

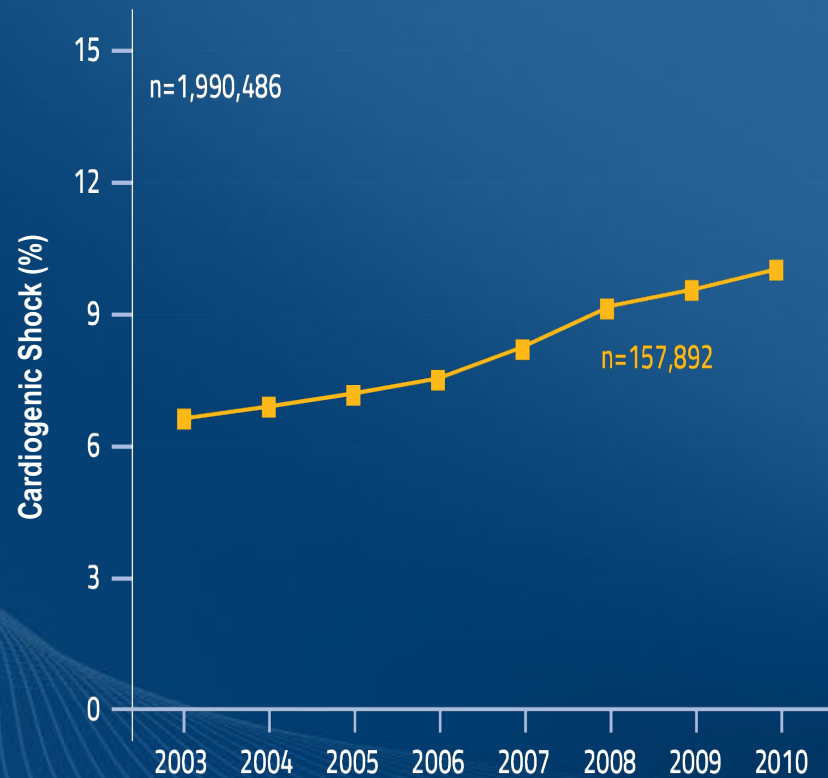
Cardiogenic Shock

DEFINITION OF CARADIOGENIC SHOCK

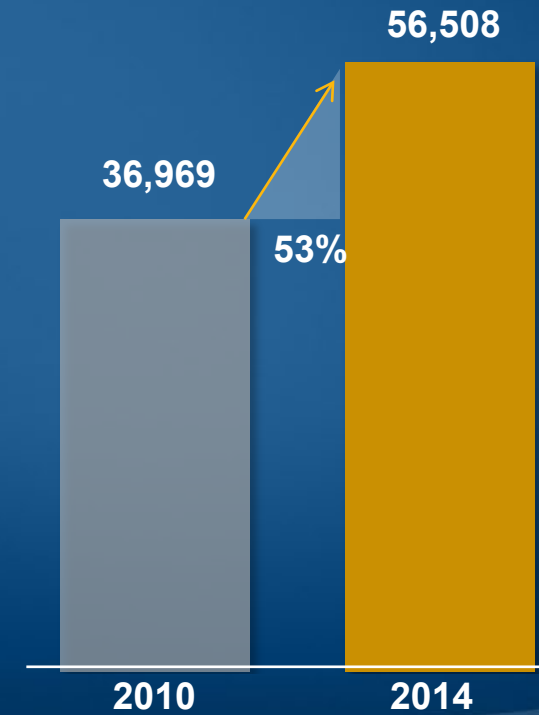
Clinical Trial/Guideline	CS Criteria
<p>SHOCK Trial (1999) N Engl J Med. 1999; 341:625–634.</p>	<ul style="list-style-type: none"> •SBP <90 mm Hg for >30 min or vasopressor support to maintain SBP >90 mm Hg •Evidence of end-organ damage (UO <30 mL/h or cool extremities) •Hemodynamic criteria: CI <2.2 and PCWP >15 mm Hg
<p>IABP-SOAP II (2012) N Engl J Med. 2012; 367:1287–1296.</p>	<ul style="list-style-type: none"> •MAP <70 mm Hg or SBP <100 mm Hg despite adequate fluid resuscitation (at least 1 L of crystalloids or 500 mL of colloids) •Evidence of end-organ damage (AMS, mottled skin, UO <0.5 mL/kg for 1 h, or serum lactate >2 mmol/L)

INCIDENCE OF CARDIOGENIC SHOCK GROWING

Cardiogenic Shock in STEMI Increasing ¹



STEMI Cardiogenic Shock in Medicare Age Increasing ²

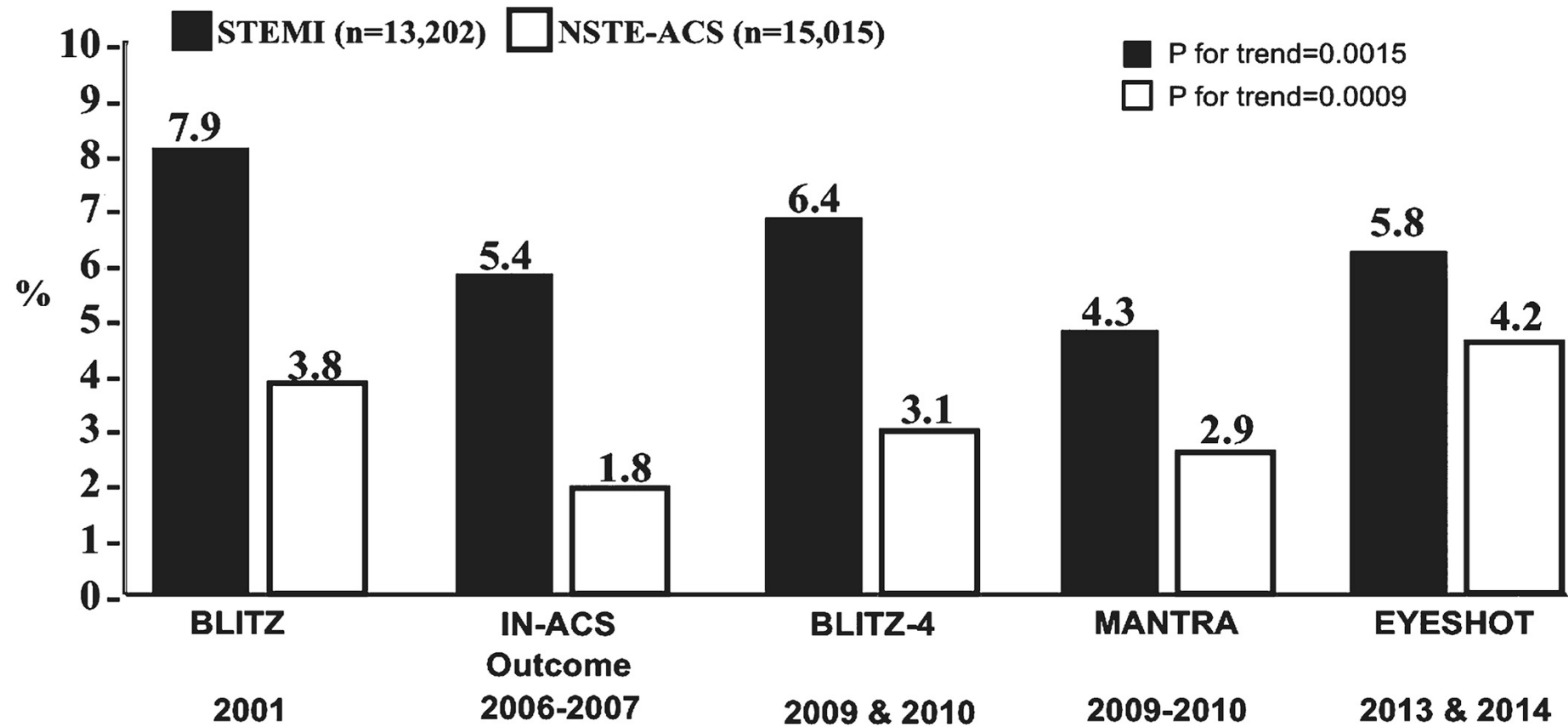


Age ≥ 65 only, excludes non-Medicare population

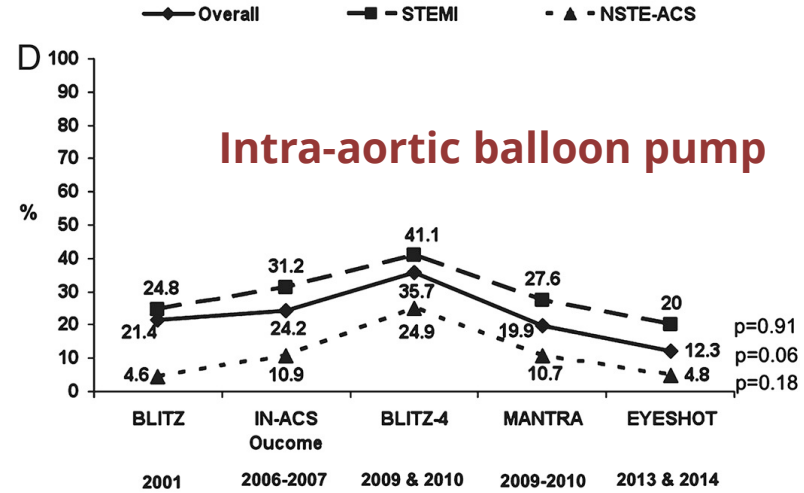
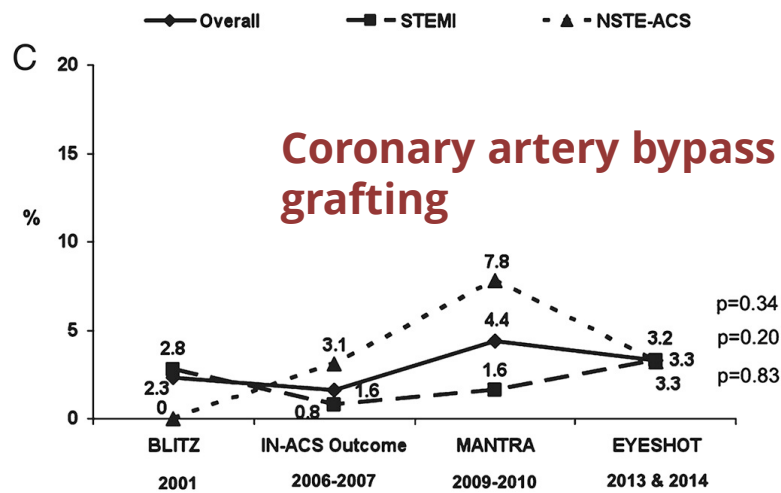
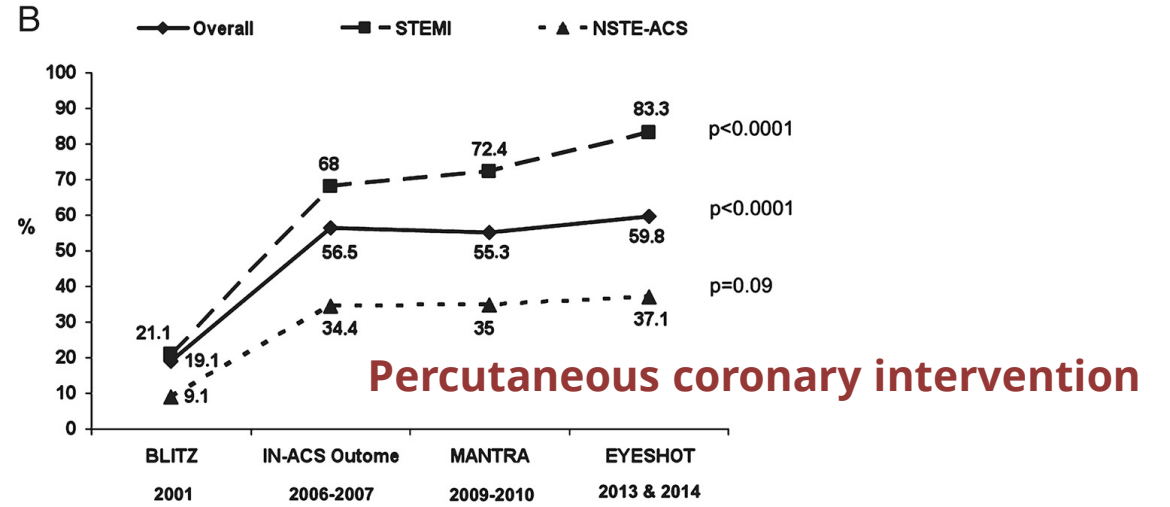
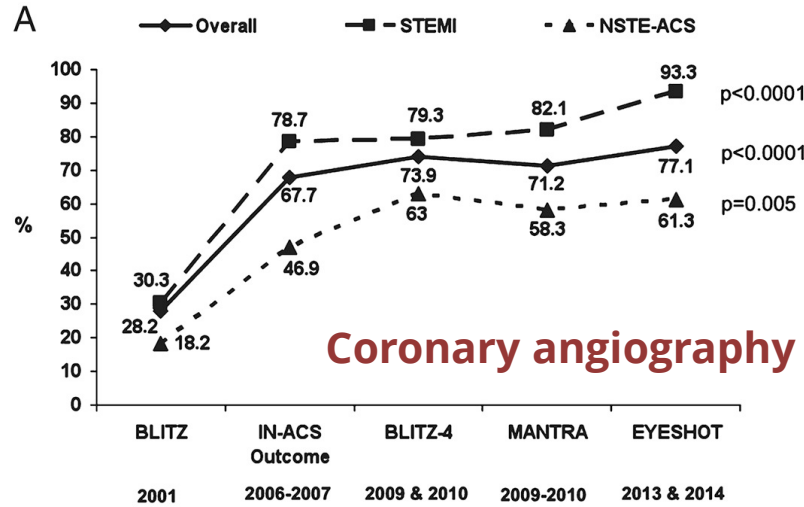
1. Dhaval Kolte et al. J Am Heart Assoc 2014 NATIONWIDE INPATIENT SAMPLE
2. Centers for Medicare and Medicaid database, MEDPAR FY14

Improved diagnosis and better access to care are both likely contributory

Temporal trends in the epidemiology, management, and outcome of patients with cardiogenic shock complicating acute coronary syndromes



Temporal trends in the epidemiology, management, and outcome of patients with cardiogenic shock complicating acute coronary syndromes



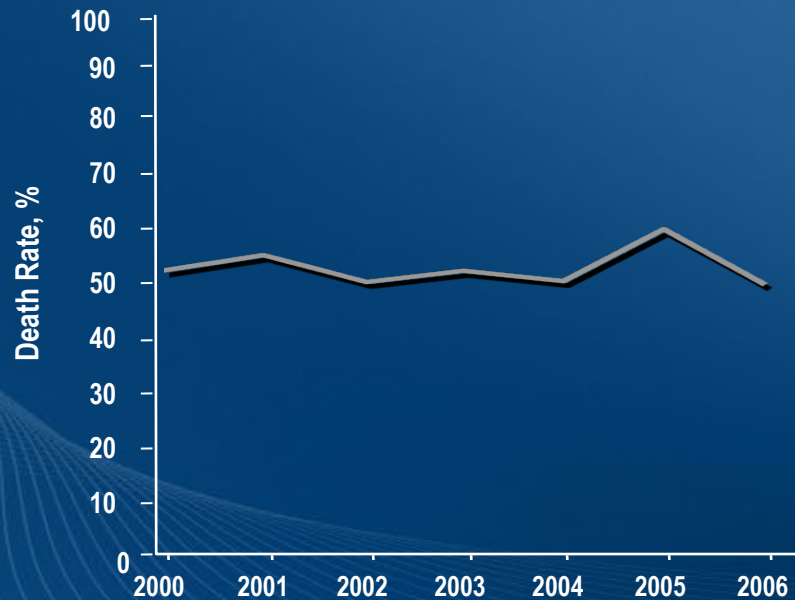
CARDIOGENIC SHOCK

Acute myocardial infarction (MI) accounts for 81% of patient in CS.

CARDIOGENIC SHOCK REMAINS LEADING CAUSE OF MORTALITY IN ACUTE MYOCARDIAL INFARCTION

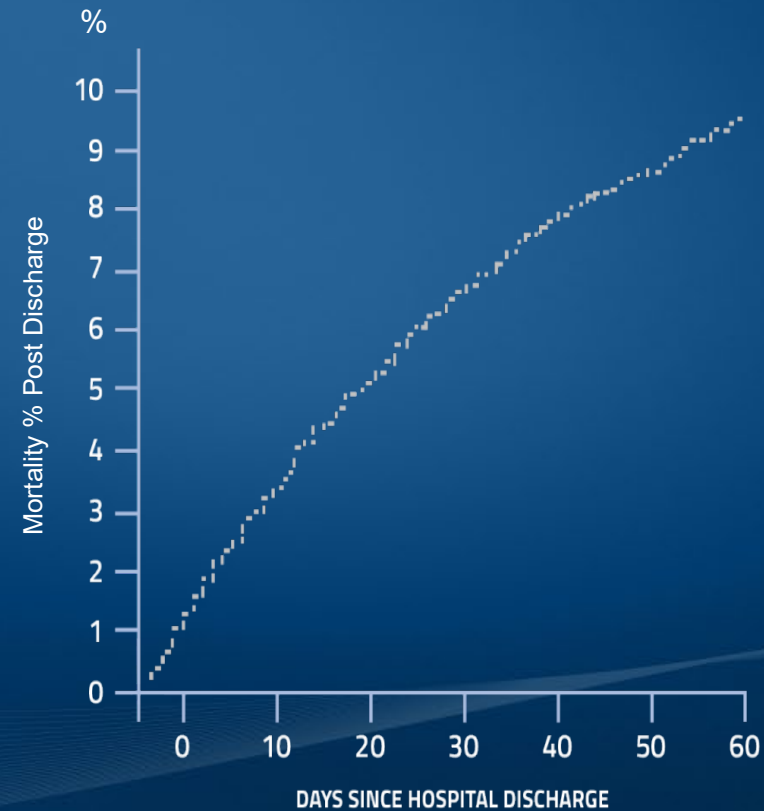
High In-Hospital Mortality During AMI Cardiogenic Shock¹

N = 23,696



... and Ongoing Hazard Post Discharge after AMI Cardiogenic Shock²

N = 112,668

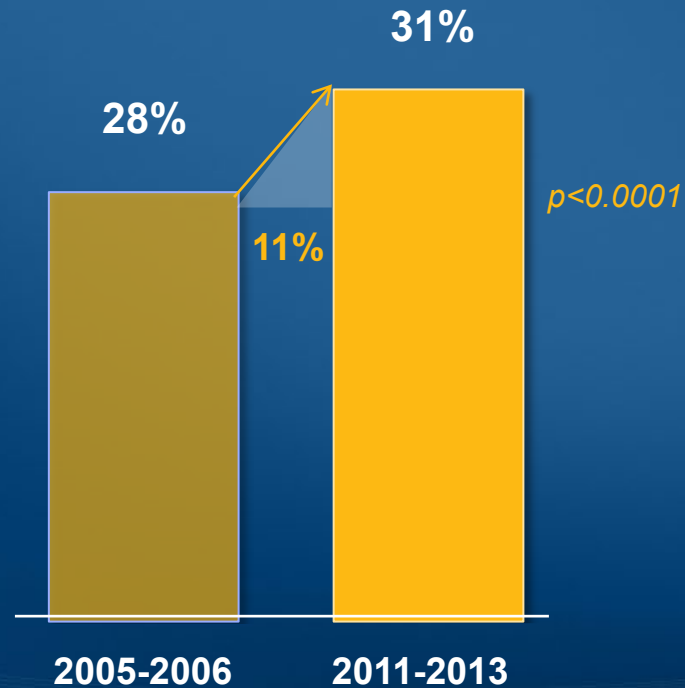


1. Jeger, et al. Ann Intern Med. 2008
2. Shah, et al. JACC 2016 NCDR Registry

MORTALITY IN PCI WITH CARDIOGENIC SHOCK REMAINS A CLINICAL CHALLENGE

In-Hospital Mortality AMI Cardiogenic Shock with PCI

N = 32,598



AMI Cardiogenic Shock with PCI only; **Overall mortality >50%**

Potential hemodynamic presentations of cardiogenic shock.

		Volume Status	
		Wet	Dry
Peripheral Circulation	Cold	Classic Cardiogenic Shock (↓CI; ↑SVRI; ↑PCWP)	Euvolemic Cardiogenic Shock (↓CI; ↑SVRI; ↔PCWP)
	Warm	Vasodilatory Cardiogenic Shock or Mixed Shock 25% (↓CI; ↓/↔SVRI; ↑PCWP)	Vasodilatory Shock (Not Cardiogenic Shock) (↑CI; ↓SVRI; ↓PCWP)

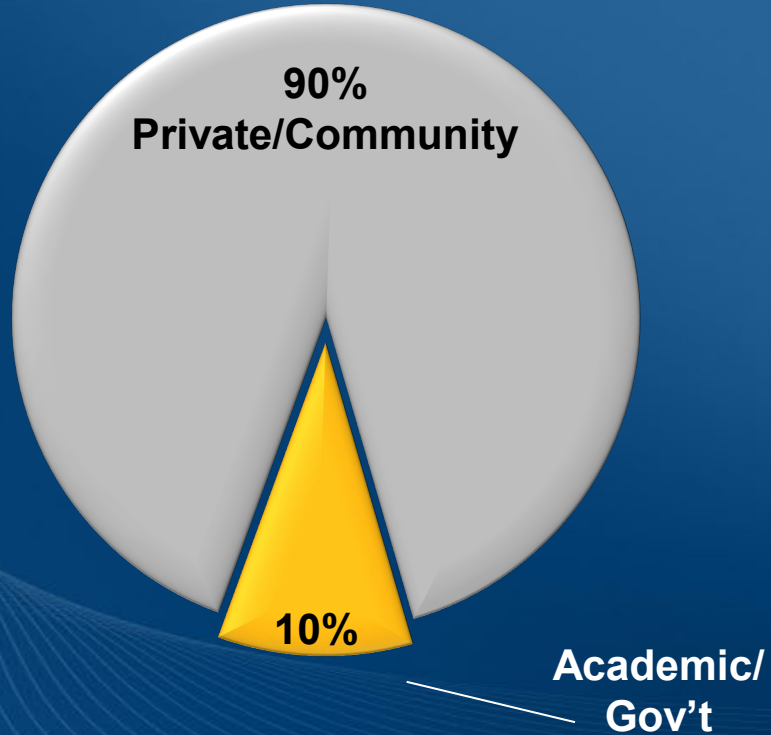
Systemic inflammatory response syndrome
reaction in conjunction with an MI



AMI SHOCK OFTEN TREATED IN COMMUNITY HOSPITALS

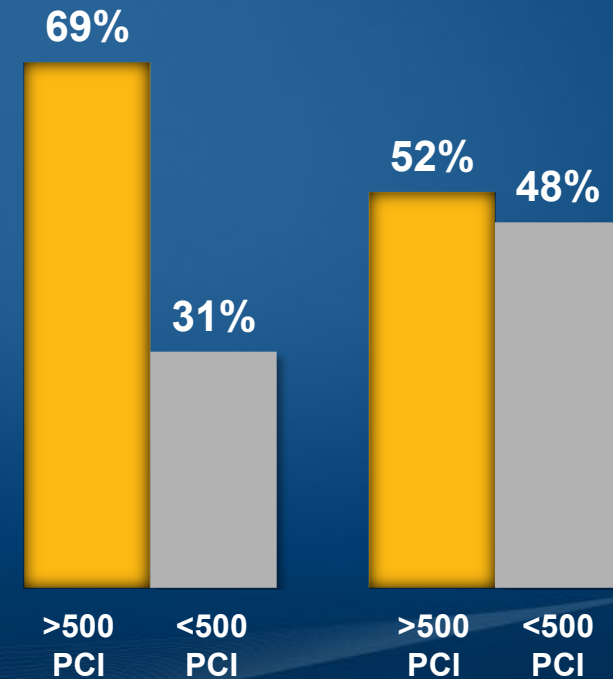
AMI Cardiogenic Shock with PCI

N = 56,497



2005-06

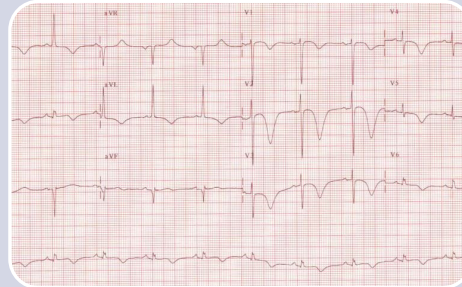
2011-13



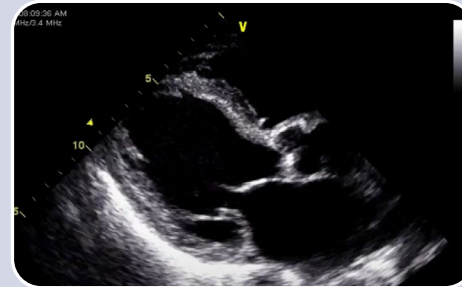
Case Presentation



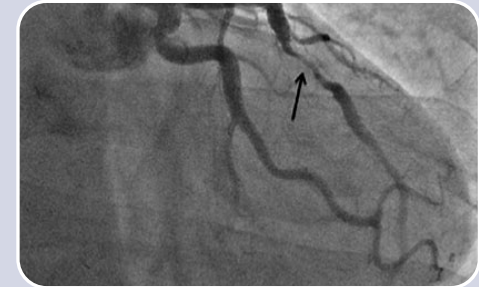
65 year old male with severe substernal chest pain, a heart rate of 100 per minute and a blood pressure of 80/60. Initial troponin is 5.1 nanograms/mL.



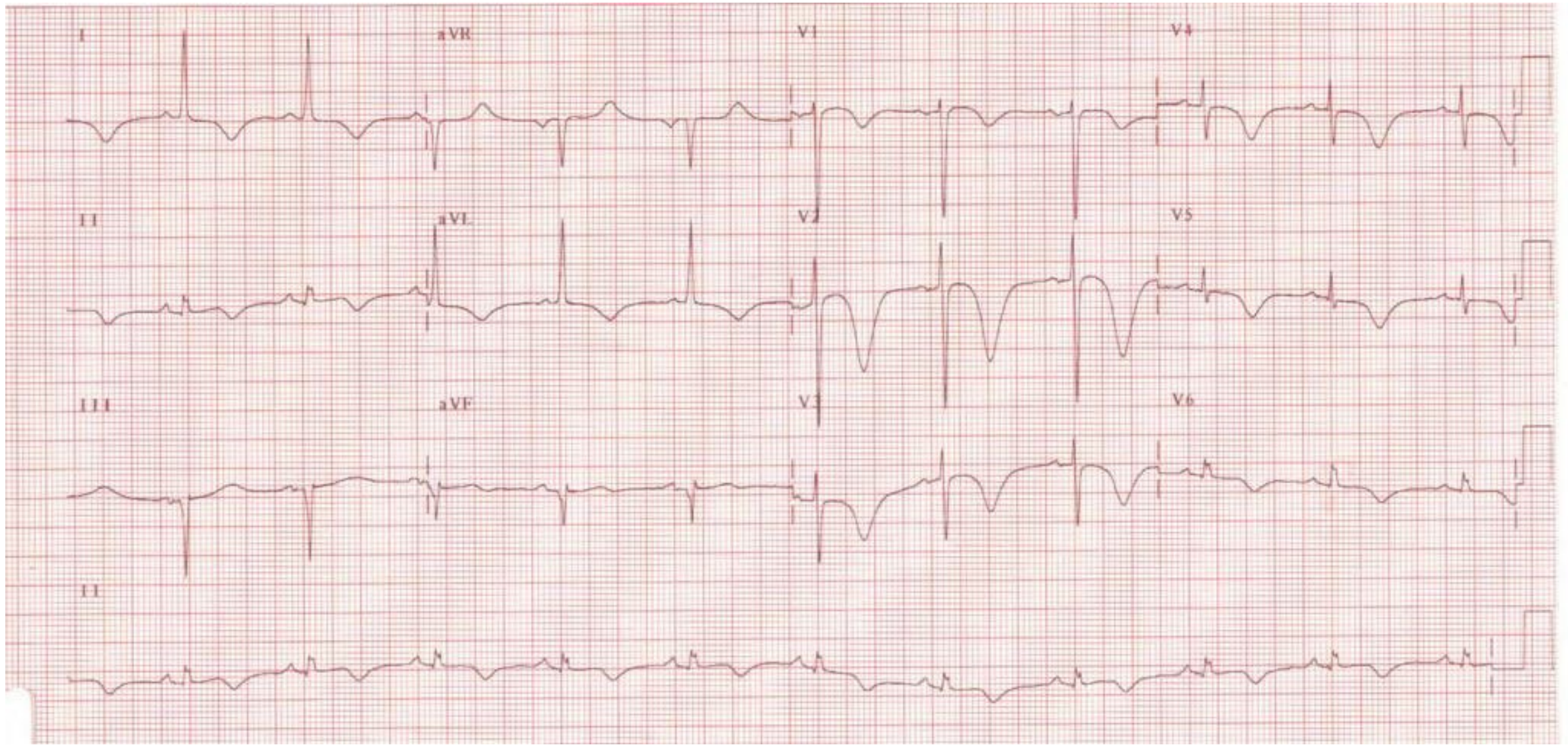
Physical examination reveals cool extremities and lung crackles throughout both lung fields. EKG and CXR done



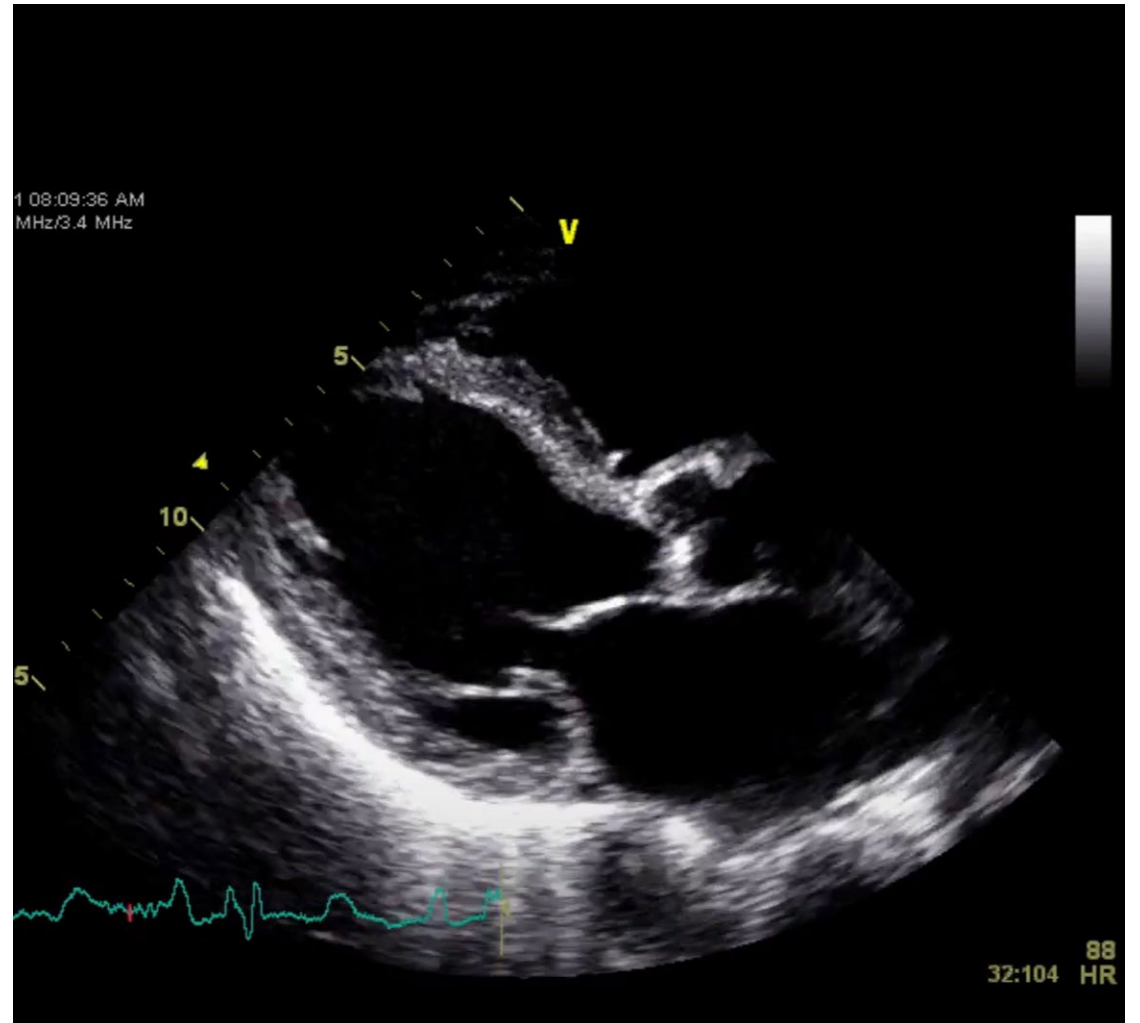
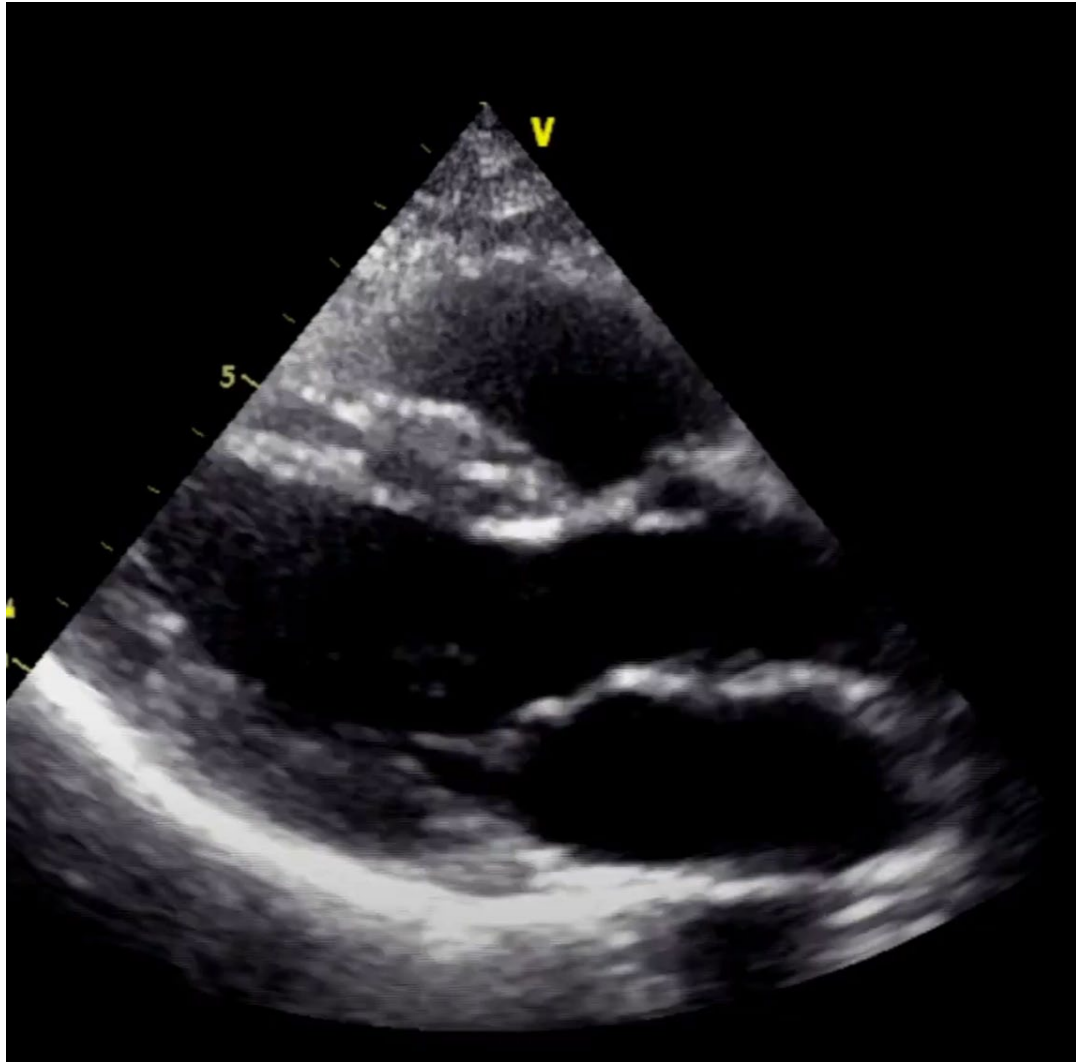
Echocardiogram shows no valvular abnormalities, no shunts, and a left ventricular ejection fraction of 20%.



Cardiac catheterization reveals three vessel coronary artery disease, 80% stenosis in the left anterior descending coronary artery







Which of the following is true regarding the use of vasopressor support?

- A. There are no difference in adverse events between dopamine and norepinephrine
- B. Dopamine is preferred over norepinephrine as it may improve survival
- C. Phenylephrine is associated with better outcome as it dose not increase cardiac oxygen demand
- D. Norepinephrine is preferred over dopamine as it is associated with a lower arrythmias

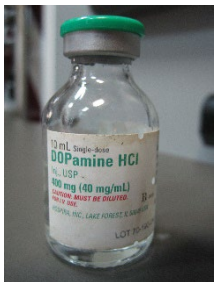
Comparison of Dopamine and Norepinephrine in the Treatment of Shock



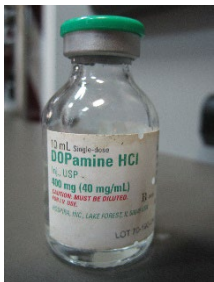
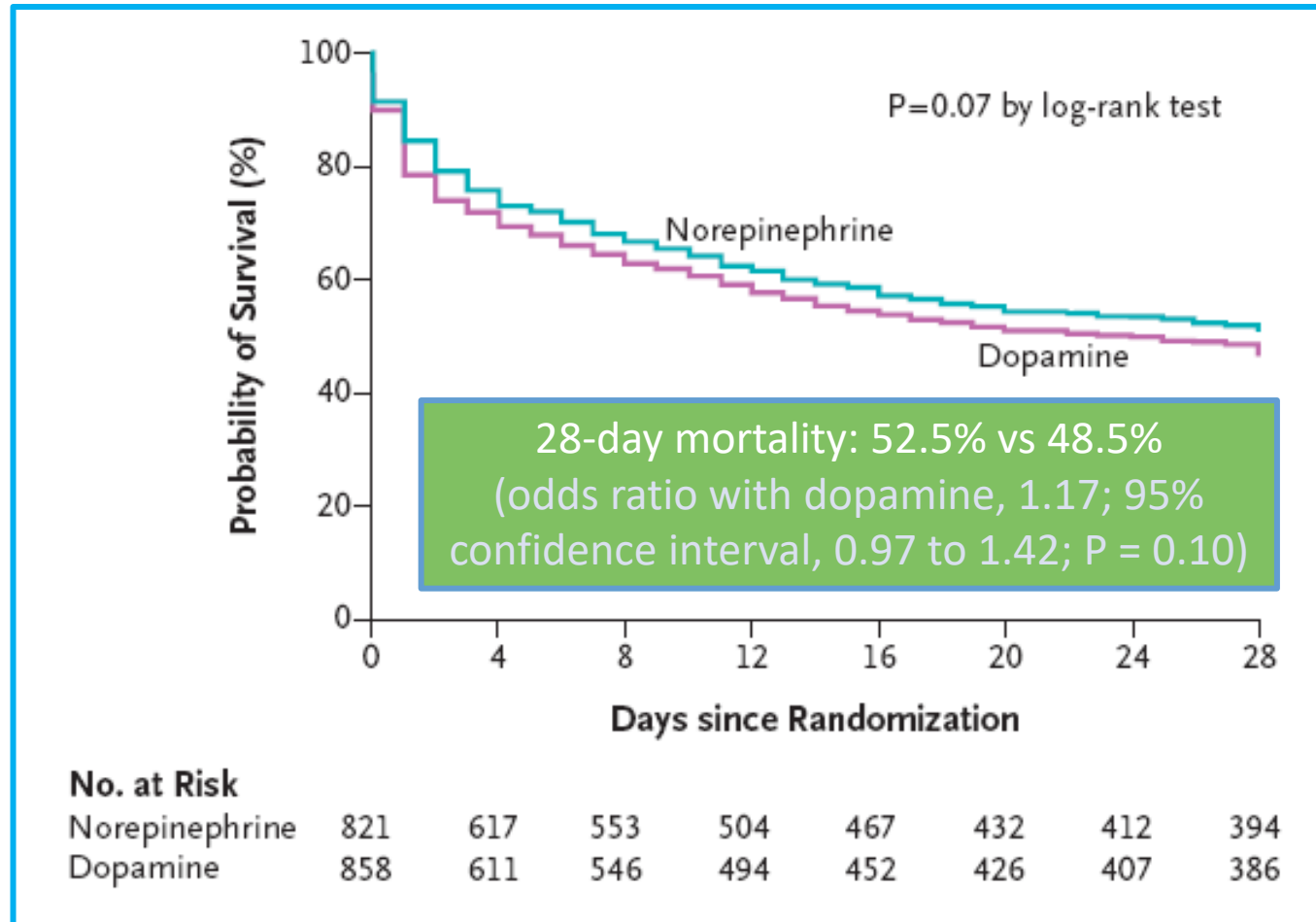
SOAP II Trial

1679 patients with septic shock, 8 centers Dec 2003 to Oct 2007		
	Dopamine	Norepinephrine
# of Patients	858	821
28 Day Mortality	52.5%	48.5%

X



Comparison of Dopamine and Norepinephrine in the Treatment of Shock

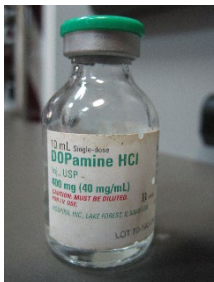


Comparison of Dopamine and Norepinephrine in the Treatment of Shock

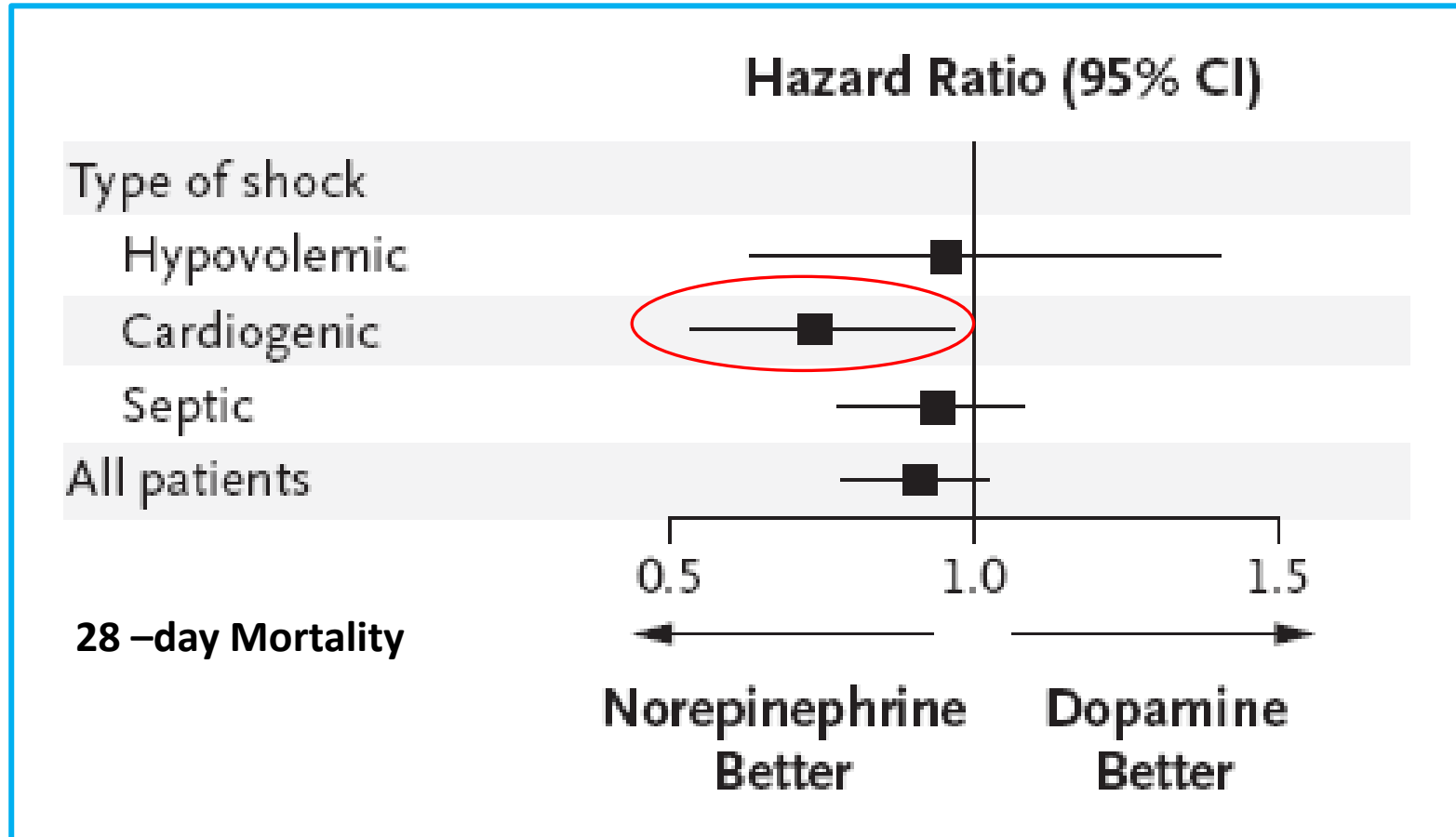
SOAP II Trial

1679 patients with septic shock, 8 centers Dec 2003 to Oct 2007		
	Dopamine	Norepinephrine
# of Patients	858	821
Arrhythmias	24.1%	12.4%

✓ <0.001



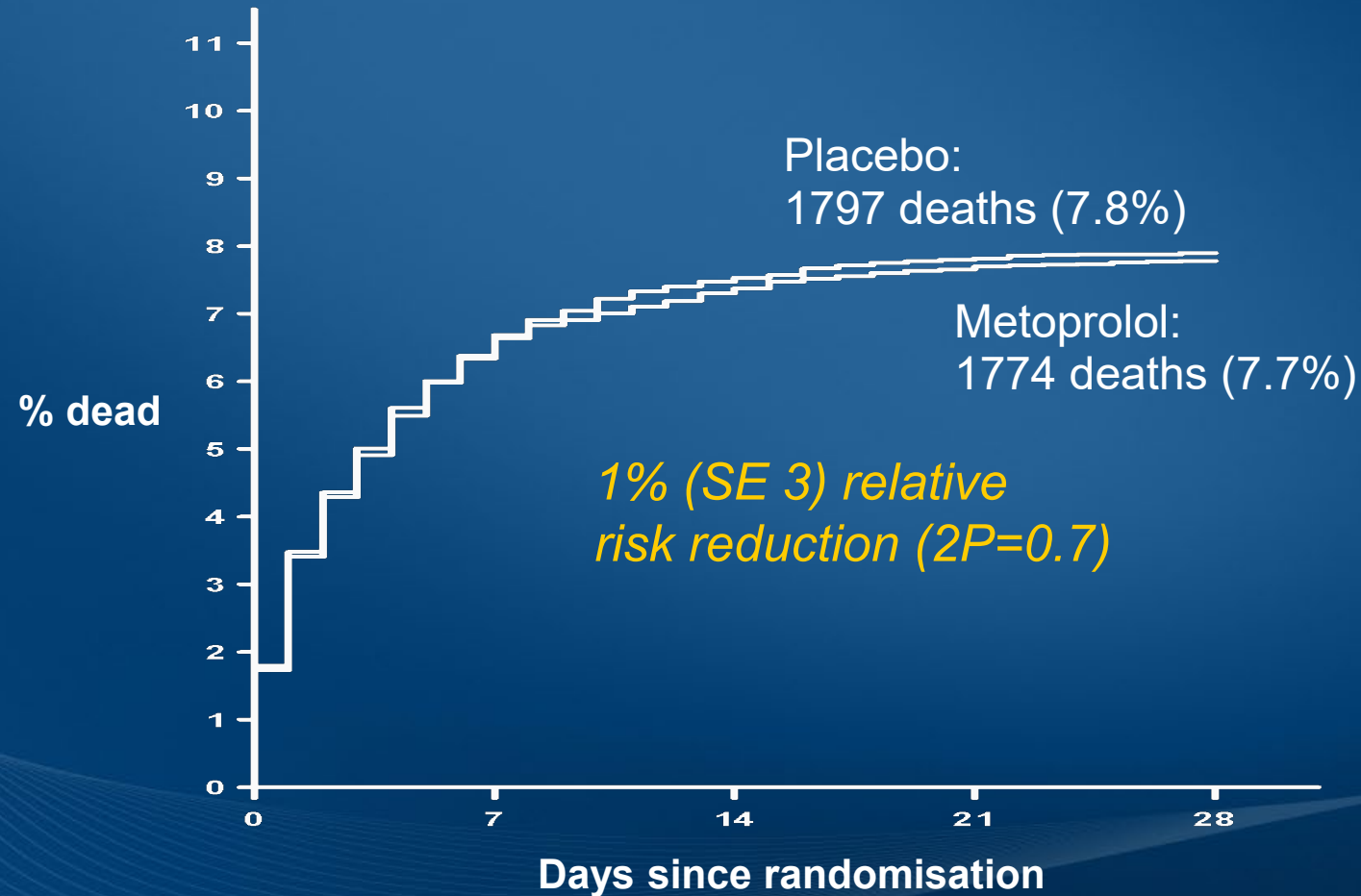
Comparison of Dopamine and Norepinephrine in the Treatment of Shock



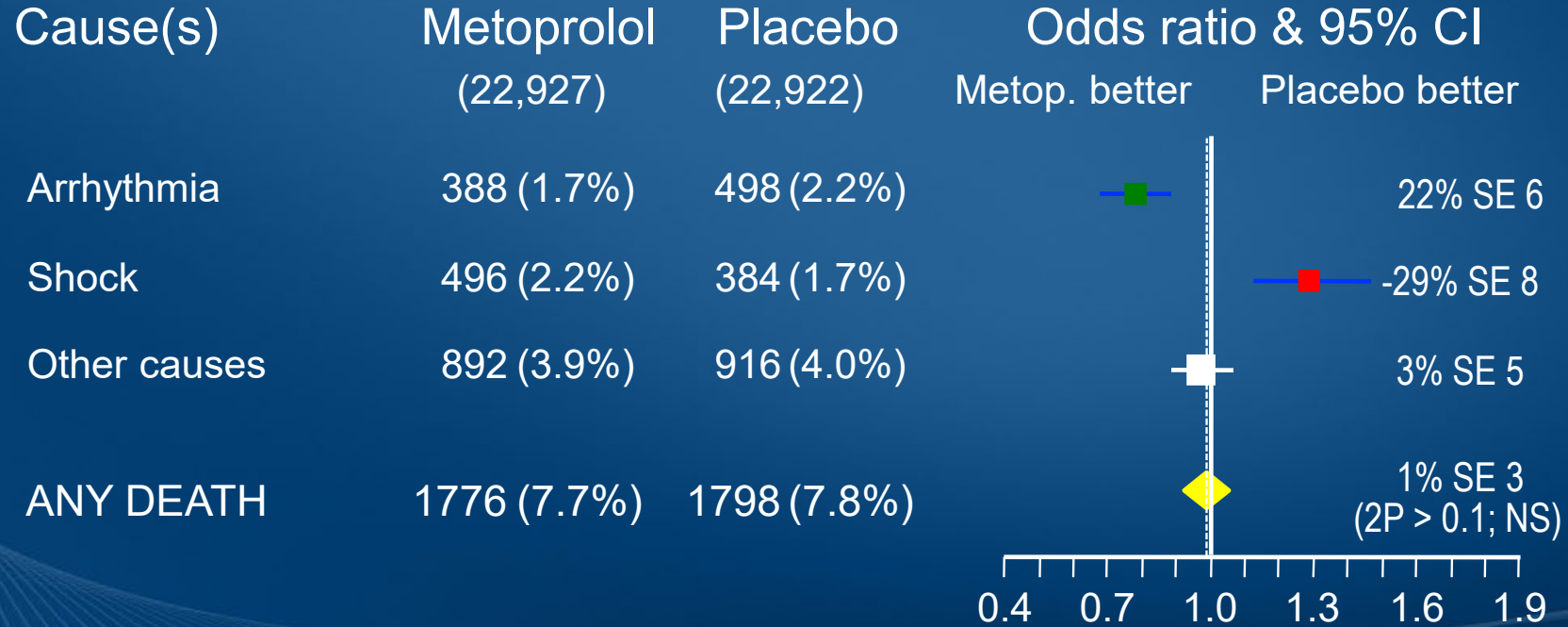
Regarding the use of metoprolol in this patient:

- A. Metoprolol should be administered within 2 hours
- B. Metoprolol should be used within the first 24 hours of admission
- C. Metoprolol would have been indicated within the first 24 hours if the patient was not in shock
- D. Metoprolol use is not indicated at this stage.

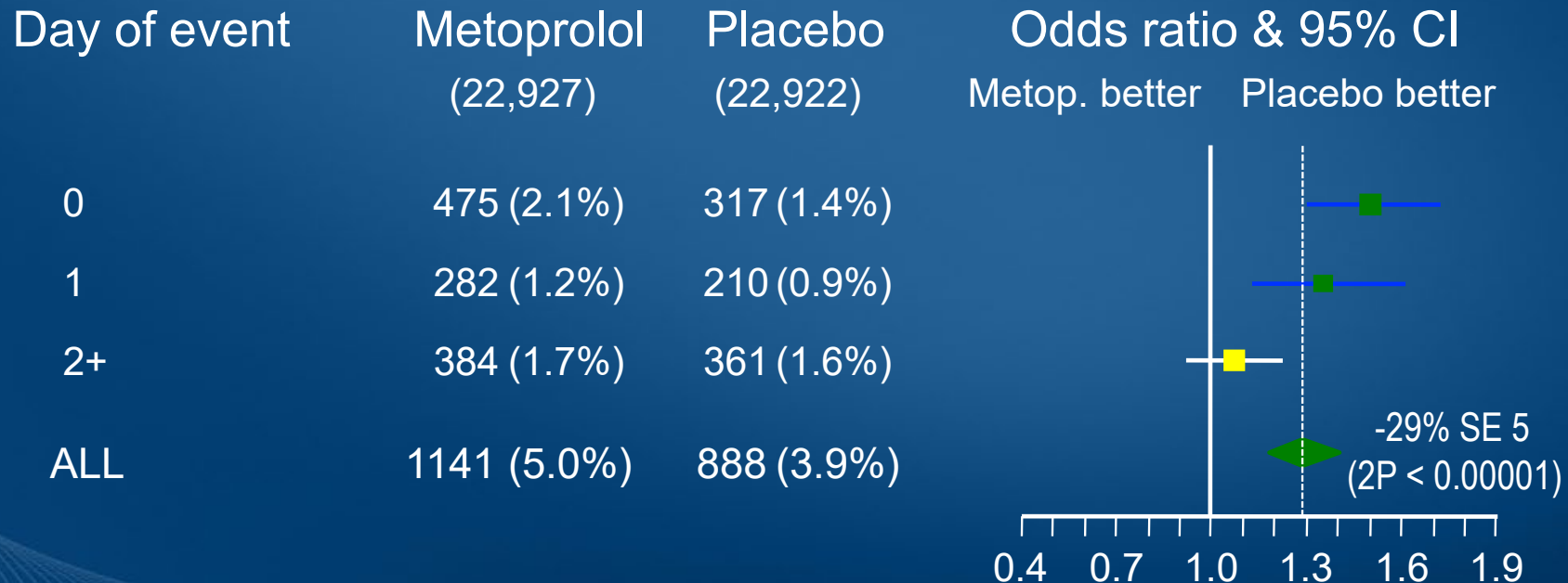
COMMIT: EFFECTS OF EARLY USE OF METOPROLOL ON DEATH IN HOSPITAL



COMMIT: EFFECTS OF METOPROLOL ON DEATH BY ATTRIBUTED CAUSE(S)

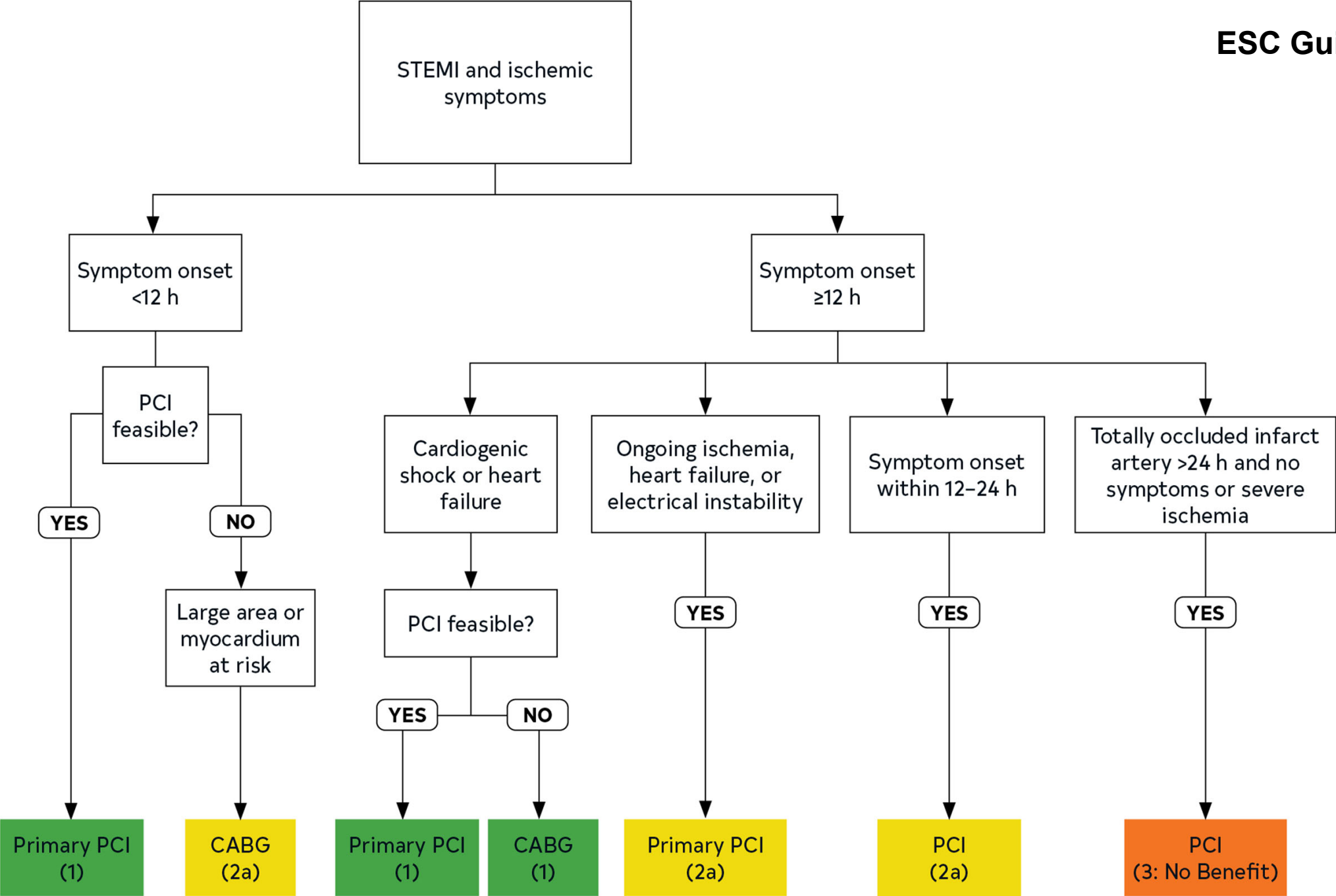


COMMIT: EFFECTS OF METOPROLOL ON CARDIOGENIC SHOCK BY DAY OF EVENT



What revascularization strategy would you do for this patient?

- A. Immediate invasive strategy
- B. Early invasive strategy within 24 hours
- C. Invasive strategy at a planned time
- D. I do not know



NSTE-ACS

ESC Guidelines

Cardiogenic shock

Refractory angina
or hemodynamic or
electrical instability



Immediate invasive
strategy
(1)

At high risk
(e.g., GRACE score*
>140) of clinical events

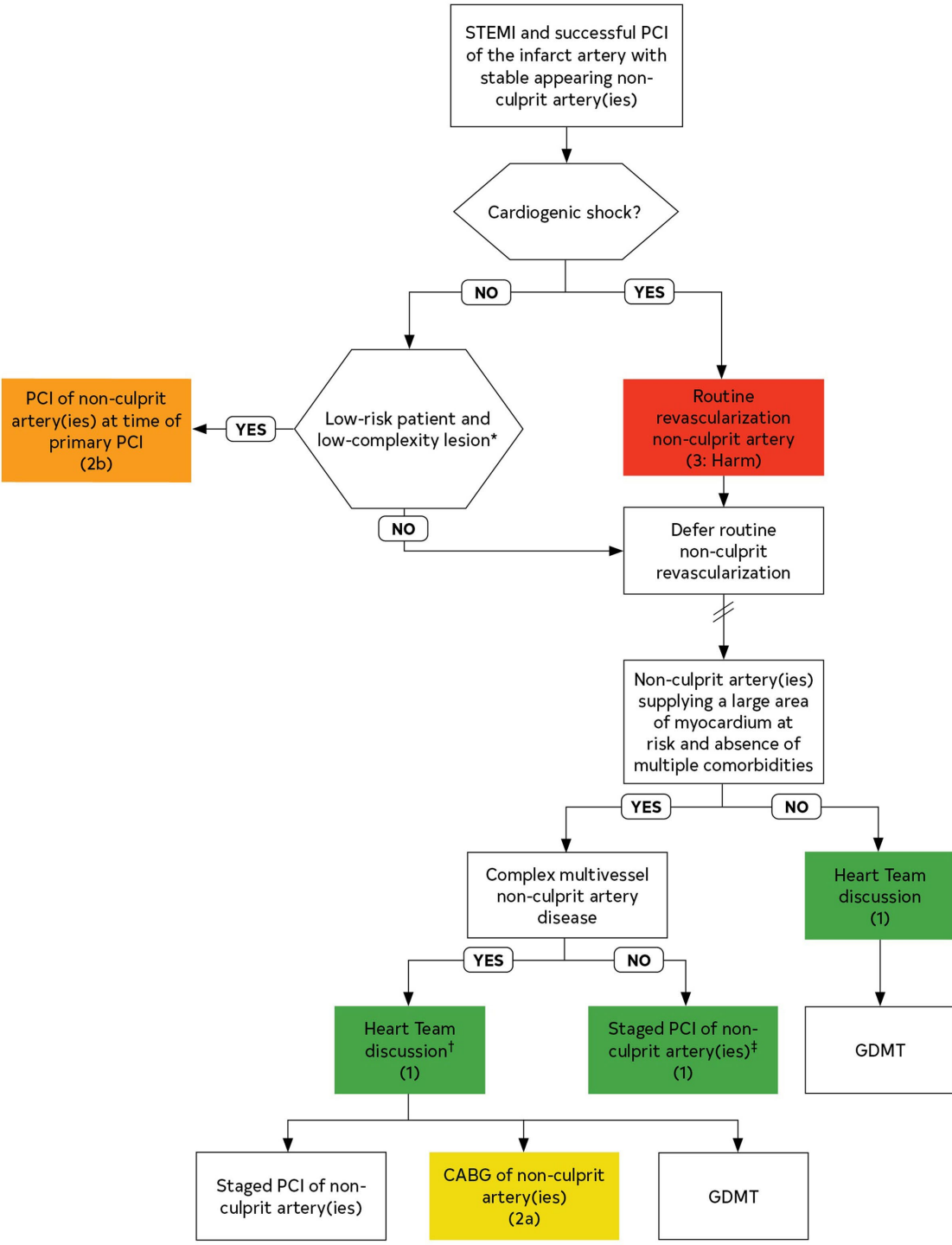


Early invasive strategy
within 24 h
(2a)

In initially stabilized
patients who are at
intermediate or low
risk of clinical events



Invasive strategy with
intent to perform
revascularization
before hospital
discharge
(2a)



The New England Journal of Medicine

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VOLUME 341

AUGUST 26, 1999

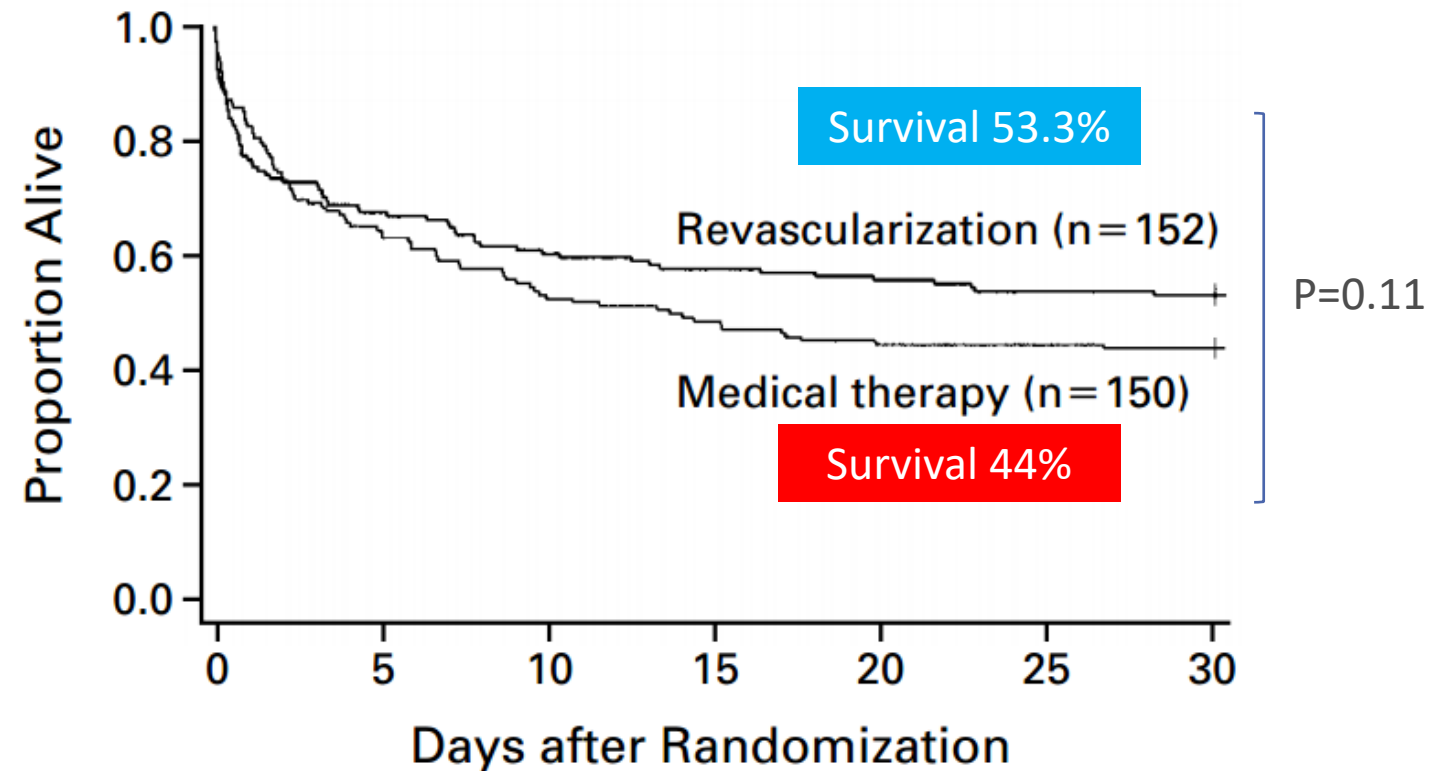
NUMBER 9



EARLY REVASCULARIZATION IN ACUTE MYOCARDIAL INFARCTION COMPLICATED BY CARDIOGENIC SHOCK

JUDITH S. HOCHMAN, M.D., LYNN A. SLEEPER, Sc.D., JOHN G. WEBB, M.D., TIMOTHY A. SANBORN, M.D.,
HARVEY D. WHITE, D.Sc., J. DAVID TALLEY, M.D., CHRISTOPHER E. BULLER, M.D., ALICE K. JACOBS, M.D.,
JAMES N. SLATER, M.D., JACQUES COL, M.D., SONJA M. MCKINLAY, Ph.D., AND THIERRY H. LEJEMTEL, M.D.,
FOR THE SHOCK INVESTIGATORS*

Early Revascularization in Acute Myocardial Infarction Complicated by Cardiogenic Shock



Early Revascularization in Acute Myocardial Infarction Complicated by Cardiogenic Shock

TABLE 4. MORTALITY AMONG STUDY PATIENTS.*

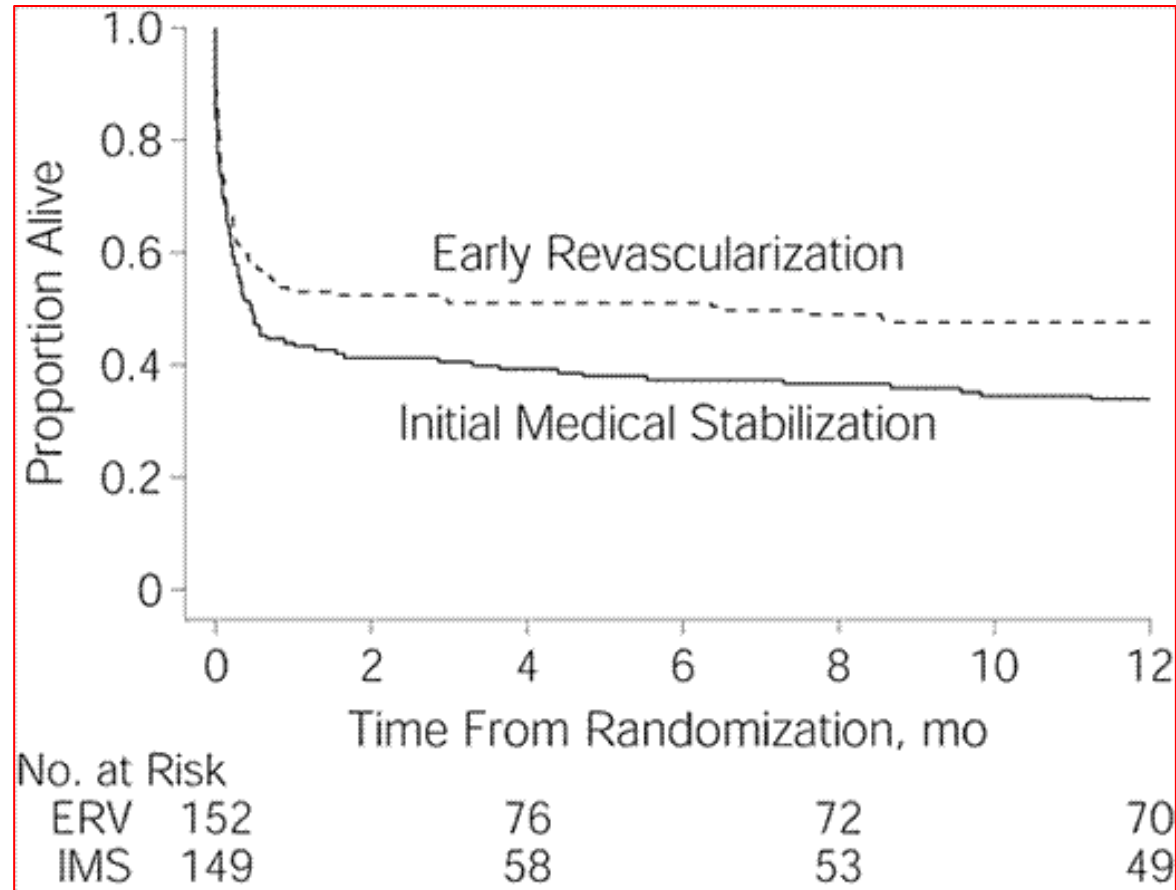
OUTCOME AND SUBGROUP	REVASCUARIZATION	MEDICAL THERAPY	DIFFERENCE BETWEEN GROUPS (95% CI)	RELATIVE RISK (95% CI)	P VALUE
	percent (number in subgroup)		percent		
30-day mortality					
Total	46.7 (152)	56.0 (150)	-9.3 (-20.5 to 1.9)	0.83 (0.67 to 1.04)	0.11
Age <75 yr	41.4 (128)	56.8 (118)	-15.4 (-27.8 to -3.0)	0.73 (0.56 to 0.95)	0.01†
Age ≥75 yr	75.0 (24)	53.1 (32)	+21.9 (-2.6 to 46.4)	1.41 (0.95 to 2.11)	
6-mo mortality‡					
Total	50.3 (151)	63.1 (149)	-12.8 (-23.2 to -0.9)	0.80 (0.65 to 0.98)	0.027
Age <75 yr	44.9 (127)	65.0 (117)	-20.1 (-31.6 to -7.1)	0.70 (0.56 to 0.89)	0.003†
Age ≥75 yr	79.2 (24)	56.3 (32)	+22.9 (0.7 to 46.6)	1.41 (0.97 to 2.03)	

*CI denotes confidence interval.

†Appropriate subgroup-analysis P values (for the interaction between treatment and the subgroup variable) are shown. Univariate P values for the comparison between treatments within subgroups were as follows: for 30-day mortality, P=0.02 for patients <75 years of age and P=0.16 for those ≥75 years of age; and for 6-month mortality, P=0.002 for patients <75 years of age and P=0.09 for those ≥75 years of age.

‡The data are based on 300 patients; 2 patients (0.7 percent) were lost to follow-up.

One-Year Survival Following Early Revascularization for Cardiogenic Shock



Early Revascularization

Initial Medical Stabilization

How do you approach the non-culprit lesions in this patient?

-
- A. Multivessel PCI at the time of primary PCI
 - B. PCI of the infarct artery only followed by staged PCI ischemia-guided approach of a non-infarct artery
 - C. I do not know

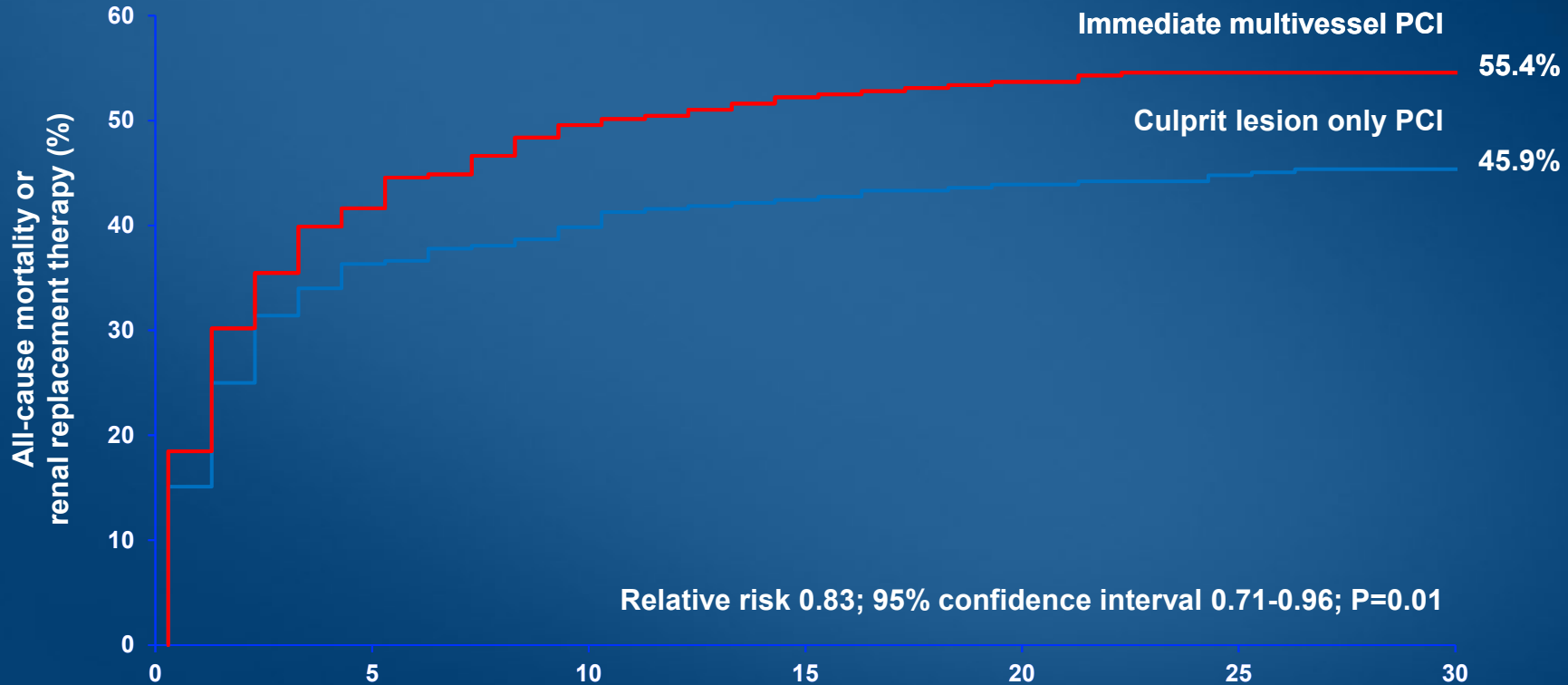
ORIGINAL ARTICLE

PCI Strategies in Patients with Acute Myocardial Infarction and Cardiogenic Shock

Holger Thiele, M.D., Ibrahim Akin, M.D., Marcus Sandri, M.D., Georg Fuernau, M.D., Suzanne de Waha, M.D., Roza Meyer-Saraei, Ph.D., Peter Nordbeck, M.D., Tobias Geisler, M.D., Ulf Landmesser, M.D., Carsten Skurk, M.D., Andreas Fach, M.D., Harald Lapp, M.D., [et al.](#), for the CULPRIT-SHOCK Investigators*

Primary Study Endpoint

All-Cause Mortality or Renal Replacement Therapy



Number at risk:

	0	5	10	15	20	25	30
Culprit lesion only PCI	344	219	207	198	192	189	184
Immediate multivessel PCI	341	199	172	162	156	153	152

THE USE OF IABP IN CARDIOGENIC SHOCK COMPLICATING MYOCARDIAL INFARCTION IS ASSOCIATED WITH:

- A. Improved long term (6-years) survival but not short-term
- B. Improved long term (6-years) survival and short-term
- C. No improvement in short- or long-term survival
- D. I do not know

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JOURNAL *of* MEDICINE

ESTABLISHED IN 1812

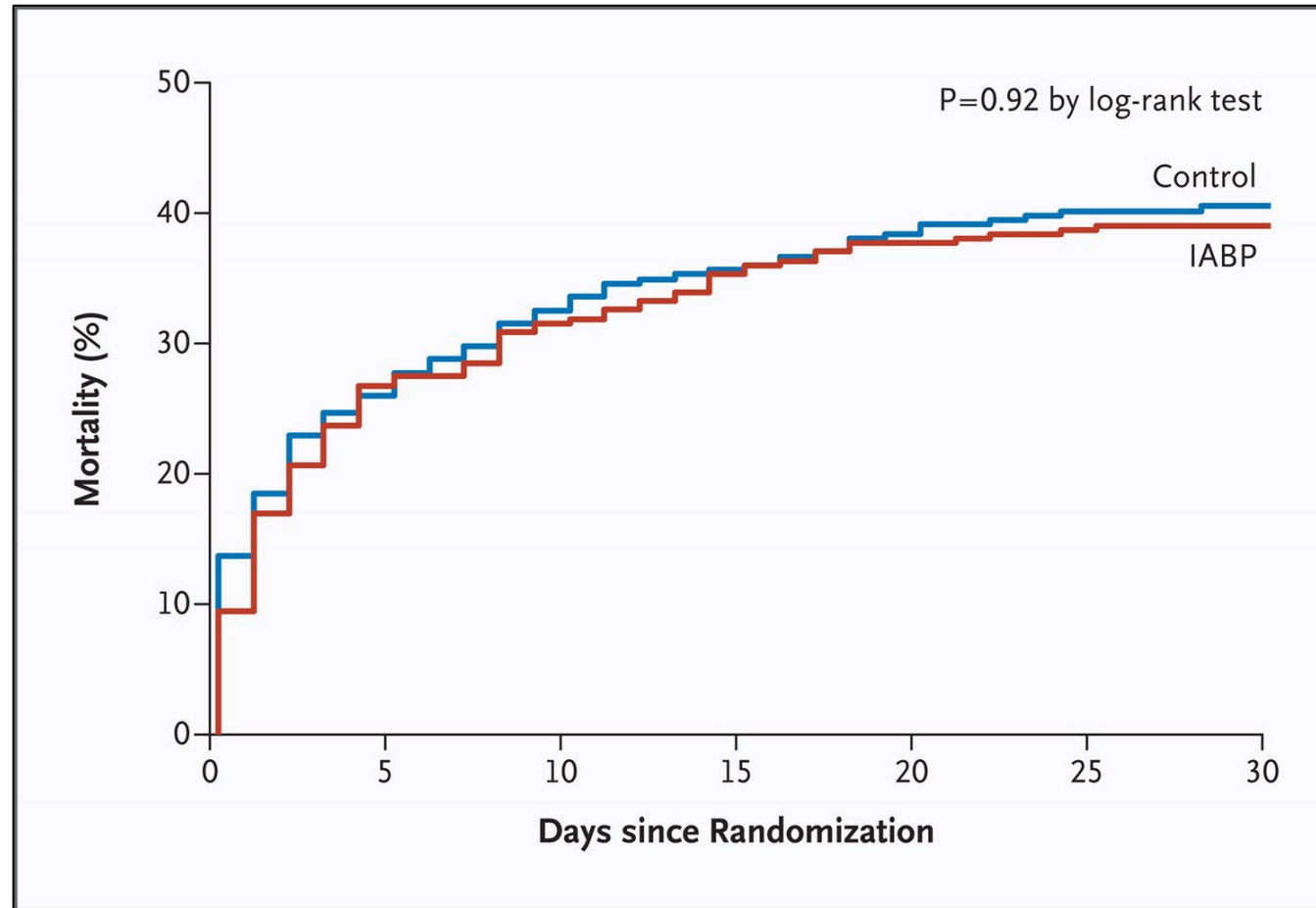
OCTOBER 4, 2012

VOL. 367 NO. 14

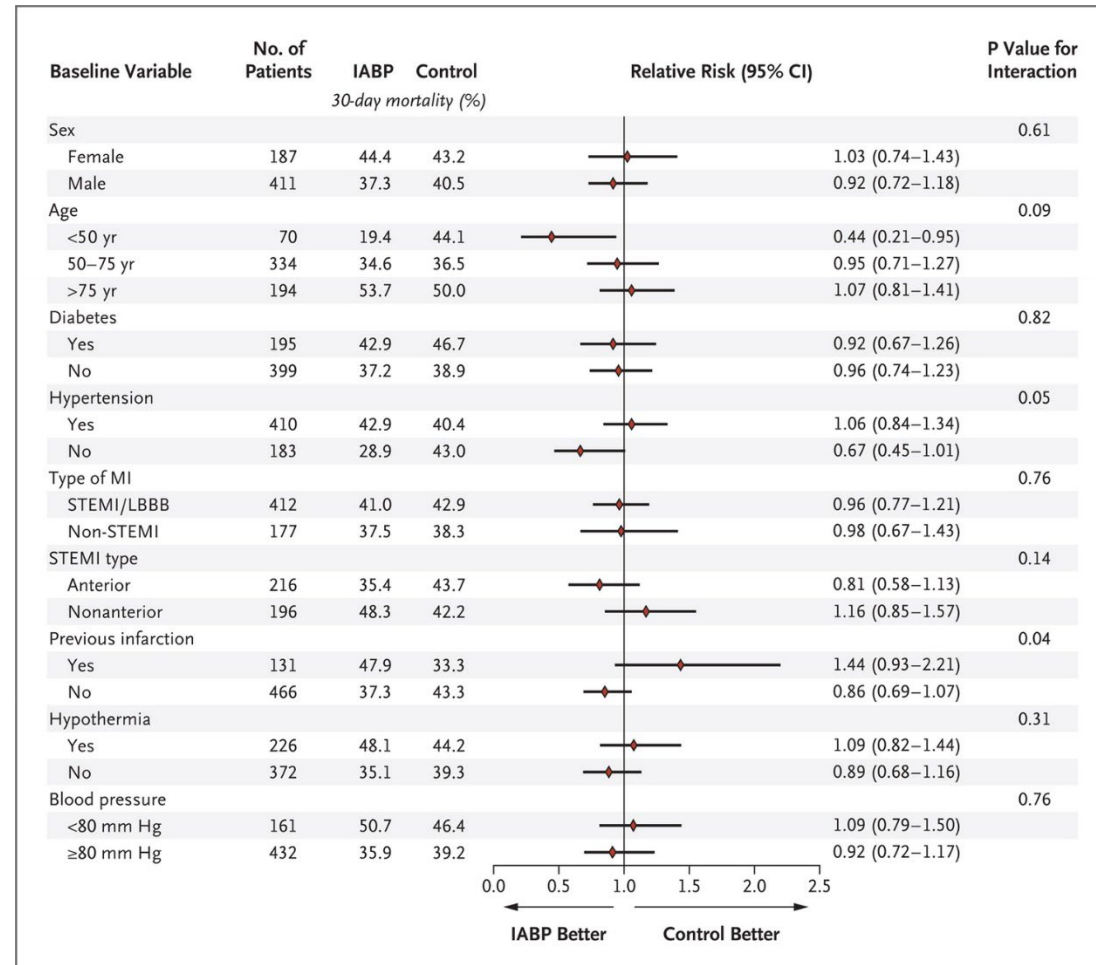
Intraaortic Balloon Support for Myocardial Infarction
with Cardiogenic Shock

Holger Thiele, M.D., Uwe Zeymer, M.D., Franz-Josef Neumann, M.D., Mirosław 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 Ebel, M.D., Steffen Schneider, Ph.D., Gerhard Schuler, M.D., and Karl Werdan, M.D.,
for the IABP-SHOCK II Trial Investigators*

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

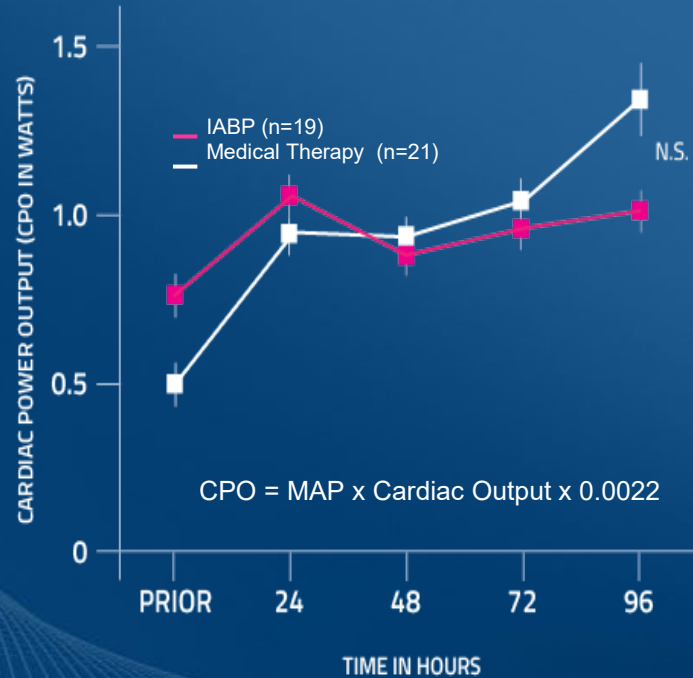


Subgroup Analyses of the Primary End Point

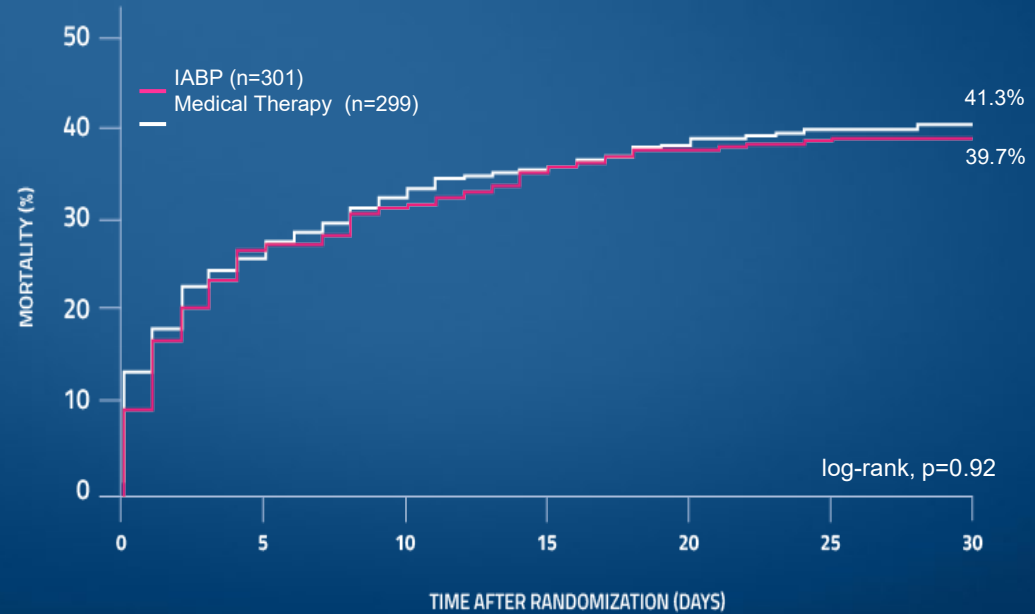


IABP IN AMI CARIOGENIC SHOCK: NO HEMODYNAMIC OR SURVIVAL BENEFIT

IABP SHOCK I Randomized Controlled Trial¹ N = 40



IABP-SHOCK II Randomized Controlled Trial² N = 600

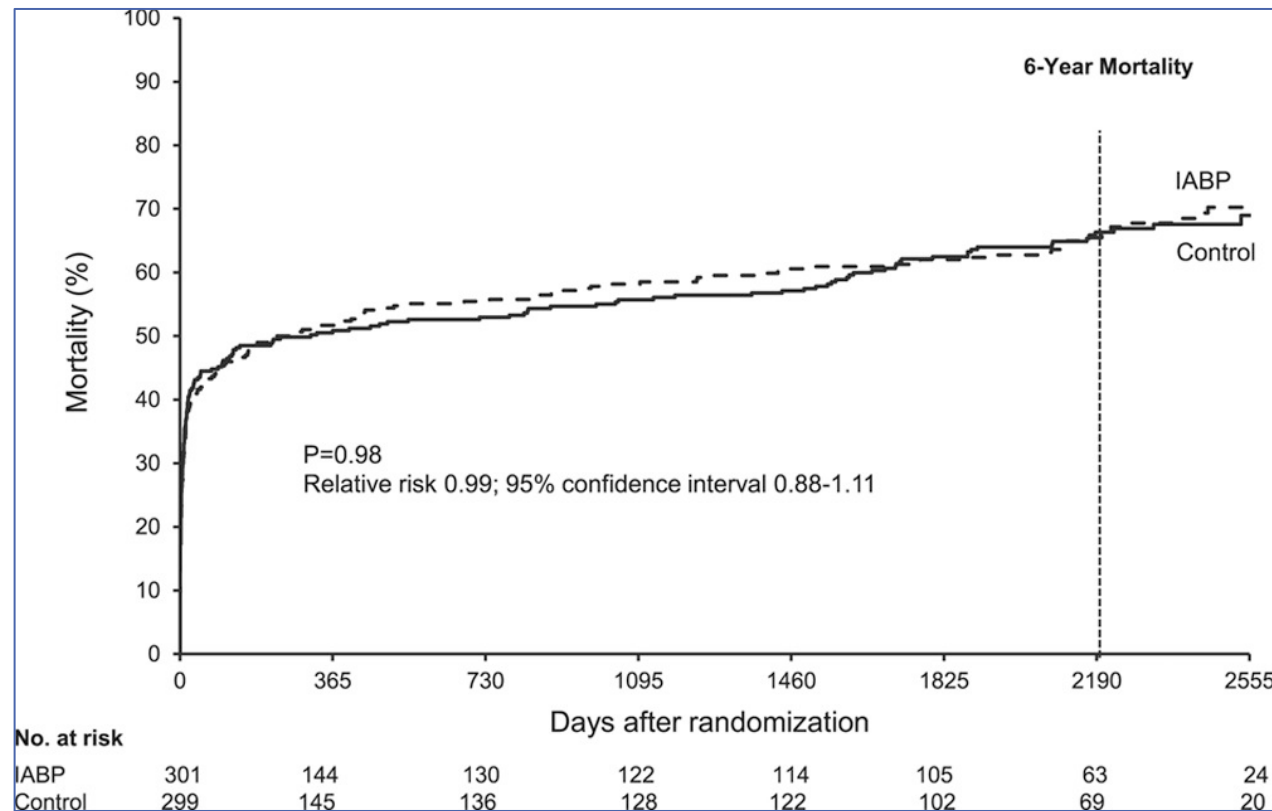


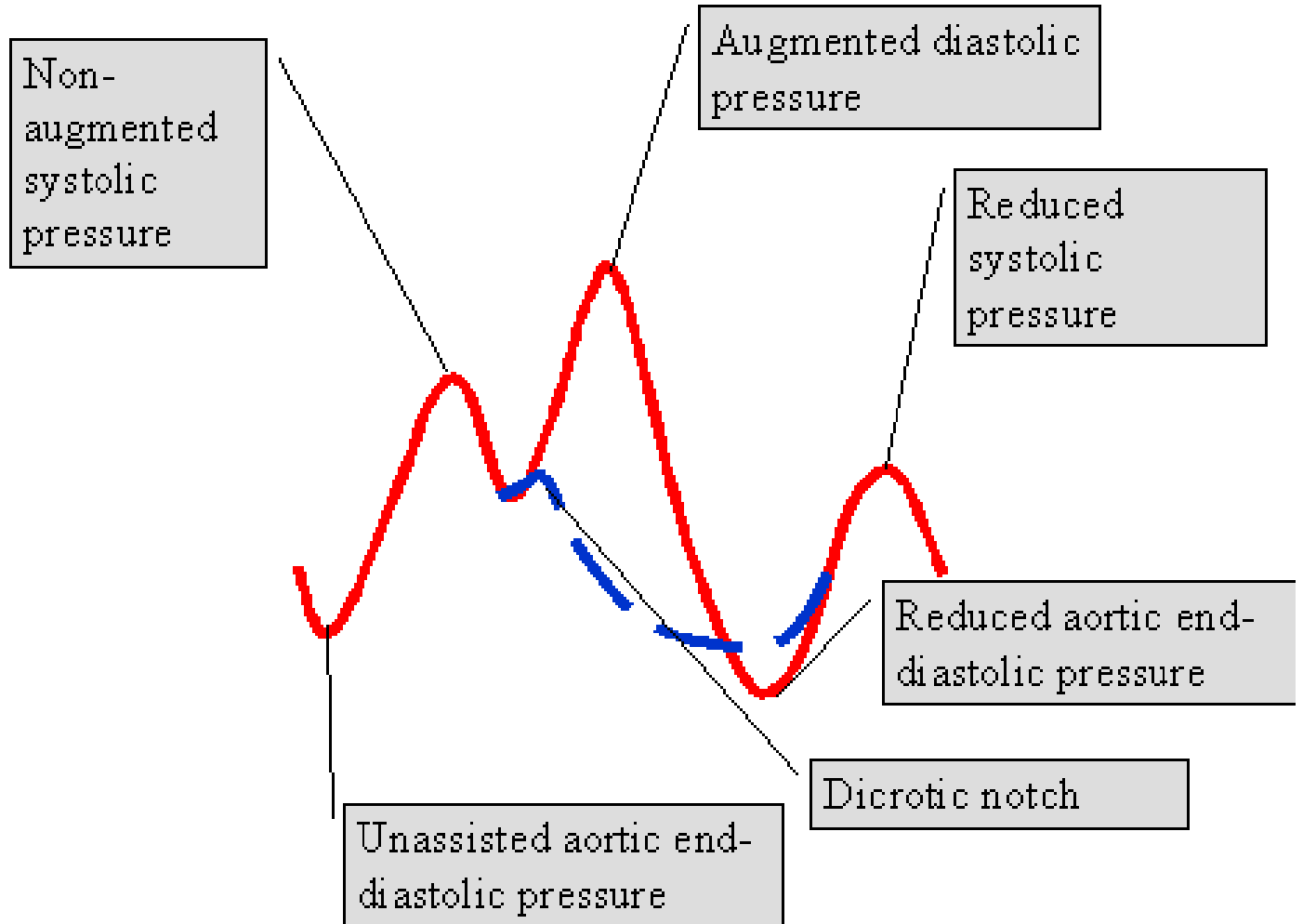
IABP Increased hazard risk of stroke, downgraded to Class III (harm), Level of Evidence A, ESC STEMI Guidelines 2014

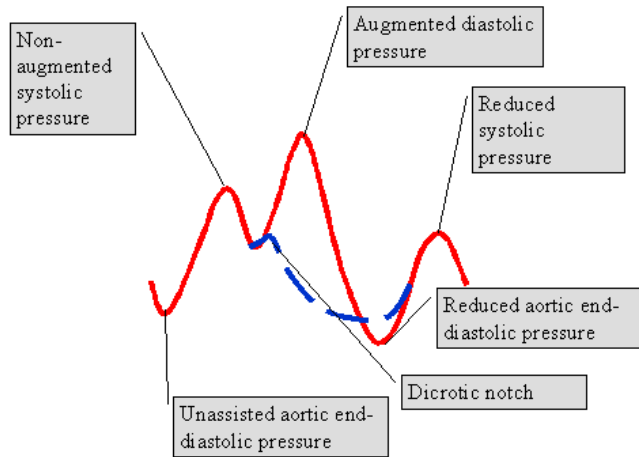
1- Prondzinsky R. et al. Jn Critical Care Medicine IABP SHOCK I 2010 – Clinicaltrial.gov # NCT00469248

2- Thiele H et al. NEJM 2012 - Clinicaltrial.gov # NCT00491036

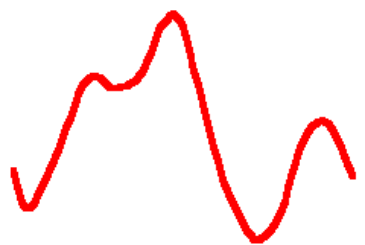
Long-Term 6-Year Outcome of the Randomized IABP-SHOCK II Trial



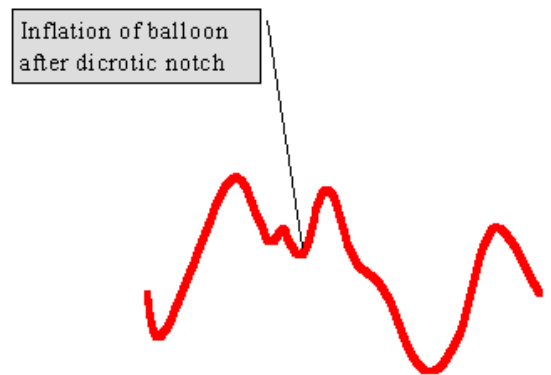




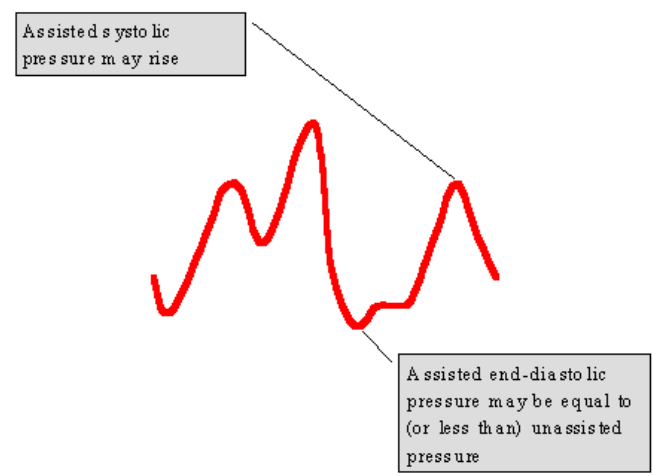
Early Inflation



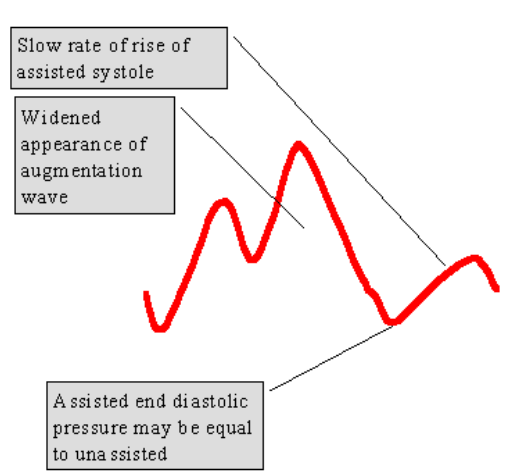
Late Inflation



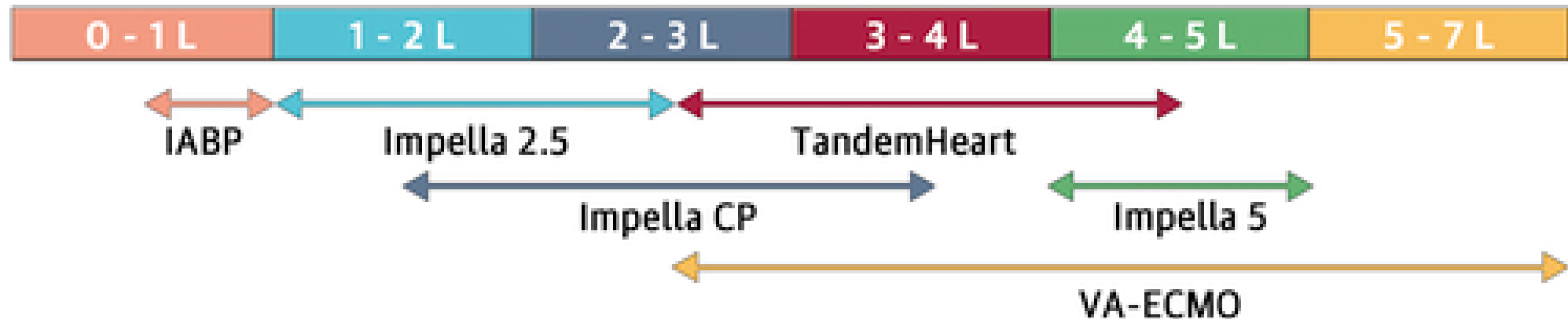
Early Deflation



Late Deflation



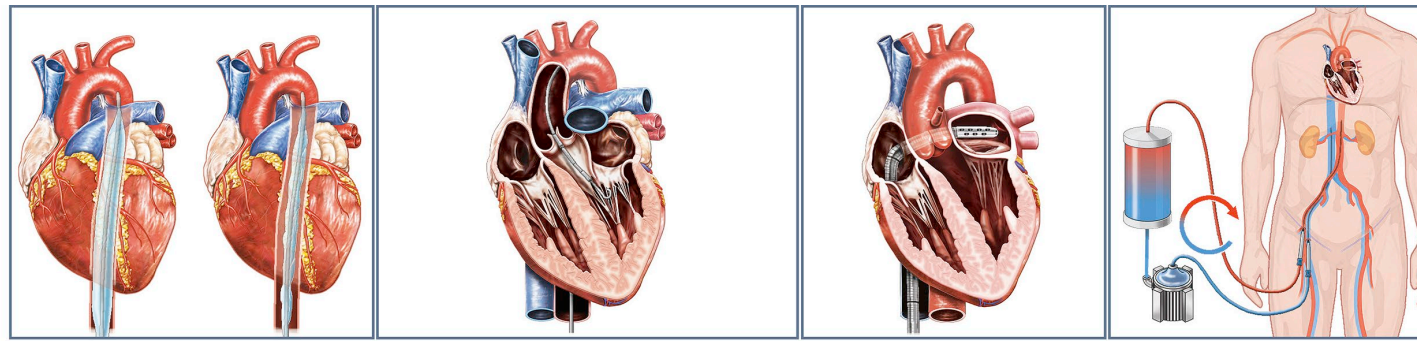
Comparison of MCS Devices and Their Impact on Cardiac Flow



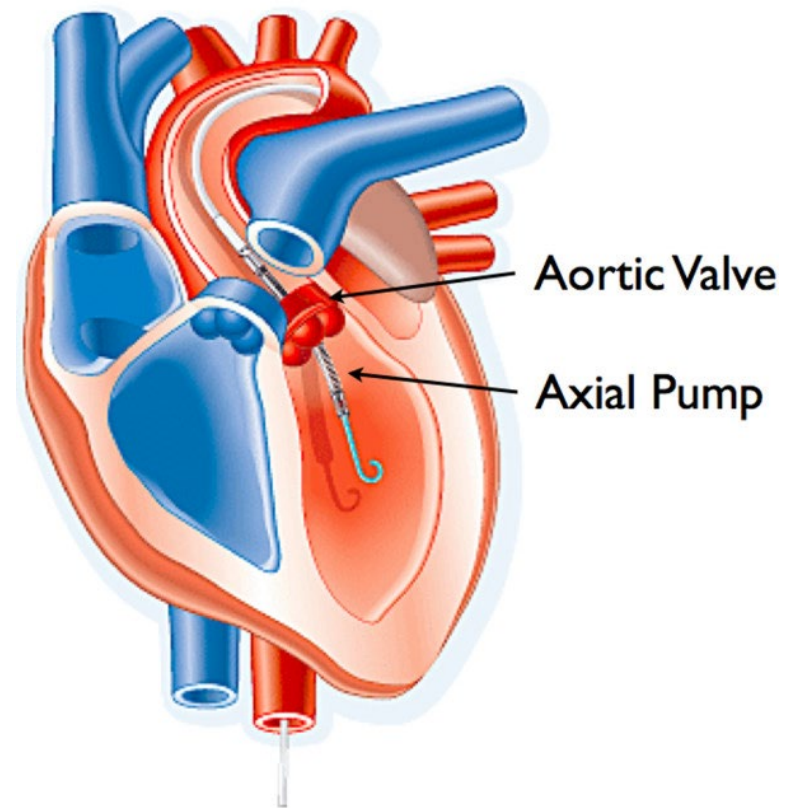
Tamara M. Atkinson et al. *J Am Coll Cardiol Interv* 2016; 9:871-883.



JACC
Cardiovascular Interventions



	IABP	IMPELLA	TANDEMHEART	VA-ECMO
Cardiac Flow	0.3-0.5 L/ min	1-5L/ min (Impella 2.5, Impella CP, Impella 5)	2.5-5 L/ min	3-7 L-min
Mechanism	Aorta	LV → AO	LA → AO	RA → AO
Maximum implant days	Weeks	7 days	14 days	Weeks
Sheath size	7-8 Fr	13-14 Fr Impella 5.0 - 21 Fr	15-17 Fr Arterial 21 Fr Venous	14-16 Fr Arterial 18-21 Fr Venous
Femoral Artery Size	>4 mm	Impella 2.5 & CP - 5-5.5 mm Impella 5 - 8 mm	8 mm	8 mm
Cardiac synchrony or stable rhythm	Yes	No	No	No
Afterload	↓	↓	↑	↑↑↑
MAP	↑	↑↑	↑↑	↑↑
Cardiac Flow	↑	↑↑	↑↑	↑↑
Cardiac Power	↑	↑↑	↑↑	↑↑
LVEDP	↓	↓↓	↓↓	↔
PCWP	↓	↓↓	↓↓	↔
LV Preload	---	↓↓	↓↓	↓
Coronary Perfusion	↑	↑	---	---
Myocardial oxygen demand	↓	↓↓	↔↓	↔



FDA INDICATION

- The Impella 2.5™, Impella CP®, Impella 5.0™ and Impella LD™ catheters, in conjunction with the Automated Impella Controller console, are intended for short-term use (≤ 4 days for the Impella 2.5 and Impella CP and ≤ 6 days for the Impella 5.0 and Impella LD) and indicated for the treatment of ongoing cardiogenic shock that occurs immediately (< 48 hours) following acute myocardial infarction (AMI) or open heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures with or without an intra-aortic balloon pump.
- The intent of the Impella system therapy is to reduce ventricular work and to provide the circulatory support necessary to allow heart recovery and early assessment of residual myocardial function.
- * Optimal medical management and conventional treatment measures include volume loading and use of pressors and inotropes, with or without IABP

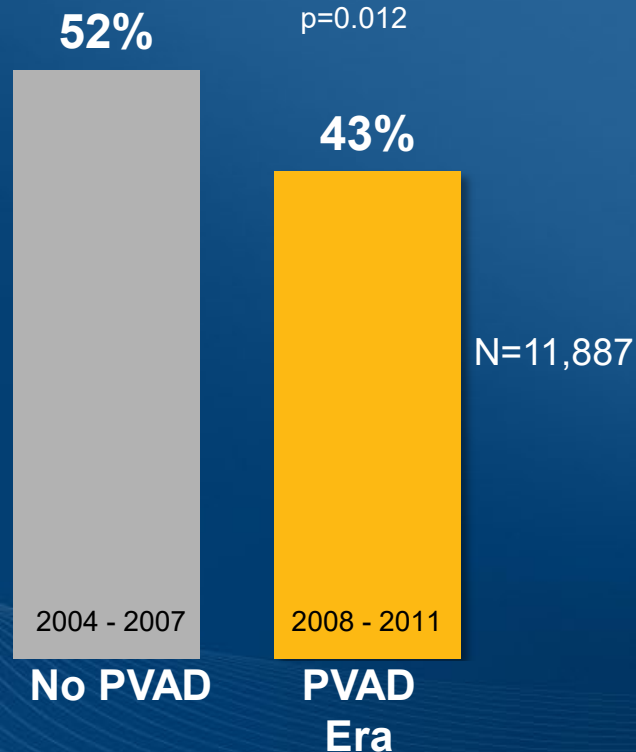
DATA SUPPORTING FDA INDICATIONS

	Scientific Evidence	Total # of Patients	# of Impella Patients
Cardiogenic Shock	Recover I FDA Study	17	17
	ISAR Shock RCT	26	13
	U.S. Impella Registry	401	401
	Literature review	<u>2,537</u>	<u>692</u>
	Total	2,981	1,123
Protected PCI	Protect I FDA Study	20	20
	Protect II FDA Study	452	225
	U.S. Impella Registry	1,322	637
	Literature review	<u>2,537</u>	<u>756</u>
	Total	4,331	1,638

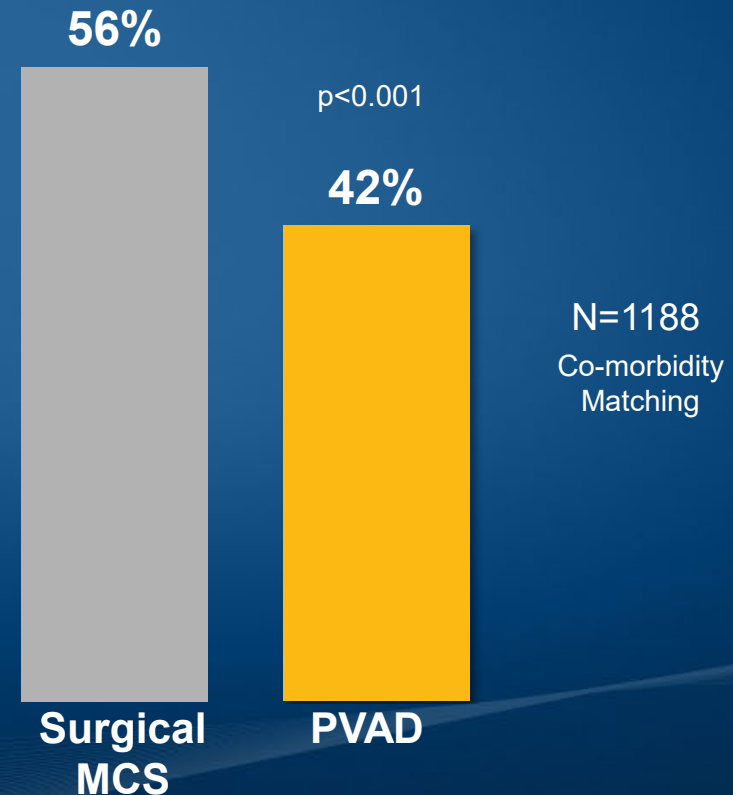
24,000 Patients from FDA medical device reporting (MDR) database

POPULATION STUDIES SHOW REDUCED MORTALITY WITH PVAD IN AMI CARDIOGENIC SHOCK

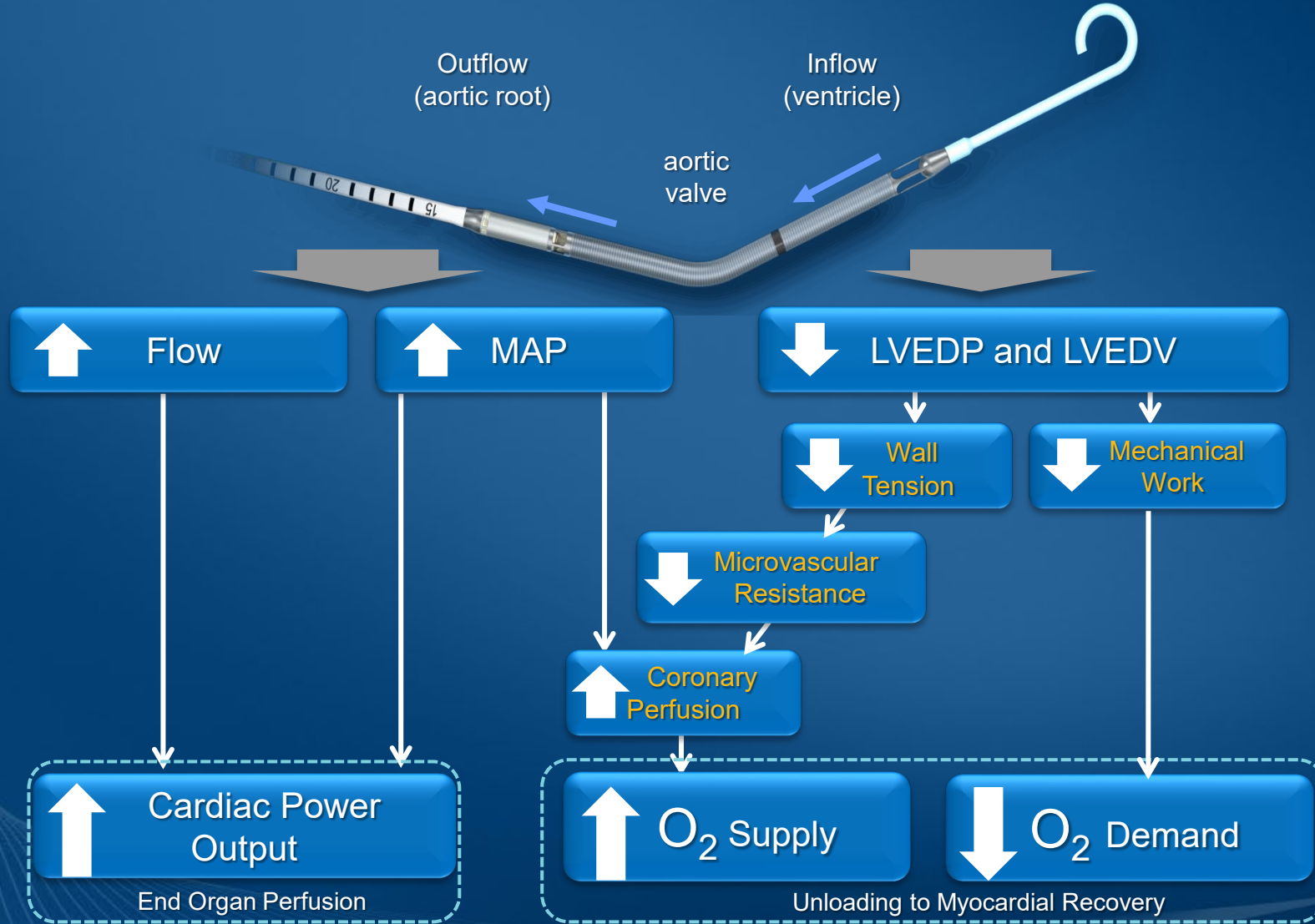
Mortality AMI Cardiogenic Shock Pre/Post PVAD Era



Mortality In AMI Cardiogenic Shock ECMO/eLVAD vs. PVAD



HEMODYNAMIC EFFECTS OF IMPELLER® SUPPORT



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Long-term 5-year outcome of the randomized IMPRESS in severe shock trial: percutaneous mechanical circulatory support vs. intra-aortic balloon pump in cardiogenic shock after acute myocardial infarction

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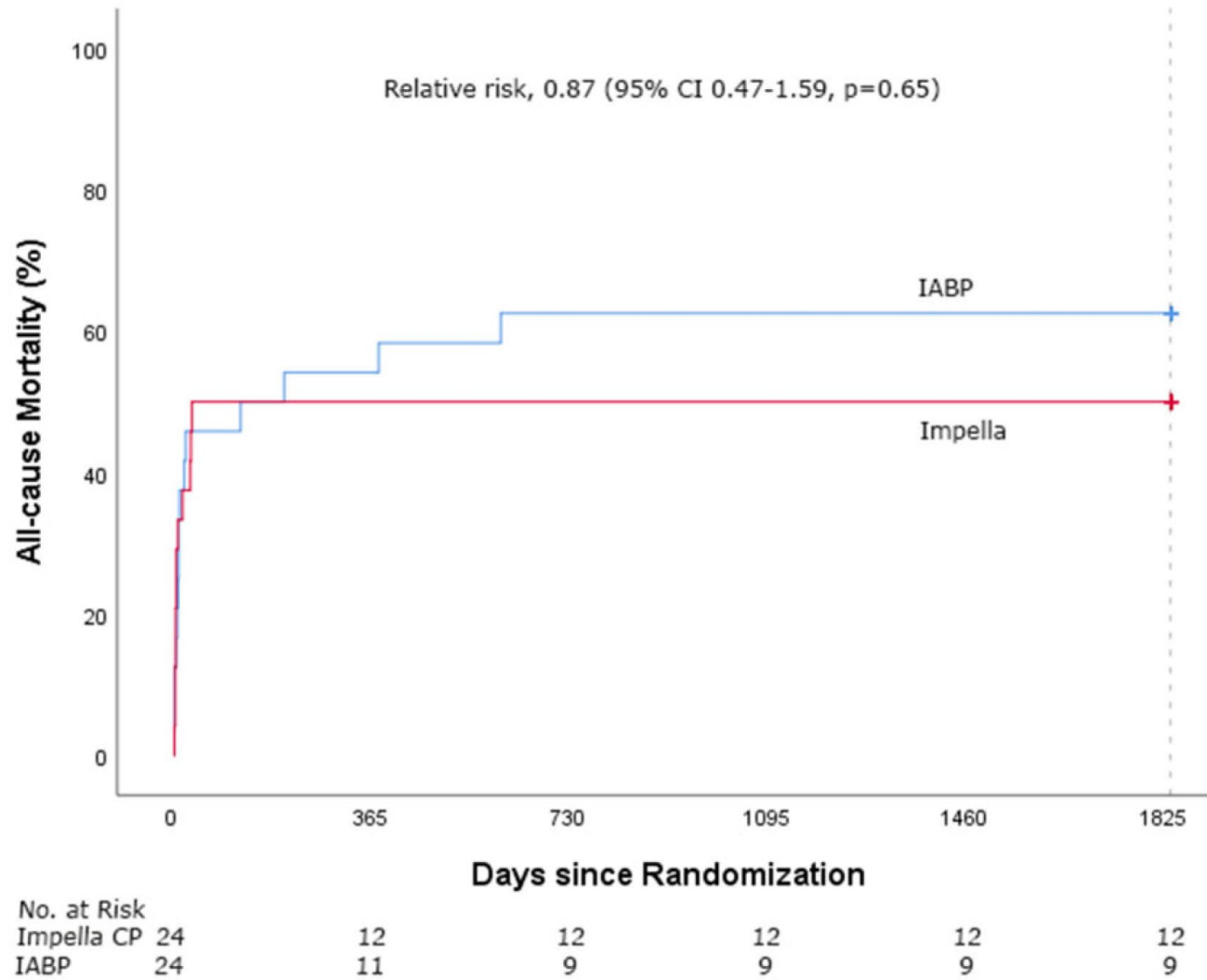


Figure 1 Time-to-event Kaplan–Meier curves of all-cause mortality in Impella CP and intra-aortic balloon pump-treated patients.

Conclusion

Cardiogenic Shock remains lethal

Dopamine is associated with worse outcome compared to metoprolol

Early Revascularization improves survival

Mechanical Circulatory Support requires further investigations

Protocol-driven approach should be accommodated



Thank You