Διαδερμικές συσκευές μηχανικής υποστήριξης (pVAD) στις διαδερμικές στεφανιαίες επεμβάσεις

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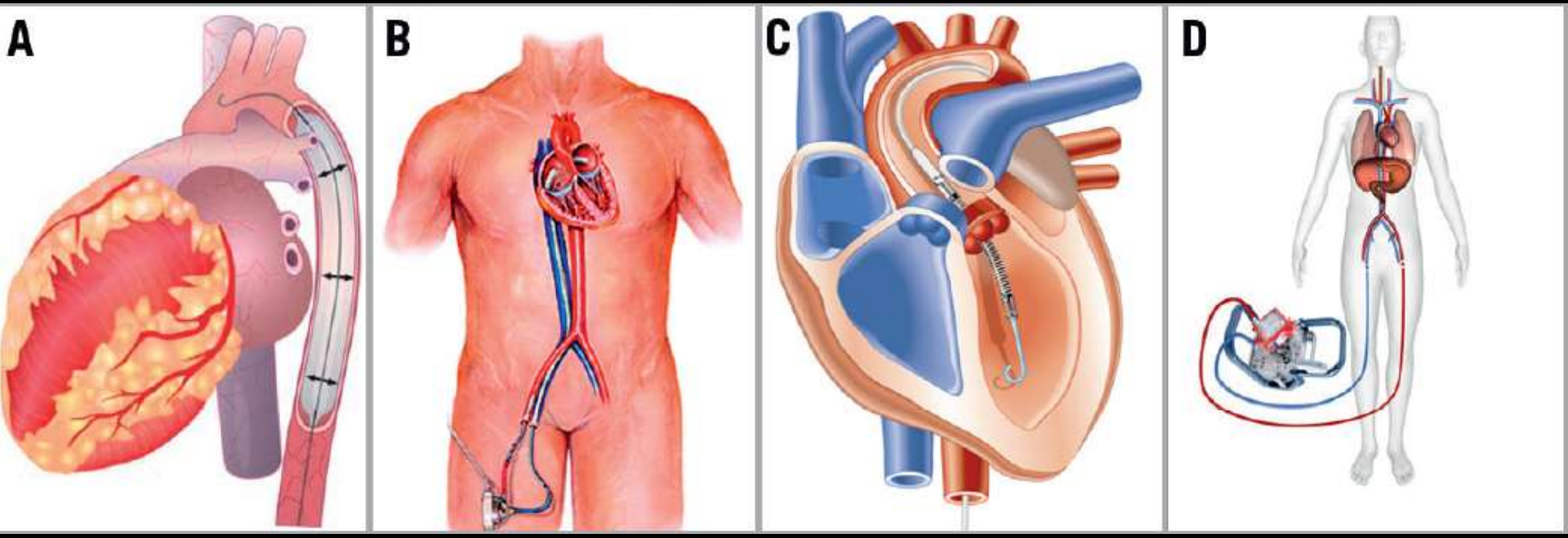
Why pVAD during PCI?

- AMI with shock
  - To reduce mortality
- Large AMI without shock
  - To prevent hemodynamic deterioration and negative left ventricular remodeling
- During high-risk PCI
  - To perform PCI in the ULM / last remaining patent vessel / 3VD, or in patients with very poor left ventricular function

Percutaneous circulatory support



IABP TANDEM HEART IMPELLA 2.5 l/min ECMO

Thiele H et al, EuroInterv 2011;7:636-7

Table 1. Technical features of currently available percutaneous LVADs for haemodynamic support in the cathlab.

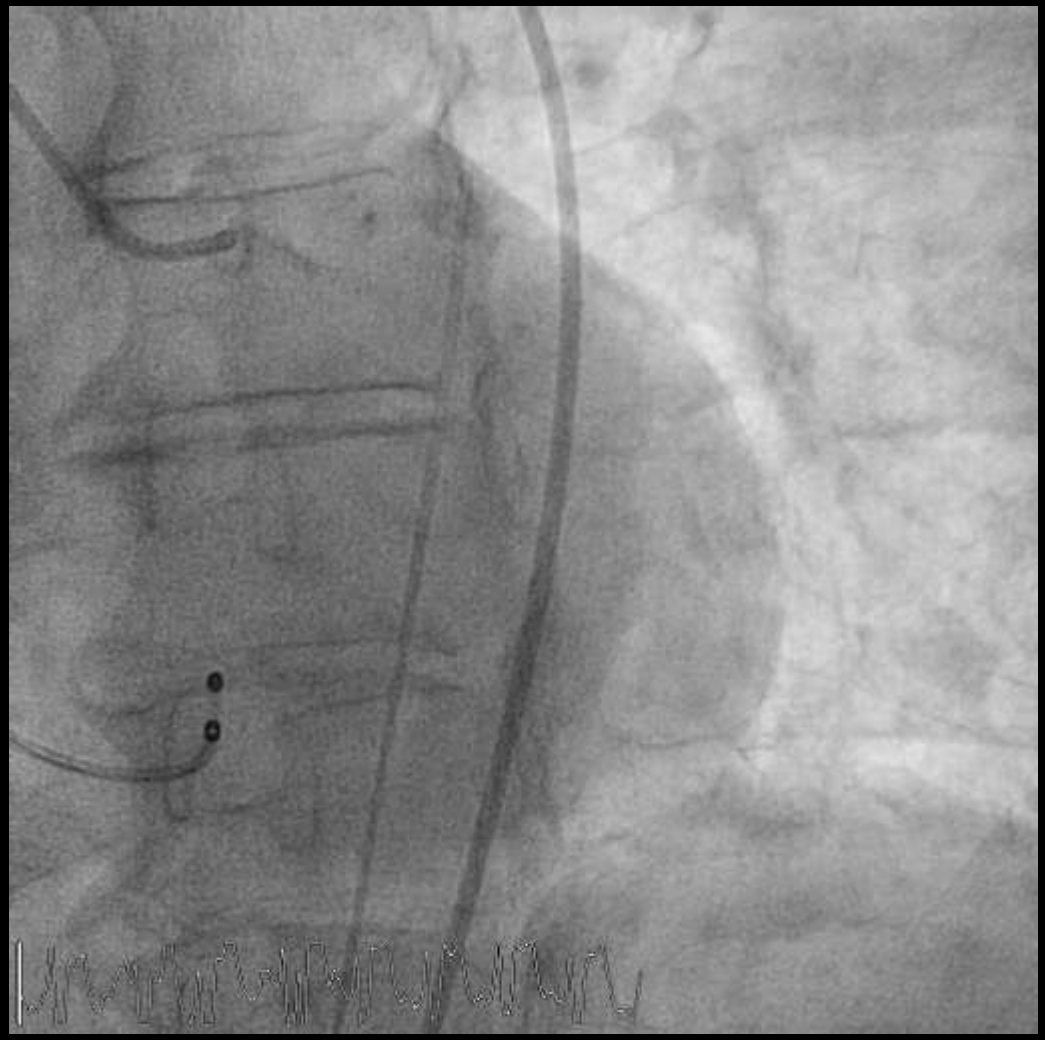
	IABP	Tandem Heart™	Impella Recover® LP 5.0	Impella Recover® LP 2.5	ECMO (multiple systems)
Catheter size (French)	7-8 (sheathless insertion possible)	–	9	9	
Cannula size (French)	–	21 venous 12-19 arterial	21	12	17-21 venous 16-18 arterial
Flow (l/min)	0	Max. 4.0	Max. 5.0	Max. 2.5	Max. 7.0
Pump speed (rpm)	0	Max. 7,500	Max. 33,000	Max. 51,000	Max. 5,000
Insertion/Placement	Percutaneous (femoral artery)	Percutaneous (femoral artery + left atrium after transseptal puncture)	Peripheral surgical cut-down (femoral artery)	Percutaneous (femoral artery)	Percutaneous (femoral artery and vein)
Anticoagulation	±	+	+	+	+
Recommended duration of use	– 30 days (no upper limit)	– 14 days	10 days	10 days	– 7 days
CE-certification	+	+	+	+	+
FDA	+	+	+	+	+
Relative costs in comparison to IABP	-	+++++	++++	+++	+(+) Depending on system

IABP: intra-aortic balloon pump; ECMO: extracorporeal membrane oxygenation; CE: conformité européenne/ European conformity marking

Thiele H et al, EuroInterv 2011;7:636-7

Acute heart failure-C. shock

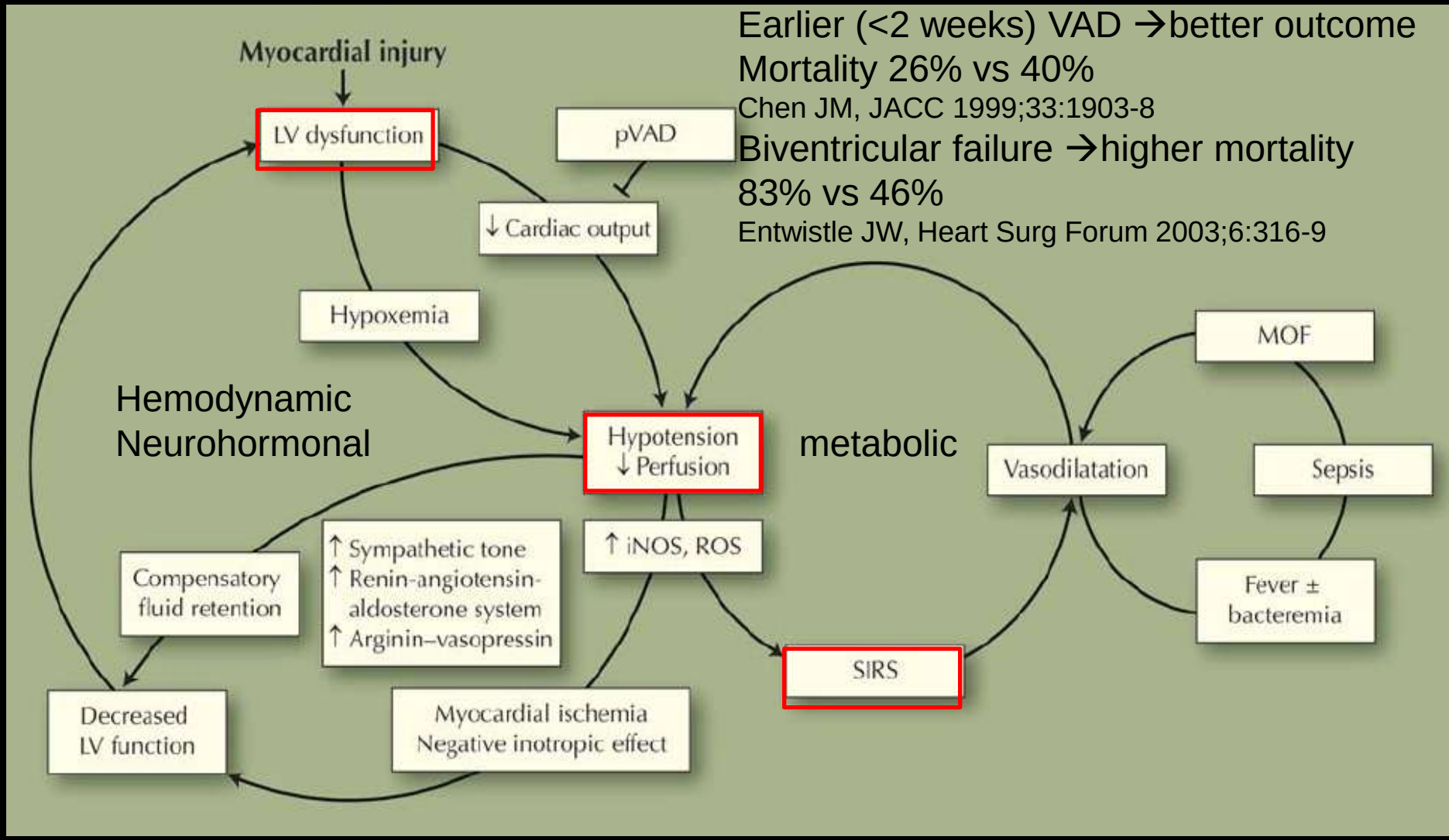
- 59 yo woman
- Dyslipedemia
- Recent abdominal surgery
- 4-hour chest pain and syncope
- In ER oriented with undetectable blood pressure, cold skin
- ECG ST V1-V4
- DAPT, dobutamine



Acute heart failure-C. shock

- IABP, PM, met. acidosis
- Thrombus aspiration
- GP 2b/3a I
- Stent prox LAD (TIMI 1-2)
- Hypoxemia→intubation
- Unable to recanalize dLCx (TIMI 0)
- SAP 70 mmHg
- After 6 hours ECMO
- Next day DIC, death

Cardiogenic shock



Earlier (<2 weeks) VAD →better outcome
Mortality 26% vs 40%
Chen JM, JACC 1999;33:1903-8
Biventricular failure →higher mortality
83% vs 46%
Entwistle JW, Heart Surg Forum 2003;6:316-9

Cook S, Curr Cardiol Rep 2009;11:369-76

Is IABP beneficial in STEMI complicated with shock?

Trial	IABP n/N	no IABP n/N	30-day mortality risk difference
No reperfusion			
Moloupoulos	24/34	15/15	
Overall	24/34	15/15	−0.29 (−0.47 to −0.12)
Thrombolysis			
Stomel	28/51	10/13	
Kovack	10/27	13/19	
Bengtson	48/99	58/101	
Waksman	11/20	17/21	
GUSTO-1	30/62	146/248	
SHOCK registry	220/439	300/417	
NRMI-2 TT	1068/2180	2346/3501	
Overall	1415/2878	2890/4320	−0.18 (−0.20 to −0.16)
Primary PCI			
NRMI-2 PCI	956/2035	401/955	
AMC CS	93/199	26/93	
Overall	1049/2234	427/1048	0.06 (0.03 to 0.10)
Overall	2488/5146	3332/5383	−0.11 (−0.13 to −0.09)

−1 −0.5 0 0.5 1

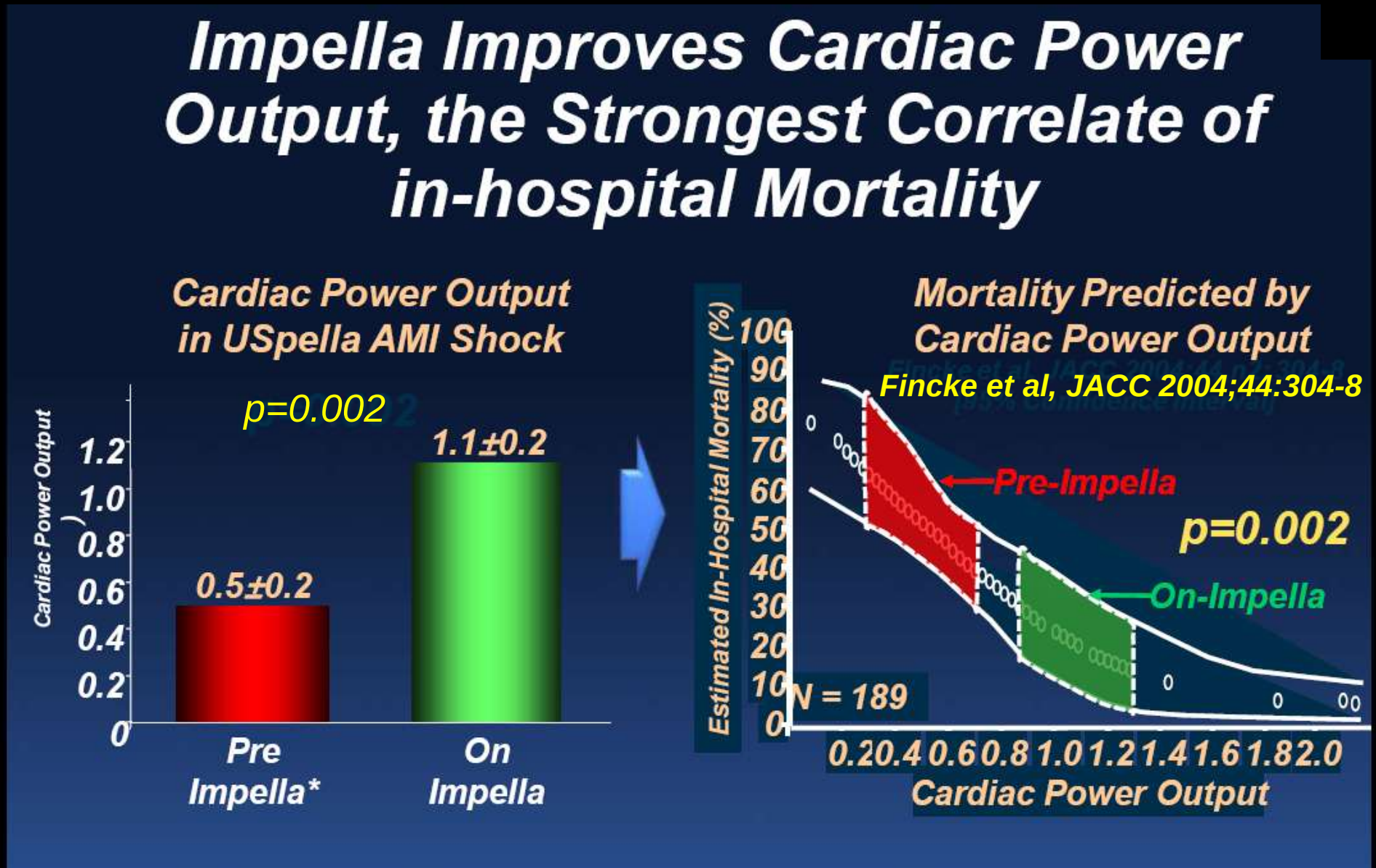
IABP Better

no IABP Better

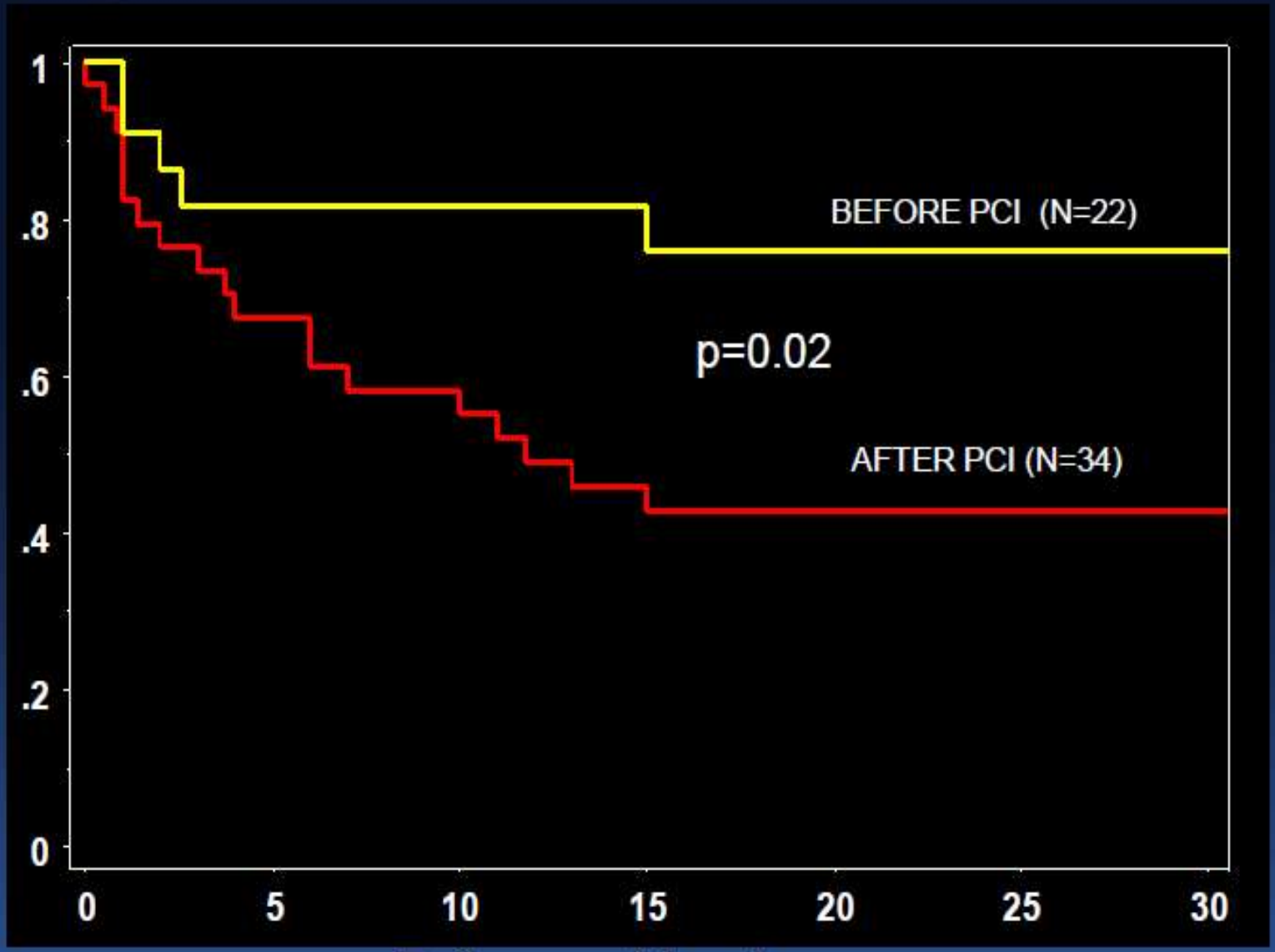
P (heterogeneity)<0.0001
I^2=93.6%
P (overall effect)<0.0001

Sjauw KD et al, EHJ 2009;30:459-68

USpella AMI shock (N=43)



Timing of Insertion vs Outcome in AMI Shock



W. O'Neill for the USPELLA Investigators TCT 2010

Reversal of Cardiogenic Shock by Percutaneous Left Atrial–to–Femoral Arterial Bypass Assistance

Holger Thiele, MD; Bernward Lauer, MD; Rainer Hambrecht, MD; Enno Boudriot, MD; Howard A. Cohen, MD; Gerhard Schuler, MD

- 18 Consecutive patients with CGS and AMI (44-89yo)
- 5/18 Ventricular septal rupture
- Mean duration of support 4 ± 3 days
- Survival at 30 days 56% (77% excluding VSD pts)

CI

mAP

PCW

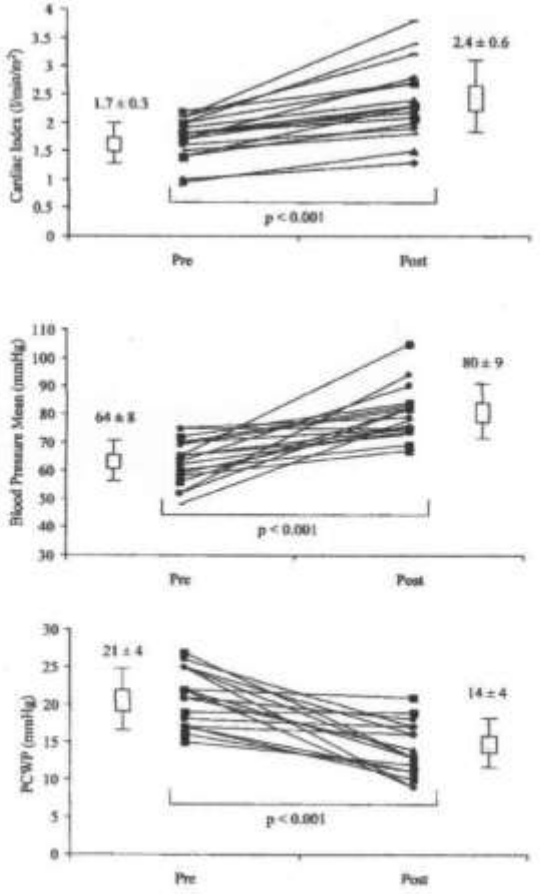


Figure 2. Hemodynamic parameters before and after VAD implantation.

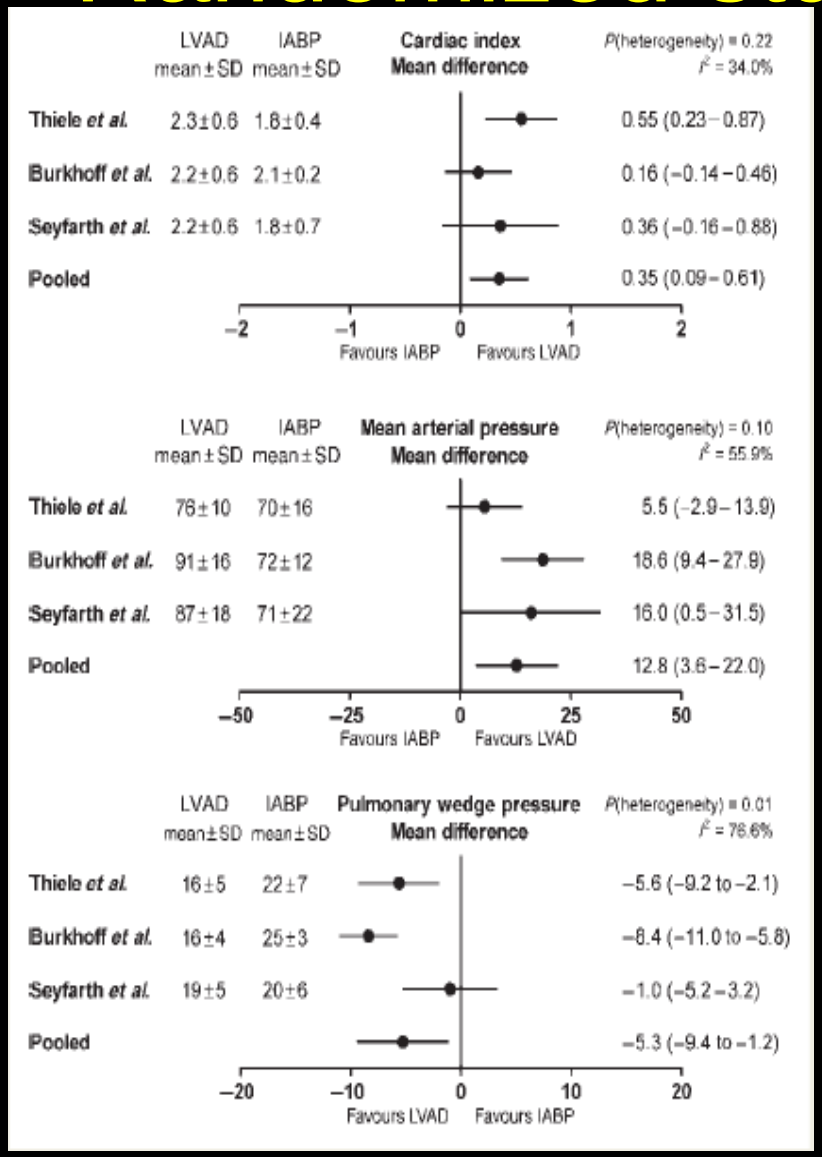
Circulation 104:2917-2922, 2001

Metaanalysis in cardiogenic shock: Randomized studies pVAD vs IABP

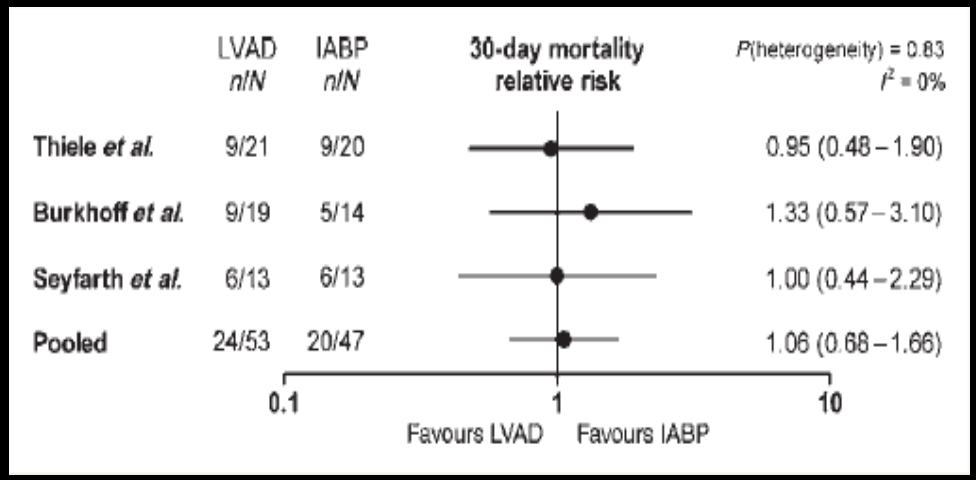
	Thiele *et al.*[16] TandemHeart		Burkhoff *et al.*[17] TandemHeart		Seyfarth *et al.*[18] Impella		Pooled (fixed effect model)			Pooled (random effects model)		
	LVAD ($n = 21$)	IABP ($n = 20$)	LVAD ($n = 19$)	IABP ($n = 14$)	LVAD ($n = 13$)	IABP ($n = 13$)	Mean difference/ relative risk		*P*-value	Mean difference/ relative risk		*P*-value
Haemodynamics												
CI ± SD (L/min/m^2)	2.3 ± 0.6	1.8 ± 0.4	2.2 ± 0.6	2.1 ± 0.2	2.2 ± 0.6	1.8 ± 0.7	0.35	(0.14; 0.55)	<0.001	0.35	(0.09; 0.61)	<0.01
MAP ± SD (mmHg)	76 ± 10	70 ± 16	91 ± 16	72 ± 12	87 ± 18	71 ± 22	12.1	(6.3; 17.9)	<0.001	12.8	(3.6; 22.0)	<0.01
PCWP ± SD (mmHg)	16 ± 5	22 ± 7	16 ± 4	25 ± 3	19 ± 5	20 ± 6	−6.2	(−8.0; −4.3)	<0.001	−5.3	(−9.4; −1.2)	<0.05
Clinical outcome												
30-day mortality, *n* (%)	9 (43)	9 (45)	9 (47)	5 (36)	6 (46)	6 (46)	1.06	(0.68; 1.66)	0.80	1.06	(0.68; 1.66)	0.80
Reported adverse events												
Leg ischaemia, *n* (%)	7 (33)	0 (0)	4 (21)	2 (14)	1 (8)	0 (0)	2.59	(0.75; 8.97)	0.13	2.59	(0.75; 8.97)	0.13
Bleeding, *n* (%)	19 (90)	8 (40)	8 (42)	2 (14)			2.35	(1.40; 3.93)	<0.01	2.35	(1.40; 3.93)	<0.01
Fever of sepsis, *n* (%)	17 (81)	10 (50)	4 (21)	5 (36)			1.38	(0.88; 2.15)	0.16	1.11	(0.43; 2.90)	0.83

Cheng JM et al, EHJ 2009;2102-8

Metaanalysis in cardiogenic shock: Randomized studies pVAD vs IABP



No mortality benefit



Cheng JM et al, EHJ 2009;2102-8

Management of acute myocardial infarction in patients presenting with persistent ST-segment elevation

Treatment of shock (Killip class IV)		
O_2	I	C
Mechanical ventilatory support according to blood gasses	I	C
Haemodynamic assessment with balloon floating catheter	IIb	C
Inotropic agents: dopamine	IIb	B
and dobutamine	IIa	C
Intra-aortic balloon pump	I	C
LV assist devices	IIa	C
Early revascularization	I	B

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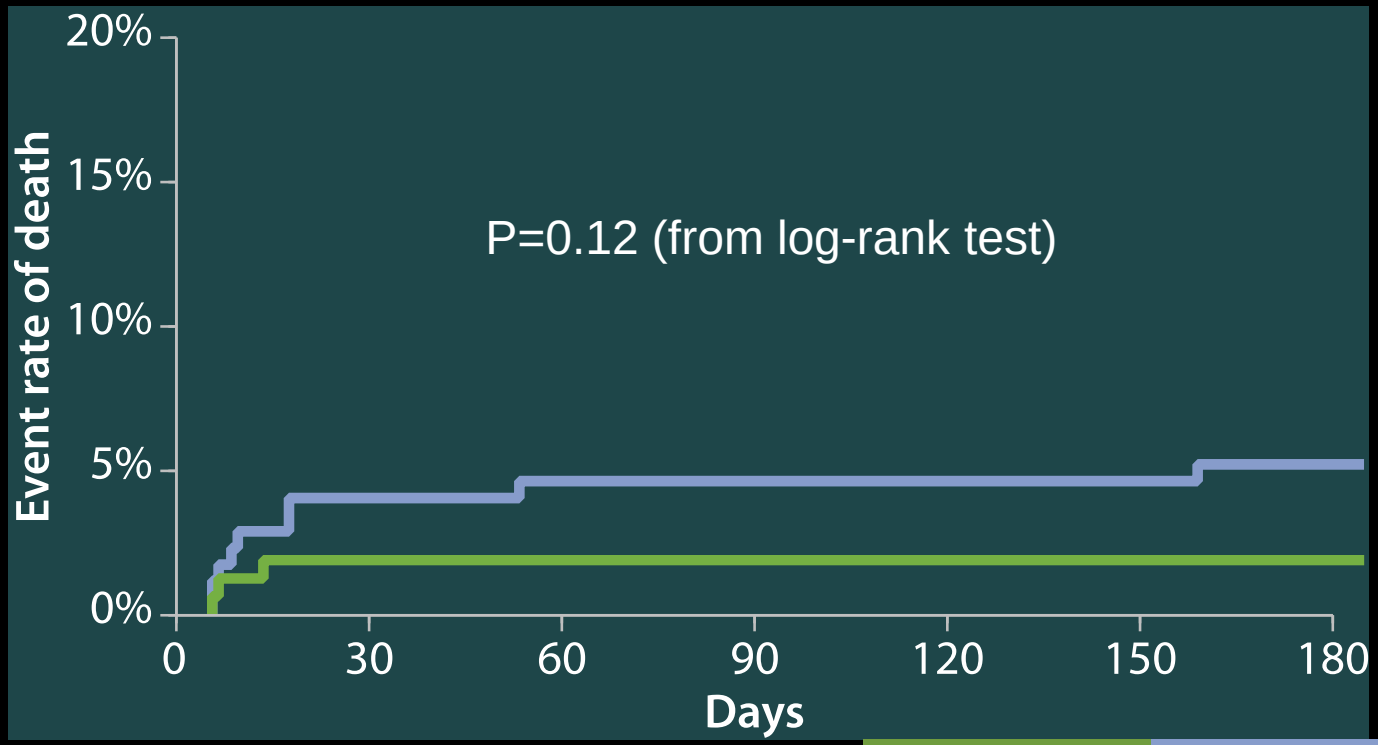
European Heart Journal (2008) **29**, 2909–2945
doi:10.1093/eurheartj/ehn416

CRISP AMI IABP(AWMI-no shock))
All Cause Death – 6 months

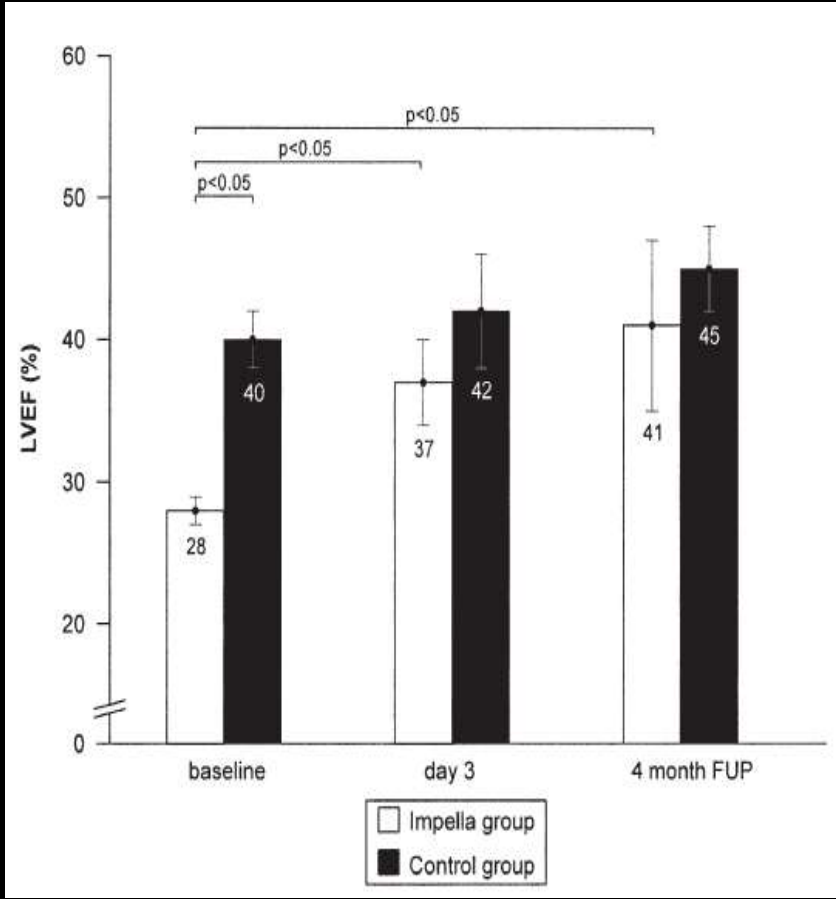


	IABC (N=161)	SOC (N=176)	P Value
Death, %	1.9*	5.2*	0.12*
Death/recurrent MI/new or worsening CHF, %	6.3*	10.9*	0.15*
Death/shock/new or worsening CHF, %†	5.0*	12.0*	0.03*

**From KM curves and log-rank test.* *†Exploratory analysis.*

Huber K, TCT 2011

Impella 2,5 in STEMI without shock



- First anterior STEMI
- 10 pts Impella
- 10 pts routine care ± IABP
- No difference in outcome

Sjauw KD, JACC 2008;51:1044-6

Impella assisted PCI

- 50 y. old male
- History of AWMI and IWMI
- pLAD 70%, mLAD 95%, p LCx 80%, p RCA 80%
- LV 72/70mm, LVEF<20%
- DSE: viability ALW, scar IPW
- pLAD stent 3.5X9 mm
- mLAD stent 2.5X24 mm
- No troponin release
- Discharged on 3rd day

Impella in high-risk PCI

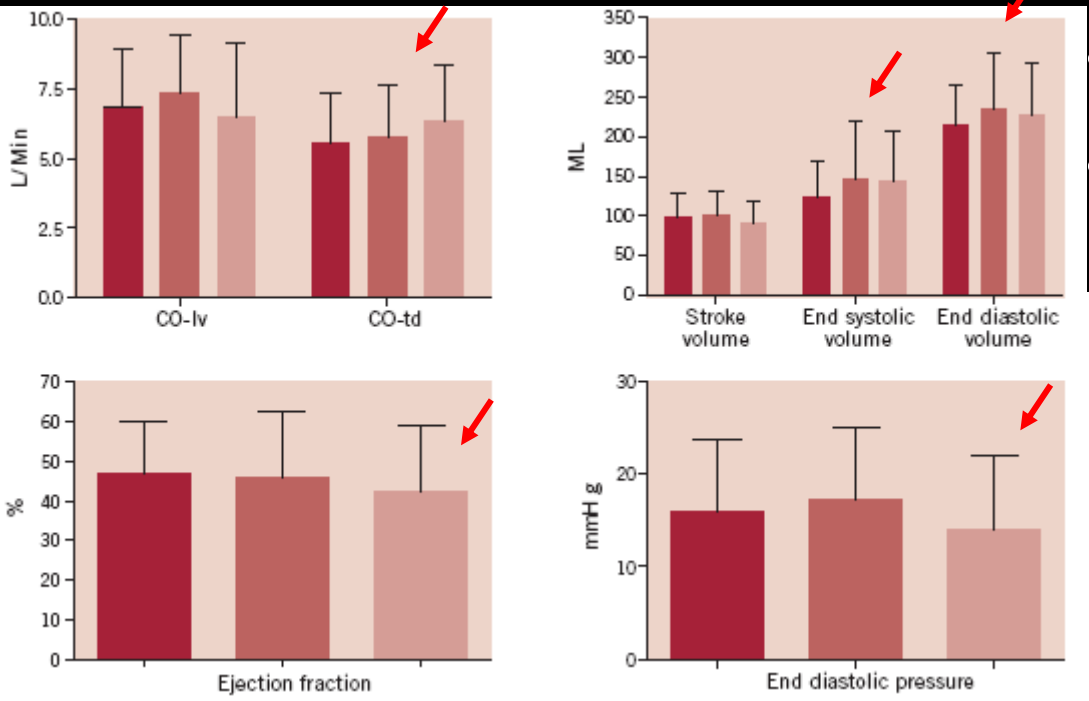
- 20 patients
- Elective PCI of ULM or last patent vessel
- LVEF <35%

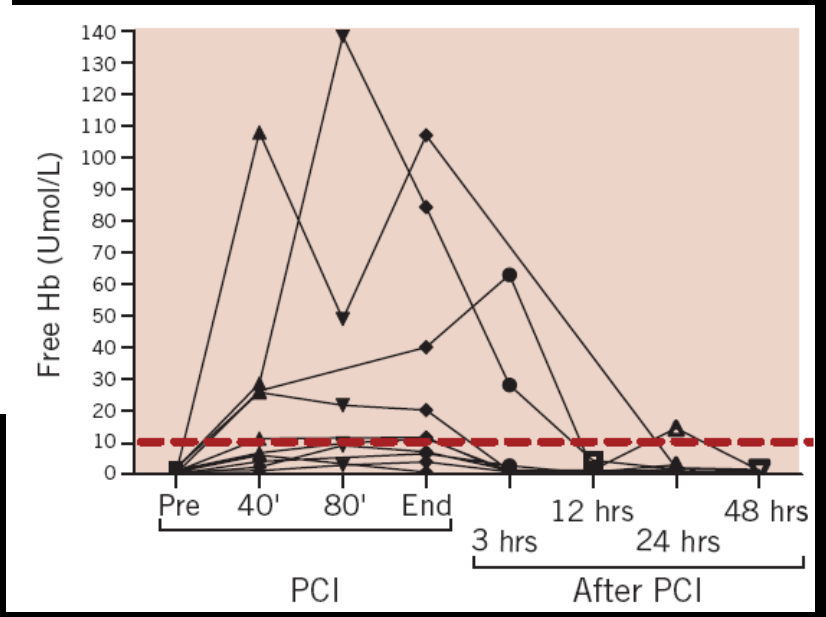
- All Impella implantations successful
- Support ~ 1.7 h
- Flow 2.2 lpm
- 2 peri-PCI AMI
- 2 deaths
- 10 mild hemolysis
- No hemodynamic compromise

Dixon SR et al, JACC Interv 2009;2:91-6

Impella in high-risk PCI

- N=10
- AR upon insertion
- No clear benefit in PCI





Valgimigli M, EuroIntervention 2006;2:91-100

pVADs in high-risk PCIs

61%-100%

Study	Year	*N*	Device	30-day survival, *n* (%)
Vranckx et al. [51]	2003	3	TH	3 (100)
Aragon et al. [52]	2005	8	TH	7 (87)
Giombolini et al. [53]	2006	3	TH	3 (100)
Kar et al. [54]	2006	7	TH	6 (86)
Kar et al. [55]	2006	5	TH	4 (80)
Vranckx et al. [56]	2008	23	TH	14 (61*)
Rajdev et al. [57]	2008	20	TH	19 (95)
Al-Husami et al. [58]	2008	6	TH	5 (83)
Gimelli and Wolff [34]	2008	10	TH	10 (100)
Vranckx et al. [59]	2009	9	TH	8 (89)
Cook et al. [60]	2007	19	TH/IP	15 (79*)
Henriques et al. [61••]	2006	19	IP	11(89%)
Remmelink et al. [62]	2007	11	IP	11 (100)
Thomopoulou et al. [35]	2008	3	IP	2 (67)
Valgimigli et al. [6]	2006	10	IP	—
Burzotta et al. [63]	2008	10	IP	10 (100)
Vecchio et al. [64]	2008	7	IP	7 (100)
Eichhöfer et al. [65]	2008	2	IP	2 (100)
Dixon et al. [66]	2009	20	IP	18 (90)

Cook S, Curr Cardiol Rep 2009;11:369-76

The Europella Registry during high-risk PCI

N=144

PCI procedure	
Time of PCI procedure (min)	114.7 ± 55.2
Number of target lesions	
1	42 (29.2)
2	47 (32.6)
>3	55 (38.2)
EuroSCORE: standard	8.2 ± 3.4
EuroSCORE: logistic (%)	15.0 ± 12.2
Qualification for high-risk PCI	
Left main coronary artery PCI	76 (52.8)
Last patent vessel PCI	25 (17.4)
Multivessel disease	118 (81.9)
Low LVEF	51 (35.4)
Other	12 (8.3)
Refused for CABG	62 (43.1)

Values are mean ± SD or n (%).

Variables	All SAEs
Primary safety end point—MACCE, n (%)	
Death	8 (5.5)
Bleeding requiring transfusion	8 (5.5)
Bleeding requiring surgery	1 (0.7)
MI	0 (0)
Urgent CABG	0 (0)
Stroke	1 (0.7)
Secondary safety end point, n (%)	
Device malfunction	0 (0)
Infection	1 (0.7)
Vascular complication	6 (4.0)
Renal failure	3 (2.1)
Hemolysis requiring transfusion	1 (0.7)
Primary efficacy end point	
Impella implantation rate—easy/suitable/difficult (%)	86.8/12.5/0.7
Impella explantation rate*—easy/suitable/difficult (%)	93.7/5.6/0.7
Impella support time (min)	87.8 ± 50.7

Sjauw *et al.*
The Europella Registry

JACC Vol. 54, No. 25, 2009
December 15/22, 2009:2430–4

PROTECT II Study Flow

Lasala JM and O' Neil W
TCT 2011

Assessed for Eligibility
N=1082

Not Eligible: N=635
- 47.8% Met Exclusion criteria
- 30% Patient refusal, MD decision
- 13% Unknown
- 9.2% Referred for CABG

Randomized Intent-to-Treat N=447

Intent-To-Treat (ITT) population (N=447)

IABP
N= 223
90day F/U, N=220

IMPELLA
N= 224
90day F/U, N=222

(N=12)
- 2 withdrew consent post PCI (alive)
- 3 EF >=35%
- 3 Not 3VD or ULM
- 1 Active MI
- 2 Severe PVD or AS
- 1 Platelets<70000

(N=9)
- 1 withdrew consent post PCI (alive)
- 1 EF >=35%
- 1 Not 3VD or ULM
- 3 Active MI
- 1 Severe PVD
- 1 Platelets<70000
- 1 Creatinine>4

Per Protocol (PP) population (N=426)

IABP
30day N= 211
90day F/U, N=210

IMPELLA
30day N= 215
90day F/U, N=213

Per Protocol population= Patients that met all inclusion and exclusion criteria.
Per Protocol population was pre-specified and patients were identified prospectively prior to the statistical analysis.

PROTECT II Outcome** (PP)

Lasala JM and O' Neil W
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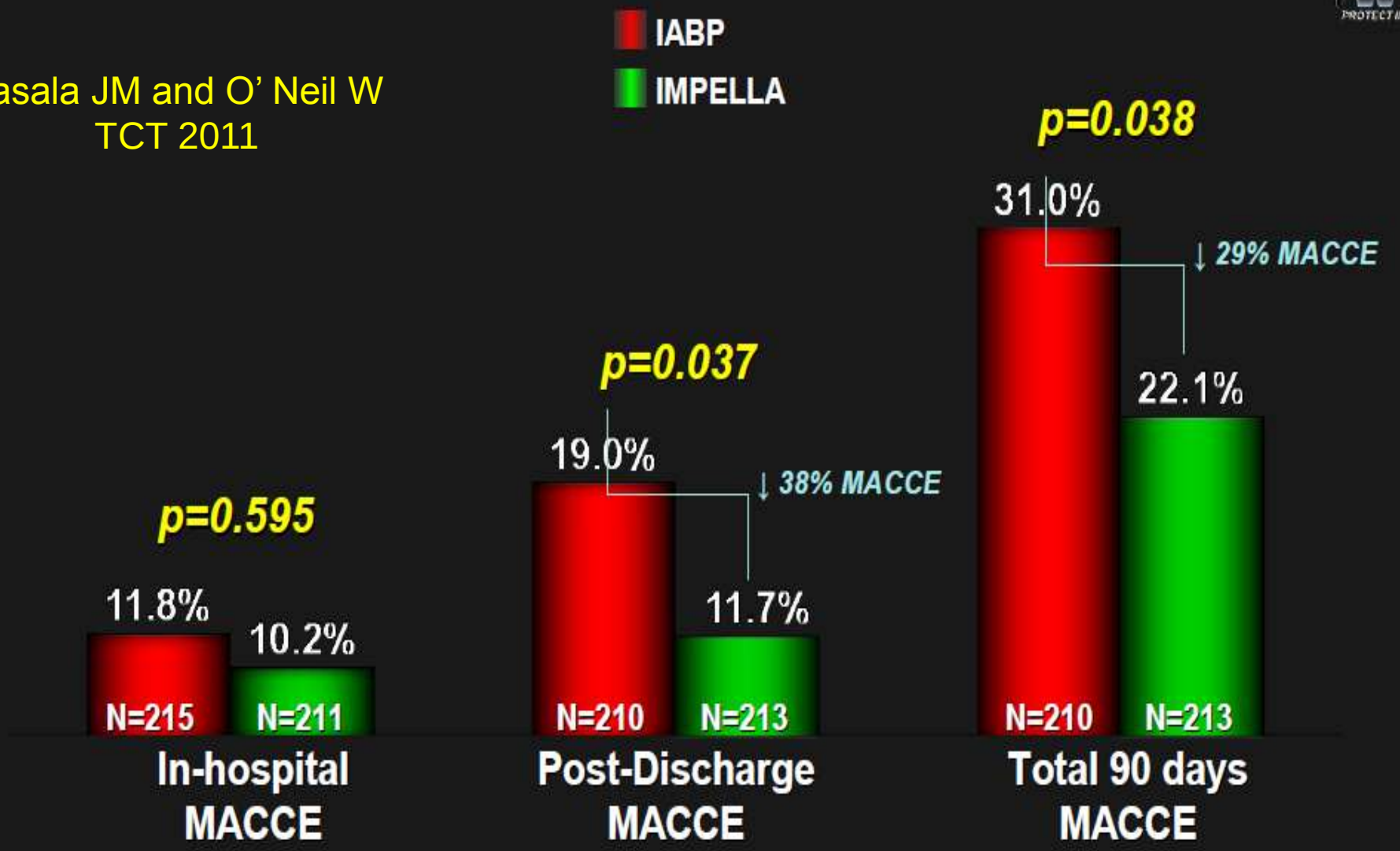

MACCE = Death/Stroke or TIA/MI/Repeat Revascularization

***Using x8ULN for biomarkers or Q-wave for Peri-procedural MI (Stone et al Circulation 2001;104:642-647) and 2xULN for Spontaneous MI (Universal MI definition)*

Conclusions: pVAD during PCI?

- VADs (Impella, TandemHeart) better hemodynamics vs IABP
- Inadequate data from randomized studies
- AMI with shock
  - Mortality benefit not yet demonstrated
  - Early VAD implementation and transition to higher level VAD beneficial?
- Large AMI without shock
  - VAD not recommended
- During high-risk PCI
  - Powerful VAD (Impella) possibly beneficial vs IABP