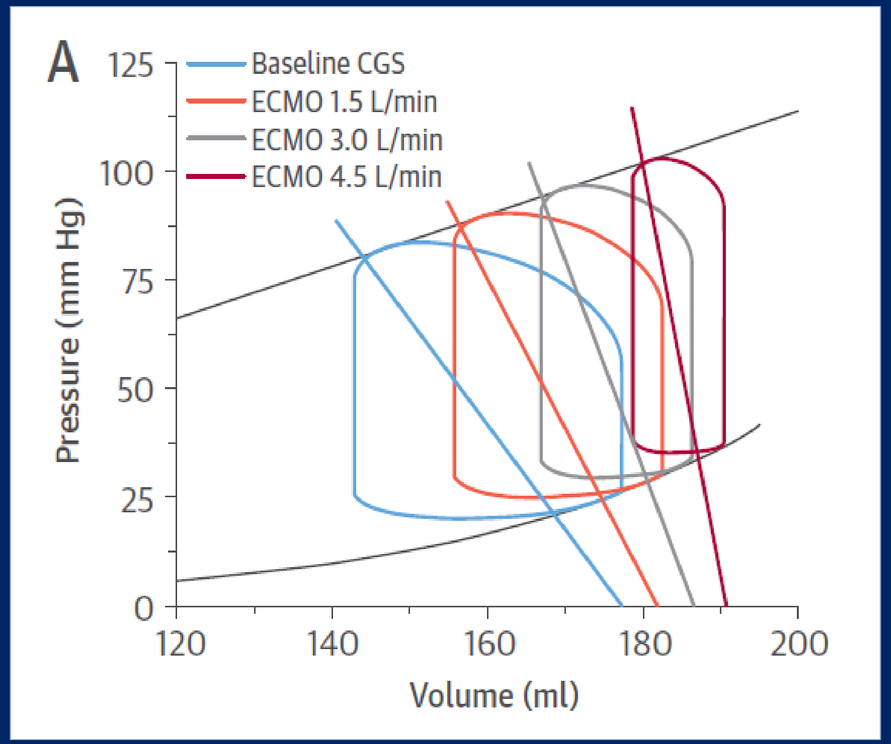
- Allows for minimally invasive
- Rapid bedside application
- Biventricular support
- Pulmonary support
- Low initial cost
- Transport capabilities

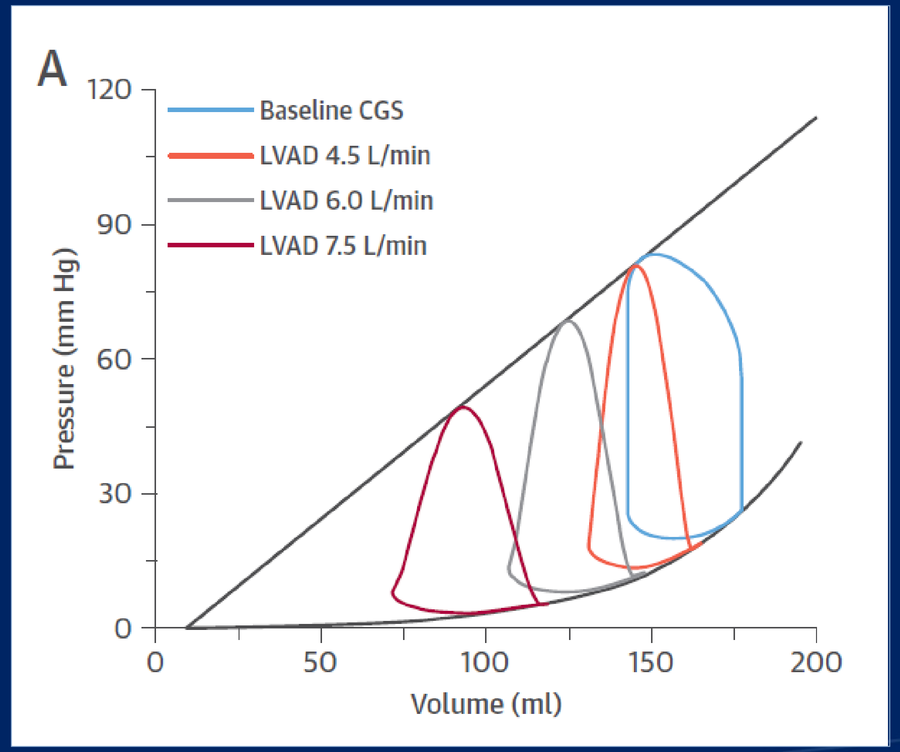
ECMO Advantages

ECMO Disadvantages

- Historically high complication rates
- Bleeding / thrombosis / stroke / sepsis / limb ischemia
- LV distension / thrombosis / impaired recovery
- Cerebral hypoxia
- Immobilization
- Labor intensive
- High cost with prolonged support
- Limited duration of support

ECMO Disadvantages

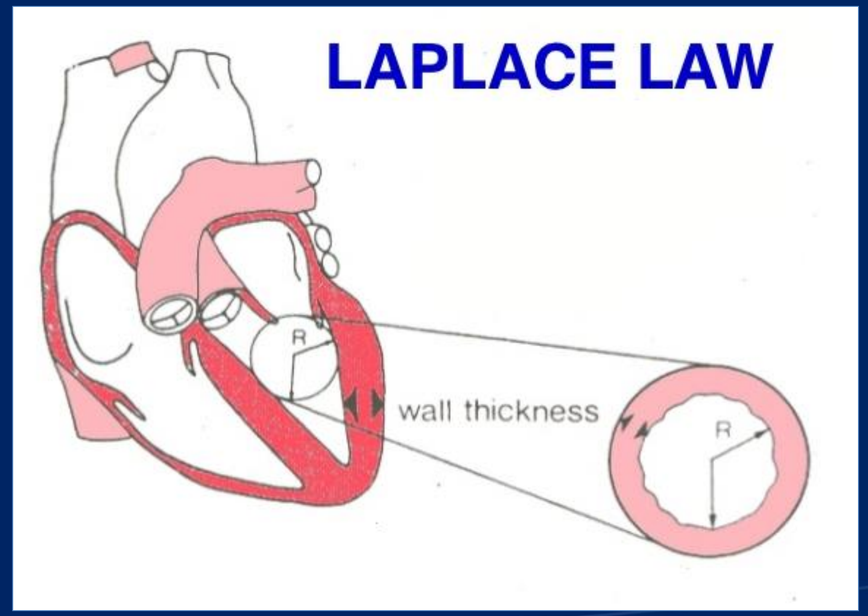




Burkhoff et al, J Am Coll Cardiol. 2015

LV Distension

- Reduce flow
- Inotropes
- Minimize vasoconstrictors
- Central cannulation
- LV vent insertion
- Impella / Tandem Heart
- LVAD conversion



ECMO Studies in PCS

Table 2
Characteristics and Outcomes Reported in Studies Included in the Present Meta-Analysis

First Author	Year	Study Quality	No. of Patients	Mean Age (y)	ECMO Started at Surgery (%)	IABP (%)	Peripheral ECMO (%)	Mean ECMO Duration (d)	Weaned From ECMO (%)	Hospital Survival (%)	1-Year Survival (%)
Ariyaratnam[5]	2014	Poor	14	65.6	–	–	–	5.6	50	14	–
Bakhtiary[9]	2008	Good	45	60.1	67	67	82	6.4	56	29	27
Beiras-Fernandez[10]	2011	Good	73	49.3	–	49	–	4.4	–	23	–
Biancari[11]	2017	Good	148	65.4	51	32	60	6.4	–	36	31
Distelmaier[12]	2016	Good	385	–	–	–	90	4	–	56	40
Elsharkawy[13]	2010	Good	233	–	–	–	67	–	–	36	–
Hsu[14]	2009	Good	51	63.0	–	100	–	7.5	53	33	29
Khorsandi[15]	2016	Fair	15	–	–	–	–	5.4	–	27	–
Ko[16]	2002	Good	76	56.8	51	58	80	10.5	55	26	25
Lamarche[17]	2010	Good	24	52.5	67	–	63	–	63	25	–
Li[18]	2015	Good	123	56.2	50	59	100	4.4	56	34	–
Liden[19]	2009	Good	33	52.4	–	42	36	5.5	79	45	36
Liu[20]	2009	Good	14	55.7	64	71	100	3.0	64	50	43
Loforte[21]	2014	Fair	155	55.0	–	100	51	8.2	57	51	–
Luo[22]	2009	Good	36	–	–	31	–	–	67	61	–
Meyer[23]	2009	Poor	18	50	–	–	100	4	67	39	–
Mikus[24]	2013	Fair	14	53.1	86	100	43	9	50	50	–
Papadopoulos[25]	2015	Good	360	62	–	22	90	7	58	28	26
Park[26]	2014	Good	115	61.7	36	–	100	3.0	41	28	–
Peigh[27]	2015	Good	13	–	–	–	–	–	–	38	–
Pokersnik[28]	2012	Good	49	65	–	59	65	3.8	55	33	–
Rastan[29]	2010	Good	517	63.5	42	74	39	3.3	63	25	17
Rousse[30]	2015	Good	41	47	–	12	90	–	37	41	–
Slottosch[31]	2012	Good	77	60	44	94	100	3.3	62	30	–
Truby[32]	2015	Good	70	–	–	–	–	–	–	31	–
Unosawa[33]	2012	Fair	47	64.4	70	–	68	2.6	62	30	30
Wang[34]	2009	Good	62	51	–	31	–	2.5	65	55	52
Wu[35]	2010	Good	110	60.6	–	–	100	6.0	61	42	–
Yang[36]	2014	Fair	12	60.4	–	100	100	5.2	100	67	–
Zhang[37]	2006	Good	32	55.4	–	–	59	2.9	44	25	–
Zhao[38]	2015	Fair	24	59.3	37	88	96	4.8	67	33	–

Abbreviations: ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump.

Biancari et al, J Cardiothorac Vasc Anesth. 2018

ECMO Outcomes in PCS

Table 3
Pooled Rates of Early Outcomes

Outcomes	No. of Studies	No. of Patients	Proportion/Mean (95% CI)	I^2
Hospital survival, %	31	2,986	36.1 (31.5-40.8)	84%
Weaning from VA-ECMO, %	24	2,049	59.5 (54.6-64.3)	77%
Reoperation for bleeding, %	18	1,779	42.9 (34.2-51.5)	93%
RBC units transfused	11	1,241	17.7 (13.3-22.1)	99%
Major neurological event, %	16	1,736	11.3 (7.8-14.8)	79%
Limb ischemia, %	16	1,909	10.8 (8.0-13.5)	70%
Lower limb amputation, %	5	330	1.1 (0.0-2.3)	0%
Deep sternal wound infection/mediastinitis, %	4	490	14.7 (4.0-25.4)	92%
Renal replacement therapy, %	19	1,979	47.1 (38.9-55.2)	92%
Ventricular assist device, %	21	1,685	2.3 (1.3-3.4)	57%
Heart transplantation, %	21	1,685	1.9 (1.0-2.8)	50%
Intensive care unit stay, d	10	589	13.3 (10.2-16.4)	95%
In-hospital stay, d	9	1,154	22.5 (17.7-27.3)	95%

NOTE. Pooled estimates are reported as percentages or means with 95% confidence intervals (CIs).
Abbreviations: RBC, red blood cell; VA-ECMO, venoarterial extracorporeal membrane oxygenation.

Biancari et al, J Cardiothorac Vasc Anesth. 2018

ECMO Outcomes in PCS

Table 1. Studies Included in Analysis: Baseline Characteristics

Study	Number of Patients	Patient Type	Average Age (y)	Age Range (y)	Males (%)	Peripheral ECMO (n, %)	IABP (n, %)	Average Time on ECMO (h)	Survival to D/C (n, %)	Bridged to VAD (n, %)/Survival to D/C (n, %)	Bridged to HTP (n, %)/Survival to D/C (n, %)
Bakhtiary et al [1]	45	PCCS	60.1 ± 13.6	Adults	78	29 (64)	30 (67)	153.6	13 (28.9)	5 (11.1)/3 (60)	2 (4.4)/1 (50)
Belle et al [20]	51	Mixed	51 ± 15	≥18	75	51 (100)	5 (10)	–	14 (27.5)	–	–
Bermudez et al [9]	42	Mixed	53.5	28–80	83	37 (88)	37 (88)	67.1	–	22 (52.4)/–	–
Elsharkawy et al [2]	233	PCCS	57	Adults	67	156 (67)	22 (9.4)	–	84 (36.1)	–	–
Hei et al [19]	68	PCCS	49.2 ± 13.3	≥18	76	67 (99)	11 (16)	114.6	43 (63.2)	–	8 (11.8)/6 (75)
Hsu et al [3]	51	PCCS	63 ± 15.7	Adults	71	51 (100)	–	180	17 (33.3)	–	3 (5.9)/3 (100)
Kagawa et al [21]	77	CA	61.9	18–74	71	77 (100)	52 (68)	–	16 (20.8)	4 (5.2)/–	–
Kim et al [10]	27	AMI	63.7 ± 11	45–81	59	27 (100)	2 (7)	30.2	16 (59.3)	–	–
Loforte et al [17]	73	Mixed	60.3 ± 11.6	23–84	75	73 (100)	73 (100)	261.6	33 (45.2)	3 (4.1)/2 (66.7)	0 (0)/N/A
Moraca et al [22]	26	Mixed	57	18–76	69	24 (92)	21 (80)	72	17 (65.4)	9 (34.6)/6 (66.7)	1 (3.8)/1 (100)
Pagani et al [11]	33	Mixed	47 ± 11	Adults	70	22 (67)	20 (61)	65	12 (36.4)	10 (30.3)/8 (80)	7 (21.2)/7 (100)
Rastan et al [4]	517	PCCS	63.5 ± 11.2	18–84	72	141 (27)	383 (74)	78.7	128 (24.8)	15 (2.9)/3 (20)	5 (1)/2 (40)
Schmidt et al [27]	220	Mixed	49 ± 16	Adults	67	–	–	320.9	–	–	–
Slottosch et al [23]	77	Mixed	60 ± 13	25–83	77	–	72 (94)	79	–	–	–
Smith et al [24]	17	PCCS	66.6 ± 13.6	37–83	76	11 (65)	14 (82)	86	7 (41.2)	–	–
Unosawa et al [25]	47	PCCS	64.4 ± 12.5	22–83	74	32 (68)	39 (83)	63.5	14 (29.8)	–	–
Wang et al [5]	62	PCCS	51 ± 15	Adults	52	–	19 (31)	61	34 (54.8)	–	–
Wu et al [6]	110	PCCS	60 ± 14	Adults	71	–	–	143.3	46 (41.8)	–	–
Wu et al [13]	60	Mixed	51.33	19–83	67	–	44 (73)	97.3	32 (53.3)	–	3 (5)/2 (66.7)
Zhang et al [7]	32	PCCS	55.4 ± 11.9	30–75	56	17 (53)	–	64.8	8 (25.0)	–	–

ACS = acute coronary syndrome; AMI = acute myocardial infarction; CA = cardiac arrest; D/C = hospital discharge; ECMO = extracorporeal membrane oxygenation; HTP = heart transplant; IABP = intraaortic balloon pump; Mixed = mixed population; N/A = not applicable; PCCS = postcardiotomy cardiogenic shock; VAD = ventricular assist device.

Cheng et al, Ann Thorac Surg. 2014

ECMO Complications

Table 2. Rates of Complications of Venoarterial Extracorporeal Membrane Oxygenation in Cardiogenic Shock and Cardiac Arrest

Complications	Number of Studies	Reported Rate Minimum, Maximum (%)	Cumulative Complication Rate	Cochran's Q	*p* Value Heterogeneity	I-Squared (%)	Pooled Estimate Rate (%)	95% Confidence Interval (%)
LEI	13	3.7, 37.5	112 of 677	29.2	0.004	58.9	16.9	12.5–22.6
LEF	5	5.4, 20.7	33 of 335	4.4	0.350	9.9	10.3	7.3–14.5
LEA	5	0, 8.1	7 of 192	2.4	0.658	0	4.7	2.3–9.3
Stroke	3	3.9, 9.7	36 of 630	2.1	0.346	5.9	5.9	4.2–8.3
Neurologic	9	5.9, 22.1	151 of 1,019	18.4	0.018	56.5	13.3	9.9–17.7
AKI	6	29.9, 86.7	197 of 380	64.9	<0.001	92.3	55.6	35.5–74.0
Requiring RRT	15	7.84, 86.7	758 of 1,452	138.0	<0.001	89.9	46.0	36.7–55.5
Bleeding	5	14.8, 63.6	120 of 260	22.0	<0.001	81.8	40.8	26.8–56.6
Re-Thx for bleed	6	16.1, 86.7	409 of 828	86.9	<0.001	94.2	41.9	24.3–61.8
Significant infection	10	13.7, 64.5	321 of 922	130.6	<0.001	93.1	30.4	19.5–44.0

AKI = acute kidney injury; LEA = lower extremity amputation; LEF = lower extremity fasciotomy or compartment syndrome; LEI = lower extremity ischemia; Re-Thx = rethoracotomy for bleeding or tamponade; RRT = renal replacement therapy.

Cheng et al, Ann Thorac Surg. 2014

Extracorporeal Membrane Oxygenation Support in Postcardiotomy Elderly Patients: The Mayo Clinic Experience

Pankaj Saxena, FRACS, PhD, James Neal, CCP, Lyle D. Joyce, MD, PhD, Kevin L. Greason, MD, Hartzell V. Schaff, MD, Pramod Guru, MD, William Y. Shi, MBBS, Harold Burkhart, MD, Zhuo Li, Willian Roxann B. Pike, MD, Dawit T. Haile, MD, and Gregory J. Schears, MD

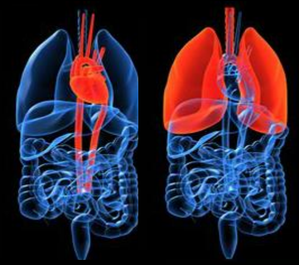
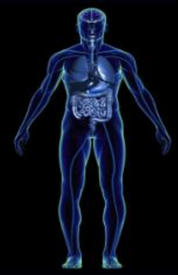
Division of Cardiovascular Surgery, Perfusion Services, and Departments of Anesthesiology and Critical Care Medicine and Biostatistics, Mayo Clinic, Rochester, Minnesota; and University of Melbourne, Melbourne, Australia

(Ann Thorac Surg 2015;99:2053–60)

- Retrospective review from the Mayo Clinic of ECMO for PCCS in >70 y/o
- 45 patients VA-ECMO post op
  - 21 patients (46.6%) died on ECMO
  - In hospital mortality was 76%
- Poor outcomes were associated with pre-op A-fib, chronic renal injury, high lactate levels, elevated inflammatory markers, and high transfusion volumes

Summary: ECMO Clinical Outcomes

Morbidity and mortality rates have not improved over time or with newer technology

Brain	Blood	Kidney	Limb	Heart/Lung	Death
					
Neuro Complications 33% [22,24]	**Bleeding** 21-50% [3,4,13]	**Renal Failure** 32-87% [2,25]	**Amputation** 5-7% [12,4]	**Heart Recovery** 7-29% [4,25]	**Mortality** 47-79% [14,21,27]
Brain Death 18% [4]			**Limb Ischemia** 5-21% [12,21]	Require LVAD or Transplant 5-52% [4,26]	

Mortality increases with duration of support (>2 days) and patient age (> 65)

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CentriMag™ Acute Circulatory Support System

2ND GENERATION SYSTEM: EQUIPMENT

BLOOD PUMP

- 31 mL
- Disposable
- Centrifugal
- Fully Magnetically Levitated

MOTOR

- Each pump requires a separate motor

CONSOLE

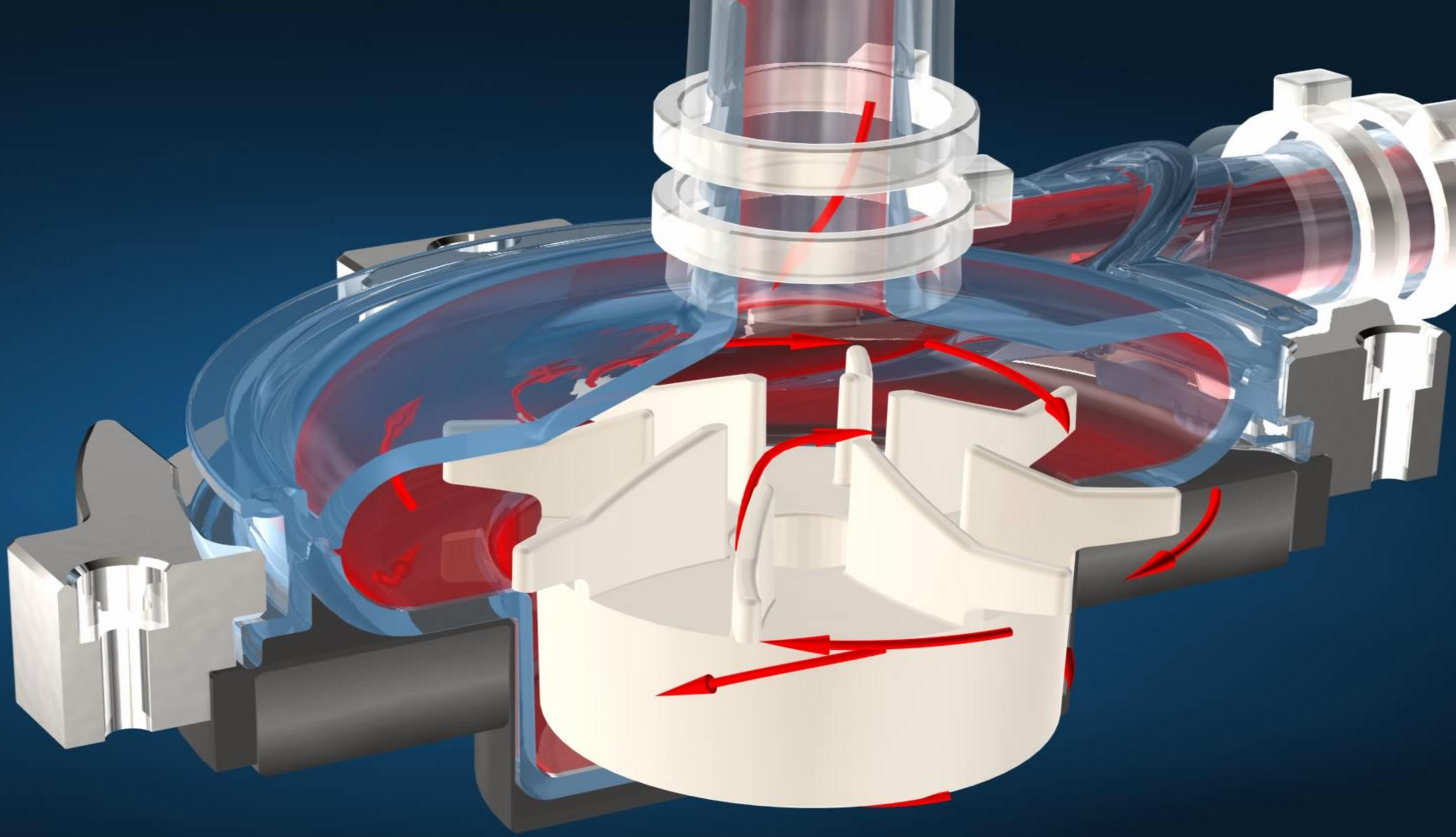
- Each Console supports one CentriMag™ System
- Second console required for backup
- Interface to adjust pump, provides power to the motor and displays pump parameters

OPTIONAL

MONITOR

- **Optional** component
- CentriMag values can be viewed and adjusted in one location

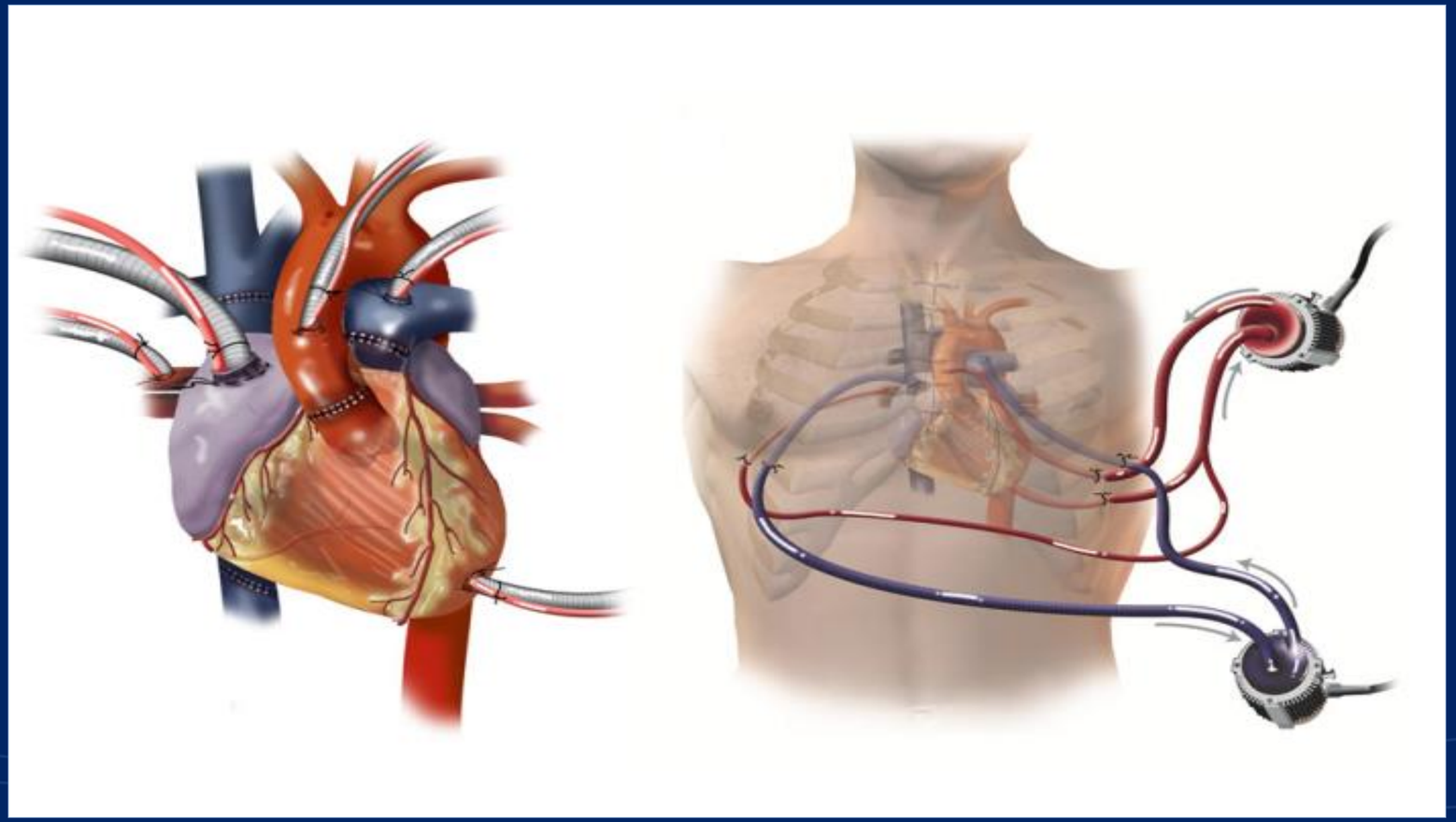
2nd Generation CentriMag™ System Operating Manual (US)



CentriMag LVAD Characteristics

- Magnetically levitated centrifugal blood pump
- Low shear stress of blood components
- LVAD, RVAD or BiVAD
- Allows ECMO (oxygenator)
- Flows up to 10 L/min
- Optimal LV decompression
- Offers longer duration of support
- Bridge to recovery, transplant or long term device

CentriMag LVAD



CentriMag LVAD Disadvantages

- Invasive surgical technique
- Higher incidence of bleeding
- No pulmonary support
- Thromboembolic complications
- Immobilization
- Higher initial cost than ECMO
- May select patients with no exit strategy

CentriMag LVAD Outcomes

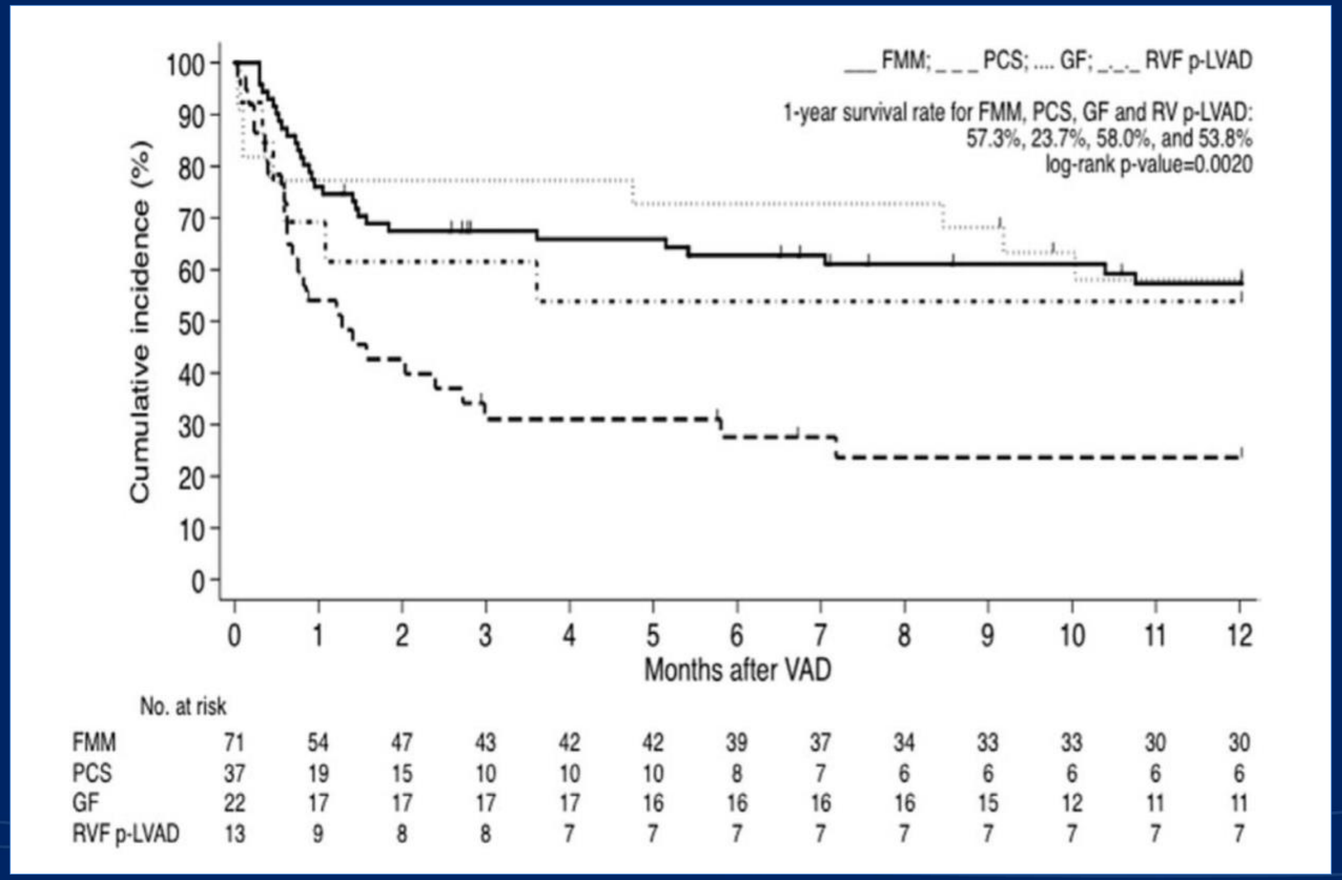
Preoperative Patient Characteristics P/D1

	Overall	FMM	PCS	GF	RVF-p-iLVAD	*P* Value
n	143	71 (AMI 45.1%, DCM 31.0%, ICM 11.3%, other 12.7%)	37 (CABG 35.1%, valve 16.2%, CABG plus valve 27.0%, aorta 13.5%, other 8.1%)	22 (early 72.7%, late 27.3%)	13	
Age, y, mean±SD	52±16	49.9±17.6	58.5±12.5	49.5±15.8	53.8±14.8	0.048
Male sex, %	69.9	73.2	54.1	77.3	84.6	0.082
Whites, %	46.2	45.1	46.0	45.5	53.9	0.95
BMI, kg/m^2, mean±SD	27.4±6.3	26.7±6.8	29.5±6.2	26.3±5.1	26.3±4.4	0.11
CAD, %	54.6	52.1	75.7	36.3	38.5	0.011
Hypertension, %	51.1	45.1	75.7	40.9	30.8	0.005
Hyperlipidemia, %	46.9	40.9	54.1	59.1	38.5	0.32
Diabetes mellitus, %	32.2	33.8	35.1	22.7	30.8	0.77
INTERMACS 1, %	70.6	63.3	83.8	77.3	61.5	0.12
Intubated, %	62.9	70.4	62.2	50.0	46.2	0.18
CVVH, %	22.4	11.3	37.8	27.3	30.8	0.012
IABP, %	54.6	59.2	51.4	59.1	30.8	0.27
ECMO, %	19.6	22.5	21.6	13.6	7.7	0.54
No. of pressors, median (IQR)	2 (1–2)	1 (1–2)	2 (1–3)	2 (1–3)	2 (1–2)	0.057
No. of pressors and inotropes, median (IQR)	3 (2–4)	2 (1–3)	4 (2–4)	3 (2–4)	3 (2–3.5)	0.049

AMI indicates acute myocardial infarction; BMI, body mass index; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CVVH, continuous veno-venous hemofiltration; DCM, dilated cardiomyopathy; ECMO, extracorporeal membrane oxygenation; FMM, failure of medical management; GF, graft failure; IABP, intra-aortic baloon pump; ICM, ischemic cardiomyopathy; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support; IQR, interquartile range; PCS, postcardiotomy shock; and RVF-p-iLVAD, right ventricular failure postimplantable left ventricular assist devices.

Takayama et al, Circ Heart Fail. 2014

CentriMag LVAD Outcomes



Takayama et al, Circ Heart Fail. 2014

CentriMag LVAD Outcomes

Complications

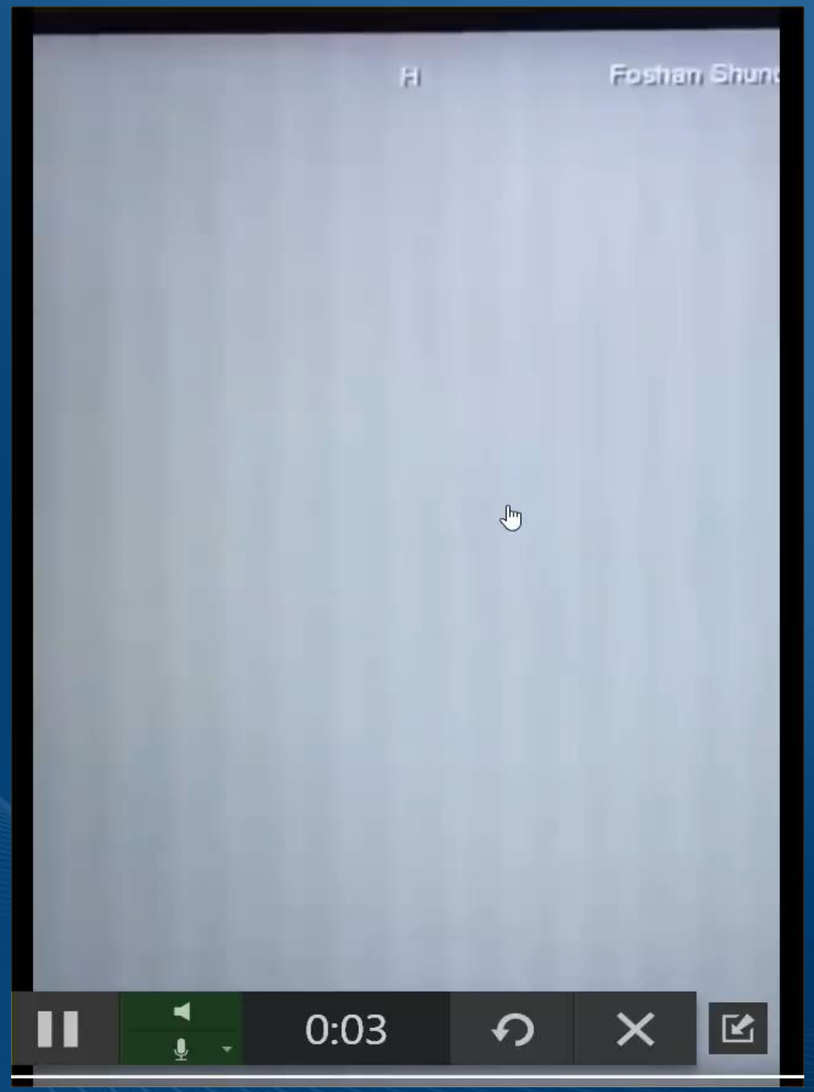
n	All device runs (158)	BiVAD (105)	LVAD (12)	RVAD (41)
Duration of support in days, mean (±SD), range, median (IQR)	20.5 (±20.6), <1–145, 14.0 (8.0–26.0)	21.1 (±20.8), 0–145, 14.0 (8.0–27.0)	18.8 (±17.1), 1–56, 15.5 (7.5–22.0)	19.5 (±21.4), 1–104, 12.0 (7.0–22.0)
Hemorrhagic, %				
Mediastinal re-exploration	20.9	21.9	16.7	19.5
GI bleeding	9.5	11.4	0	7.3
Major bleed	32.9	34.3	16.7	34.2
Neurological, %				
CVA	13.9	16.2	16.7	7.3
Infection, %				
UTI	24.8	25	25	24.4
Pneumonia	27.9	22.9	33.3	39
Mediastinitis	3.8	3.8	8.3	2.4
Bacteremia	16.5	13.3	8.3	2.8

BiVAD indicates biventricular assist device; CVA, cerebrovascular accident; GI, gastrointestinal; IQR, interquartile range; LVAD, left ventricular assist device; RVAD, right ventricular assist device; and UTI, urinary tract infection.

Takayama et al, Circ Heart Fail. 2014

ABIOMED®

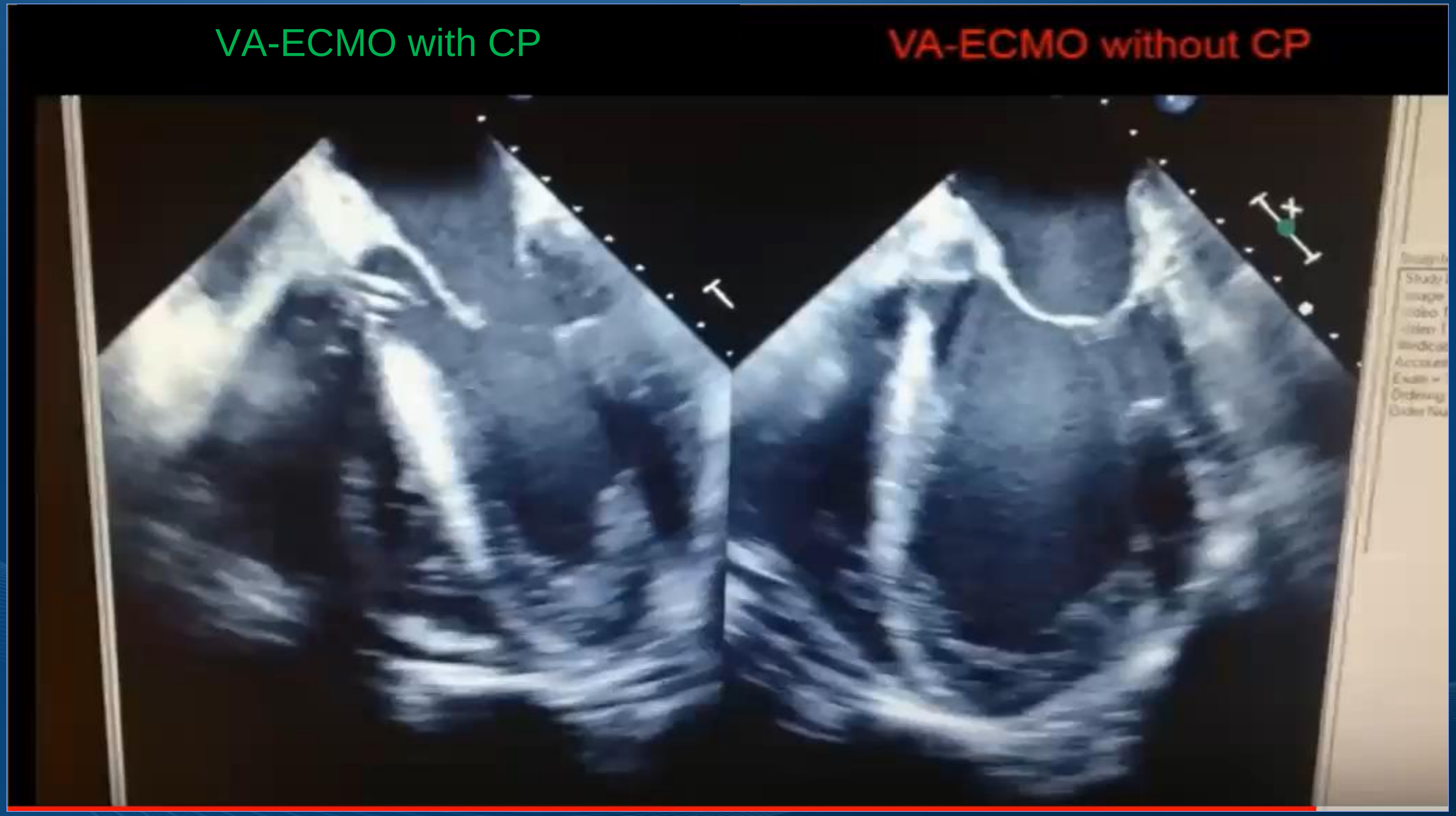
Retrograde Perfusion During ECMO



- Note pigtail via axillary artery in ascending aorta
- Dye injected into ascending aorta is static
- Aortic valve opening very little
- Note flow coming up from below from ECMO
- Finally, note the dye entering the innominate artery supplying the brain
- If all the dye containing blood was deoxygenated, the heart and brain would be at risk

30

LV VENTING: IMPELLA® + ECMO



Courtesy of Navin Kapur, MD

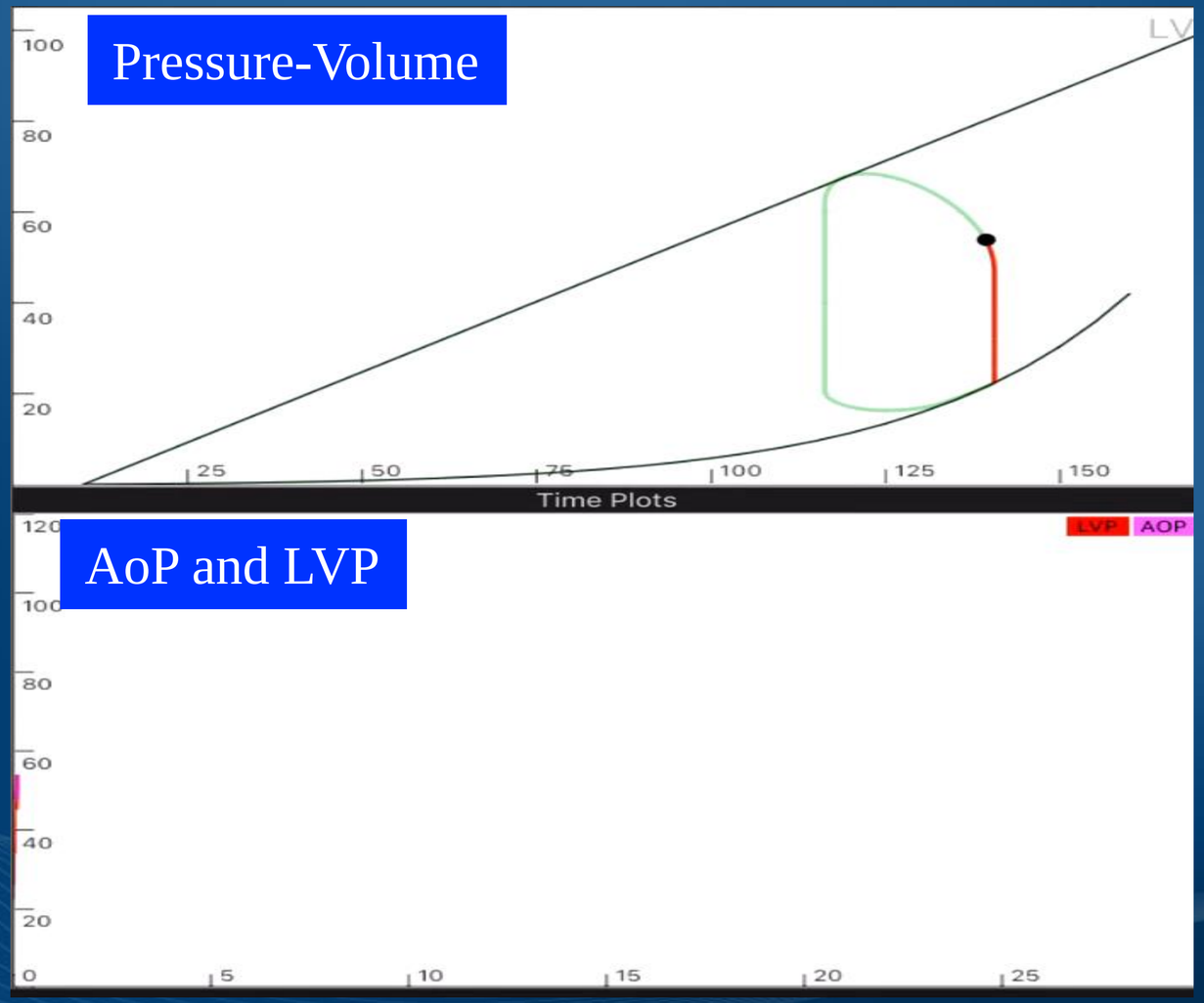
Energetics of ECMO – LV Loading

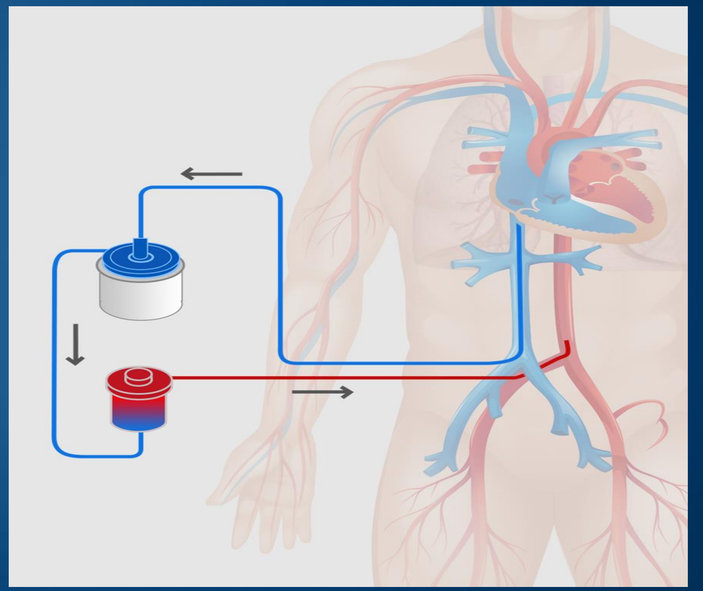
↑ **Afterload**

↑ **Preload**

↑ **AoP**

↑ **LVP**





Hemodynamic Effects of ECMO

Flow

AOP

EDV, EDP

Wall Tension

Mechanical Work

Microvascular Resistance

Coronary Flow

Cardiac Power Output

O_2 Supply

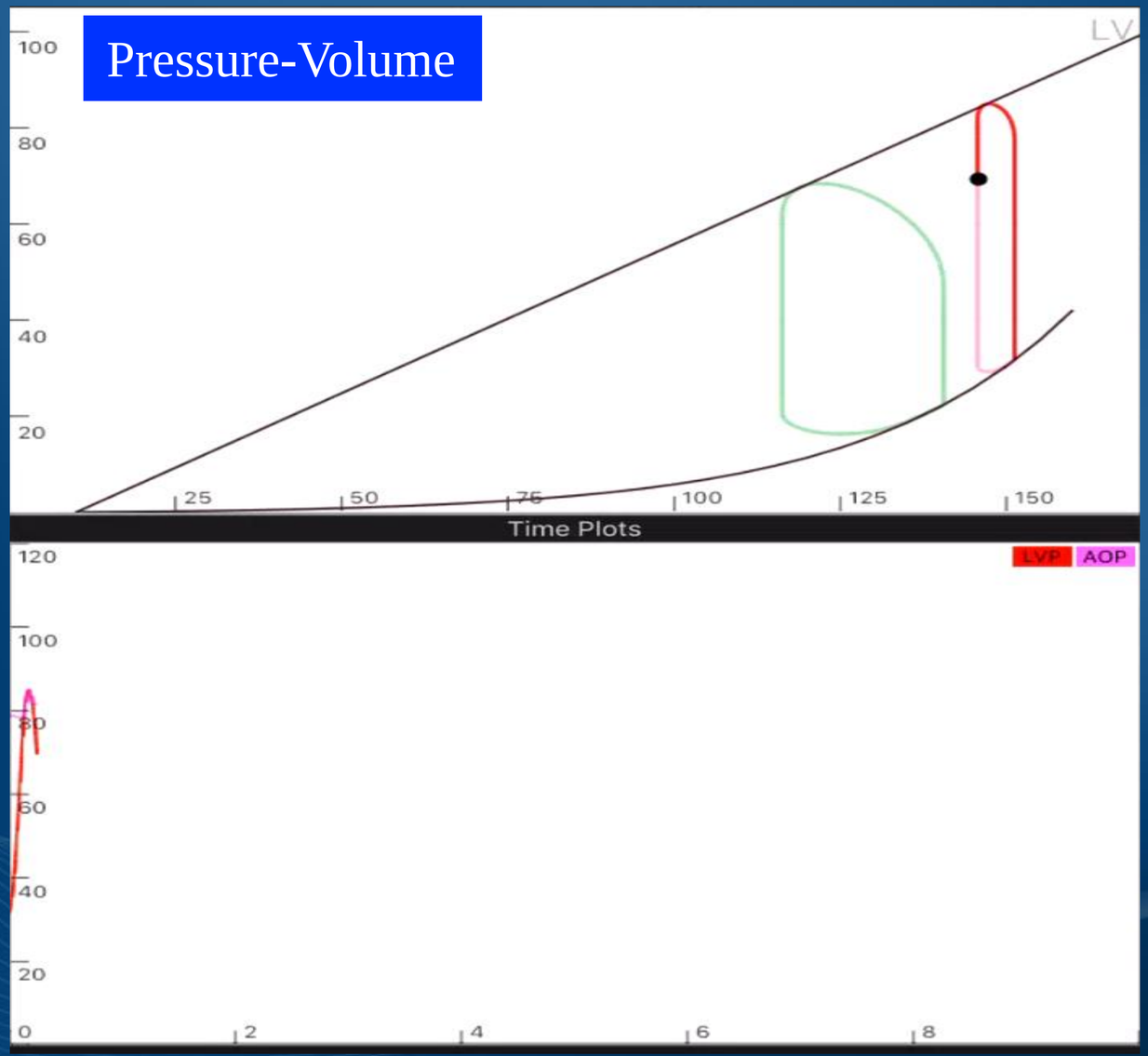
O_2 Demand

Hemodynamic Protection

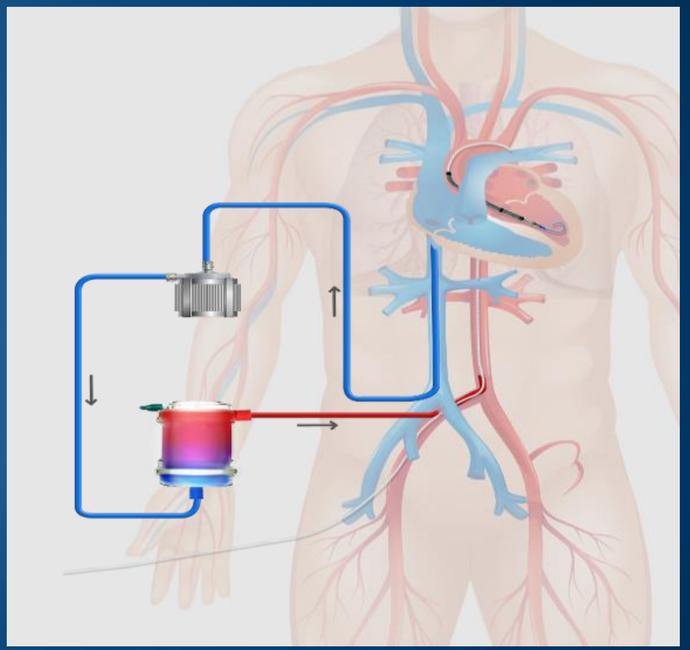
Loads the Heart

Simultaneous Impella® + ECMO Unloading

↑ **Afterload**
↑ **Preload**



AoP
LVP

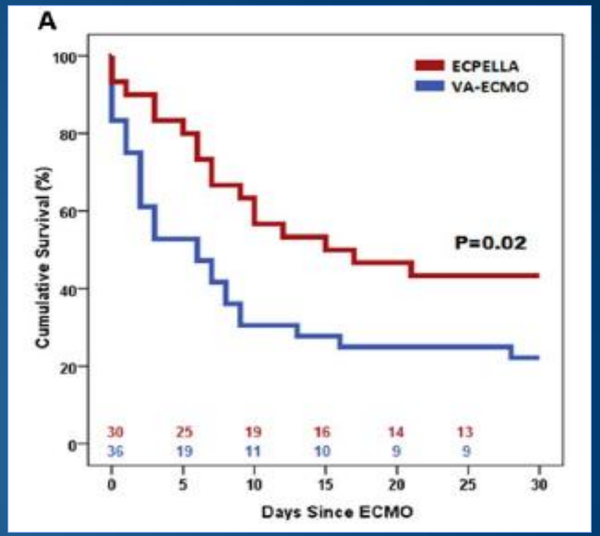


ASAIO Journal 2018 Adult Circulatory Support

Simultaneous Venoarterial Extracorporeal Membrane Oxygenation and Percutaneous Left Ventricular Decompression Therapy with Impella Is Associated with Improved Outcomes in Refractory Cardiogenic Shock

Sandeep M. Patel,* Jerry Lipinski,† Sadeer G. Al-Kindi,‡ Toral Patel,§ Petar Saric,§ Jun Li,‡ Fahd Nadeem,‡ Thomas Ladas,§ Amer Alaiti,‡ Ann Phillips,‡ Benjamin Medalion,‡ Salil Deo,‡ Yakov Elgudin,‡ Marco A. Costa,‡ Mohammed Najeeb Osman,‡ Guilherme F. Attizzani,‡ Guilherme H. Oliveira,‡ Basar Sareyyupoglu,‡ and Hiram G. Bezerra‡

- Retrospective review from UH Cleveland of 66 ECMO patients
- 30 ECMO+Impella® and 36 VA-ECMO
- Demonstrated benefits of ECMO+Impella vs VA-ECMO
  - Survival – 43% vs 22% (p=0.02)
  - Survival – HR 0.52 (0.29-0.93); p=0.027
    - Suggests a 50% mortality reduction with ECMO+Impella
    - More ECMO+Impella patients wean than VA-ECMO (70% VS 44%; p = 0.048)
  - Heart recovery - 40% vs 22% Maximal inotropic score after day 1 was higher in VA-ECMO
  - No differences in major complication rates including hemolysis



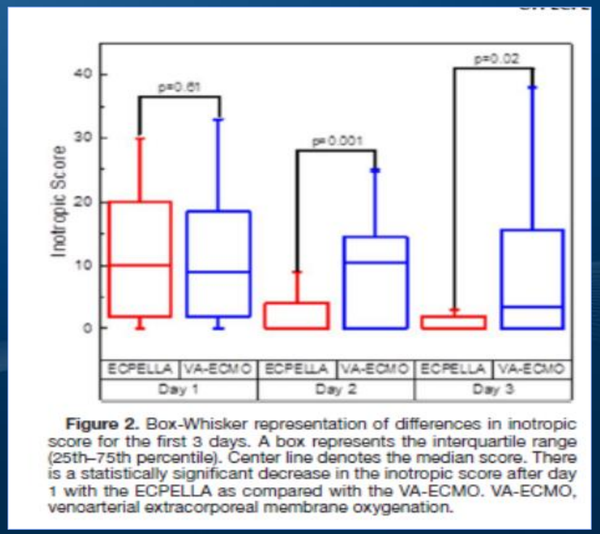


Figure 2. Box-Whisker representation of differences in inotropic score for the first 3 days. A box represents the interquartile range (25th–75th percentile). Center line denotes the median score. There is a statistically significant decrease in the inotropic score after day 1 with the ECPELLA as compared with the VA-ECMO. VA-ECMO, venoarterial extracorporeal membrane oxygenation.

European Journal of Heart Failure (2016)
doi:10.1002/ejhf.668

Concomitant implantation of Impella® on top of veno-arterial extracorporeal membrane oxygenation may improve survival of patients with cardiogenic shock

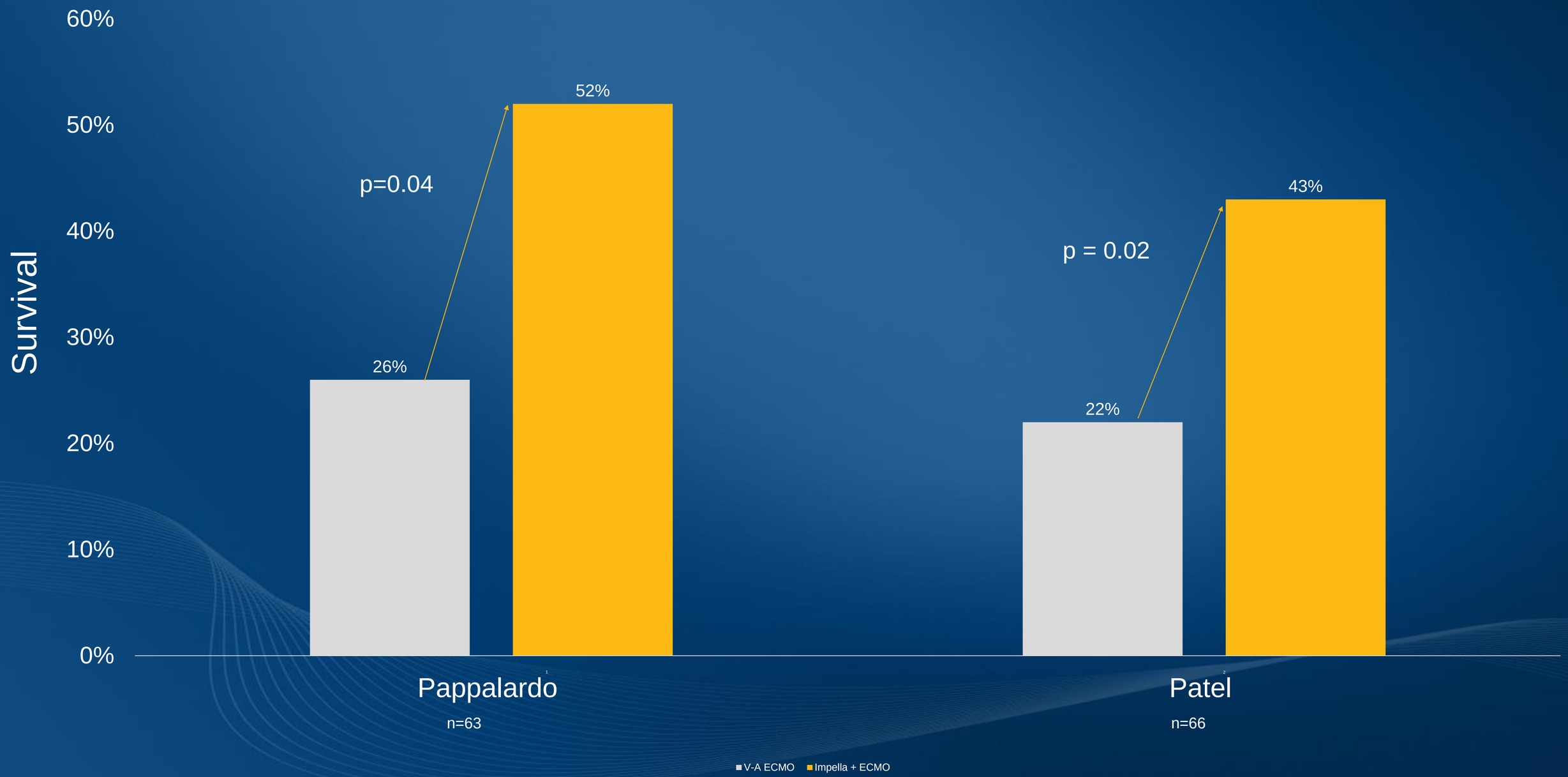
Federico Pappalardo[1†*], Christian Schulte[2†], Marina Pieri[1], Benedikt Schrage[2], Rachele Contri[3], Gerold Soeffker[4], Teresa Greco[1], Rosalba Lembo[1], Kai Müllerleile[2], Antonio Colombo[3], Karsten Sydow[2], Michele De Bonis[5], Florian Wagner[6], Hermann Reichenspurner[6], Stefan Blankenberg[2,7], Alberto Zangrillo[1], and Dirk Westermann[2,7*]

Table 3 Comparison of major outcomes between patients treated with veno-arterial extracorporeal membrane oxygenation (ECMO) and Impella and patients treated with veno-arterial ECMO only in the propensity score matching sample ($n = 63$)

Parameter	Total ($n = 63$)	ECMO + Impella ($n = 21$)	ECMO ($n = 42$)	P-value
Hospital mortality, *n* (%)	41 (65)	10 (48)	31 (74)	0.04
Bridge to next therapy or recovery, *n* (%)	28 (44)	13 (62)	15 (36)	0.048
Weaning from MCS, *n* (%)	26 (41)	10 (48)	16 (28)	0.047
Bridge to recovery, *n* (%)	19 (30)	8 (38)	11 (26)	0.3
Bridge to VAD, *n* (%)	8 (13)	4 (19)	4 (9.5)	0.5
Bridge to cardiac transplantation, *n* (%)	0	0	0	
Duration of ECMO, h	120 (36–234)	148 (72–239)	73.5 (29–217)	0.2
Duration of MV, h	93 (29–228)	163 (90–228)	48 (17–265)	0.04
CVVH, *n* (%)	18 (29)	10 (48)	8 (19)	0.02
Haemolysis, *n* (%)	30 (48)	16 (76)	14 (33)	0.004
Major bleeding, *n* (%)	20 (32)	8 (38)	12 (29)	0.6
Minor bleeding, *n* (%)	14 (22)	4 (19)	10 (24)	0.8
LVEF at weaning, %	45.5 (30–55)	52.5 (47–55.5)	37.5 (25–50)	0.13

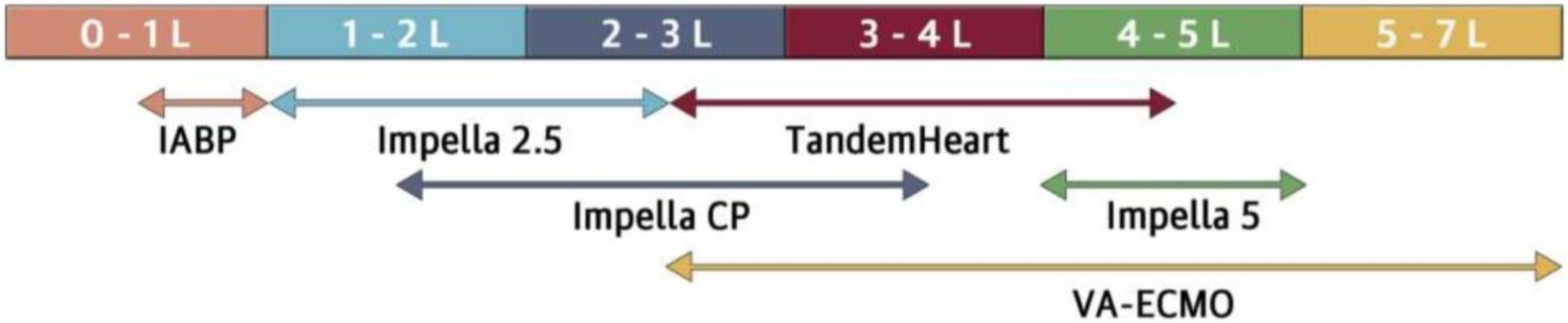
CVVH, continuous veno-venous haemofiltration; MCS, mechanical circulatory support; MV, mechanical ventilation; VAD, ventricular assist device.

IMPROVED SURVIVAL WITH IMPELLA® + ECMO

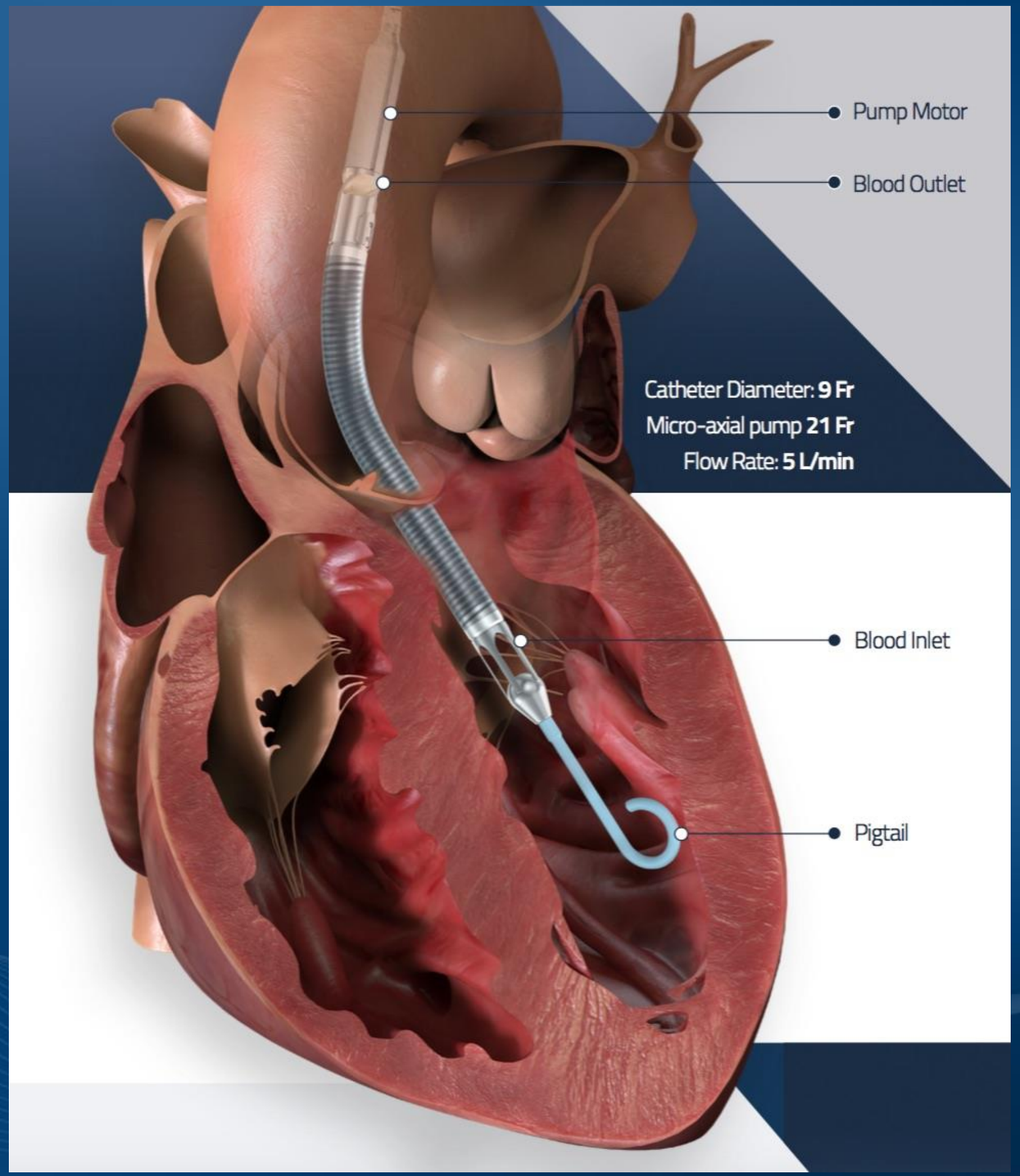


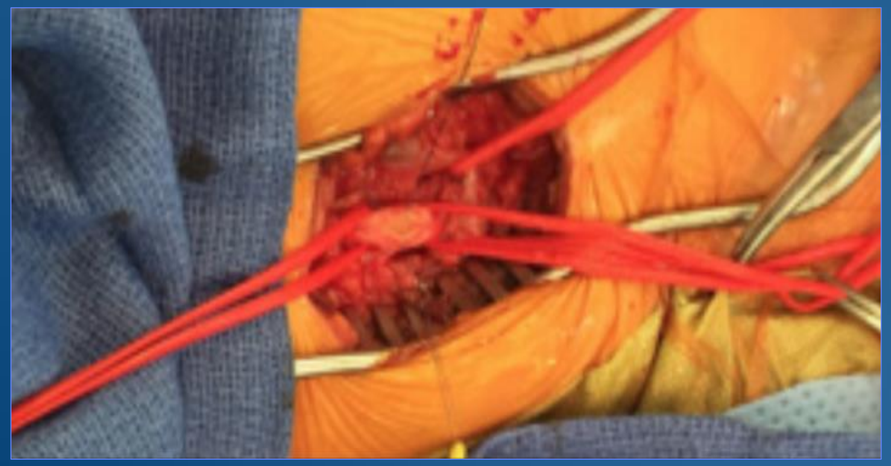
1. Pappalardo F, Schulte C, Pieri M, et.al. Concomitant implantation of Impella on top of veno-arterial extracorporeal Membrane oxygenation may improve survival of patients with cardiogenic shock. European Journal of Heart Failure (2017) 19, 404-412
2. Patel S, Lipinski J, Al-Kindi S et.al. Simultaneous Venoarterial Extracorporeal Membrane Oxygenation and Percutaneous Left Ventricular Decompression Therapy with Impella Is Associated with Improved Outcomes in Refractory Cardiogenic Shock. ASAIO 2018

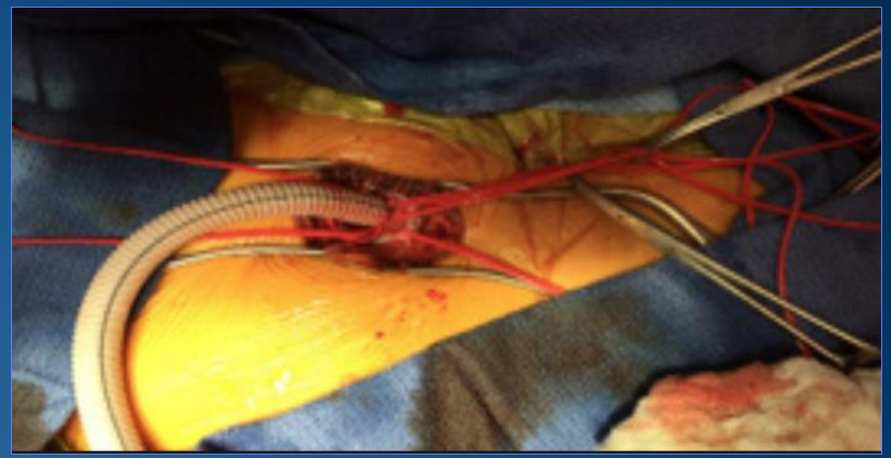
IMPELLA DEVICES

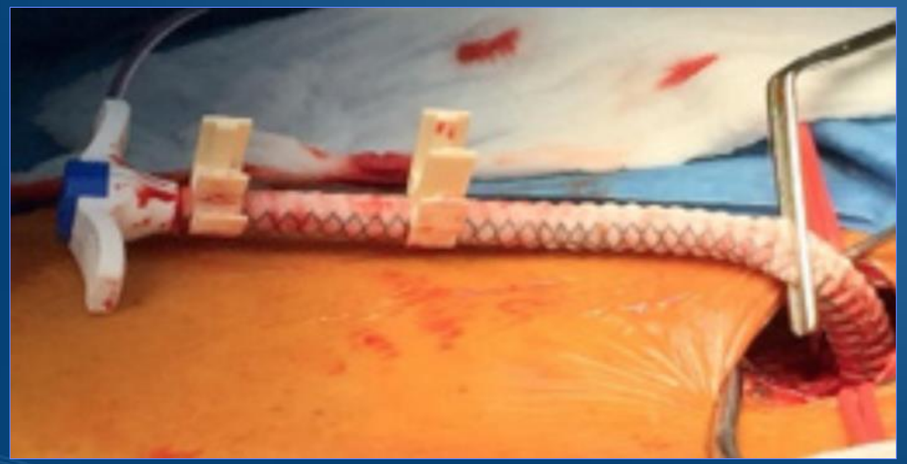


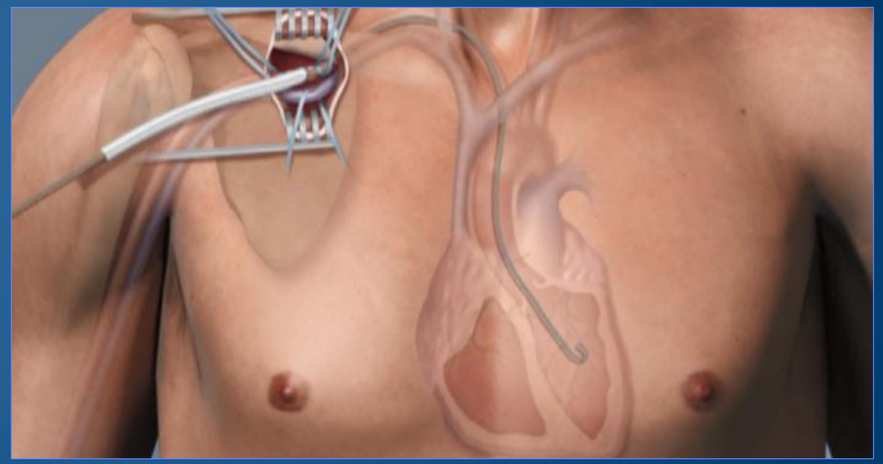
O'Neil W et al, J Am Coll Cardiol Intv. 2016;9(9):871-883

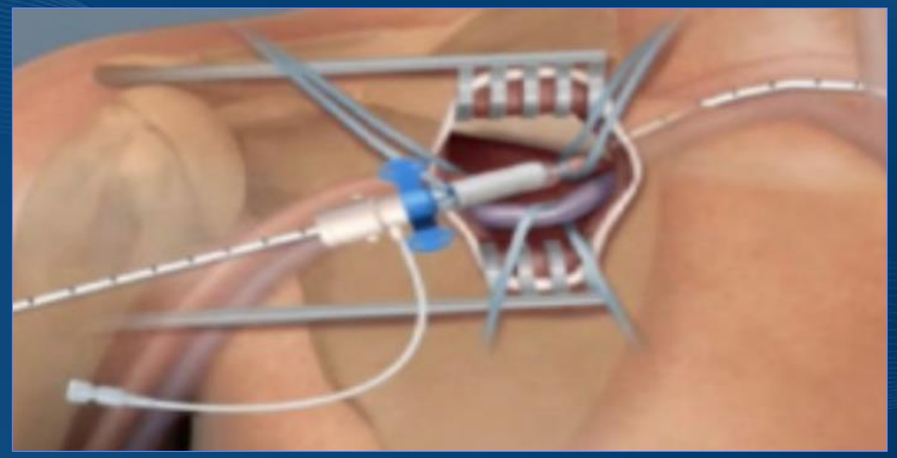

Pump Motor
Blood Outlet
Catheter Diameter: 9 Fr
Micro-axial pump 21 Fr
Flow Rate: 5 L/min
Blood Inlet
Pigtail

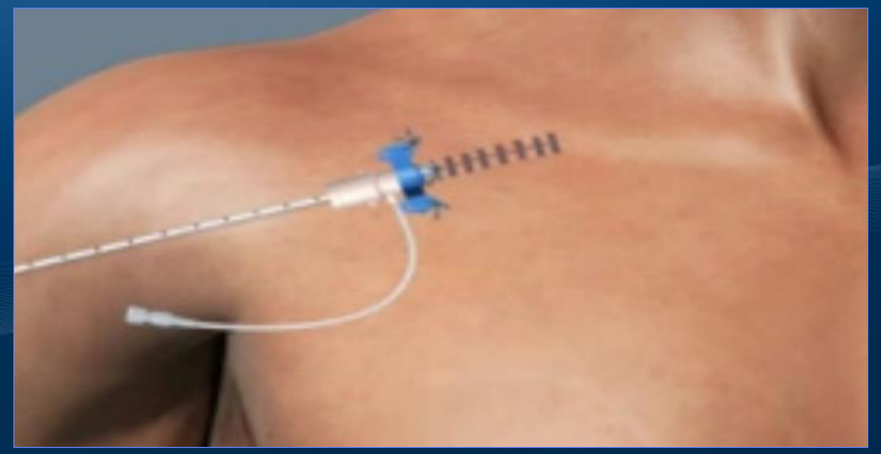












Impella 5.0 Outcomes

The RECOVER I: A multicenter prospective study of Impella 5.0/LD for postcardiotomy circulatory support

Bartley P. Griffith, MD,[a] Mark B. Anderson, MD,[b] Louis E. Samuels, MD,[c] Walter E. Pae, Jr, MD,[d] Yoshifumi Naka, MD, PhD,[e] and O. Howard Frazier, MD[f]

Objectives: Cardiogenic shock after cardiac surgery is accompanied by a high mortality rate. Early institution of hemodynamic support with a versatile, easy to insert left ventricular assist device might help bridge patients to recovery or to the next therapy, and improve the outcomes.

Methods: Patients developing cardiogenic shock or low cardiac output syndrome after being weaned off cardiopulmonary bypass were enrolled in a prospective single-arm feasibility study (RECOVER I). The primary safety endpoint was the frequency of major adverse events (death, stroke) at 30 days or discharge, whichever was longer. The primary efficacy endpoint was survival of the patient to implementation of the next therapy, which included recovery at 30 days after device removal and bridge-to-other-therapy.

Results: Sixteen patients provided informed consent and were enrolled in the study. Hemodynamics improved immediately after the initiation of mechanical support: cardiac index, 1.65 versus 2.7 L/min/m^2 ($P = .0001$); mean arterial pressure, 71.4 versus 83.1 mm Hg ($P = .01$); and pulmonary artery diastolic pressure, 28.0 versus 19.8 mm Hg ($P < .0001$). The pump provided an average of 4.0 ± 0.6 L/min of flow for an average duration of 3.7 ± 2.9 days (range, 1.7–12.6). The primary safety endpoint occurred in 2 patients (13%; 1 stroke and 1 death). For the primary efficacy endpoint, recovery of the native heart function was obtained in 93% of the patients discharged, with bridge-to-other-therapy in 7%. Survival to 30 days, 3 months, and 1 year was 94%, 81%, and 75%, respectively.

Conclusions: The use of the Impella 5.0/left direct device is safe and feasible in patients presenting with postcardiotomy cardiogenic shock. The device was rapidly inserted, enabled early support, and yielded favorable outcomes. (J Thorac Cardiovasc Surg 2013;145:548-54)

Impella 5.0 Outcomes

TABLE 1. Patient Characteristics and Outcomes Reported in Studies Included in the Meta-analysis

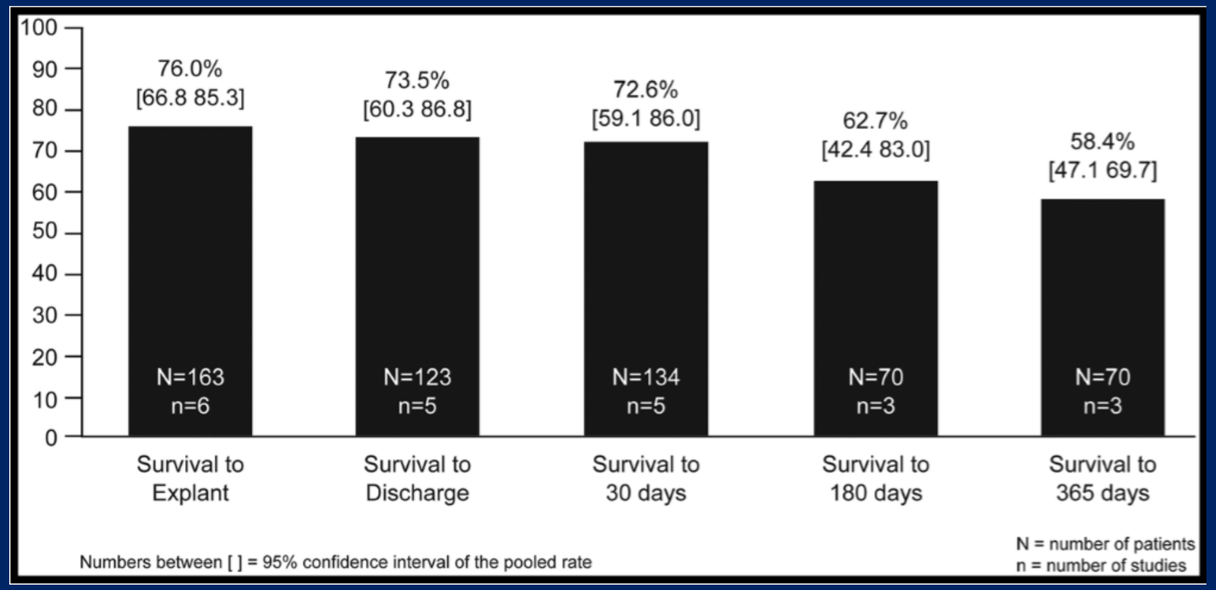
First Author (Year)	Year of Publication (Patient Enrolment)	No. Patients	Indications of Support (No. Patients)	Type of Impella	Access Site	Age, Mean ± SD or Median (IQR), y	Baseline LVEF, Mean ± SD or Median (IQR), %	Duration of Support, Mean ± SD or Median (IQR), d	Survival to Device Removal	Survival to Discharge	30-Day Survival
Higgins[16]	2011 (2007–2009)	29	AMICS (3) PCCS (6) ADHF (12) Other (8)	Impella 5.0	29 femoral	NA	NA	NA	72.4%	72.4%	NA
Griffith[14]*	2013 (2006–2008)	16	PCCS (16)	Impella 5.0 Impella LD	11 femoral 5 ascending aorta	58.4 ± 9	23 ± 7	3.7 ± 2.9	94%	94%	94%
Gaudard[17]	2015 (2008–2013)	40	AMICS (16) PCCS (7) ADHF (12) Other (4)	Impella 5.0	10 axillary 30 femoral	57 (48–63)	10 (7–10)	7 (5–10)	70.0%	NA	65.0%
Bansal[18]	2016 (2011–2014)	24	ADHF (24)	Impella 5.0	24 axillary	51.29 ± 13.85	11.46 ± 3.12	Mean 17.58	70.8%	62.5%	66.7%
Lima[15]	2016 (2009–2015)	40	ADHF (40)	Impella 5.0	30 axillary 10 femoral	55 ± 13	12 ± 5	7 ± 5	75.0%	67.5%	67.5%
Mastroianni[19]	2017 (2010–2012)	14	AMICS (7) PCCS (6) Other (1)	Impella 5.0	14 axillary	64 ± 15	20.7 ± 5.3	8.5 ± 4.7	78.6%	64.3%	64.3%

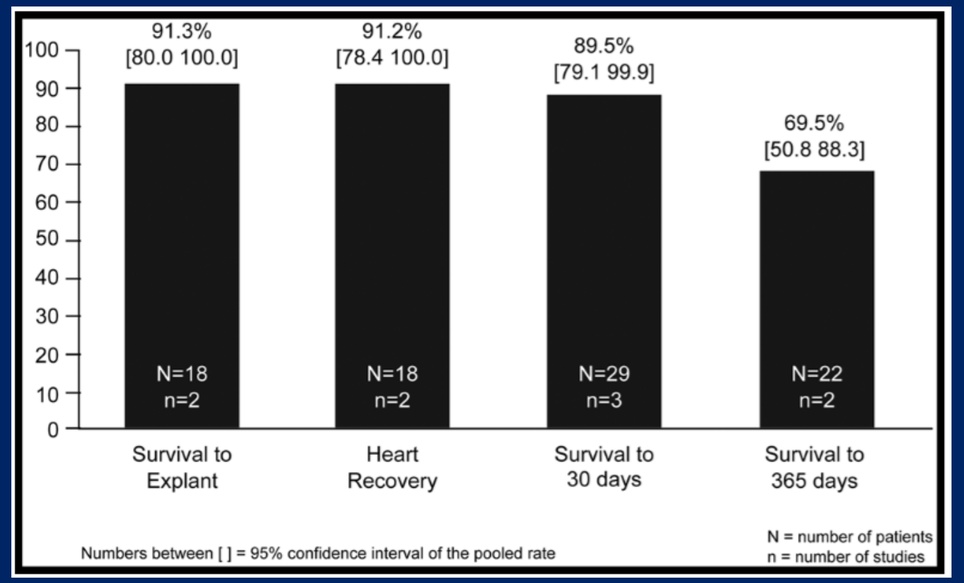
*Griffith et al. study is an Impella 5.0/LD safety and efficacy study approved by the FDA (NCT00596726).

ADHF, acute decompensated heart failure; AMICS, acute myocardial infarction complicated by cardiogenic shock; IQR, interquartile range; LVEF, left ventricular ejection fraction; NA, not applicable; PCCS, postcardiotomy cardiogenic shock.

Batsides et al, Innovations 2018

Impella 5.0 Outcomes





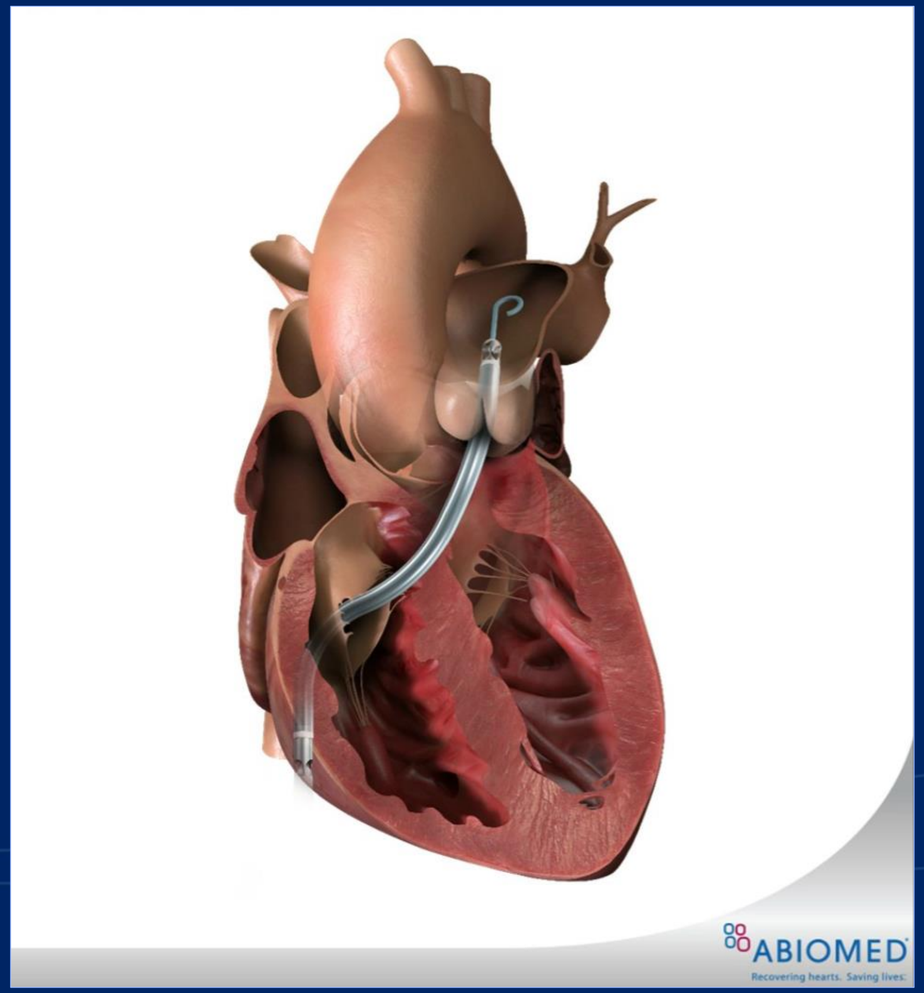
Batsides et al, Innovations 2018

Impella RP Outcomes

Outcomes of patients with right ventricular failure requiring short-term hemodynamic support with the Impella RP device

Mark Anderson, MD,[a] D. Lynn Morris, MD,[b] Daniel Tang, MD,[c] George Batsides, MD,[d] Ajay Kirtane, MD,[e] Ivan Hanson, MD,[f] Perwais Meraj, MD,[g] Navin Kapur, MD,[h] and William O'Neill, MD[i]

From the [a]Division of Cardiothoracic Surgery, Einstein Healthcare Network, Philadelphia, Pennsylvania, USA; [b]Division of Cardiology, Einstein Healthcare Network, Philadelphia, Pennsylvania, USA; [c]Division of Cardiothoracic Surgery, Virginia Commonwealth University, Richmond, Virginia, USA; [d]Division of Cardiothoracic Surgery, Rutgers / Robert Wood Johnson, New Brunswick, New Jersey, USA; [e]Division of Cardiology, Columbia University / New York-Presbyterian Hospital and the Cardiovascular Research Foundation, New York, New York, USA; [f]Department of Cardiovascular Medicine, William Beaumont Hospital, Royal Oak, Michigan, USA; [g]Division of Cardiology, Northwell Health, Manhasset, New York, USA; [h]Division of Cardiology, Tufts Medical Center, Boston, Massachusetts, USA; and the [i]Center for Structural Heart Disease, Henry Ford Hospital, Detroit, Michigan, USA.



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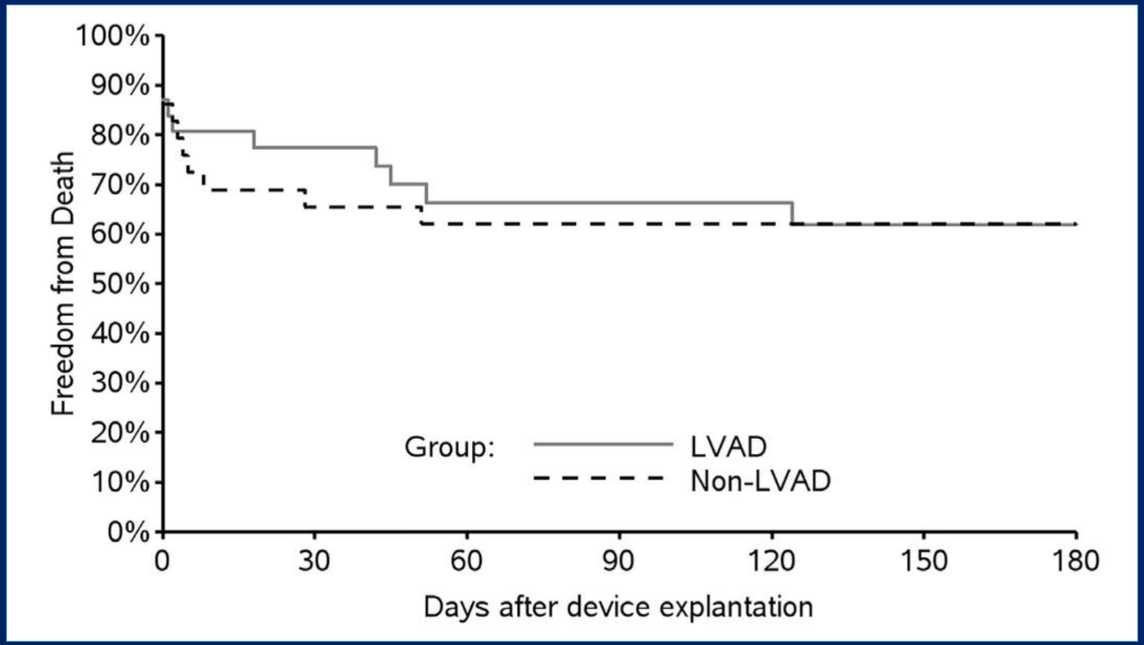

Anderson et al, J Heart Lung Transplant. 2018

Conclusions

- Post Cardiotomy shock continues to be a major clinical challenge and is associated with high mortality risk
- There are no randomized trials to help us to elaborate guidelines
- Inotropes and IABP are the first line of therapy but have limitations
- Mechanical circulatory support is necessary in patients with refractory post cardiotomy shock but is associated with high cost and complications
- ECMO is a preferred strategy at many centers but can be associated with significant complications and does not promote LV recovery

Conclusions

- CentriMag LVAD unloads the LV but requires implant and explant invasive techniques that can be associated with bleeding and trauma
- Impella 5.0 provides excellent hemodynamic support with direct unloading of the LV
- Impella 5.0 can be inserted with less surgical trauma, allows for early mobilization and may be associated with lower incidence of complications
- LV unloading with minimally invasive techniques may play a significant role in LV recovery and ultimately patient survival