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Universitäres Herzzentrum Hamburg

“ECMELLA”

Combined Impella and ECMO in Cardiogenic Shock

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The presenter has previously or currently been involved in research contracts, consulting, speakers bureau or received research and educational grants from:

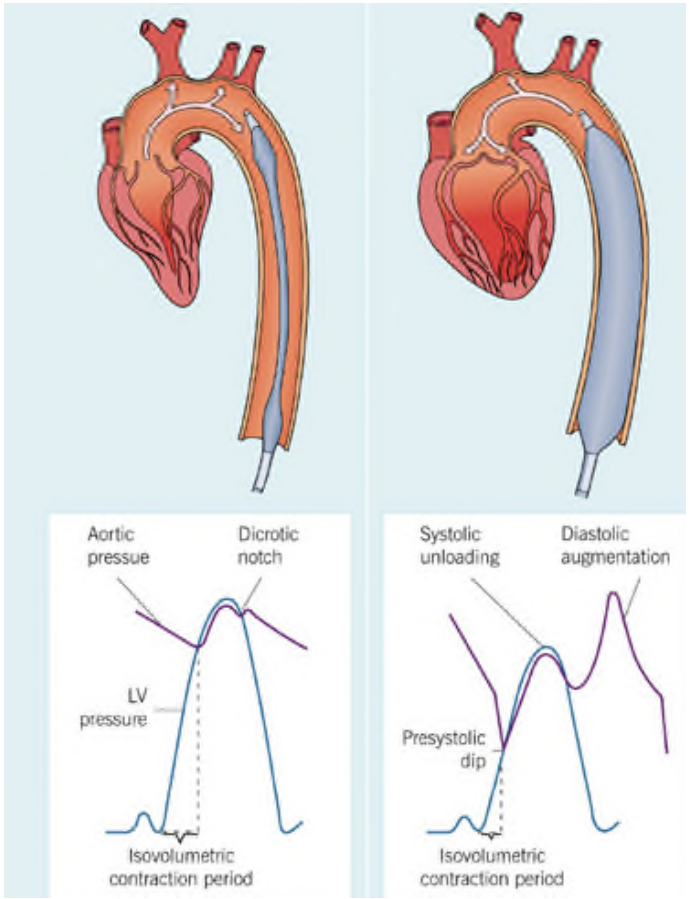
Abbott, AstraZeneca, Aventis, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Daiichi Sankyo, Eli-Lilly, Evolva, Fibrex, Janssen, Merck, Myogen, Medtronic, Mitsubishi Pharma, The Medicines Company, Nycomed, Organon, Pfizer, Pharmacia, Regado, Sanofi, Searle, Servier, ViFor Pharma.

University of Southern Denmark

Background

- IABP abandonded after 40 years
- Inotropes and vasopressors inadequate
- Move towards immediate escalation ECMO or Impella
- ECMO side effects

Intra Aortic Ballon Pump (IABP)



40 years!

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Intraaortic Balloon Support for Myocardial Infarction with Cardiogenic Shock

Holger Thiele, M.D., Uwe Zeymer, M.D., Franz-Josef Neumann, M.D., Miroslaw Ferenc, M.D., Hans-Georg Olbrich, M.D., Jörg Hausleiter, M.D., Gert Richardt, M.D., Marcus Hennersdorf, M.D., Klaus Empen, M.D., Georg Fuernau, M.D., Steffen Desch, M.D., Ingo Eitel, M.D., Rainer Hambrecht, M.D., Jörg Fuhrmann, M.D., Michael Böhm, M.D., Henning Ebelt, M.D., Steffen Schneider, Ph.D., Gerhard Schuler, M.D., and Karl Werdan, M.D., for the IABP-SHOCK II Trial Investigators*

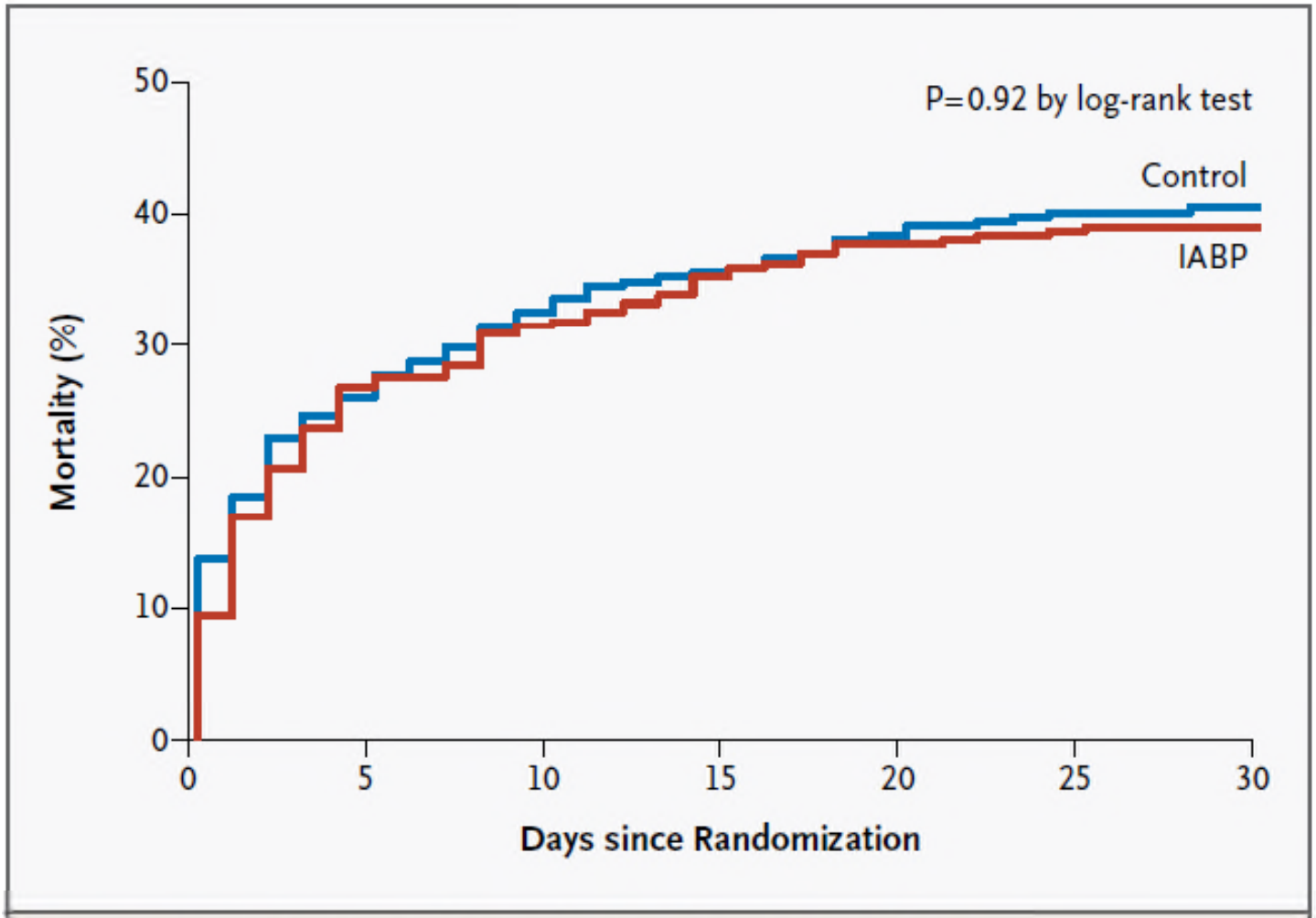
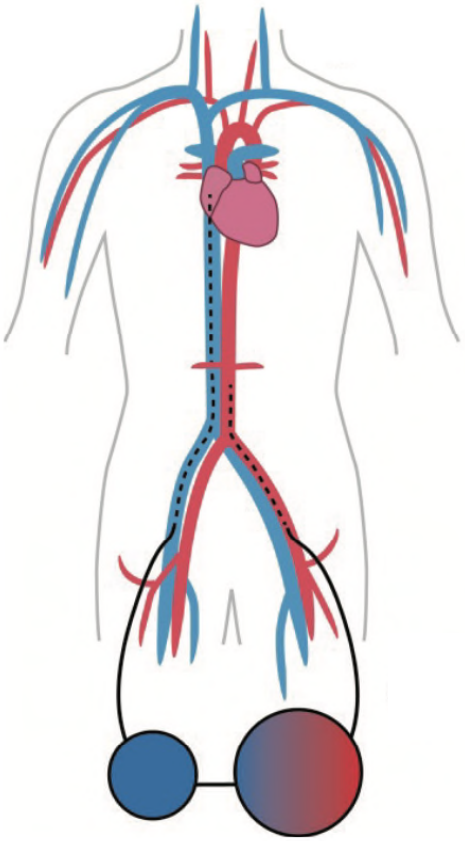


Figure 1. Time-to-Event Curves for the Primary End Point.

Time-to-event curves are shown through 30 days after randomization for the primary end point of all-cause mortality. Event rates represent Kaplan–Meier estimates.

Emergency extracorporeal oxygenation (ECMO) in patients with cardiogenic shock

Acute Cardiogenic Shock



ECMO and In-Hospital CA

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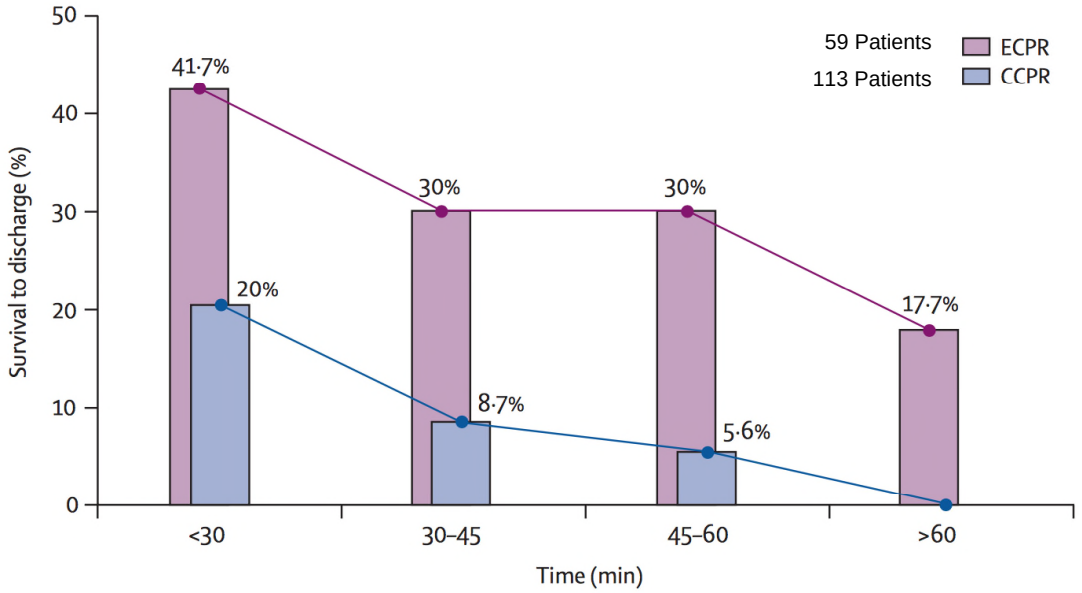
Methods:

Adults with **in-hospital** cardiac arrest of cardiac origin, aged between 18 and 75 years, who underwent CPR for longer than 10 min between Jan 1, 2004, and Dec 31, 2006.

...

Only patients who underwent **witnessed arrest** of cardiac origin and CPR duration (defined as the interval from beginning CPR to return of spontaneous circulation or death) for more than 10 min were recruited in the study cohort

ECMO therapy is associated with improved outcome?



Chen et al. Lancet 2008

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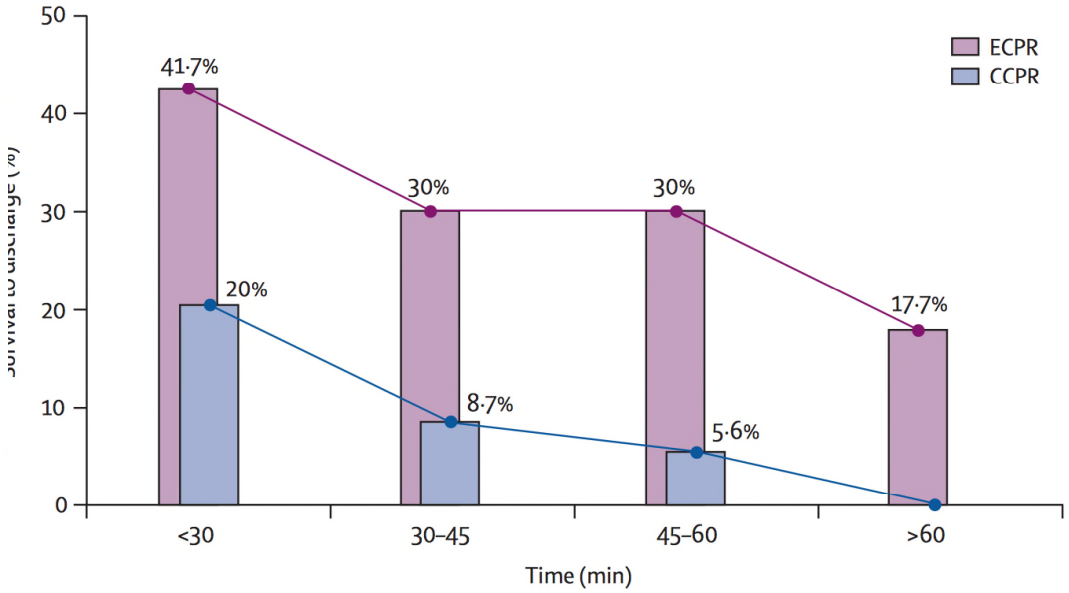
	Extracorporeal CPR-M (N=46)	Conventional CPR-M (N=46)	p
Clinical endpoints			
ROSB/ROSC†, n (%)	42 (91·3)	24 (52·2)	<0·001‡
Neurological outcome			
CPC status at discharge	n (%)	n (%)	
1 or 2	14 (30·4)	7 (15·2)	0·09
3 or 4	1 (2·2)	1 (2·2)	0·09
5 (death)	31 (67·4)	38 (82·6)	0·09
CPC status at 1 year	n (%)	n (%)	
1 or 2	9 (19·5)	5 (10·8)	0·27
3 or 4	1 (2·2)	1 (2·2)	0·27
5 (death)	36 (78·3)	40 (87·0)	0·27

ROSC=return of spontaneous circulation for conventional CPR-M. ROSB=return of spontaneous beating for extracorporeal CPR-M. *p=0·10. †Odds ratio 9·6 (95% CI 3·0–31·2). ‡p<0·05.

Table 5: Propensity analysis baseline characteristics and clinical endpoints

ECMO therapy is associated with improved outcome

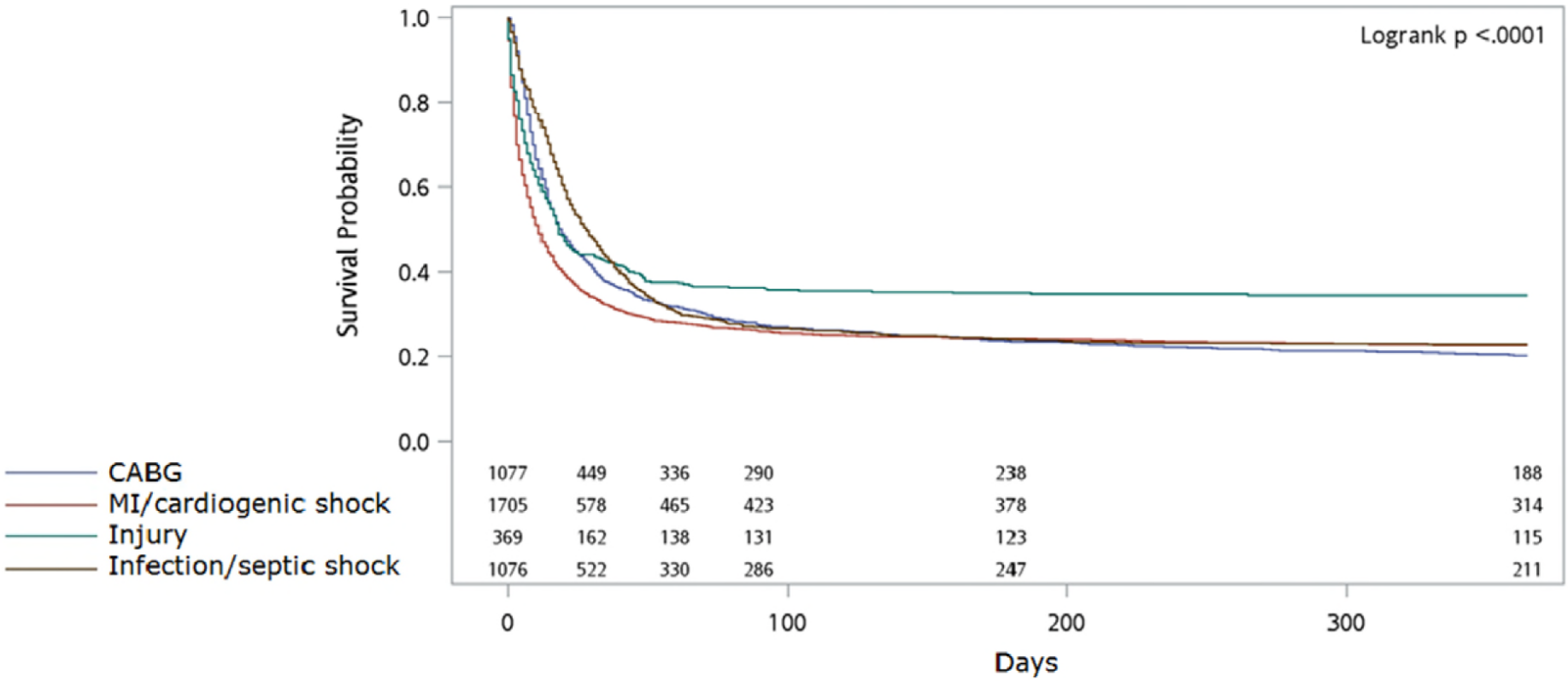


Chen et al. Lancet 2008

ECMO and Survival in Cardiogenic Shock?

4227 adult patients who received ECMO from September 1, 2002, to December 31, 2012, were identified from the Taiwan National Health Insurance Database associated with coronary artery bypass graft surgery, myocardial infarction/cardiogenic shock, injury, and infection/septic shock.

Cumulative Survival is (relatively) low despite ECMO



Chan et al. Circulation 2016

ECMO and Cardiogenic Shock Survival?

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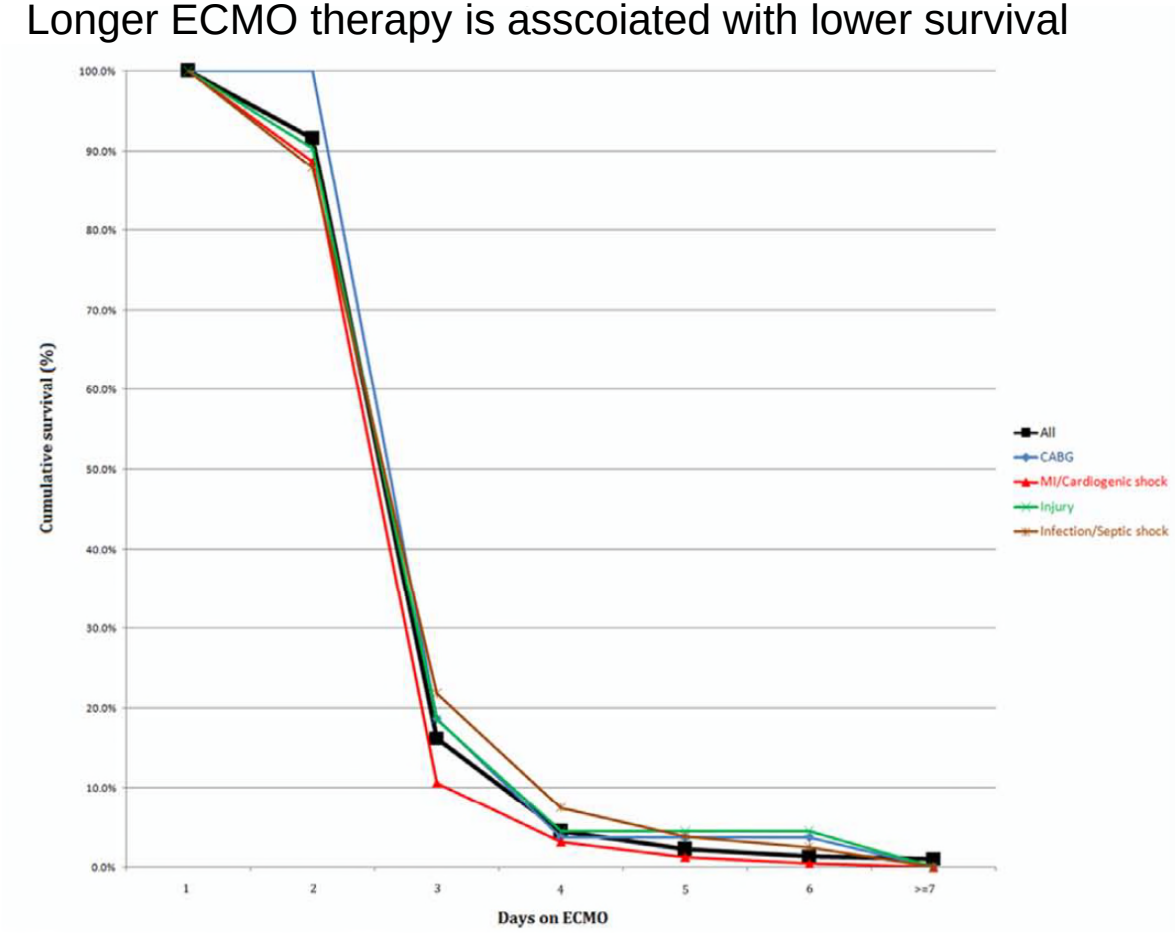
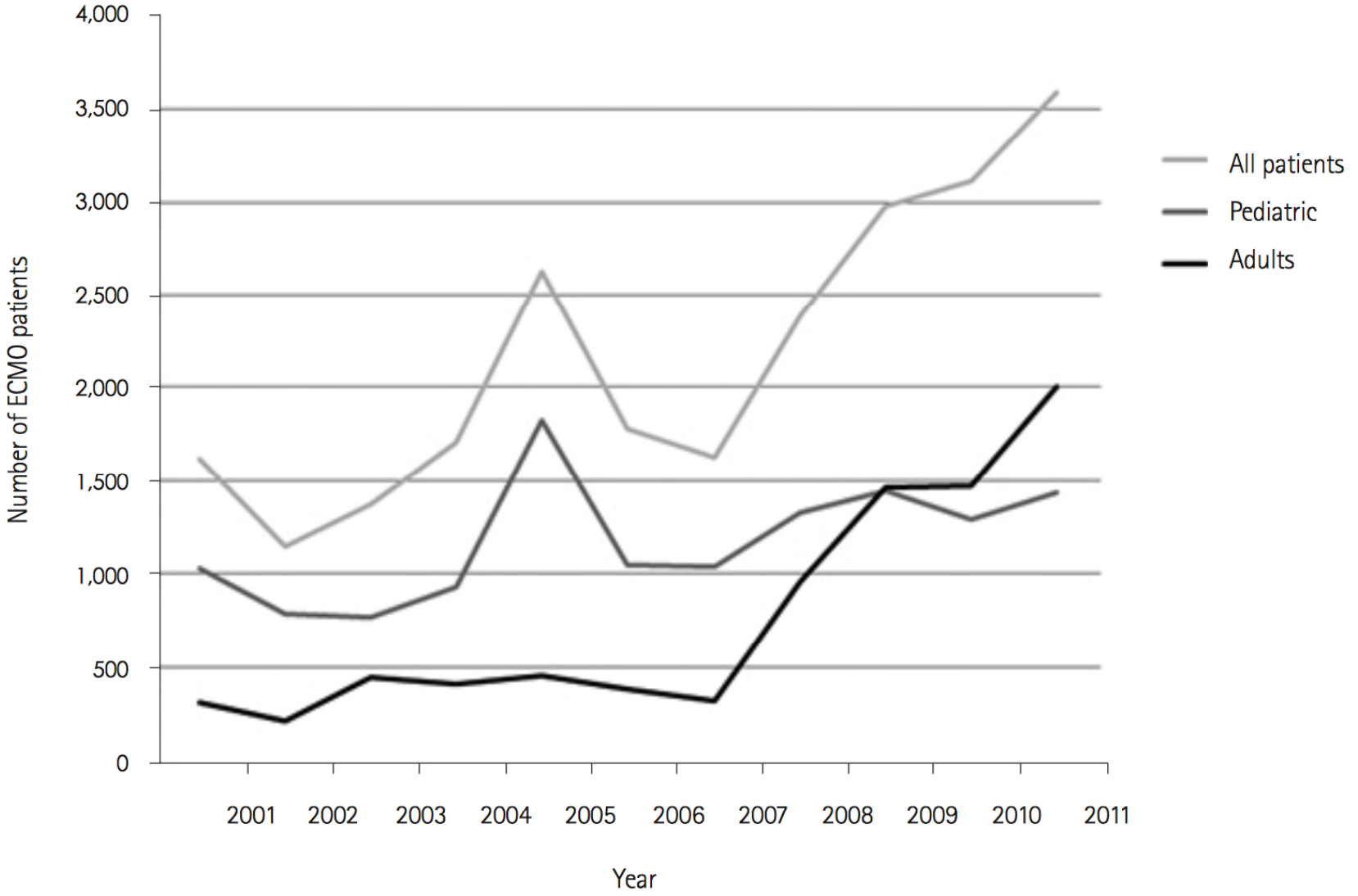
Longer ECMO therapy is asscoiated with lower survival



Chan et al. Circulation 2016

ECMO usage in the USA



Nasr et al. 2015

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ECMO Complications

- Leg Ischemia / Vascular complications
- Bleeding
- Two-Circulation Syndrome
- LV Distension / Pulmonary Odema
- Hyperfibrinolysis
- Embolism
- Abdominal Compartment Syndrome

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ECMO Contraindications

- Patient´s will
- Ehtical
- Bridge to far = nowhere
- Bleeding
- Aortic regurgitation / dissection
- LV thrombus (relative)
- Bleeding when uncontrolled (relative)

Acute Cardiogenic Shock

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Short-term mechanical circulatory support may be considered in refractory cardiogenic shock depending on patient age, comorbidities and neurological function.	IIb	C

PV loops basic

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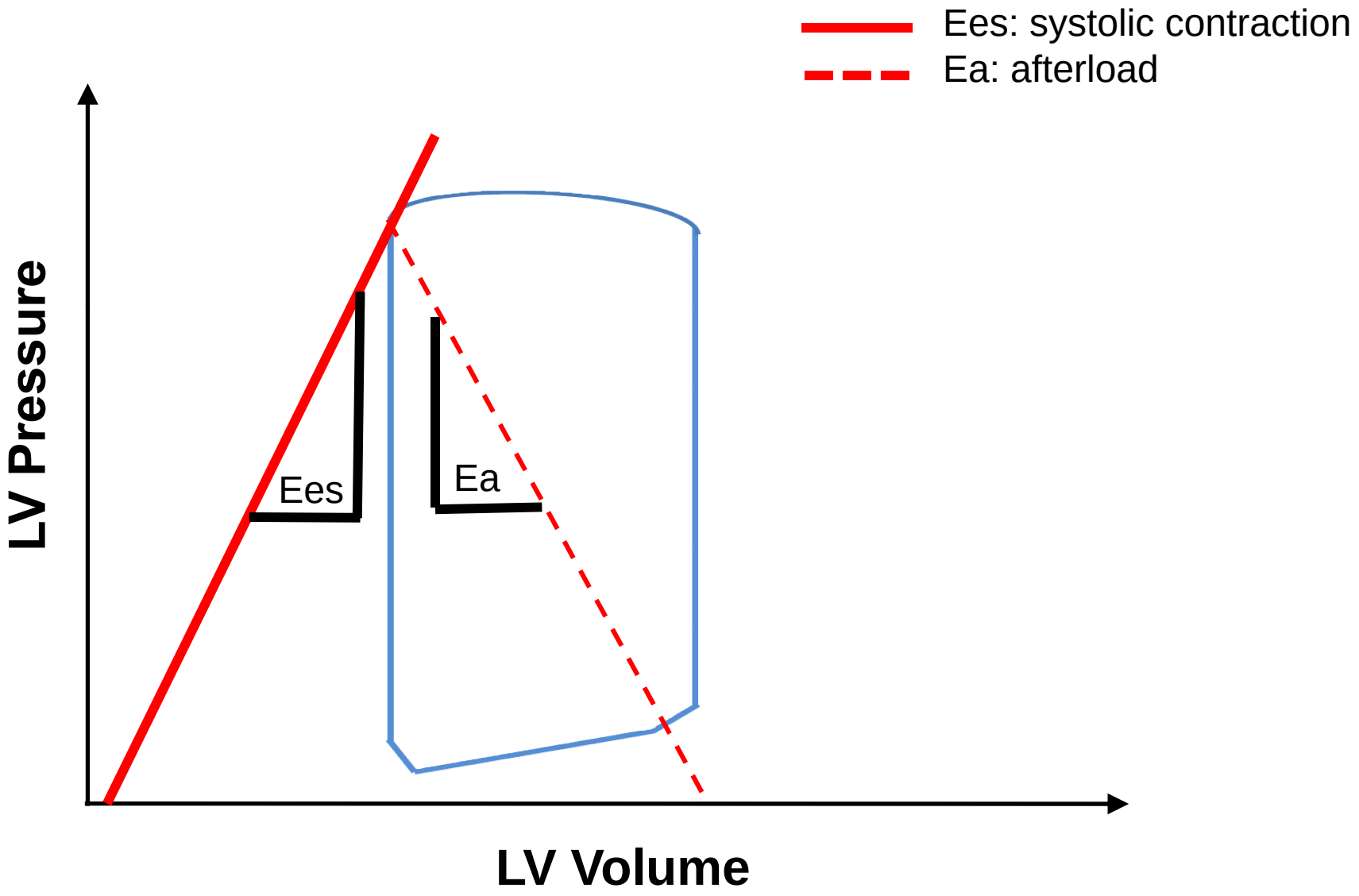

PV loops in cardiogenic shock

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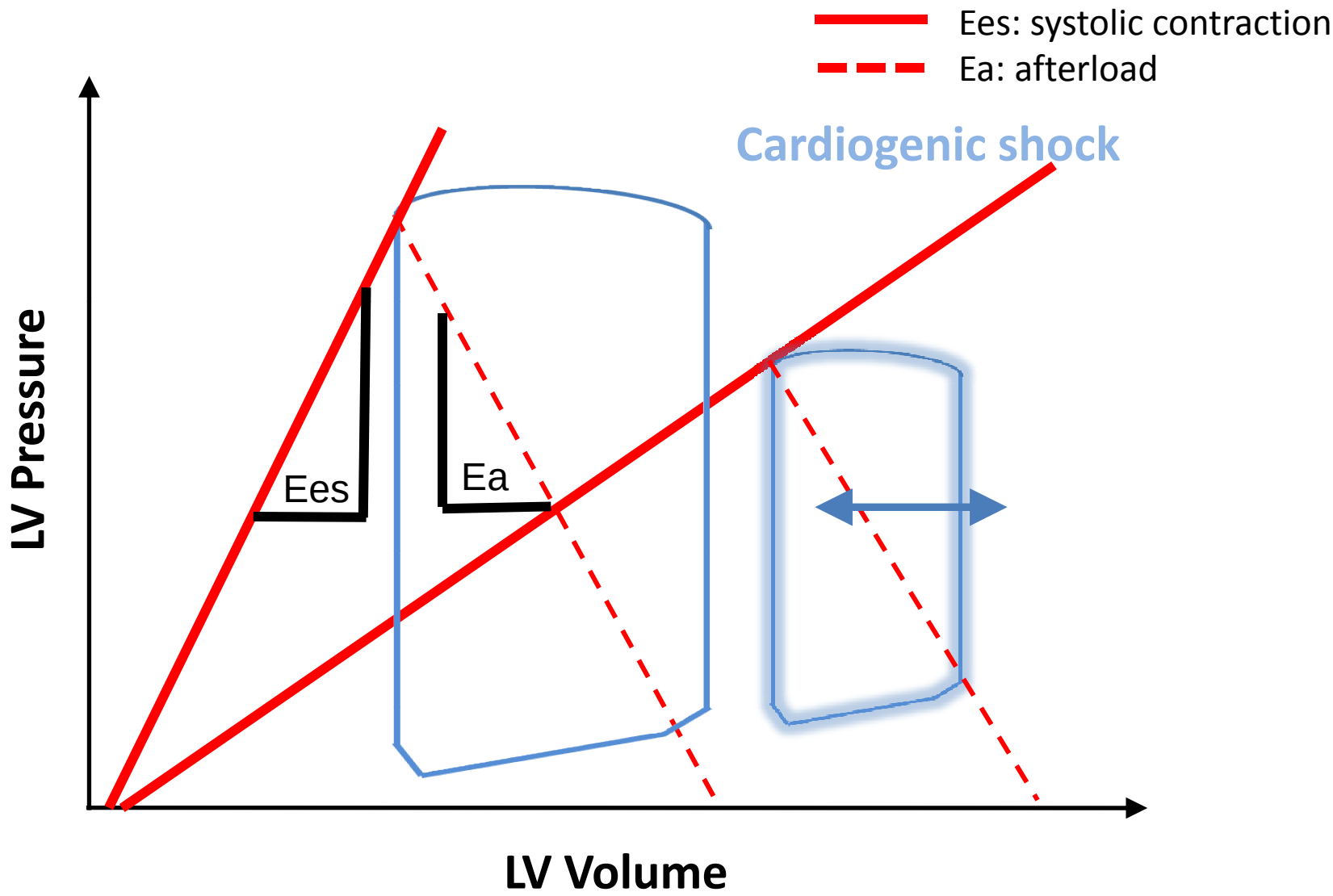

Whats is VA-ECMO doing?

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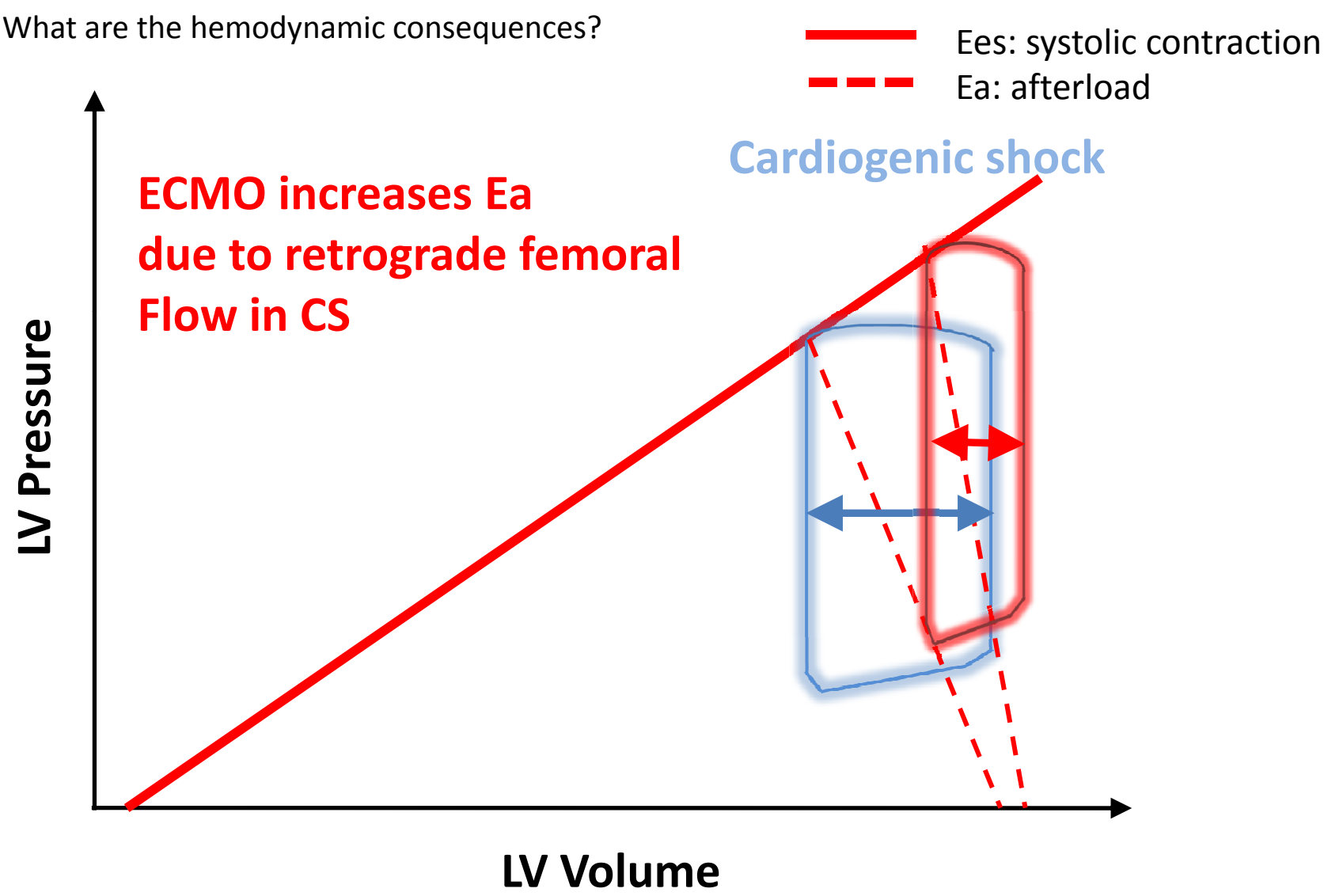
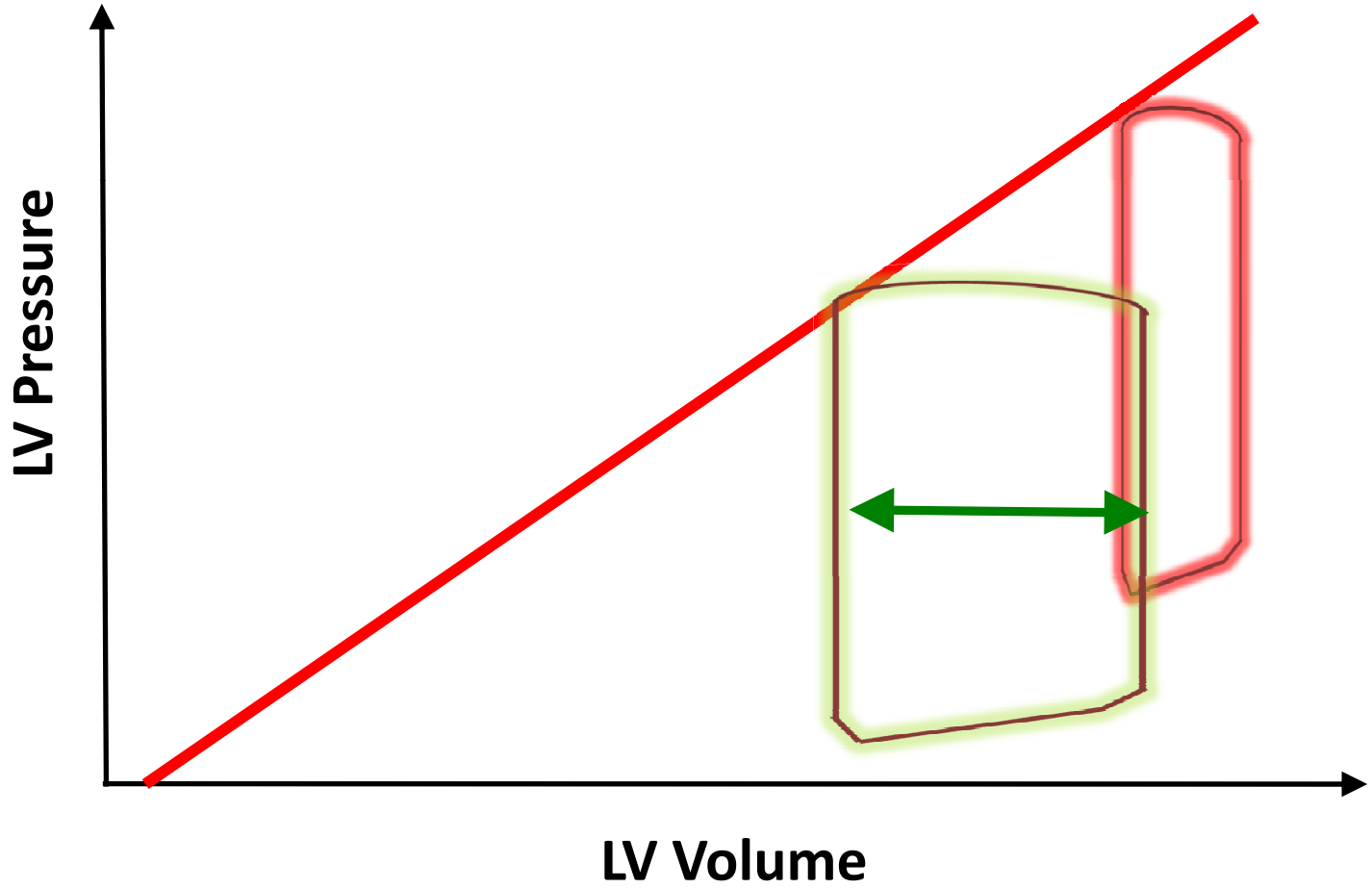
What are the hemodynamic consequences?



Target to reach in view of hemodynamics



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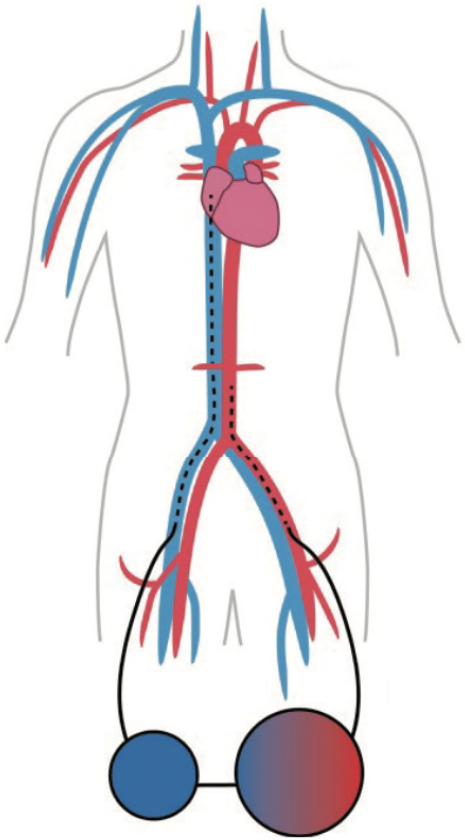
ECMO Pathophysiology

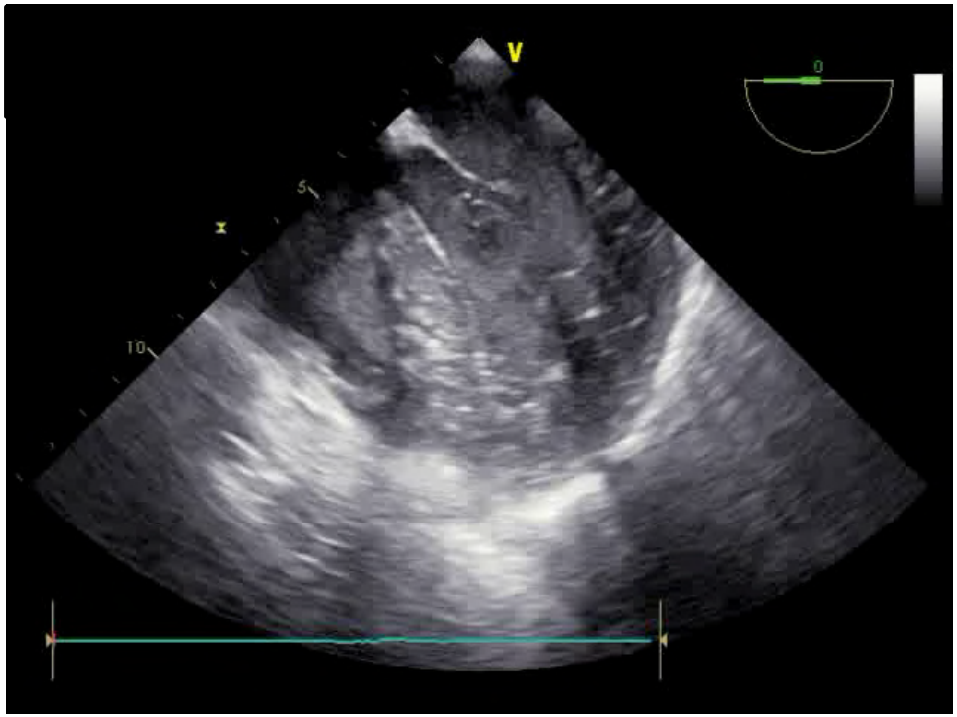
- Watershed

Napp LC et al. 2015

Acute Cardiogenic Shock



- ECMO results in acute support of organs, but highly increases afterload.
- Problems: No cardiac flow induces LV thrombus and pulmonary congestion



ECMO on top of Impella = „ECMELLA“

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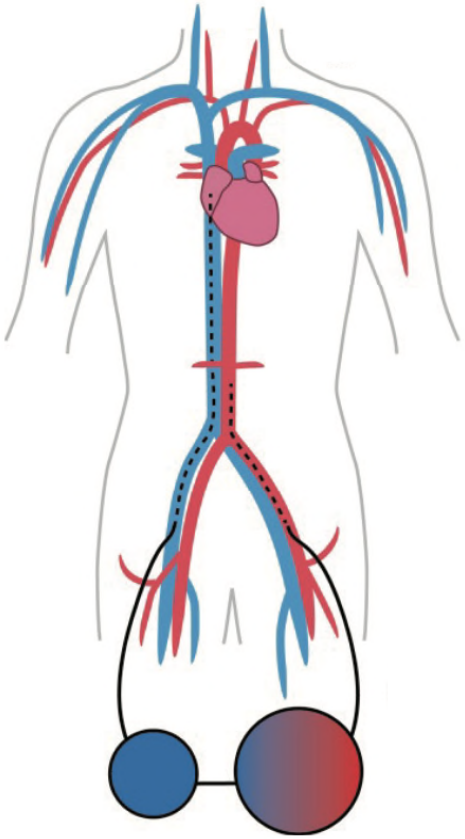
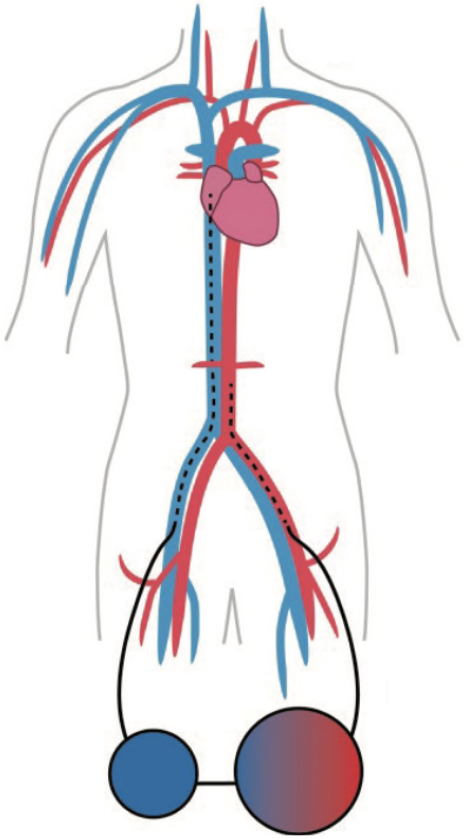


- ECMO results in acute support of organs, but highly increases afterload.
- Problems: No cardiac flow induces LV thrombus and pulmonary congestion

- Does addition of an temporal cVAD on top of ECMO improve outcome?

Pappalardo & Westermann, EJHF 2016

ECMELLA



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*]

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Between January **2013 and April 2015, 3**4 patients with severe refractory CS were treated with a combination of mechanical cardiac assist devices consisting of **an Impella 2.5 or Impella CP (ABIOMED, Danvers, USA) LV pump and VA-ECMO** in the Cardiac Intensive Care Unit of San Raffaele Scientific Institute (Milan, Italy) and the Cardiac Intensive Care Unit of the University Heart Centre Hamburg Eppendorf (Hamburg, Germany). All consecutive patients with implantation of Impella and VA-ECMO were included in this study.

were compared with a contemporary control group of **123 CS patients treated with VA-ECMO only,** which did not receive LV unloading via a percutaneous LV assist device (LVAD).

Pappalardo & Westermann, EJHF 2016

ECMELLA vs ECMO

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Parameter	Total ($n = 157$)	ECMO + Impella ($n = 34$)	ECMO ($n = 123$)	*P*-value
Age, years	55 (46–64)	54 (47–66)	55 (45–64)	0.9
Males, *n* (%)	130 (83)	28 (82)	102 (83)	0.9
CPR, *n* (%)	100 (64)	14 (41)	86 (70)	0.002
STEMI, *n* (%)	85 (54)	15 (44)	70 (57)	0.2
PCI, *n* (%)	56 (36)	16 (47)	40 (33)	0.10
pH	7.23 (6.98–7.39)	7.36 (7.08–7.41)	7.16 (6.95–7.37)	0.02
Lactates, mmol/L	9.55 (4.40–15.35)	8.96 (3.10–16.25)	10.26 (4.97–15.24)	0.4

Parameter	Total ($n = 63$)	ECMO + Impella ($n = 21$)	ECMO ($n = 42$)	*P*-value
Age, years	53 (46–65)	51 (47–61)	54.5 (46–65)	0.6
Males, *n* (%)	55 (87)	18 (86)	37 (88)	0.5
CPR, *n* (%)	40 (63)	12 (57)	28 (67)	0.5
STEMI, *n* (%)	30 (48)	10 (48)	20 (48)	1
PCI, *n* (%)	27 (43)	9 (43)	18 (43)	1
pH	7.27 (7.00–7.41)	7.31 (7.08–7.39)	7.27 (6.98–7.43)	0.7
Lactates, mmol/L	9.02 (4.05–14.17)	9.02 (4.60–11.00)	9.03 (4.05–14.17)	1
Concomitant IABP, *n* (%)	13 (21)	6 (29)	7 (17)	0.3

Pappalardo & Westermann, EJHF 2016

ECMELLA vs ECMO

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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

Pappalardo & Westermann, EJHF 2016

ECMELLA (only UHZ) including Follow-Up
Alcomer not propensity matched

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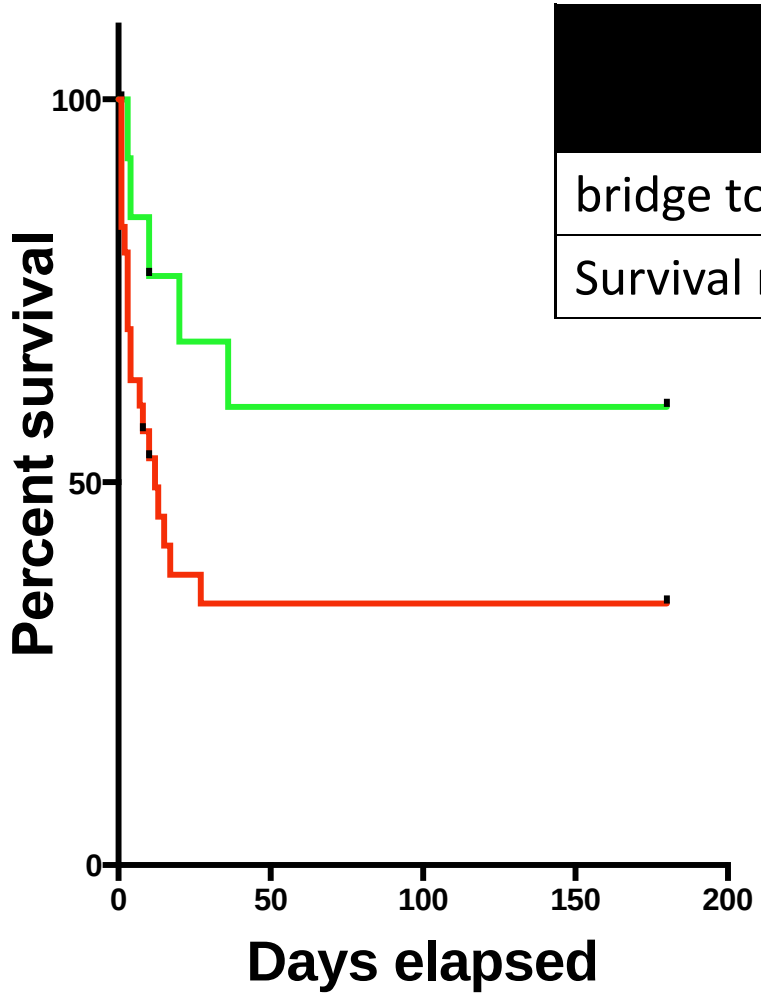
Survival proportions:

	ECMO	ECMO + Impella	
bridge to VAD	11% (n=4)	20% (n=3)	0.41
Survival rate	34,2 %	59,8 %	0,049



Future Research is clearly needed

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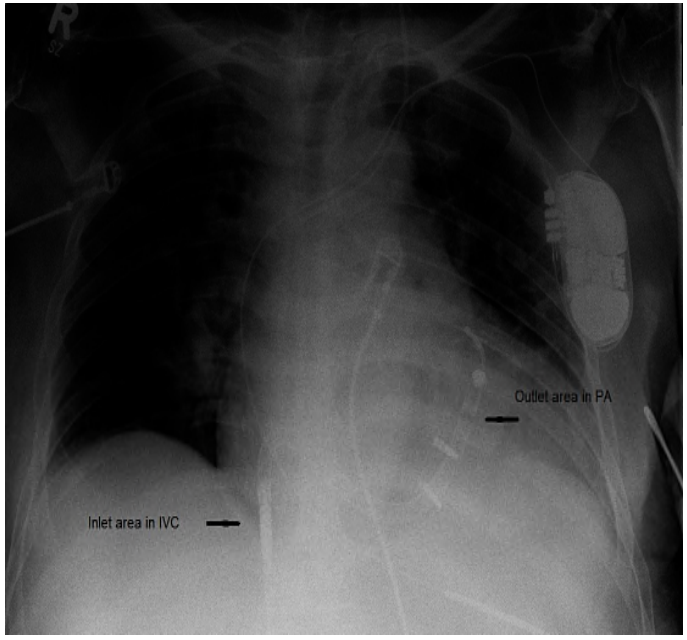
RCTs in this field are mandatory

Timing of Impella Implantation in ECMO patients?

What about RV Failure or biventricular failure?

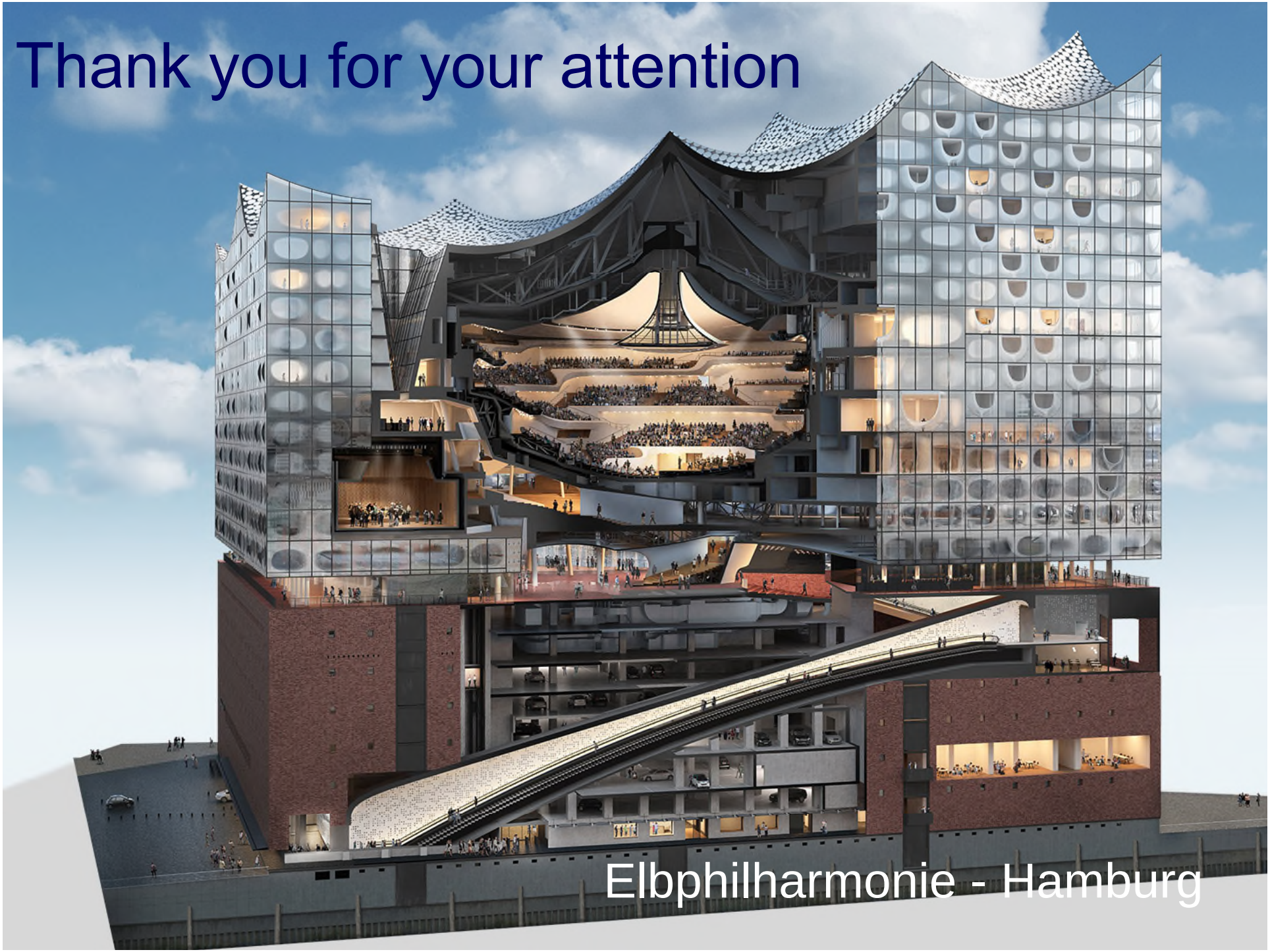


Yin & Westermann, under review, 2016

Conclusions

- ECMO therapy seems to safe life in refractory cardiogenic shock
- Definitive Data is not availabe to support this
- Venting of the LV (dysfunction) in VA-ECMO patients via Impella use seems promising for reducing mortality
- An ongoing registry and hopefully pivotal trials should prove this concept

Thank you for your attention



Elbphilharmonie - Hamburg

Thank you for your attention

Thank you very much

Universitäres Herzzentrum Hamburg
Ein Unternehmen des UKE


DZHK
DEUTSCHES ZENTRUM FÜR HERZ-KREISLAUF-FORSCHUNG E.V.

DFG Deutsche Forschungsgemeinschaft

SEVENTH FRAMEWORK PROGRAMME

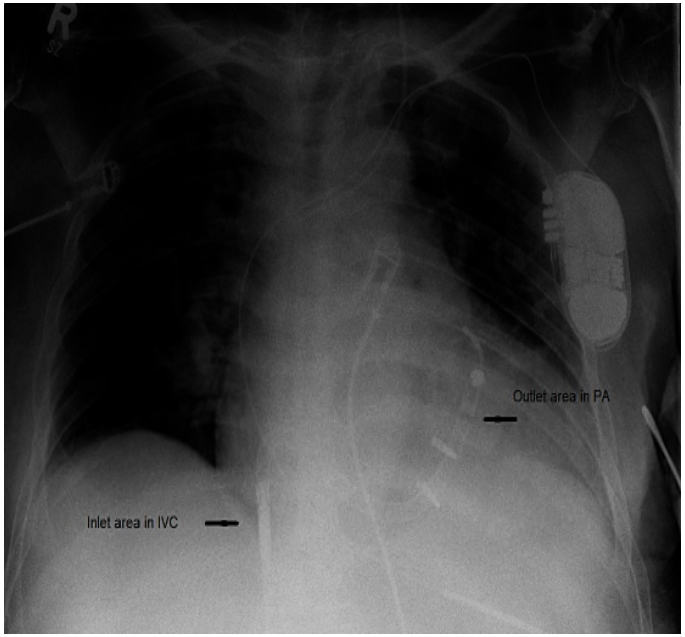



WERNER OTTO STIFTUNG
STIFTUNG DES ÖFFENTLICHEN RECHTS

Deutsche Gesellschaft für Kardiologie – Herz- und Kreislaufforschung (DGK)



Right Heart Failure



Yin & Westermann, under review, 2016