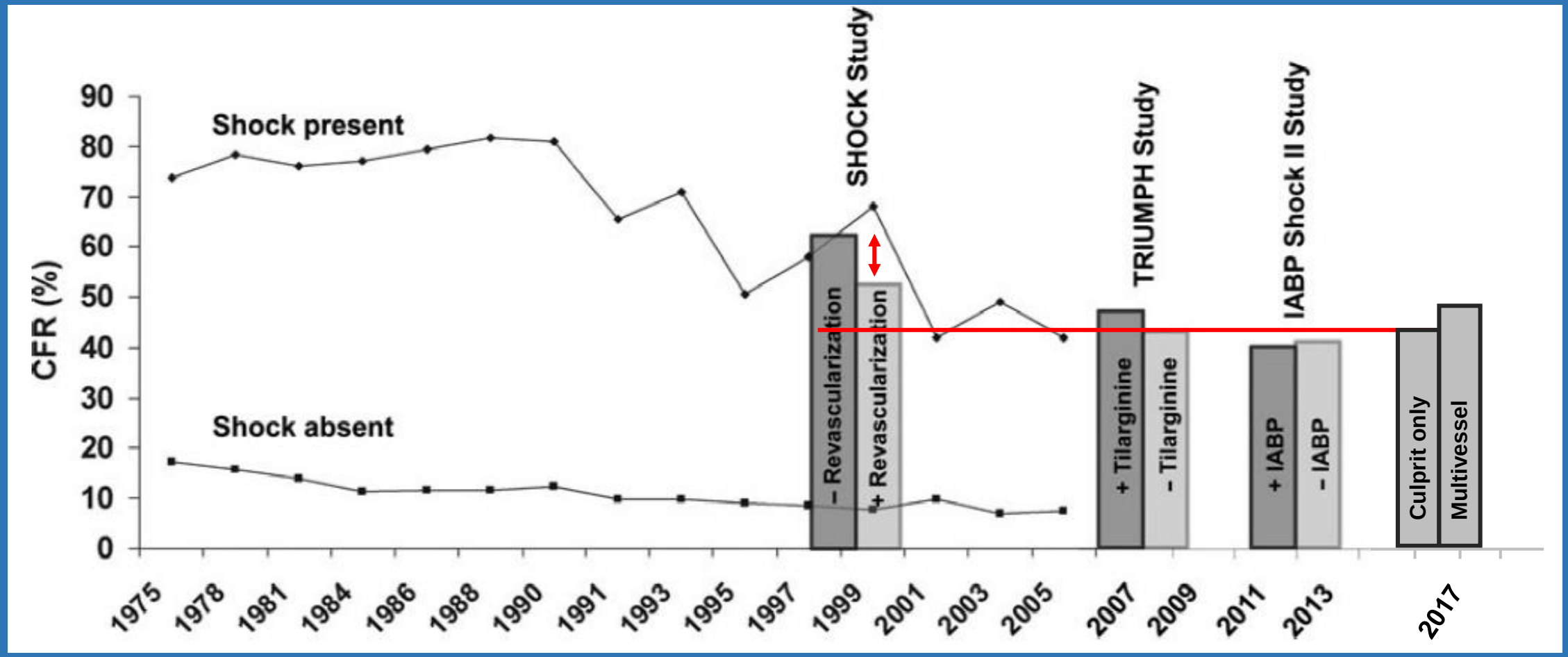
Optimal Selection of Impella Patients in Cardiogenic Shock

Selection of the right patient: What can we learn from the main registries?

Prof. Dr. Tom Adriaenssens
Dept. of Cardiovascular Medicine
University Hospitals Leuven, Belgium
10-05-2021



Werdan et al. Eur Heart J. 2014.

Lesson 1

Important additional efforts are needed to achieve better results in the treatment of cardiogenic shock (CGS)

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WORKS IN PROGRESS

A Randomized Clinical Trial to Evaluate the Safety and Efficacy of a Percutaneous Left Ventricular Assist Device Versus Intra-Aortic Balloon Pumping for Treatment of Cardiogenic Shock Caused by Myocardial Infarction

Melchior Seyfarth, MD,*† Dirk Sibbing, MD,* Iris Bauer, MS,* Georg Fröhlich, MD,† Lorenz Bott-Flügel, MD,† Robert Byrne, MB, MRCPI,* Josef Dirschinger, MD,† Adnan Kastrati, MD,* Albert Schömig, MD*†

Munich, Germany

Seyfarth et al. J Am Coll Cardiol 2008; 52: 1584-8.

Table 2 Hemodynamic Values Before and After Device Implantation

	Impella Before (n = 13)	IABP Before (n = 13)	Impella After (n = 13)	IABP After (n = 13)	p Value
CI (l/min/m^2)	1.71 ± 0.45	1.73 ± 0.59	2.20 ± 0.64	1.84 ± 0.71	0.18
CO (l/min)	3.16 ± 0.77	3.46 ± 1.46	4.12 ± 1.21	3.67 ± 1.76	0.48
Mean AP (mm Hg)	78 ± 16	72 ± 17	87 ± 18	71 ± 22	0.062
Systolic AP (mm Hg)	106 ± 22	101 ± 23	110 ± 24	97 ± 29	0.20
Diastolic AP (mm Hg)	64 ± 15	58 ± 14	74 ± 17	50 ± 16	0.001
Heart rate (beats/min)	95 ± 24	97 ± 24	103 ± 21	99 ± 22	0.68
PCWP (mm Hg)	22 ± 8	22 ± 7	19 ± 5	20 ± 6	0.67
RAP (mm Hg)	13 ± 7	12 ± 6	13 ± 3	12 ± 5	0.82
Mean PAP (mm Hg)	28 ± 8	28 ± 9	28 ± 8	30 ± 11	0.73
SVR (dyn·s·cm^{-5})	1,617 ± 385	1,546 ± 763	1,457 ± 467	1,333 ± 784	0.63

Values are mean ± SD; p values are for independent comparisons of values for Impella after and IABP after implantation.

AP = arterial pressure; CI = cardiac index; CO = cardiac output; IABP = intra-aortic balloon pump; PAP = pulmonary arterial pressure; PCWP = pulmonary capillary wedge pressure; RAP = right atrial pressure; SVR = systemic vascular resistance.

Seyfarth et al. J Am Coll Cardiol 2008; 52: 1584-8.

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Seyfarth et al. J Am Coll Cardiol 2008; 52: 1584-8.

Lesson 2 (ISAR-SHOCK)

Use of Impella 2.5: feasible and safe, improved hemodynamics (↑ CI)

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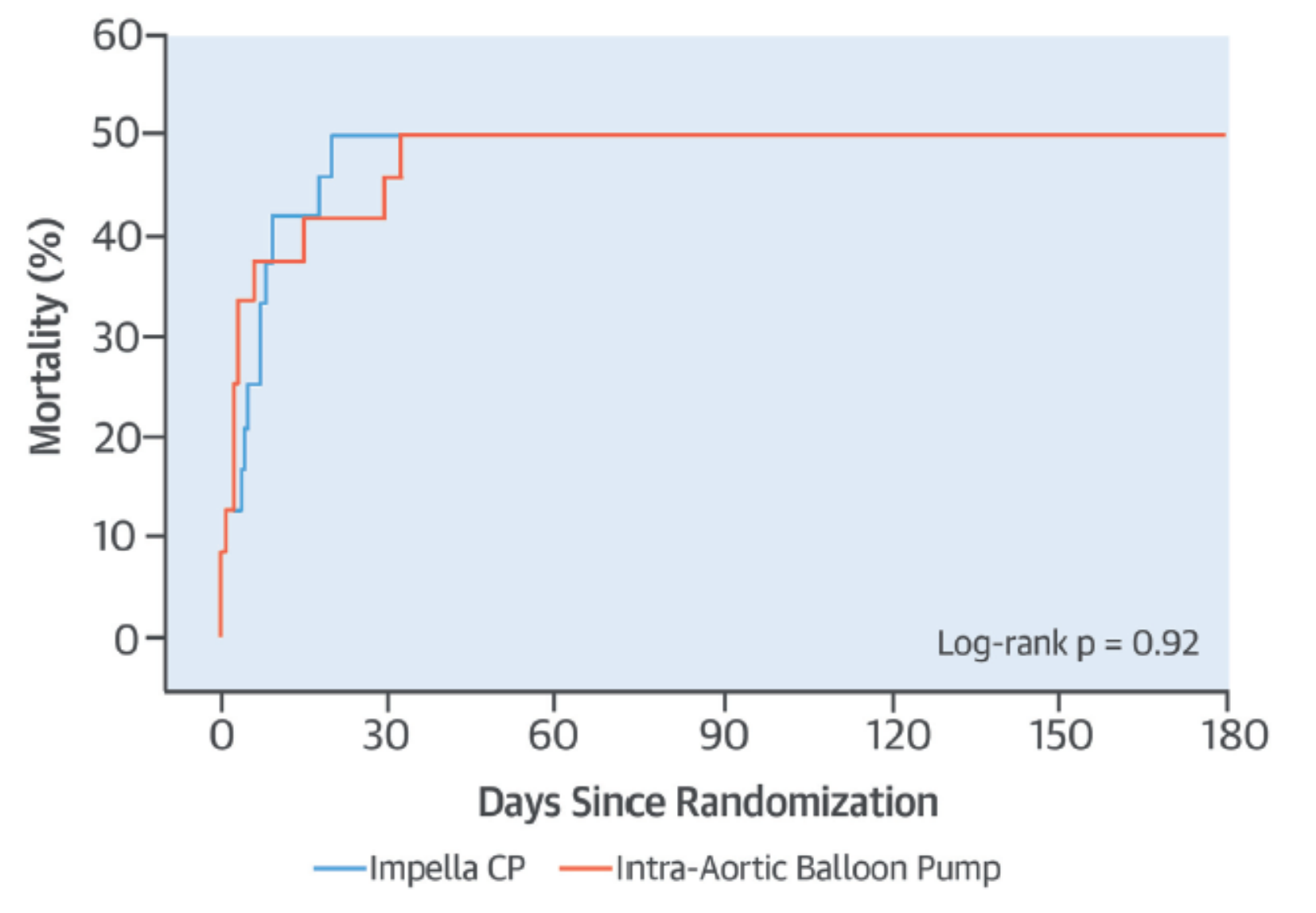
Percutaneous Mechanical Circulatory Support Versus Intra-Aortic Balloon Pump in Cardiogenic Shock After Acute Myocardial Infarction

Dagmar M. Ouweneel, MSc,[a] Erlend Eriksen, MD,[b] Krischan D. Sjauw, MD, PhD,[a] Ivo M. van Dongen, MD,[a] Alexander Hirsch, MD, PhD,[a] Erik J.S. Packer, MD,[b] M. Marije Vis, MD, PhD,[a] Joanna J. Wykrzykowska, MD, PhD,[a] Karel T. Koch, MD, PhD,[a] Jan Baan, MD, PhD,[a] Robbert J. de Winter, MD, PhD,[a] Jan J. Piek, MD, PhD,[a] Wim K. Lagrand, MD, PhD,[c] Bas A.J.M. de Mol, MD, PhD,[a] Jan G.P. Tijssen, PhD,[a] José P.S. Henriques, MD, PhD[a]

Ouweneel et al. J Am Coll Cardiol 2017; 69: 278-87.



Ouweneel et al. J Am Coll Cardiol 2017; 69: 278-87.

TABLE 3 Clinical Course During Admission

	pMCS (n = 24)	IABP (n = 24)
Hemodynamic variables before randomization		
Heart rate, beats/min	81 ± 21	83 ± 28
Mean arterial pressure, mm Hg	66 ± 15	66 ± 15
Systolic blood pressure, mm Hg	81 ± 17	84 ± 19
Diastolic blood pressure, mm Hg	58 ± 22	57 ± 13
Medical therapy before randomization		
Catecholamines or inotropes	24/24 (100)	22/24 (92)
Mechanical ventilation	24/24 (100)	24/24 (100)
Cardiac arrest before randomization	24/24 (100)	20/24 (83)
Witnessed arrest	22/24 (92)	17/20 (85)
First rhythm VT/VF	22/24 (92)	17/20 (85)
Time till return of spontaneous circulation, min	21 (15-46)	27 (15-52)
Traumatic injuries at admission	5/24 (21)	2/24 (8)
Blood values on admission*		
Lactate, mmol/l	7.5 ± 3.2	8.9 ± 6.6
Hemoglobin, mmol/l	8.6 ± 1.2	8.6 ± 1.2
Creatinine, mg/dl	96 ± 29	102 ± 22
Glucose, mmol/l	16.2 ± 4.7	14.1 ± 5.3
Arterial pH	7.14 ± 0.14	7.17 ± 0.17
Baseline echocardiography†		
Estimated left ventricular ejection fraction		
<20%	5/22 (23)	8/18 (44)
20%-40%	10/22 (46)	6/18 (33)
>40%	7/22 (32)	4/18 (22)

Ouweneel et al. J Am Coll Cardiol 2017; 69: 278-87.

TABLE 4 Clinical and Functional Outcomes

	pMCS (n = 24)	IABP (n = 24)	p Value	Hazard Ratio With pMCS (95% CI)
Mortality*				
30-day all-cause mortality	11 (46)	12 (50)	0.92	0.96 (0.42-2.18)
6-month all-cause mortality	12 (50)	12 (50)	0.92	1.04 (0.47-2.32)
Clinical outcomes at 6 months				
Cause of death				
Refractory cardiogenic shock	4 (17)	3 (13)		
Post-anoxic neurological death	5 (21)	6 (25)		
Other reason	3 (13)	3 (13)		
Stroke	1 (4)	1 (4)		
Hemorrhagic stroke	0 (0)	0 (0)		
Ischemic stroke	1 (4)	1 (4)		
Major vascular complication	1 (4)	0 (0)		
Major bleeding	8 (33)	2 (8)		
Device-related bleeding	3 (13)	1 (4)		
Retroperitoneal	1 (4)	0 (0)		
IABP/Impella puncture site	2 (8)	1 (4)		
Nondevice-related bleeding	5 (21)	1 (4)		
Gastro-intestinal bleeding	0 (0)	1 (4)		
Bleeding at other puncture site	1 (4)	0 (0)		
Other location	4 (17)	0 (0)		
Hemolysis requiring extraction of the device	2 (8)	0 (0)		

Ouweneel et al. J Am Coll Cardiol 2017; 69: 278-87.

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Hemolysis requiring extraction of the device	2 (8)	0 (0)		

Ouweneel et al. J Am Coll Cardiol 2017; 69: 278-87.

Lessons 3 & 4 (IMPRESS)

Outcome of the use of mechanical circulatory support (MCS) in CGS patients who have suffered cardiac arrest is questionable (bad neurologic outcome)

Considerable room for improvement with respect to patient management (bleeding, hemolysis,…)

Circulation

ORIGINAL RESEARCH ARTICLE

The Evolving Landscape of Impella Use in the United States Among Patients Undergoing Percutaneous Coronary Intervention With Mechanical Circulatory Support

Amin et al. Circulation 2020; 141: 273-84.

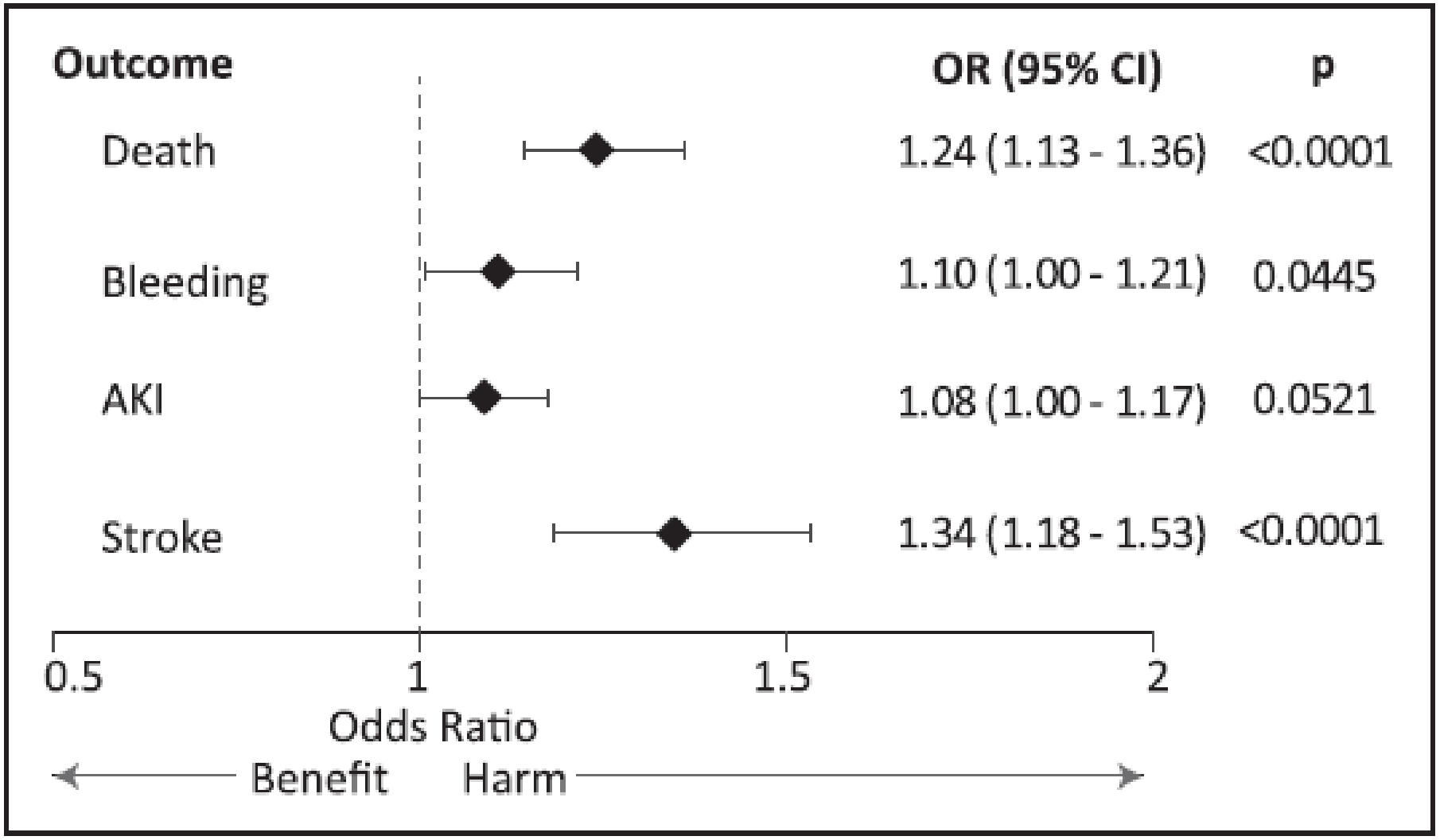


Figure 3. Association of Impella versus IABP use with clinical outcomes.

Amin et al. Circulation 2020; 141: 273-84.

Characteristic	Impella (n=4782)		Intra-Aortic Balloon Pump (n=43 524)		Total (n=48 306)	
	n	%	n	%	n	%
Percutaneous coronary intervention and lesion characteristics						
Multivessel disease	2554	53.41	10044	23.08	12598	26.08
Transradial access	529	11.06	3358	7.72	3887	8.05
Bifurcation lesion	382	7.99	1230	2.83	1612	3.34
Bare metal stents used	764	15.98	14577	33.49	15341	31.76
Chronic total occlusion	1056	22.08	6277	14.42	7333	15.18
Laser atherectomy	666	13.93	1498	3.44	2164	4.48
Rotational/orbital atherectomy	340	7.11	585	1.34	925	1.91
Mechanical ventilation	1407	29.42	16813	38.63	18220	37.72
Cardiac arrest	701	14.66	8105	18.62	8806	18.23
Cardiogenic shock	1792	37.47	22558	51.83	24350	50.41
ST-segment–elevation myocardial infarction	1267	26.5	28509	65.5	29776	61.64
Non–ST-segment–elevation myocardial infarction/unstable angina	2114	44.21	10246	23.54	12360	25.59
Indication other than acute coronary syndrome	1401	29.3	4769	10.96	6170	12.77

Amin et al. Circulation 2020; 141: 273-84.

Lesson 5

Suboptimal results, but …

- Undifferentiated use
- in a large number of centers (many low volume)
- in a broad range of presentation (definition ‘high risk PCI’ broad and unclear)
- absence of dedicated MCS ICU care in many centers
- Inheritent bias (different comparison between cases)

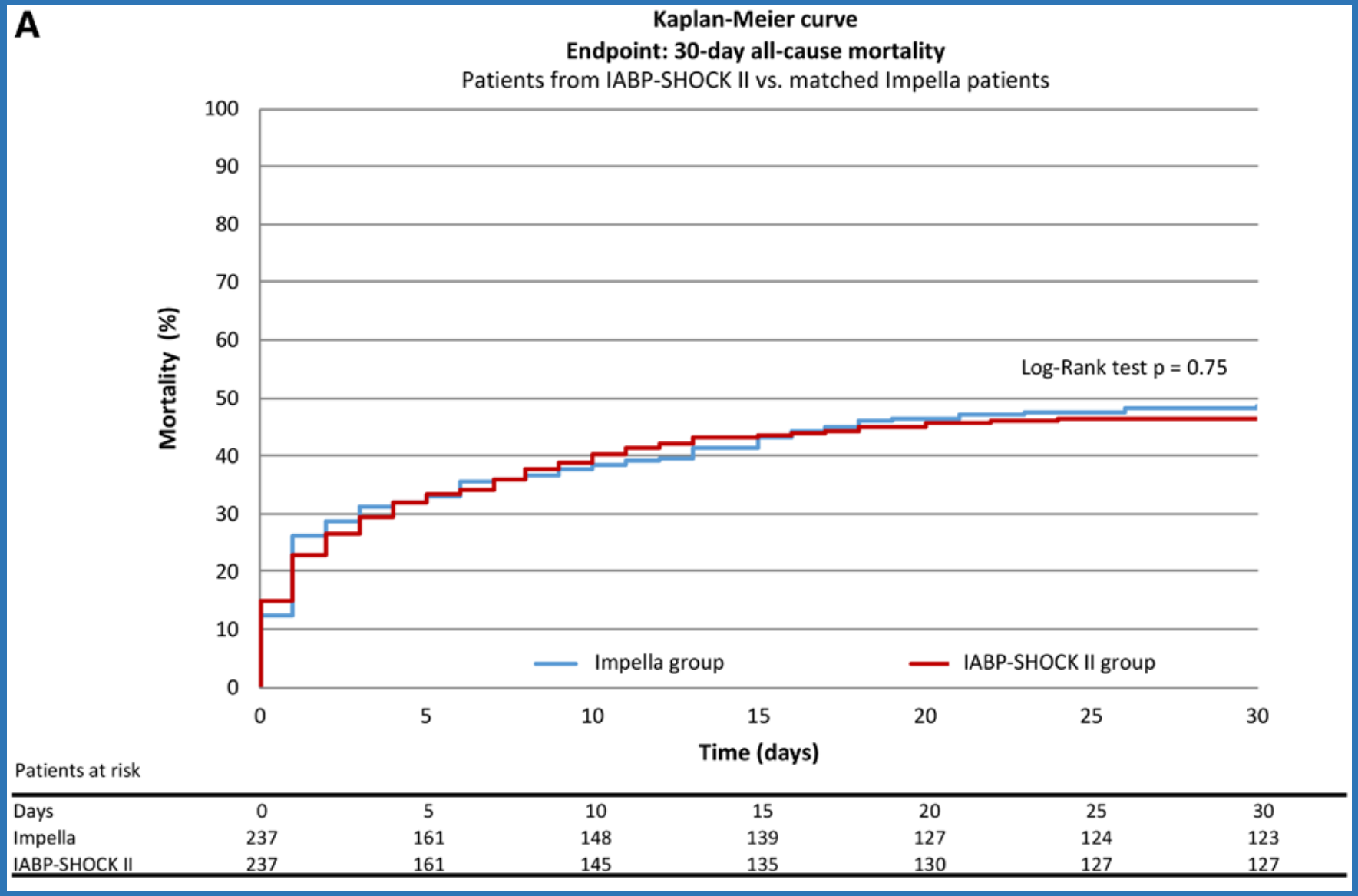
Circulation

ORIGINAL RESEARCH ARTICLE

Impella Support for Acute Myocardial Infarction Complicated by Cardiogenic Shock

Matched-Pair IABP-SHOCK II Trial 30-Day Mortality Analysis

Schrage et al. Circulation 2019; 139: 1249-58.



Schrage et al. Circulation 2019; 139: 1249-58.

JAMA | Original Investigation

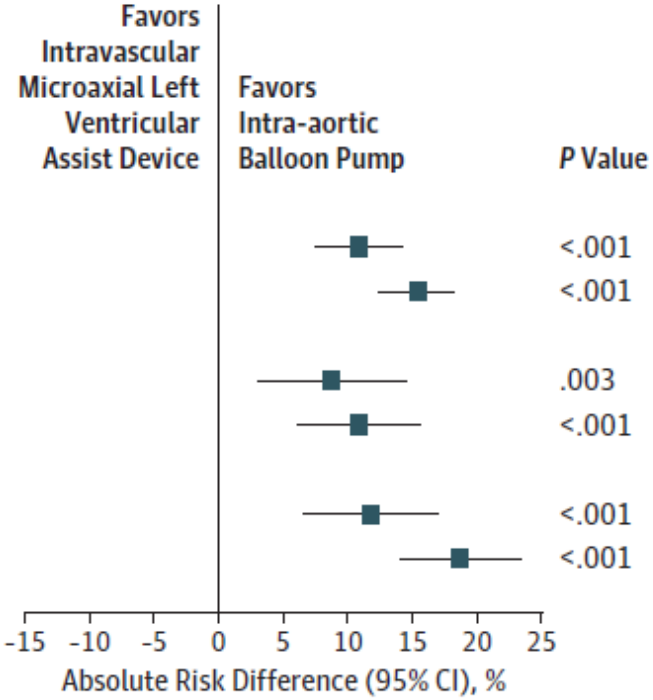
Association of Use of an Intravascular Microaxial Left Ventricular Assist Device vs Intra-aortic Balloon Pump With In-Hospital Mortality and Major Bleeding Among Patients With Acute Myocardial Infarction Complicated by Cardiogenic Shock

Sanket S. Dhruva, MD, MHS; Joseph S. Ross, MD, MHS; Bobak J. Mortazavi, PhD; Nathan C. Hurley; Harlan M. Krumholz, MD, SM; Jeptha P. Curtis, MD; Alyssa Berkowitz, MPH; Frederick A. Masoudi, MD, MSPH; John C. Messenger, MD; Craig S. Parzynski, MS; Che Ngufor, PhD; Saket Girotra, MD, SM; Amit P. Amin, MD, MSc; Nilay D. Shah, PhD; Nihar R. Desai, MD, MPH

Dhruva et al. JAMA 2020; 323 (8): 734-45.

Figure 2. In-Hospital Outcomes Among Propensity-Matched Patients With Acute Myocardial Infarction Complicated by Cardiogenic Shock Undergoing Percutaneous Coronary Intervention With Intravascular Microaxial Left Ventricular Assist Device vs Intra-aortic Balloon Pump

	Intravascular Microaxial Left Ventricular Assist Device		Intra-aortic Balloon Pump		Absolute Risk Difference (95% CI), %	*P* Value
	No. of Patients	Patients, %	No. of Patients	Patients, %		
Overall (n = 1680 matched pairs)						
Mortality	756	45.0	573	34.1	10.9 (7.6-14.2)	<.001
Major bleeding	526	31.3	268	16.0	15.4 (12.5-18.2)	<.001
Device placement before initiation of percutaneous coronary intervention (n = 573 matched pairs)						
Mortality	261	45.5	211	36.8	8.7 (3.1-14.4)	.003
Major bleeding	157	27.4	95	16.6	10.8 (6.1-15.6)	<.001
Device placement after initiation of percutaneous coronary intervention (n = 662 matched pairs)						
Mortality	291	44.0	213	32.2	11.8 (6.6-17.0)	<.001
Major bleeding	228	34.4	104	15.7	18.7 (14.2-23.3)	<.001



Dhruva et al. JAMA 2020; 323 (8): 734-45.

Lesson 6 & 7 (matched controls Impella vs IABP-SHOCK and ACC National Cardiovascular Data Registry)

Disappointing results in matched control analysis Impella vs IABP

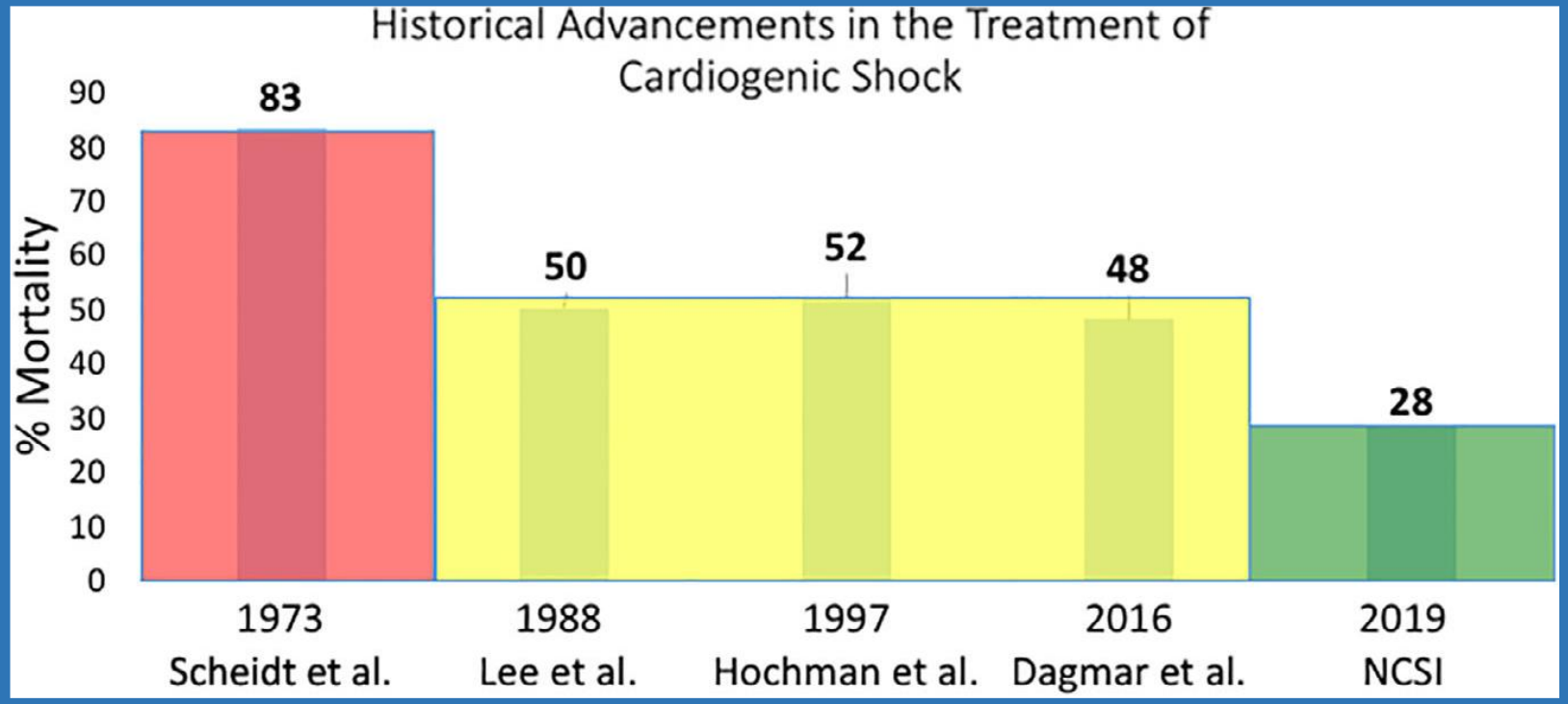
Data are observational (inheritent bias), RCTs needed to solve the issue

Attention to patient management and complications (bleeding,…) is needed

ORIGINAL STUDIES

Improved Outcomes Associated with the use of Shock Protocols: Updates from the National Cardiogenic Shock Initiative

Basir et al. CCI 2019; 93: 1173-83.



Basir et al. CCI 2019; 93: 1173-83.

National Cardiogenic Shock Initiative

1) early identification and catheterization laboratory activation in AMICS

2) early delivery of MCS (prior to PCI, prior to escalating inotropes, and as quickly from shock onset as possible, ideally within 90')

3) Routine use of invasive hemodynamics

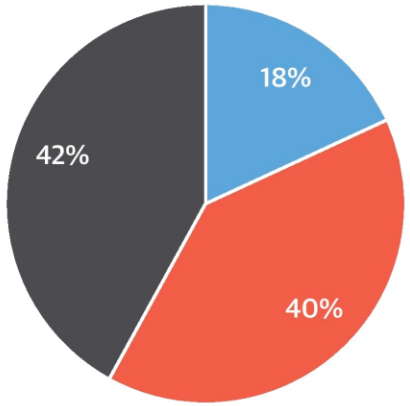
4) limiting device-related complications

Basir et al. CCI 2019; 93: 1173-83.

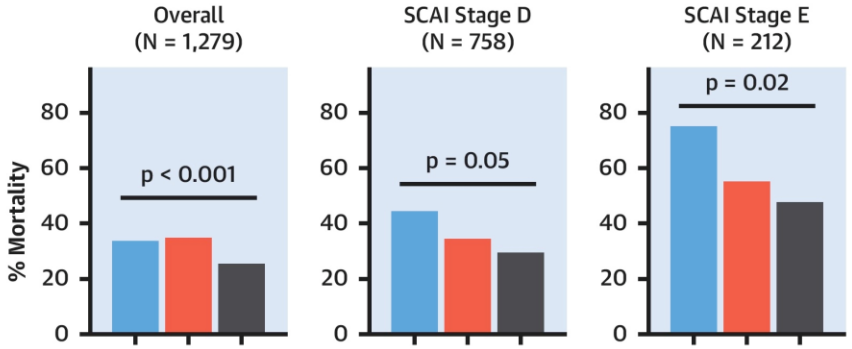
CENTRAL ILLUSTRATION: Frequency of Mortality Among PAC Use Overall and by SCAI Stage

PAC Utilization	Study Definition
None	Presence of **NONE** of the following invasive hemodynamics: • Pulmonary Artery Systolic Pressure • Pulmonary Artery Diastolic Pressure • Pulmonary Capillary Wedge Pressure • Pulmonary Artery Saturation • Right Atrial Pressure
Incomplete Assessment	Presence of **1-4** of the following invasive hemodynamics: • Pulmonary Artery Systolic Pressure • Pulmonary Artery Diastolic Pressure • Pulmonary Capillary Wedge Pressure • Pulmonary Artery Saturation
Complete Assessment	Presence of **ALL** of the following invasive hemodynamics: • Pulmonary Artery Systolic Pressure • Pulmonary Artery Diastolic Pressure • Pulmonary Capillary Wedge Pressure • Pulmonary Artery Saturation **AND** presence of Right Atrial Pressure

PAC Utilization Among Study Cohort



Association with Mortality Among Advanced Stage Patients



Garan, A.R. et al. J Am Coll Cardiol HF. 2020;8(11):903-13.

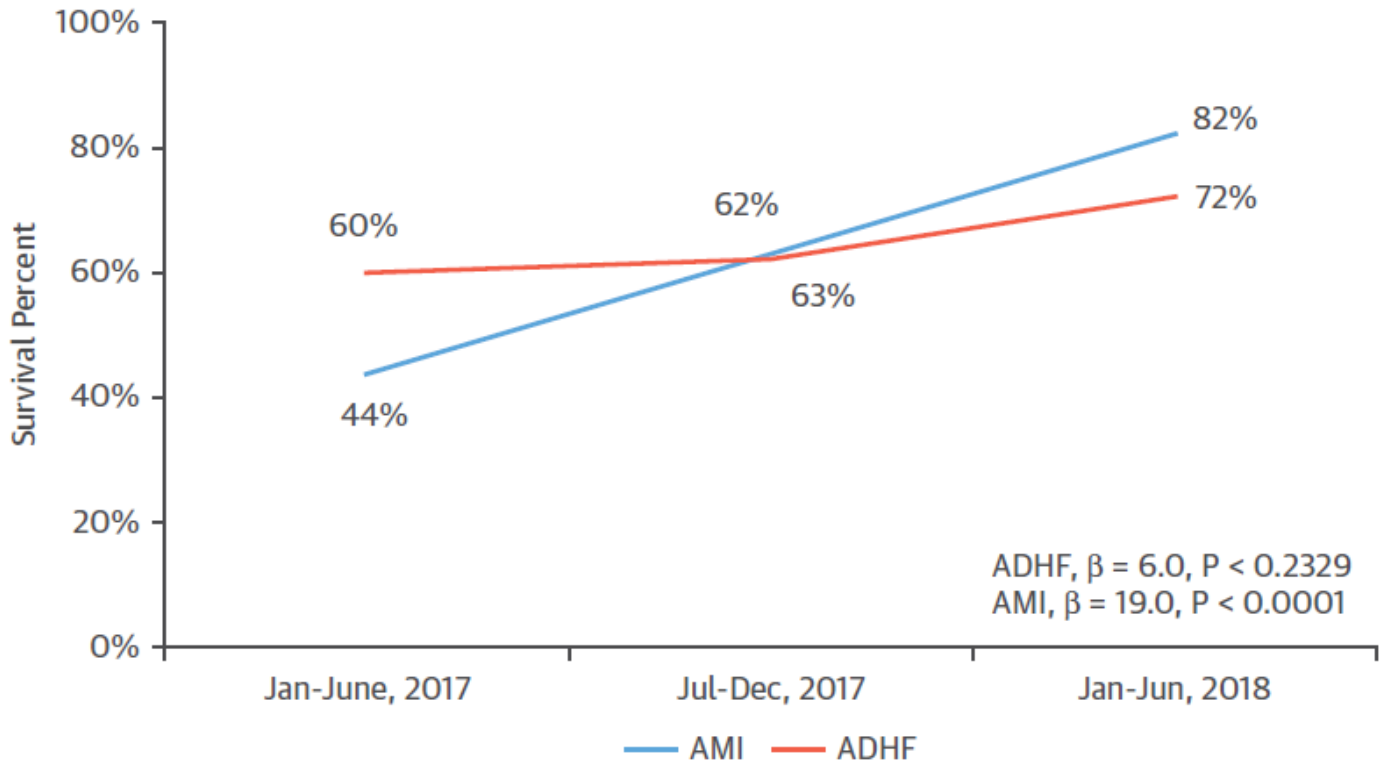
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY VOL. 73, NO. 13, 2019

Standardized Team-Based Care for Cardiogenic Shock

Behnam N. Tehrani, MD,[a] Alexander G. Truesdell, MD,[a,b] Matthew W. Sherwood, MD,[a] Shashank Desai, MD,[a] Henry A. Tran, MD,[a] Kelly C. Epps, MD,[a] Ramesh Singh, MD,[a] Mitchell Psotka, MD, PhD,[a] Palak Shah, MD,[a] Lauren B. Cooper, MD,[a] Carolyn Rosner, NP,[a] Anika Raja, BS,[a] Scott D. Barnett, PhD,[a] Patricia Saulino, RN, MPA,[a] Christopher R. deFilippi, MD,[a] Paul A. Gurbel, MD,[a] Charles E. Murphy, MD,[a] Christopher M. O'Connor, MD[a]

Tehrani et al. J Am Coll Cardiol 2019; 73 (13): 1659-69

FIGURE 1 30-Day Survival According to Group and Time Period



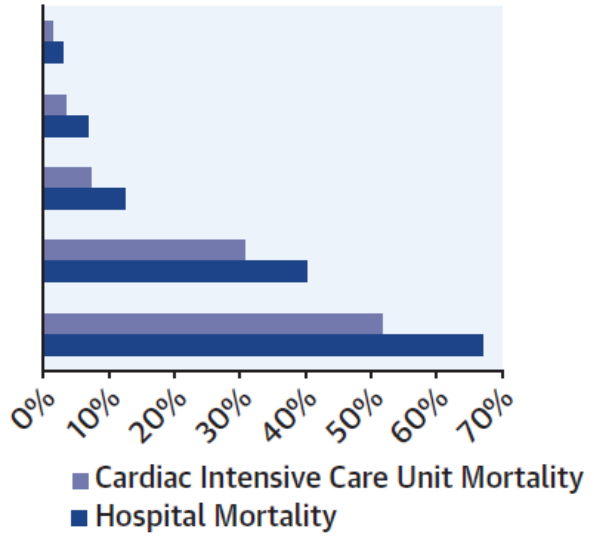
ADHF = acute decompensated heart failure; AMI = acute myocardial infarction.

Tehrani et al. J Am Coll Cardiol 2019; 73 (13): 1659-69

CENTRAL ILLUSTRATION **Definitions of SCAI Shock Stages A Through E, With Associated Cardiac Intensive Care Unit and Hospital Mortality in Each SCAI Shock Stage**

Cardiogenic Shock Stage	Study Definition
Stage A ("At risk")	Neither hypotension/tachycardia nor hypoperfusion
Stage B ("Beginning")	Hypotension/tachycardia WITHOUT hypoperfusion
Stage C ("Classic")	Hypoperfusion WITHOUT deterioration
Stage D ("Deteriorating)"	Hypoperfusion WITH deterioration NOT refractory shock
Stage E ("Extremis")	Hypoperfusion WITH deterioration AND refractory shock

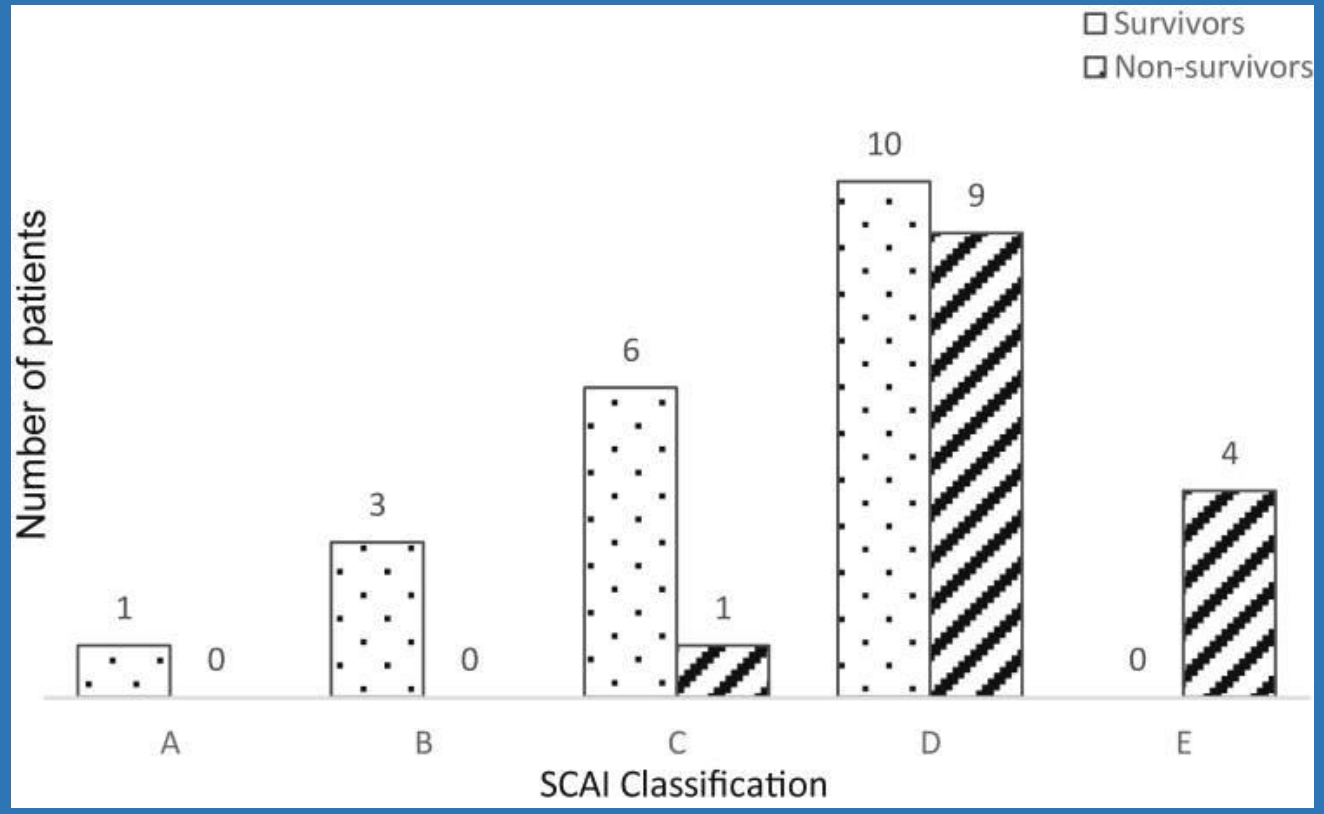
Observed Mortality in Overall Cohort

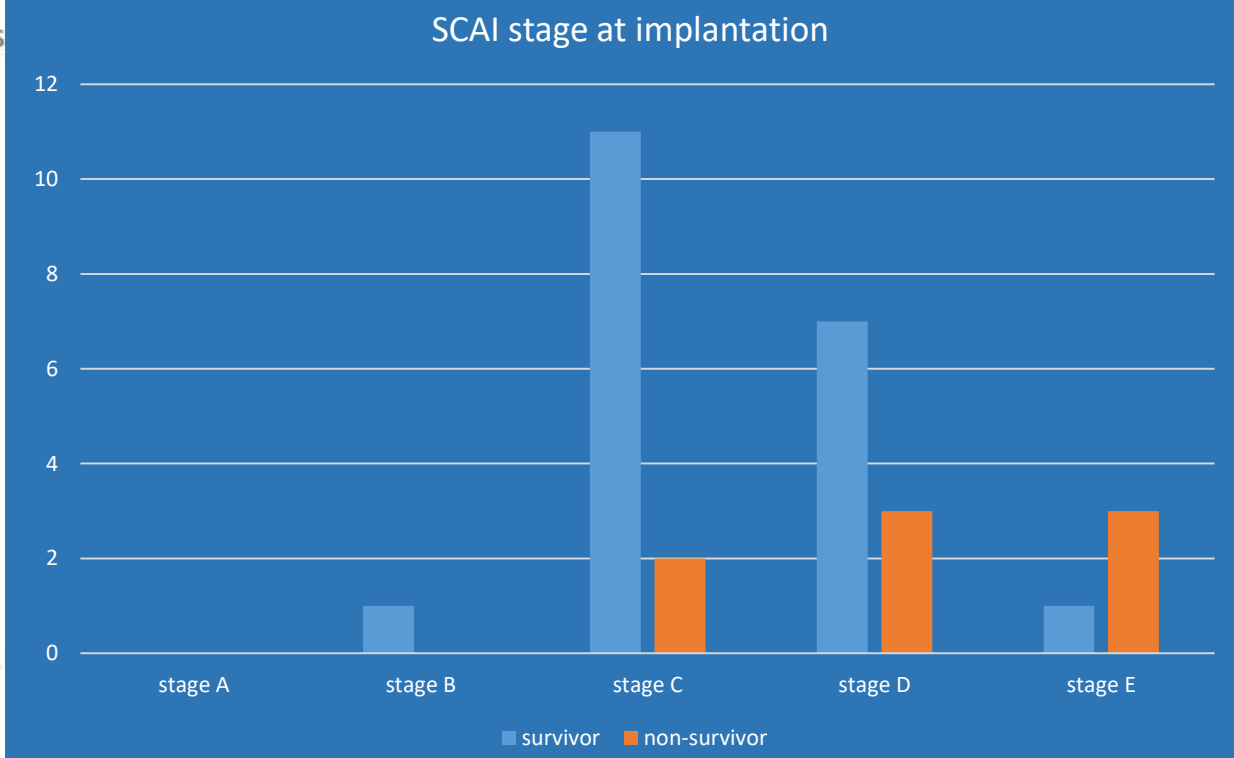


Jentzer, J.C. et al. J Am Coll Cardiol. 2019;74(17):2117-28.

Cardiac intensive care unit and hospital mortality increased as a function of higher Society for Cardiovascular Angiography and Intervention shock stage.

Jentzer. J Am Coll Cardiol 2019; 74: 2117-28.





Trpkov CJC Open 2020; 370-8

Balthazar et al. Leuven CICU Impella experience. Submitted.

Lessons 8 & 9

Improved survival using a dedicated protocol

SCAI class E associated with bad outcome

ELSEVIER

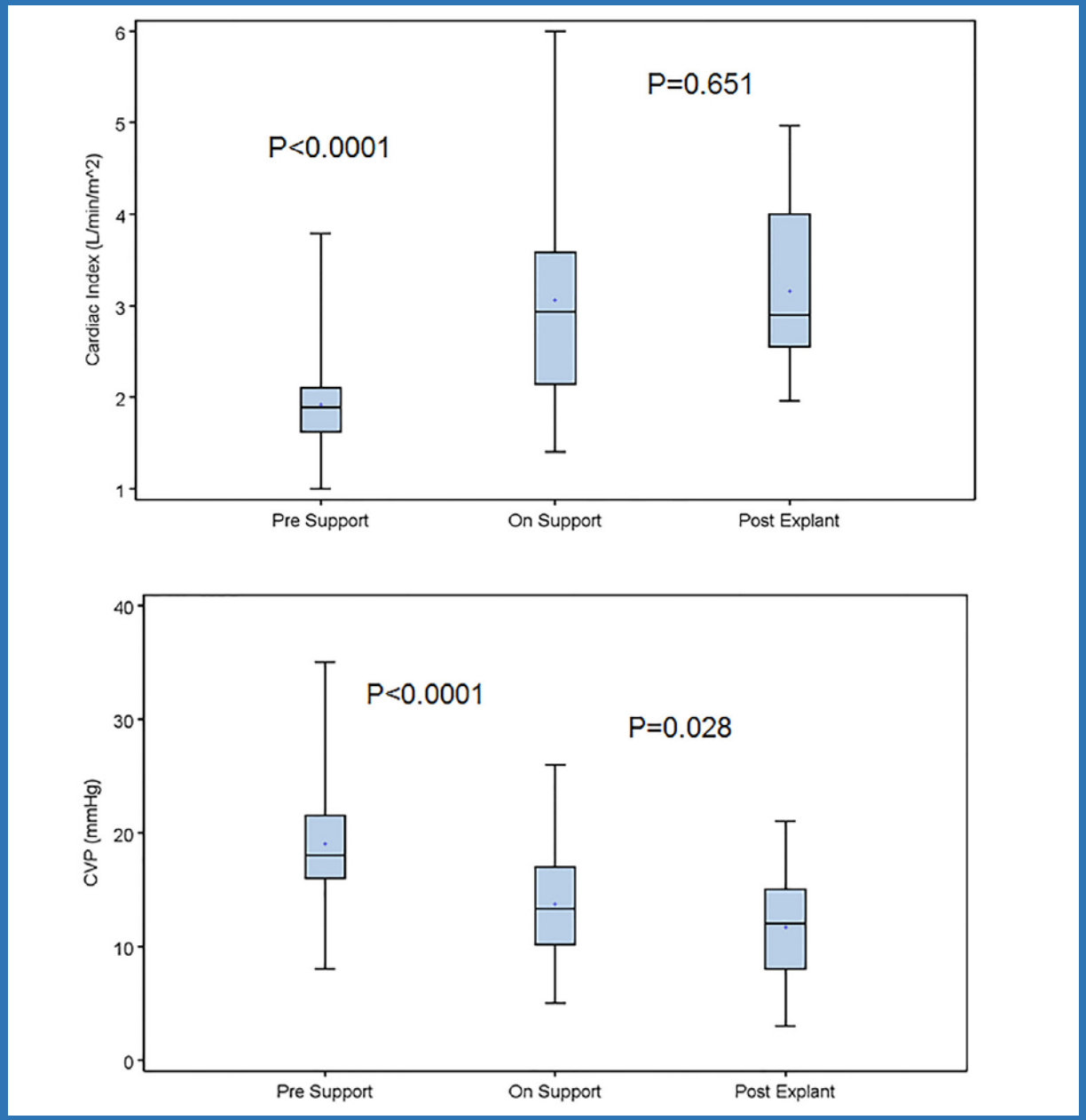
The Journal of Heart and Lung Transplantation

http://www.jhltonline.org

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 Kumar Kapur, MD,[h] and William O'Neill, MD[i]

Anderson et al. J Heart Lung Transplantation 2018; 37: 1448-58.



Anderson et al. J Heart Lung Transplantation 2018; 37: 1448-58.

Lesson 10

Impella RP promising, but limited evidence so far

Trial	Methodology	N	Results
Basir et al.	Retrospective Single arm	171	72% survival
Tehrani et al.	Retrospective Single arm	204	Increased survival: 77%
Helgestad et al.	Retrospective Patient matching	80	Increased survival: 60%
CIZ UZ Leuven	Retrospective Single arm	29	72.4% survival

- Rapid action and identification of patients
- Protocol/multidisciplinary management
- Only experienced centres

Trial	Methology	N	Results
Schrage et al.	Retrospective Patient matching	237	NS survival More compl.
Amin et al.	Retrospective Patient matching	1792	NS survival Higher costs More compl.
Dhruva et al.	Retrospective Patient matching	1680	Lower survival More compl.

- Selection based on ICD- or reimbursement codes
- Also patients from low volume centres
- Matching of patients

Courtesy T. Balthazar

JACC REVIEW TOPIC OF THE WEEK

Managing Patients With Short-Term Mechanical Circulatory Support

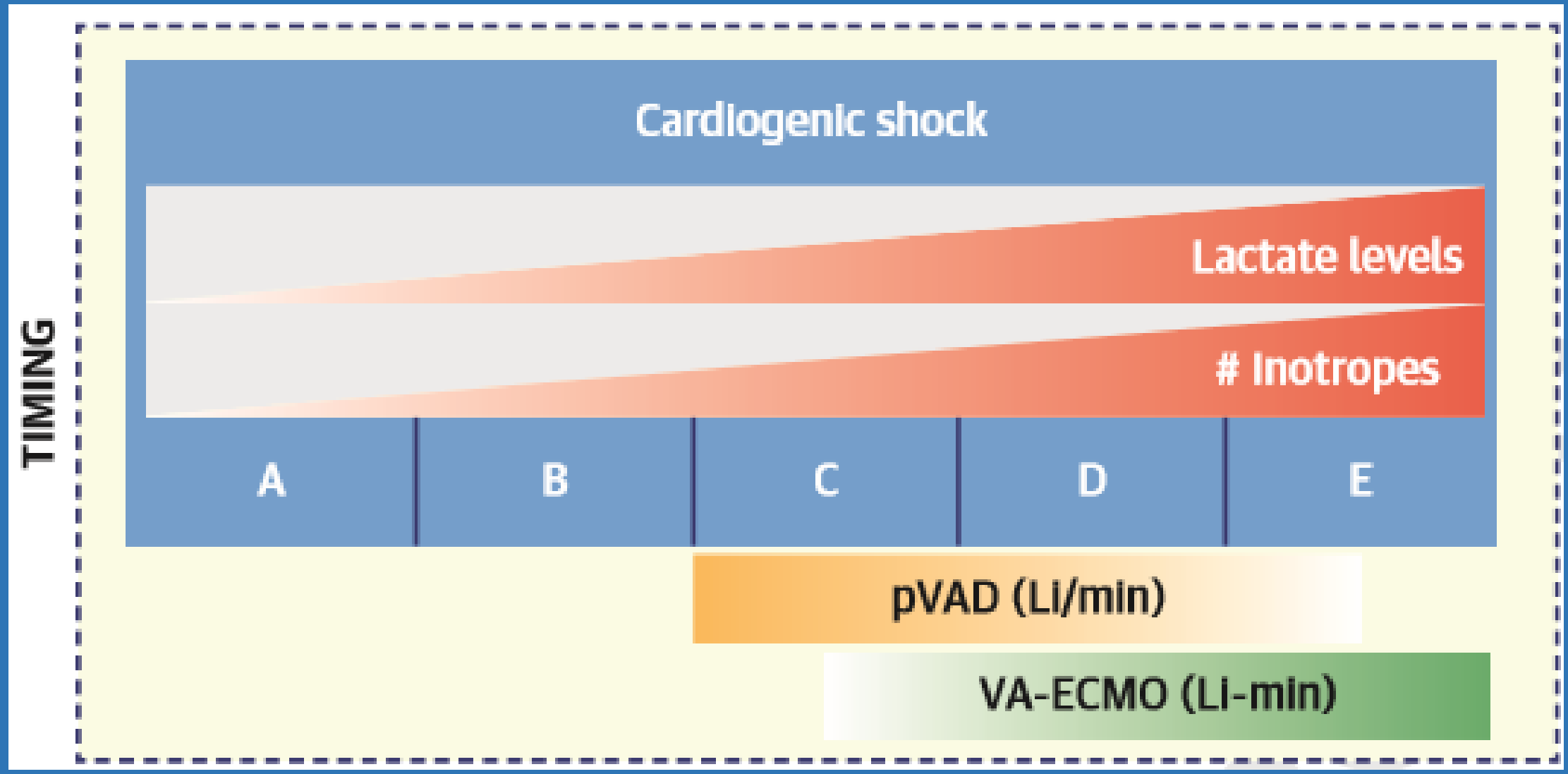
JACC Review Topic of the Week

Tim Balthazar, MD,[a] Christophe Vandenbriele, MD, PhD,[a,b] Frederik H. Verbrugge, MD, PhD,[c,d] Corstiaan Den Uil, MD, PhD,[e,f] Annemarie Engström, MD, PhD,[e,f] Stefan Janssens, MD, PhD,[a] Steffen Rex, MD, PhD,[g] Bart Meyns, MD, PhD,[h] Nicolas Van Mieghem, MD, PhD,[f] Susanna Price, MD, PhD,[b] Tom Adriaenssens, MD, PhD[a]

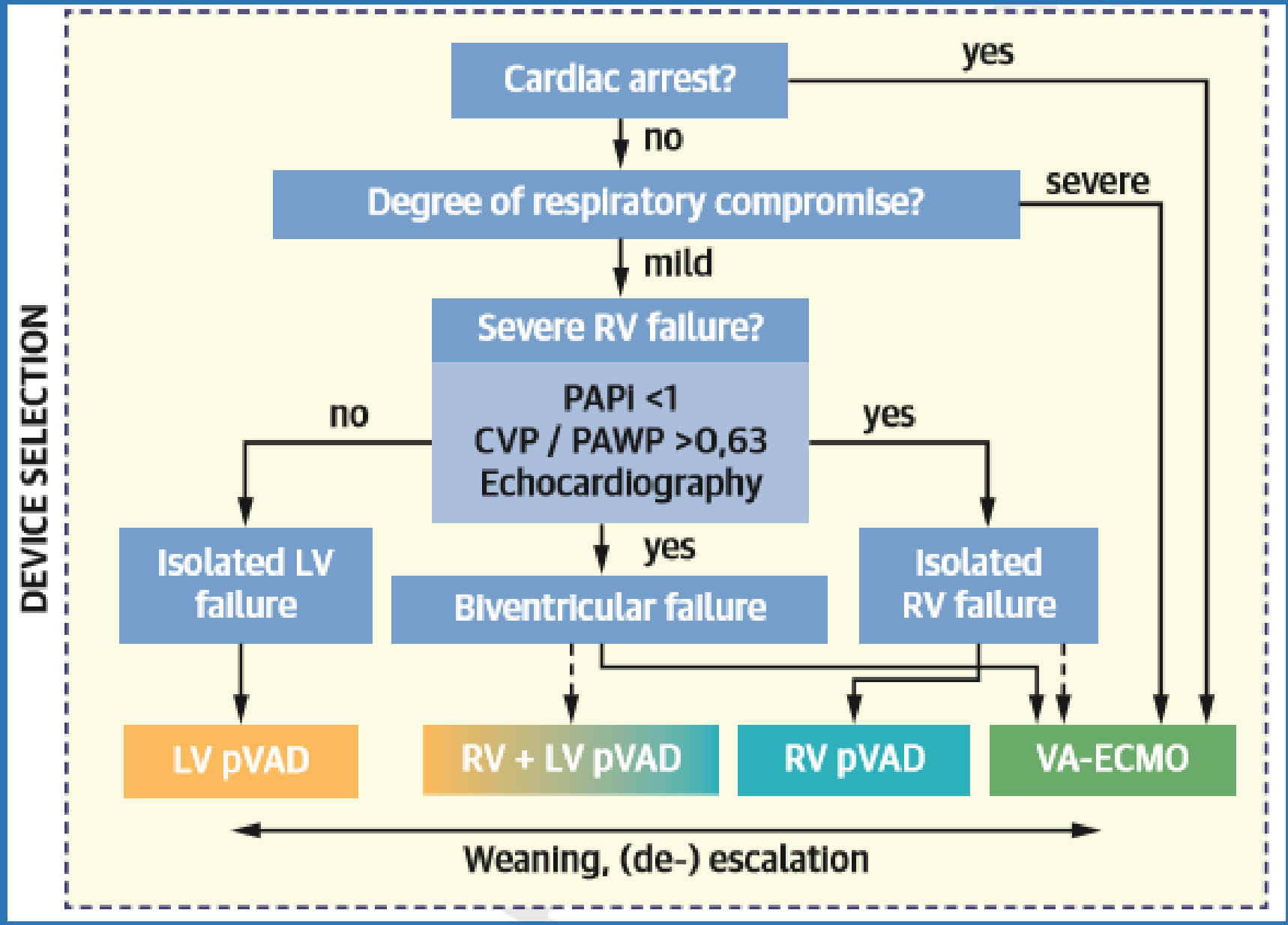
ABSTRACT

The use of mechanical circulatory support for patients presenting with cardiogenic shock is rapidly increasing. Currently, there is only limited and conflicting evidence available regarding the role of the Impella (a microaxial, continuous-flow, short-term, left or right ventricular assist device) in cardiogenic shock; further randomized trials are needed. Patient selection, timing of implantation, and post-implantation management in the cardiac intensive care unit are crucial elements for success. Particular challenges at the bedside include the practical management of anticoagulation, evaluation of correct device position, and the approach to use in a patient with signs of insufficient hemodynamic support. Profound knowledge of these issues is required to enable the maximal potential of the device. This review provides a comprehensive overview of the short-term assist device and describes a practical approach to optimize care for patients supported with the device. (J Am Coll Cardiol 2021;77:1243–56)

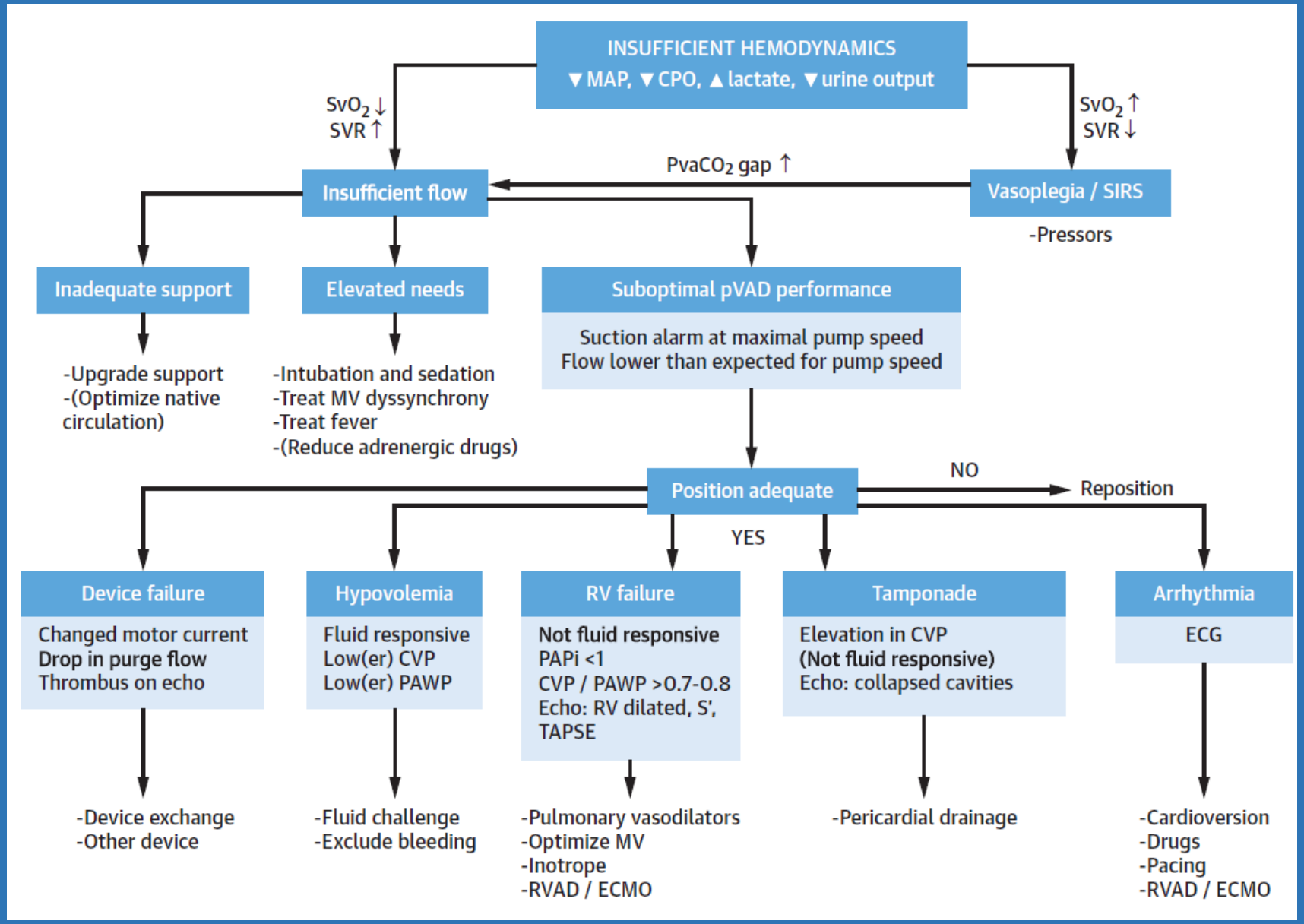
Balthazar et al. J Am Coll Cardiol 2021; 77: 1243-56.



Balthazar et al. J Am Coll Cardiol 2021; 77: 1243-56.



Balthazar et al. J Am Coll Cardiol 2021; 77: 1243-56.



Balthazar et al. J Am Coll Cardiol 2021; 77: 1243-56.

Thank you for your attention