

Temporary ventricular assist device support: device selection and pediatric experience

Katsuhide Maeda, MD. PhD

Children's Hospital of Philadelphia

Disclosures

- Surgical consultant for Abbot and Berlin Heart
- Advisory board member for Abiomed

In this presentation

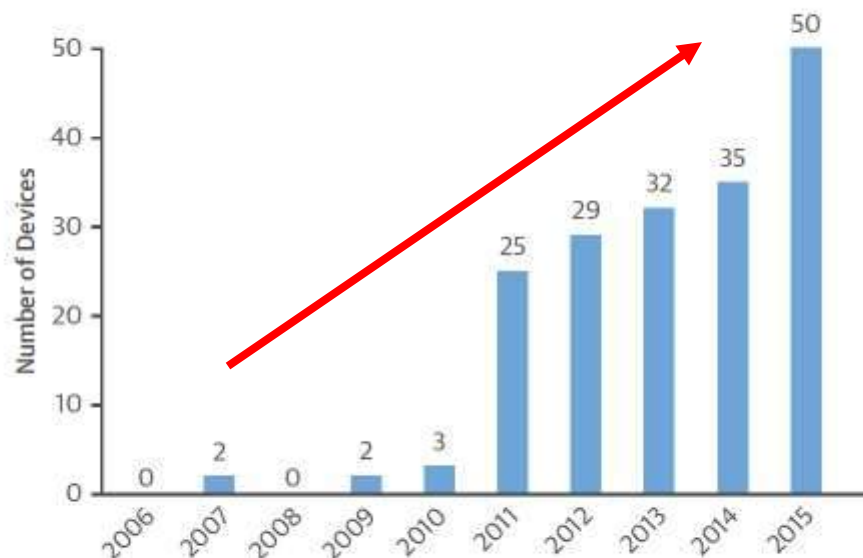
- Trend in temporary circulatory support device in pediatric population
- Device selection and its mechanism
- Pediatric use of temporary circulatory support microaxial support (Impella[®])
- Use of Impella[®] in ECMO patients (ECMELLA, ECPELLA)

Temporary Circulatory Support in U.S. Children Awaiting Heart Transplantation



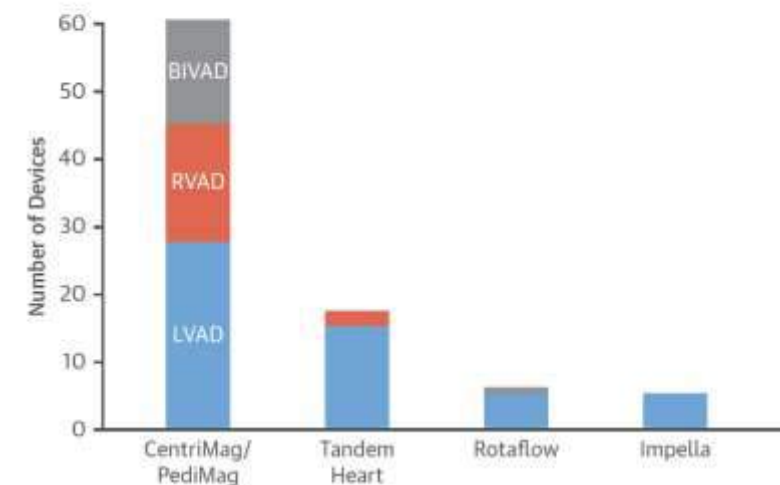
Vamsi V. Yarlagadda, MD,^{a,c} Katsuhide Maeda, MD,^{b,c} Yulin Zhang, PhD,^c Sharon Chen, MD,^{a,c} John C. Dykes, MD,^{a,c} Mary Alice Gowen, RN,^c Paul Shuttleworth, BSN,^c Jenna M. Murray, NP,^c Andrew Y. Shin, MD,^{a,c} Olaf Reinhartz, MD,^{b,c} David N. Rosenthal, MD,^{a,c} Doff B. McElhinney, MD, MS,^{a,c} Christopher S. Almond, MD, MPH^{a,c}

FIGURE 1 U.S. Growth of Temporary Circulatory Support Device Utilization as a Bridge to Transplant Over the Last 10 Years



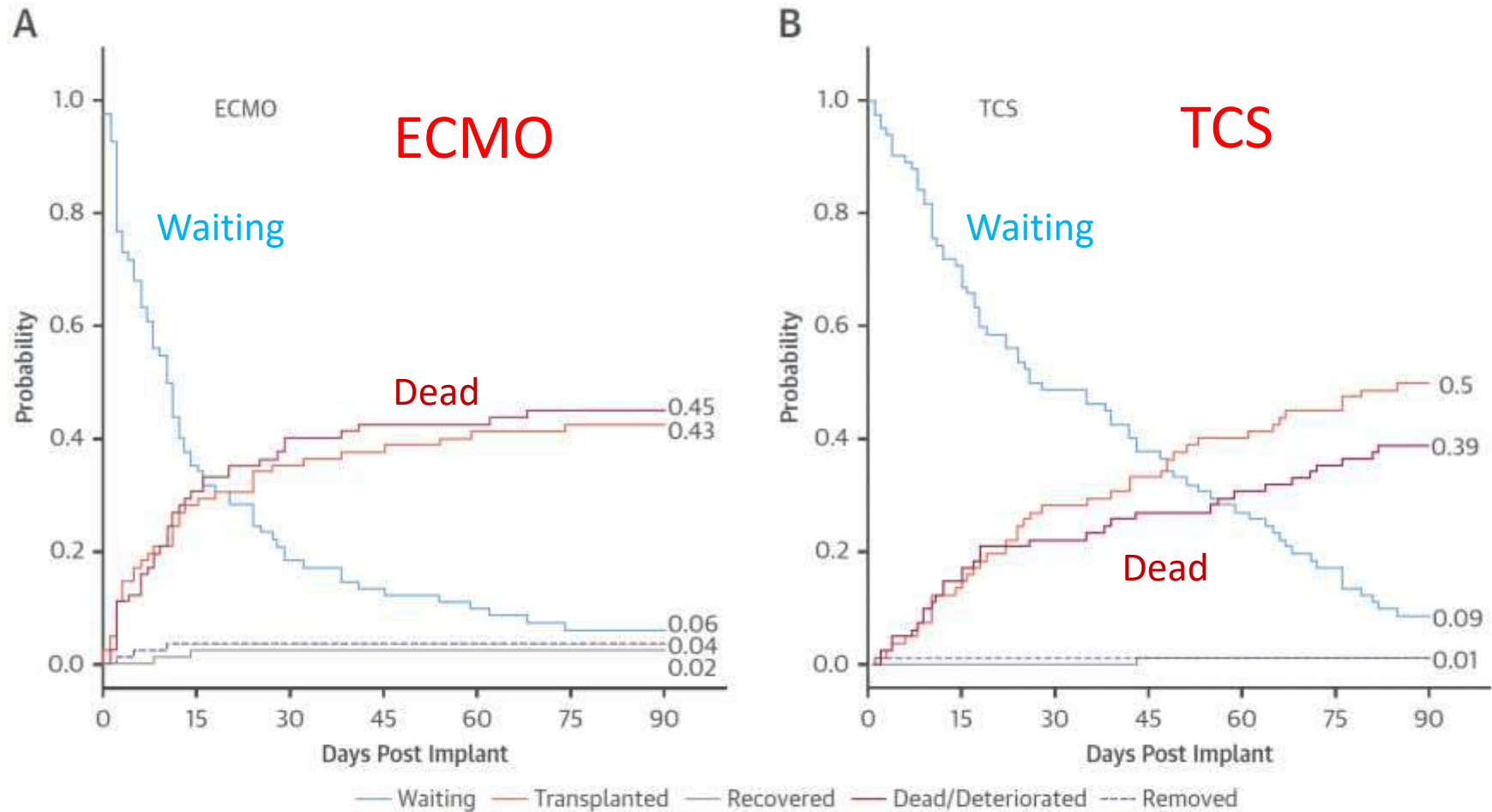
The use of temporary circulatory support devices has grown substantially over the past decade based on Organ Procurement and Transplant Network Registry data.

FIGURE 2 Type and Frequency of Temporary Circulatory Support Device Brands Used in Children as a Bridge to Transplant



The most common temporary circulatory support device brand used in children was the Thoratec CentriMag/PediMag system (Thoratec, Pleasanton, California), which accounted for the majority of device implants, followed by the TandemHeart system (CardiacAssist, Pittsburgh, Pennsylvania), the Maquet Rotaflow System (DataScope/Maquet, Rastatt, Germany), and the Impella system (Abiomed, Danvers, Massachusetts). BIVAD = biventricular assist device; LVAD = left ventricular assist device; RVAD = right ventricular assist device.

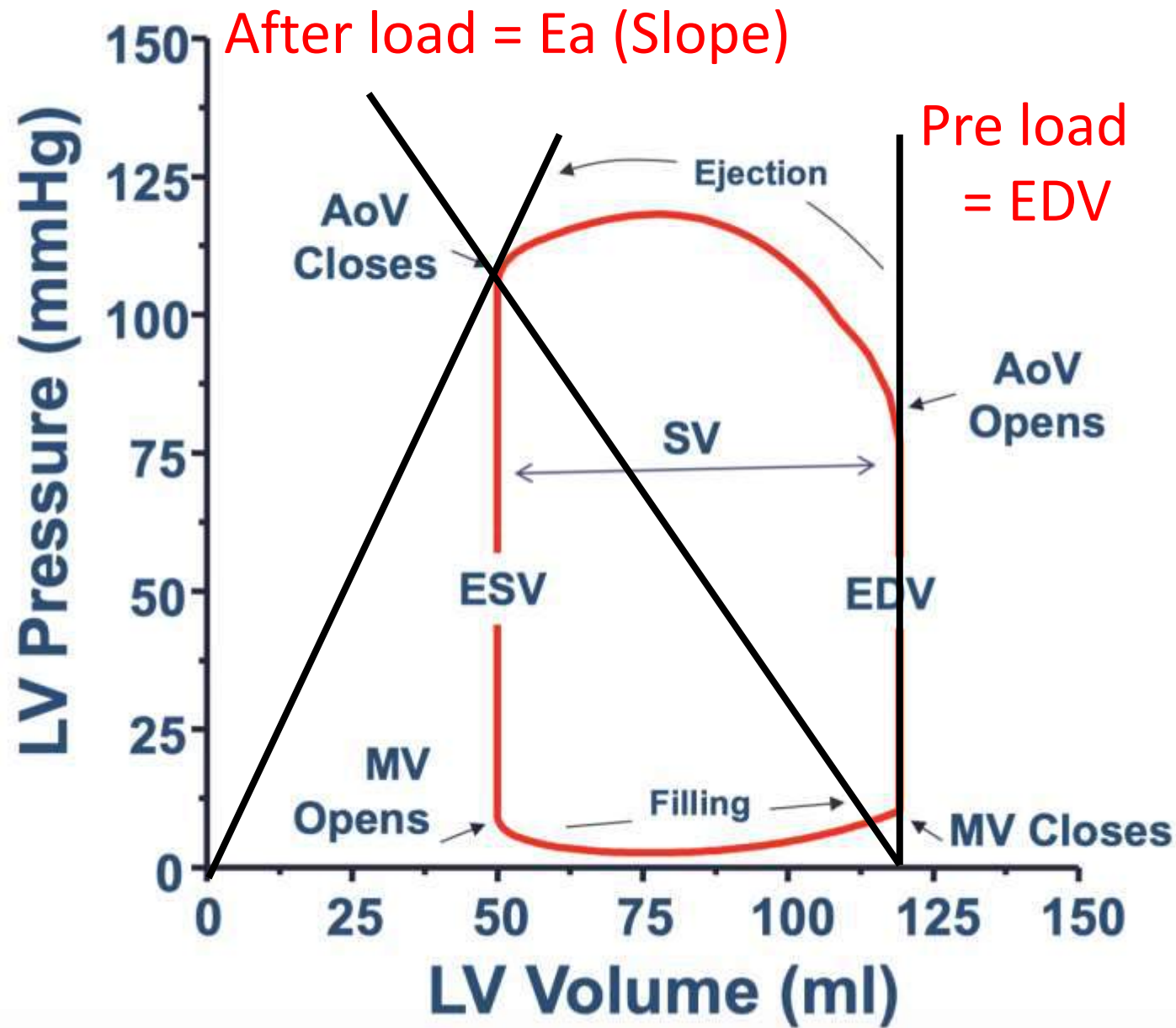
FIGURE 5 Competing Outcomes for PS-Matched Cohort of Children Supported With ECMO and a TCS Device



The x-axis represents the time interval from device implant to transplant, death, or recovery. There is a modest reduction in mortality while awaiting heart transplant for children supported with a TCS device (39%) versus an ECMO device (45%) after propensity matching. **(A)** Competing outcomes for the PS-matched ECMO cohort. **(B)** Competing outcomes for the PS-matched TCS cohort. Abbreviations as in [Figure 4](#).

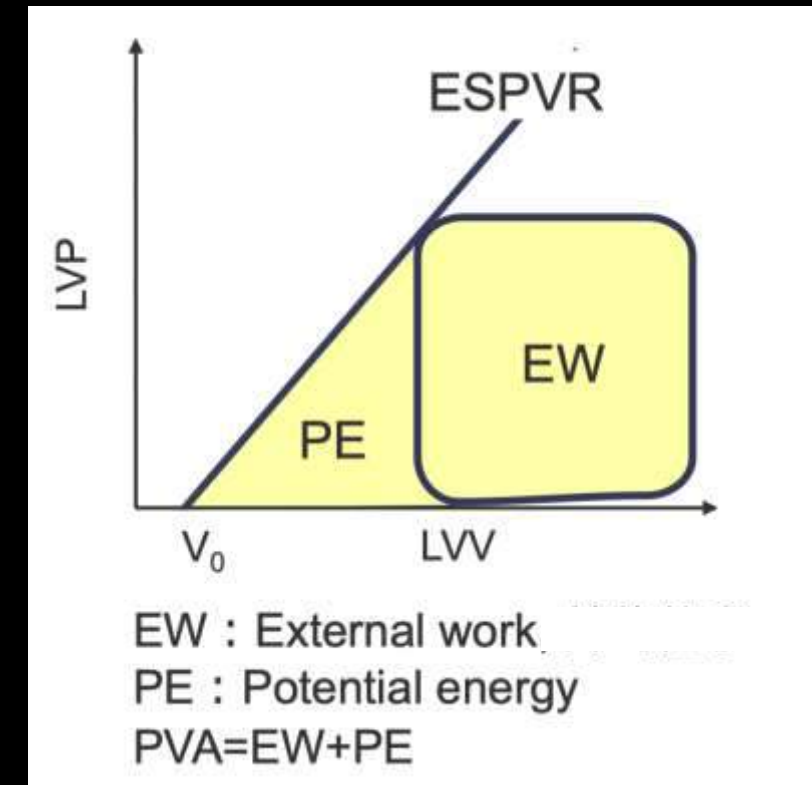
In this presentation

- Trend in temporary circulatory support device
- Device selection and its mechanism
- Pediatric use of temporary circulatory support device
- Use of Impella® in ECMO patients (ECMELLA, ECPELLA)



PV loop

MVO₂ (myocardium oxygen consumption)



Key points for MCS

1. Two separate goals...
 1. maintain systemic circulation, 2. recovery of the heart
2. Total cardiac output = MCS output + native cardiac output
3. What is good for end organs (better total cardiac output) is not necessarily mean a good thing for heart recovery
4. Maintain MVO₂ ($PVA = SW + PE$) low for cardiac recovery
5. Inflow (drainage) cannula location is important

Differences between TCS and long-term durable VAD

Temporary circulatory support (TCS) ...

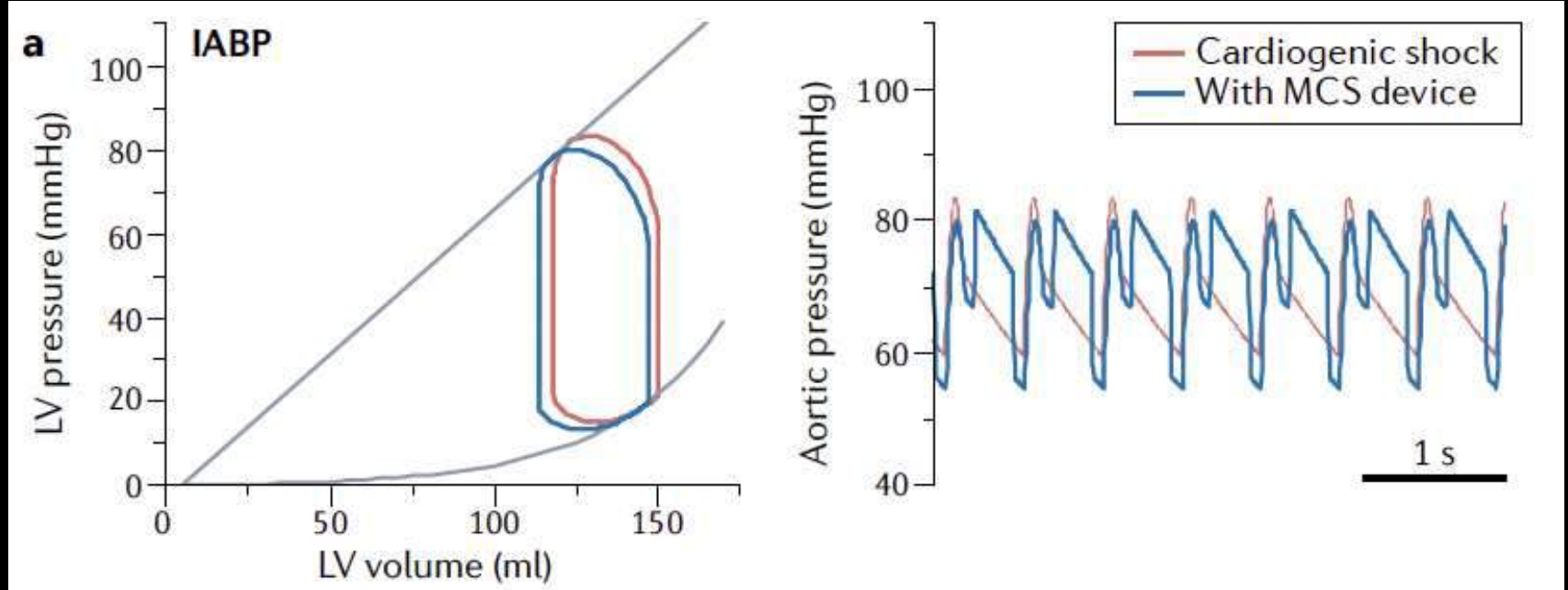
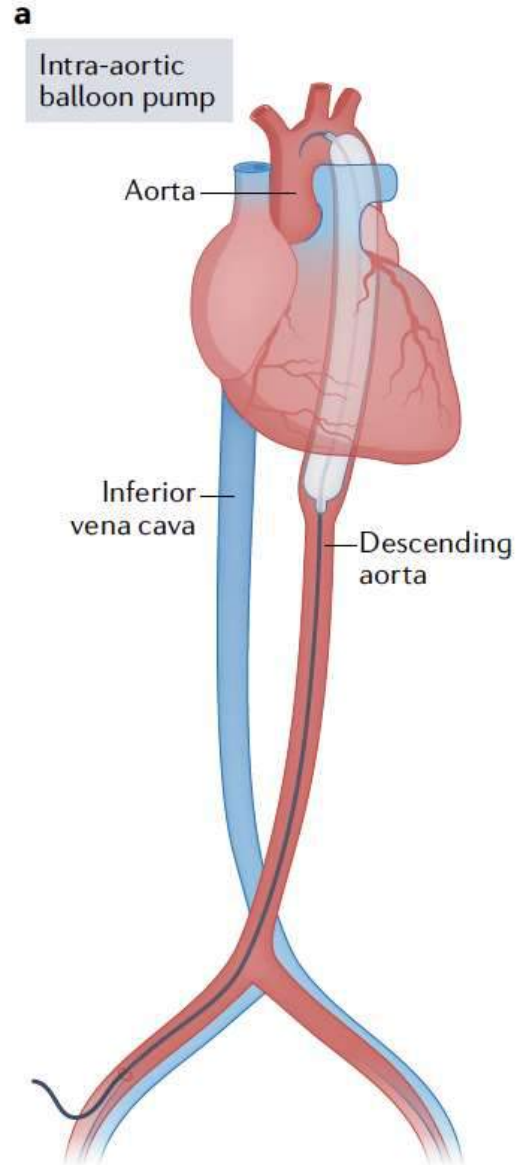
hoping for short-term heart recovery
or as a bridge to VAD/transplant

Long term durable VAD ...

more focus on maintaining systemic circulation
as a destination or a bridge to transplant
long-term heart recovery

IABP

Pulsatile-flow, percutaneous LV device



Total cardiac output ... up

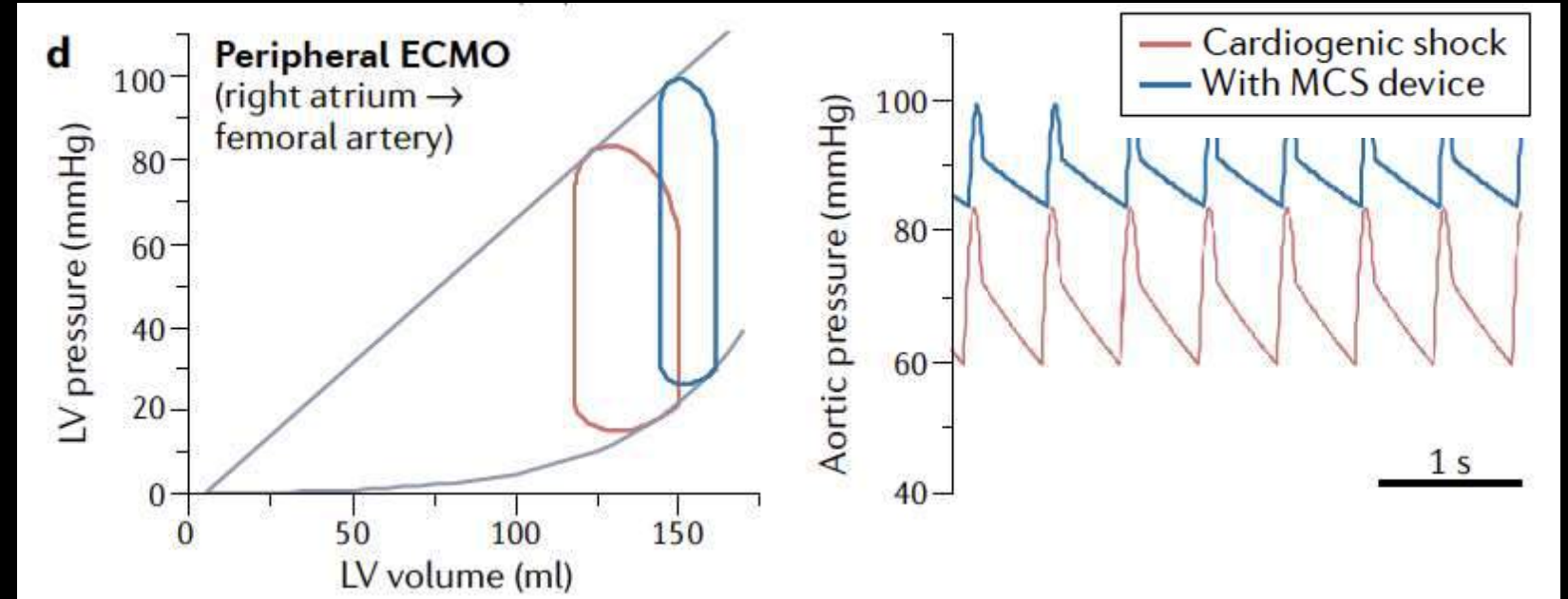
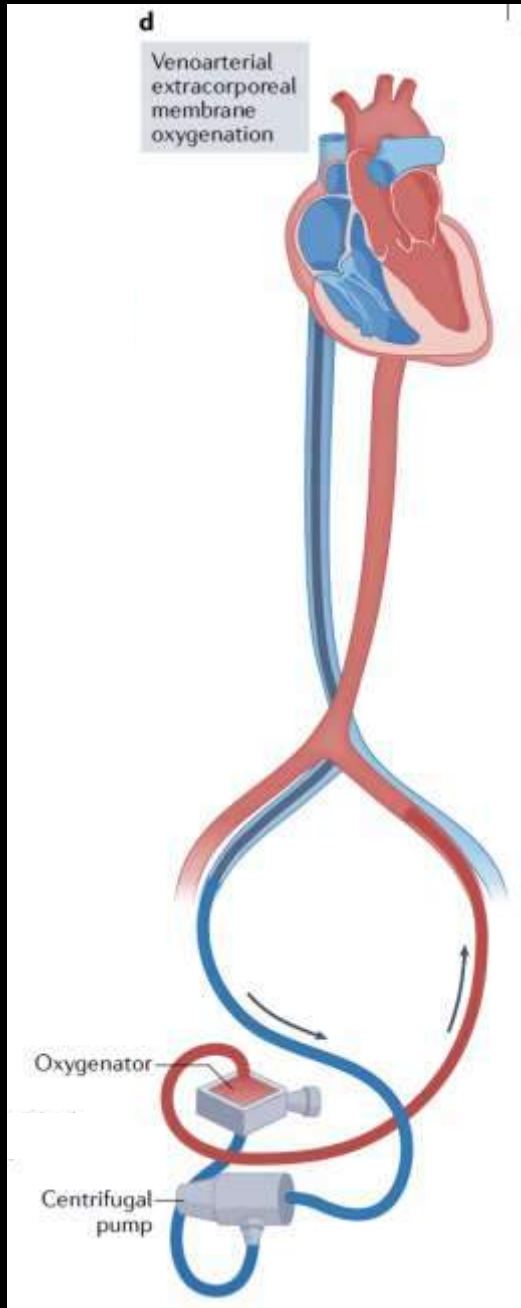
Pre load ... almost the same

After load ...slightly down

MVO₂ ...slightly down

Inflow: Aorta

ECMO



Total cardiac output ... up

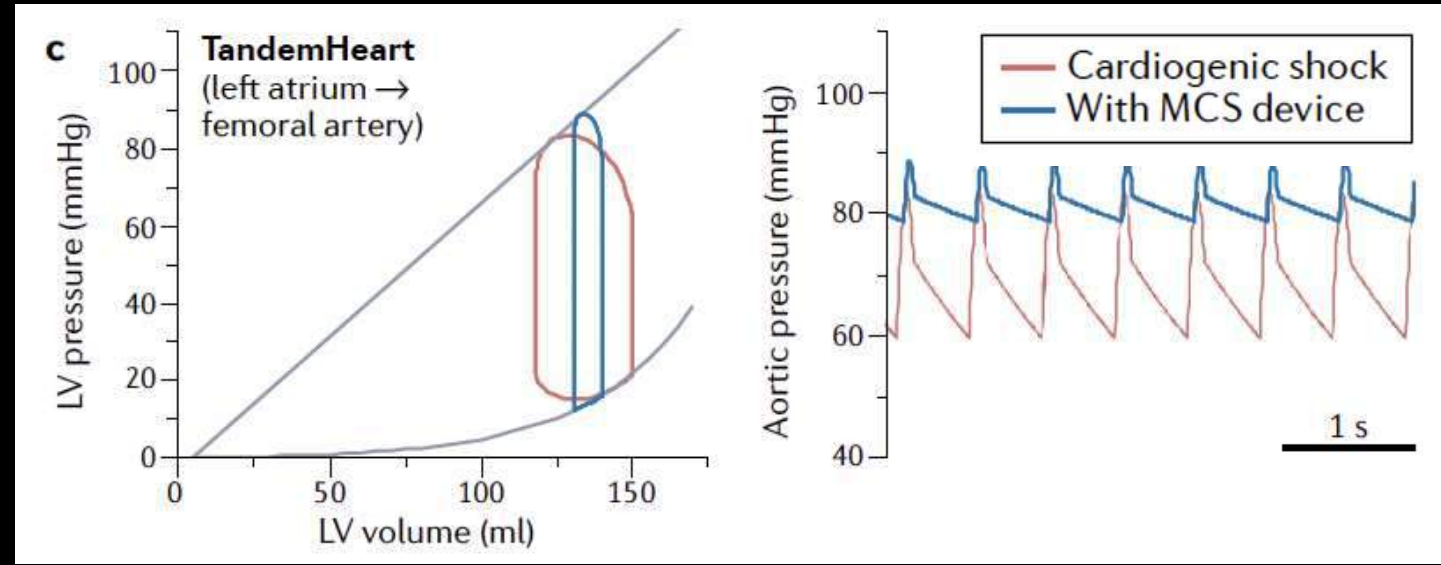
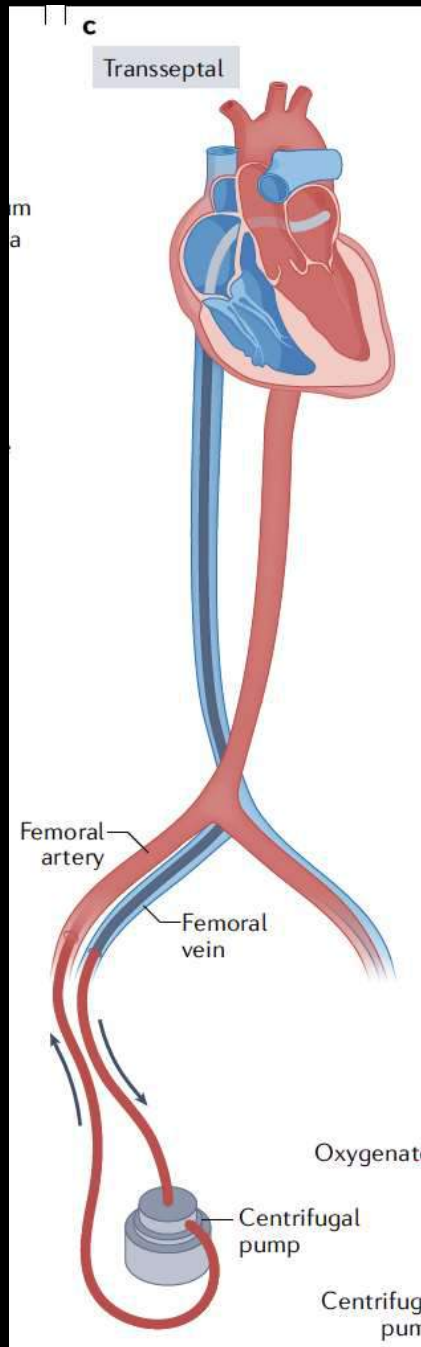
Pre load ... increase

After load ... increase

MVO₂ ... increase

Inflow: RA (SVC/IVC)

Tandem Heart (LA to Ao)



Total cardiac output ... up

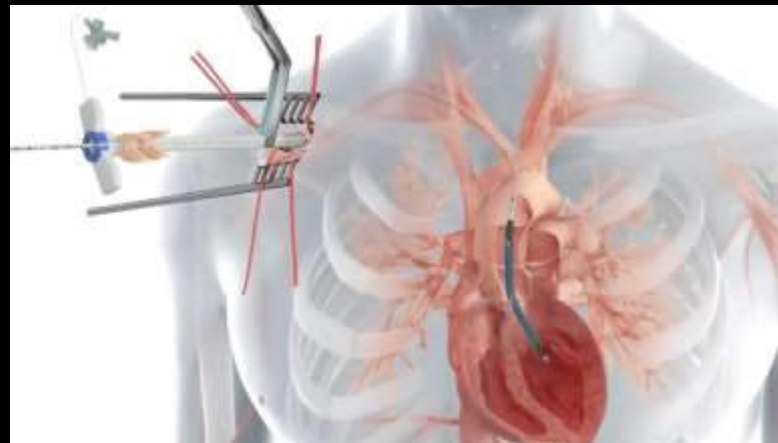
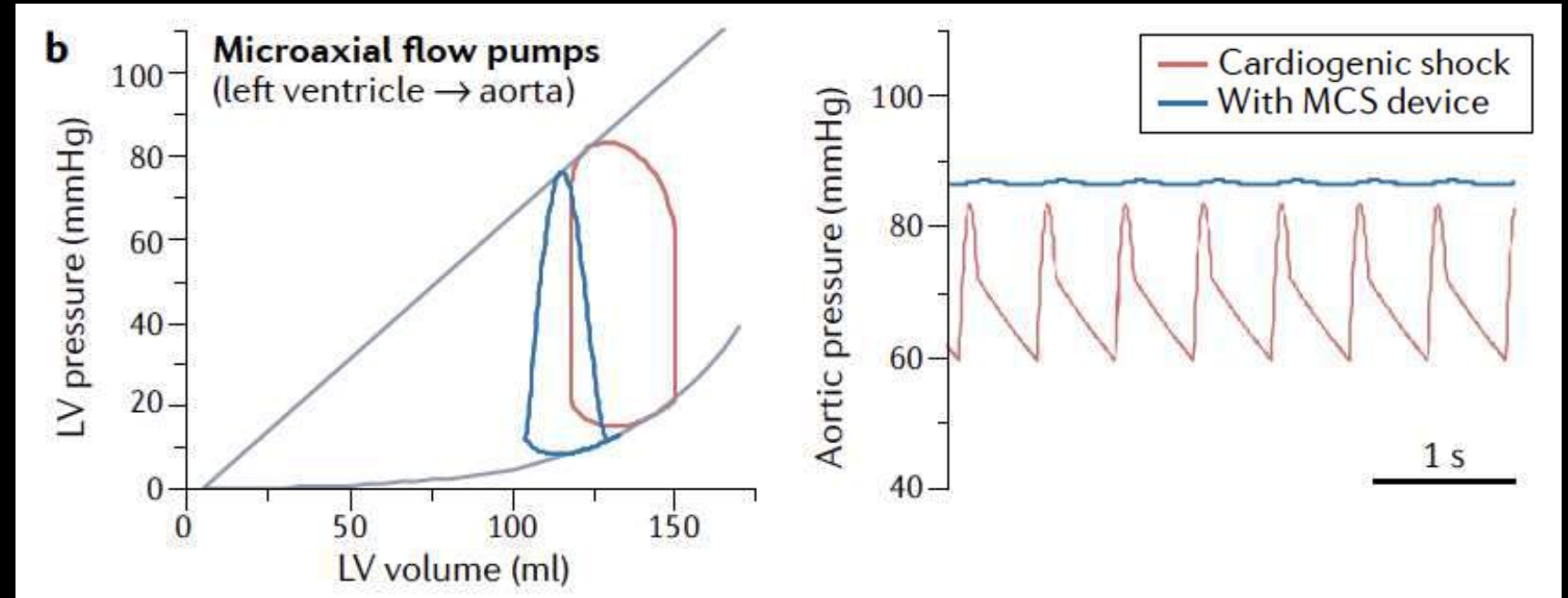
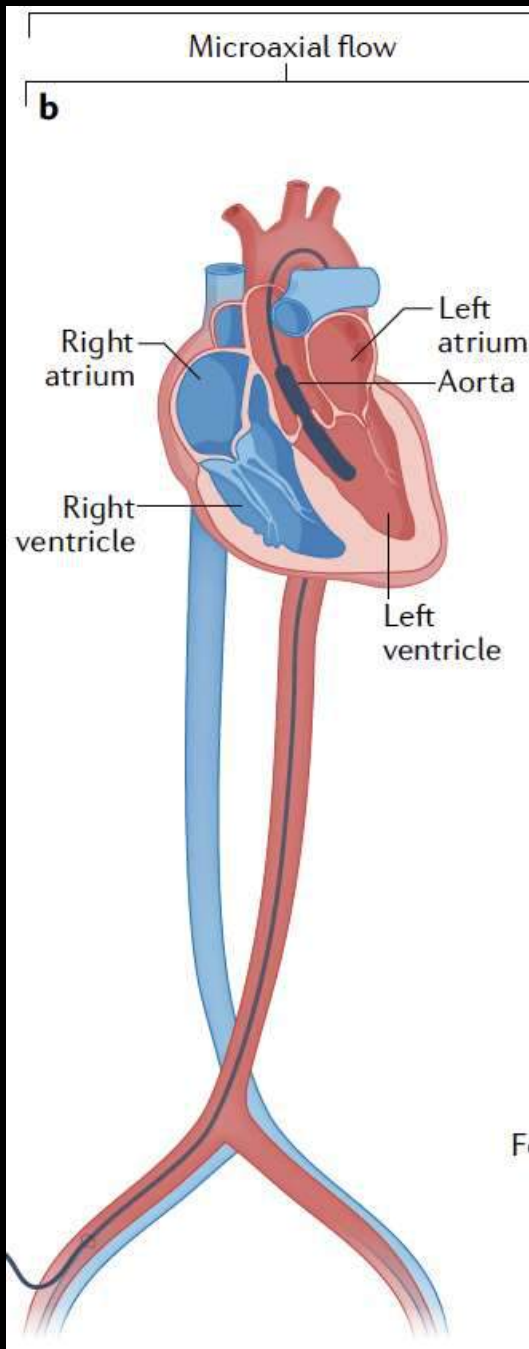
Pre load ... down

After load ... increase

MVO₂ ... down

Inflow: LA

Impella®



Total cardiac output ... up

Pre load ... down

After load ...down

MVO₂ ... down

Inflow: LV

In this presentation

- Trend in temporary circulatory support device
- Device selection and its mechanism
- Pediatric use of microaxial flow pump (Impella®)
- Use of Impella® in ECMO patients (ECMELLA, ECPELLA)

Temporary ventricular assist device support with a catheter-based axial pump: Changing the paradigm at a pediatric heart center



Sebastian C. Tume, MD,^a Andres A. Fuentes-Baldemar, MD, MMSc,^b Marc Anders, MD,^a Joseph A. Spinner, MD,^c Hari Tunuguntla, MD,^c Michiaki Imamura, MD,^b Asma Razavi, MD,^a Edward Hickey, MD,^b Gary Stapleton, MD,^c Athar M. Qureshi, MD,^{c,d} and Iki Adachi, MD^b

TABLE 1. Demographic characteristics and preimplantation variables in 37 encounters

Variable	Median [range], n (%)
Age at implantation (y)	16.8 [6.9-42.8]
Male gender (%)	28 (75.7)
Weight at implantation (kg)	61.1 [23.1-123.8]
Body surface area at implantation (kg/m ²)	1.7 [0.8-2.5]
Race/ethnicity	
Non-Hispanic White	22 (59.5)
Hispanic	8 (21.6)
Non-Hispanic Black	6 (16.2)
Asian	1 (2.7)
Etiology of circulatory failure	
Graft failure/rejection	16 (43.3)
Cardiomyopathy	7 (18.9)
Arrhythmias	6 (16.2)
Myocarditis/endocarditis	4 (10.8)
Heart failure due to CHD	4 (10.8)
Invasive mechanical ventilation pre-implantation	17 (46.0)
History of cardiac arrest	12 (32.4)

CHD, Congenital heart disease.

TABLE 2. Device characteristics (n = 43 device uses)

Variable	Median [range], n (%)
Device type	
Large (Impella 5.0/5.5, Abiomed Inc)	16 (37.2)
Medium (Impella CP)	23 (53.5)
Small (Impella 2.5)	4 (9.3)
Site of implantation	
Femoral	25 (58.1)
Percutaneous	23 (92.0)
Surgical	2 (8.0)
Subclavian/axillary	18 (41.9)
Surgical	16 (88.9)
Percutaneous	2 (11.1)
Length of support (d)	
Total	7 [1-45]
Large CBAP	14 [6-45]
Medium CBAP	5 [1-20]
Small CBAP	4 [3-5]
Median P-level flow	6 [2-8]
Indications for explantation	
Cardiac recovery	26 (60.4)
Transition to durable VAD	8 (18.6)
Device failure/upsizing	3 (7.0)
Transition to transplant	3 (7.0)
Death with device	3 (7.0)
Need for additional ECMO support after CBAP implantation	3 (7.0)

CBAP, Catheter-based axial pump; VAD, ventricular assist device; ECMO, extracorporeal membrane oxygenation.

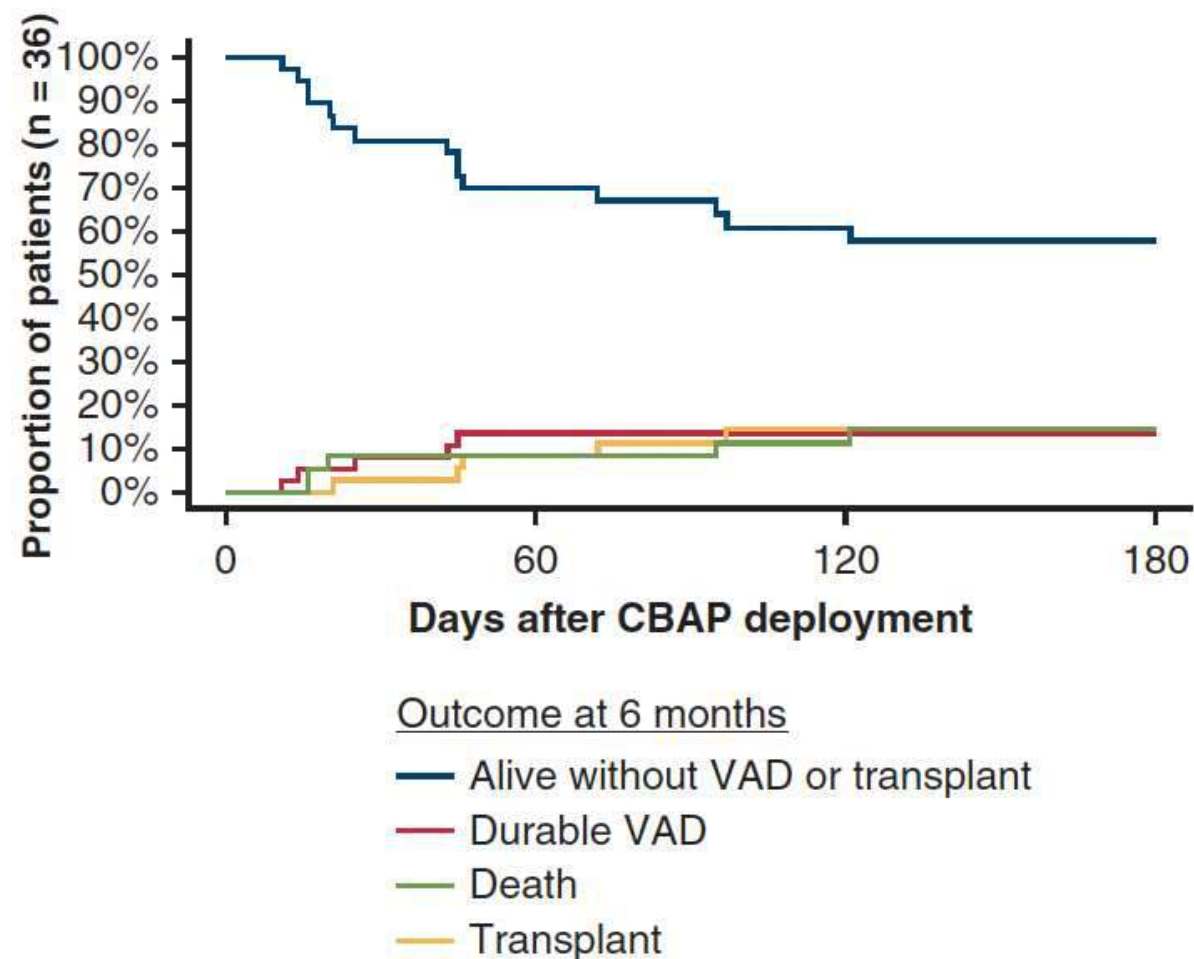


FIGURE 4. Competing outcomes analysis displaying survival free from LVAD and heart transplantation (n = 37 encounters). VAD, Ventricular assist device; CBAP, catheter-based axial pump.

TABLE 3. Device complications and patient adverse events (n = 43 device uses)

Variable	n (%)
Major device complication	9 (20.9)
Device repositioning	5 (11.7)
Motor failure	0 (0.0)
Monitoring failure	0 (0.0)
Compromise of cardiac structures	4 (9.3)
Minor device complication	6 (14.0)
Suction events	2 (4.7)
Purge fluid failure	4 (9.3)
Device repositioning	5 (11.6)
Hemolysis	20 (46.5)
Limb injury	
Ischemia*	1 (2.3)
Nerve injury	5 (11.6)
Ventricular arrhythmias*	13 (30.2)
Neurological dysfunction	
Stroke	0 (0.0)
Hemorrhage	0 (0.0)
Major bleeding*	8 (18.6)
Non-CNS thromboembolism	6 (14.0)
Insertion site infection	0 (0.0)
New-onset acute kidney injury*	3 (7.1%)

In this presentation

- Trend in temporary circulatory support device
- Device selection and its mechanism
- Pediatric use of temporary circulatory support device
- Use of Impella® in ECMO patients (ECMELLA, ECPELLA)

ADVANCES IN MECHANICAL CIRCULATORY SUPPORT

Venoarterial Extracorporeal Membrane Oxygenation for Cardiogenic Shock and Cardiac Arrest

Cardinal Considerations for Initiation and Management

ABSTRACT: Venoarterial extracorporeal membrane oxygenation (VA-ECMO)—also referred to as extracorporeal life support—is a form of temporary mechanical circulatory support and simultaneous extracorporeal gas exchange. The initiation of VA-ECMO has emerged as a salvage intervention in patients with cardiogenic shock; even cardiac arrest

Prashant Rao, MD
Zain Khalpey, MD, PhD
Richard Smith, MSEE, CCE
Daniel Burkhoff, MD, PhD
Robb D. Kociol, MD

2. As a consequence,
→ LAP and LVEDV go up
(cardiac effect)

1. As ECMO flow increases,
→ AoP goes up and CVP comes down
(systemic effect)

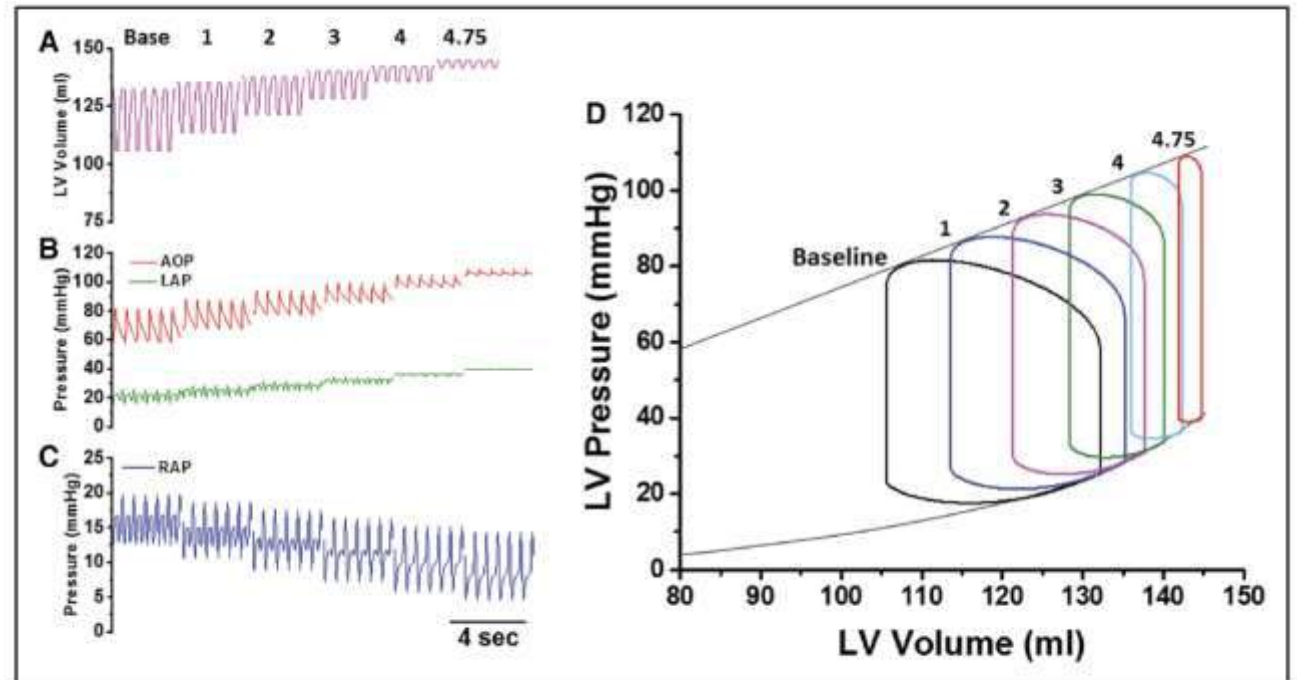


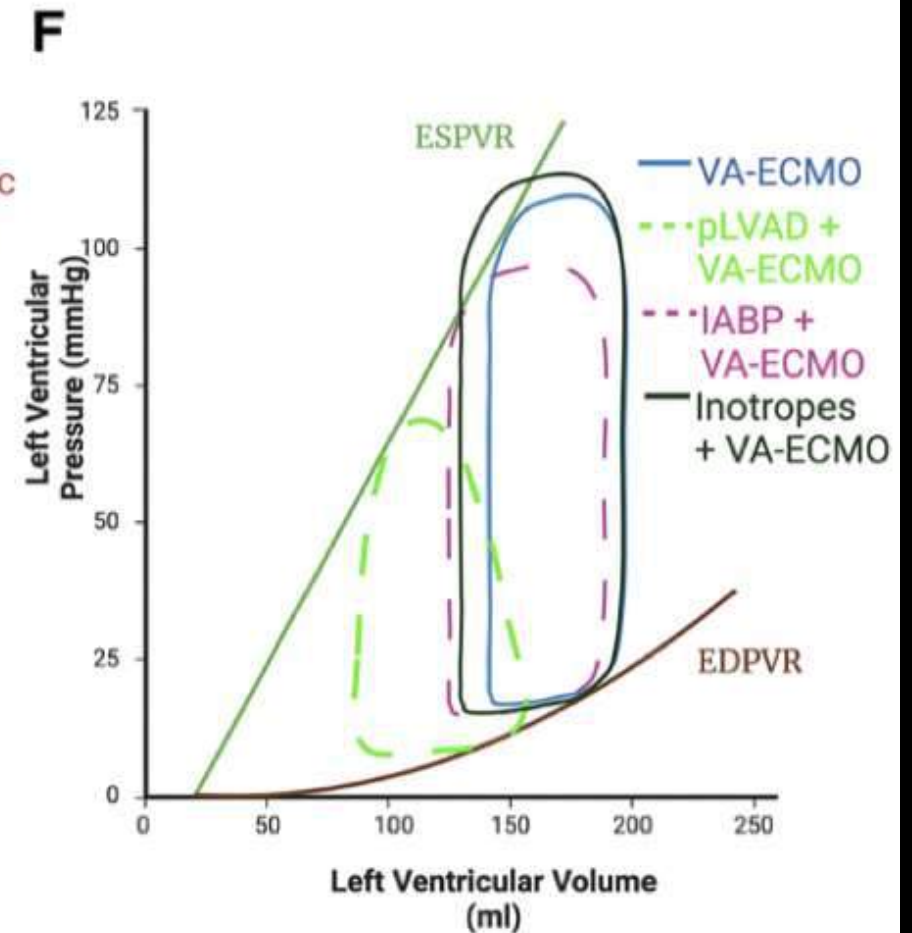
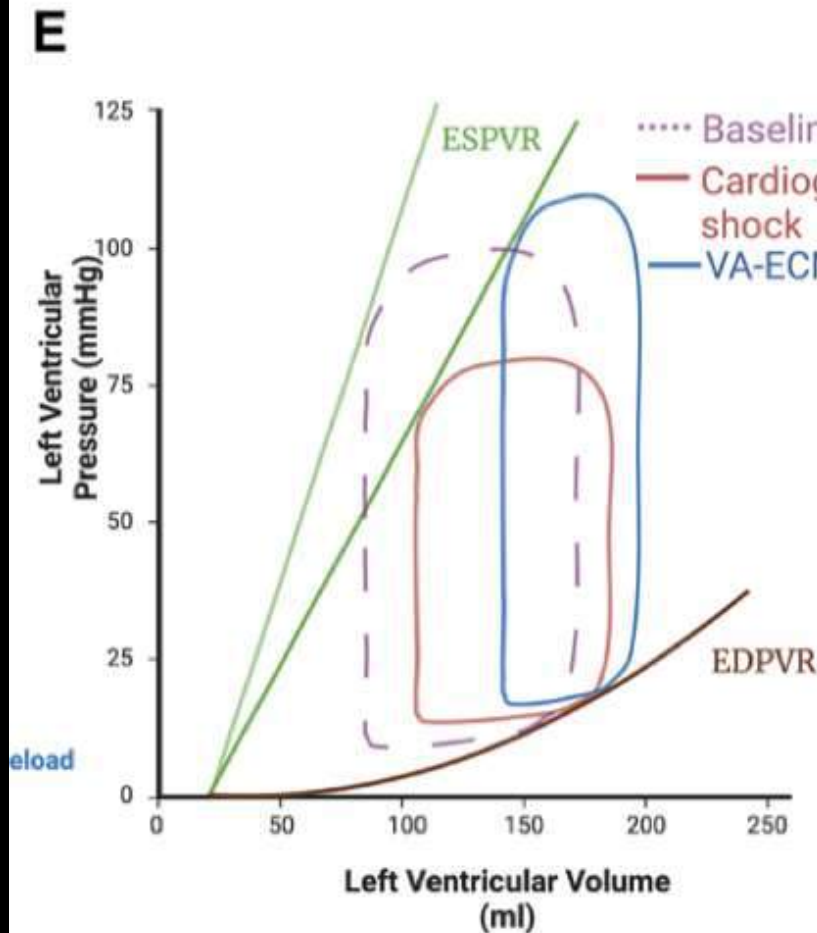
Figure 4. Hemodynamic changes that occur during acute cardiogenic shock and peripheral venoarterial extracorporeal membrane oxygenation (VA-ECMO) at increasing flow rates (1, 2, 3, 4, 4.75 L/min) with an unvented left ventricle (LV).

Unloading the Left Ventricle in Venoarterial ECMO: In Whom, When, and How?

Sead M. Ezad¹, MD; Matthew Ryan, MD, PhD; Dirk W. Donker, MD, PhD; Federico Pappalardo, MD; Nicholas Barrett², MD; Luigi Camporota³, MD, PhD; Susanna Price⁴, MD, PhD; Navin K. Kapur⁵, MD; Nicholas Barrett⁶, MD

By venting LV by Impella, preload and afterload come down.

It counteracts with downsides of ECMO and decreases myocardial oxygen consumption



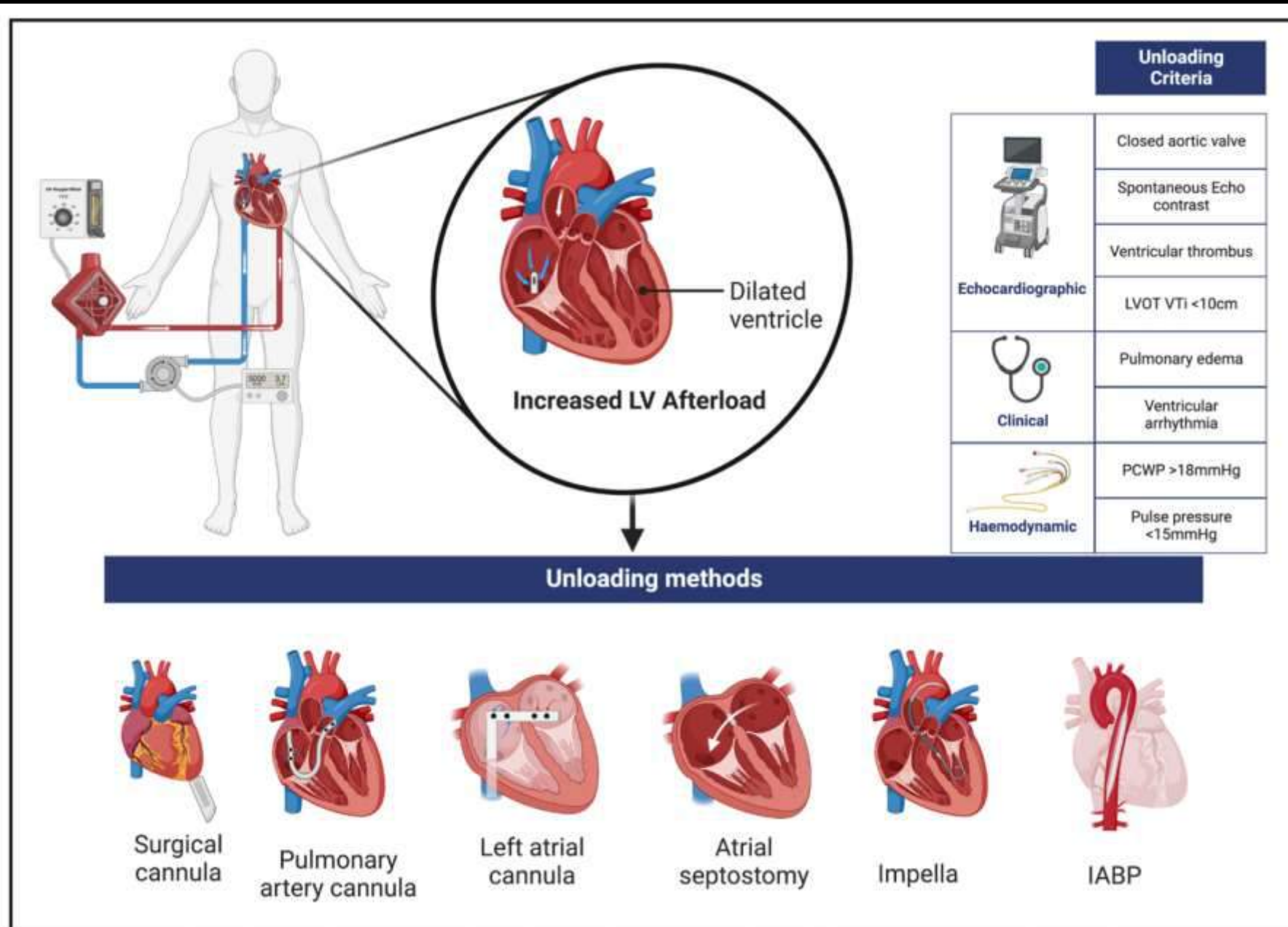


Figure 4. LV unloading criteria and methods.

Table 2. Current Randomized Clinical Trials of VA-ECMO

Trial name	Inclusion criteria	No. of participants	Intervention	Control	Institution	Primary outcome	Key secondary outcomes	Estimated study completion
EARLY-UNLOAD (NCT04775472)	Cardiogenic shock	116	VA-ECMO + atrial septostomy within 12 hours	VA-ECMO alone	Chonnam National University Hospital, Korea	All-cause mortality at 30 days	Rate of atrial septostomy in control group Incidence of cardiac death	October 2023
REVERSE (NCT03431467)	Cardiogenic shock	96	VA-ECMO + Impella CP	VA-ECMO alone	Multicenter, United States	Recovery from cardiogenic shock at 30 days (survival; free from MCS, transplant, or inotropic support)	Survival to hospital discharge	January 2025
ECLS-SHOCK (NCT03637205)	Cardiogenic shock secondary to acute myocardial infarction	420	VA-ECMO +/- LV unloading	Standard care (escalation to other MCS [eg, IABP or pLVAD] allowed)	Multicenter, Germany	All-cause mortality at 30 days	Time to death at 6- and 12-month follow-up; duration of catecholamine therapy	November 2023
ANCHOR (NCT04184635)	Cardiogenic shock secondary to acute myocardial infarction	400	VA-ECMO + IABP	Standard care (no MCS device allowed)	Multicenter, France	Treatment failure at 30 days (death in ECMO group or rescue ECMO in the control group)	Mortality at 30 days; MACE at 30 days	November 2024
HERACLES (ISRCTN82431978)	Cardiogenic shock being treated with VA-ECMO	36	VA-ECMO + Impella CP	VA-ECMO + IABP	Multicenter, United Kingdom	Change in device coronary flow reserve	Change in LVEDP; time to VA-ECMO decannulation	February 2025

Conclusion

- The use of temporary ventricular assist device has been increasing
- The effects of TCS on heart are different
- TCS has been now used in pediatric population
- Impella[®] can be effective for cardiac recovery in ECMO patients