

When Should We Consider MCS Before PCI in STEMI

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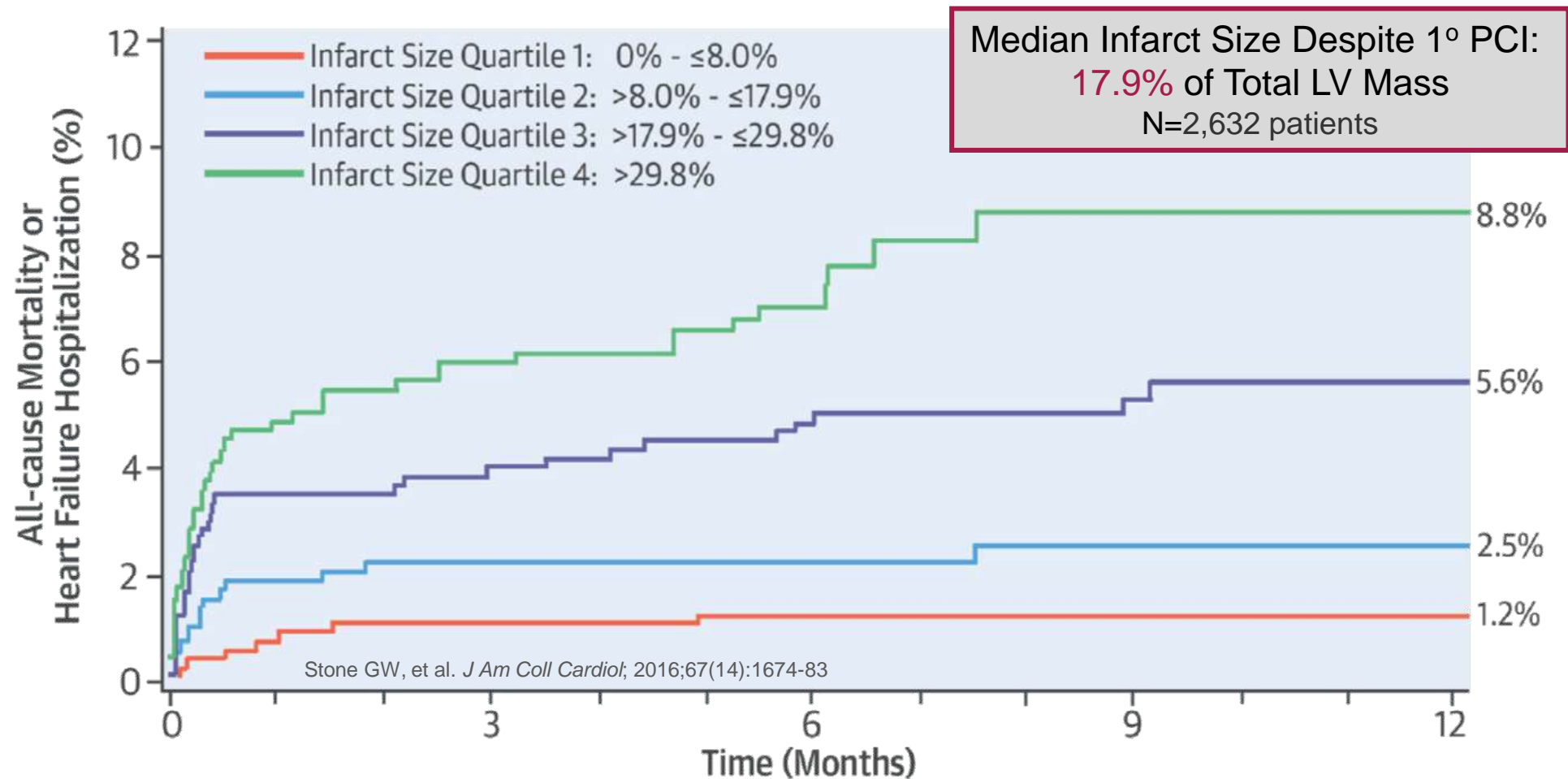
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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Grant/Research Support (<i>Institutional</i>)	NIH/NHLBI, Abbott, Philips, Boston Scientific, Abiomed, Opsens, Acist Medical, Medtronic Cardiovascular Systems Inc
Consulting Fees/Honoraria	Amgen, Astra Zeneca, Boston Scientific
Equity	Shockwave Medical

Larger Infarcts Drive Mortality + HF



For every **5% increase** in myocardial infarct size, 1-year all-cause mortality increases by 19% & HF hospitalization by 20%

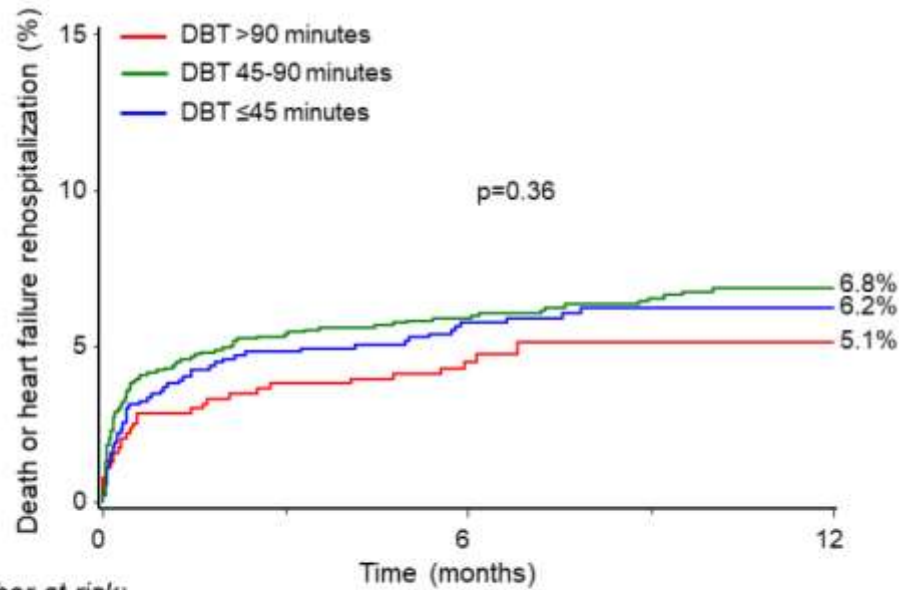
So how can we reduce infarct size?

Time Delay, Infarct Size, and Microvascular Obstruction After Primary Percutaneous Coronary Intervention for ST-Segment–Elevation Myocardial Infarction

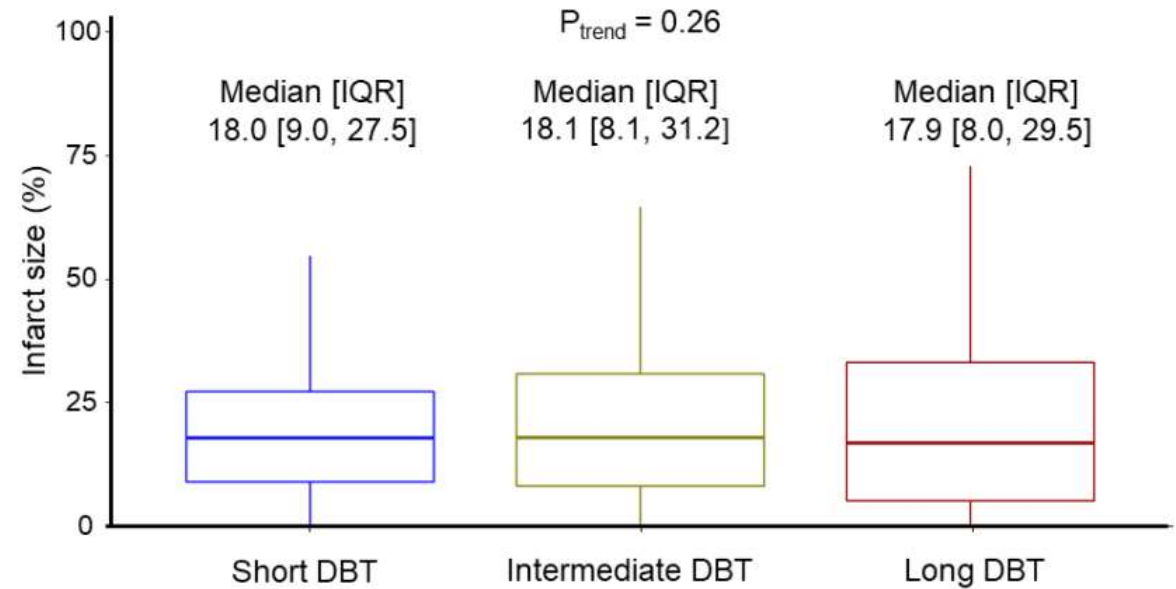
Björn Redfors, MD, PhD*; Reza Mohebi[†], MD*; Gennaro Giustino, MD; Shmuel Chen[‡], MD, PhD; Harry P. Selker, MD, MSPH; Holger Thiele[§], MD; Manesh R. Patel, MD; James E. Udelson, MD; E. Magnus Ohman, MD; Ingo Eitel[¶], MD; Christopher B. Granger^{||}, MD; Akiko Maehara, MD; Ziad A. Ali^{||}, MD, DPhil; Ori Ben-Yehuda, MD; Gregg W. Stone^{||}, MD

Door-to-balloon time						
>90 min vs ≤45 min	1.01 (0.61–1.67)	0.96	1.07 (0.60–1.92)	0.82	0.67 (0.31–1.46)	0.32
45–90 min vs ≤45 min	1.03 (0.70–1.50)	0.90	0.91 (0.57–1.48)	0.71	1.03 (0.61–1.74)	0.91
Per 10-min increase	1.02 (0.98–1.06)	0.28	1.02 (0.98–1.07)	0.23	0.99 (0.93–1.05)	0.78

Values are hazard ratio (95% CI). The multivariable models were adjusted for the following covariate set: Age, sex, hypertension, hyperlipidemia, current smoking, LAD vs non-LAD infarct artery, and prior myocardial infarction. LAD indicates left anterior descending.

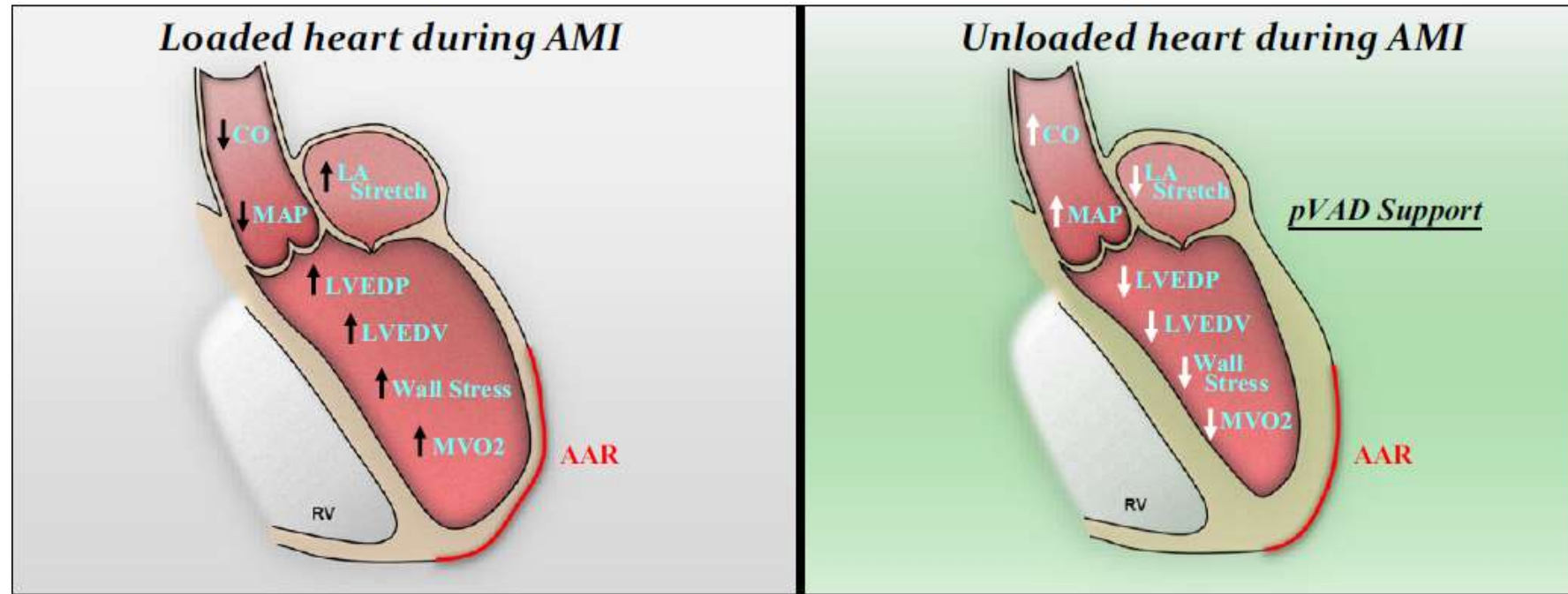


Number at risk:	0	6	12
DBT >90m	646	435	164
DBT 45-90m	913	737	440
DBT ≤45m	1,447	1,235	775



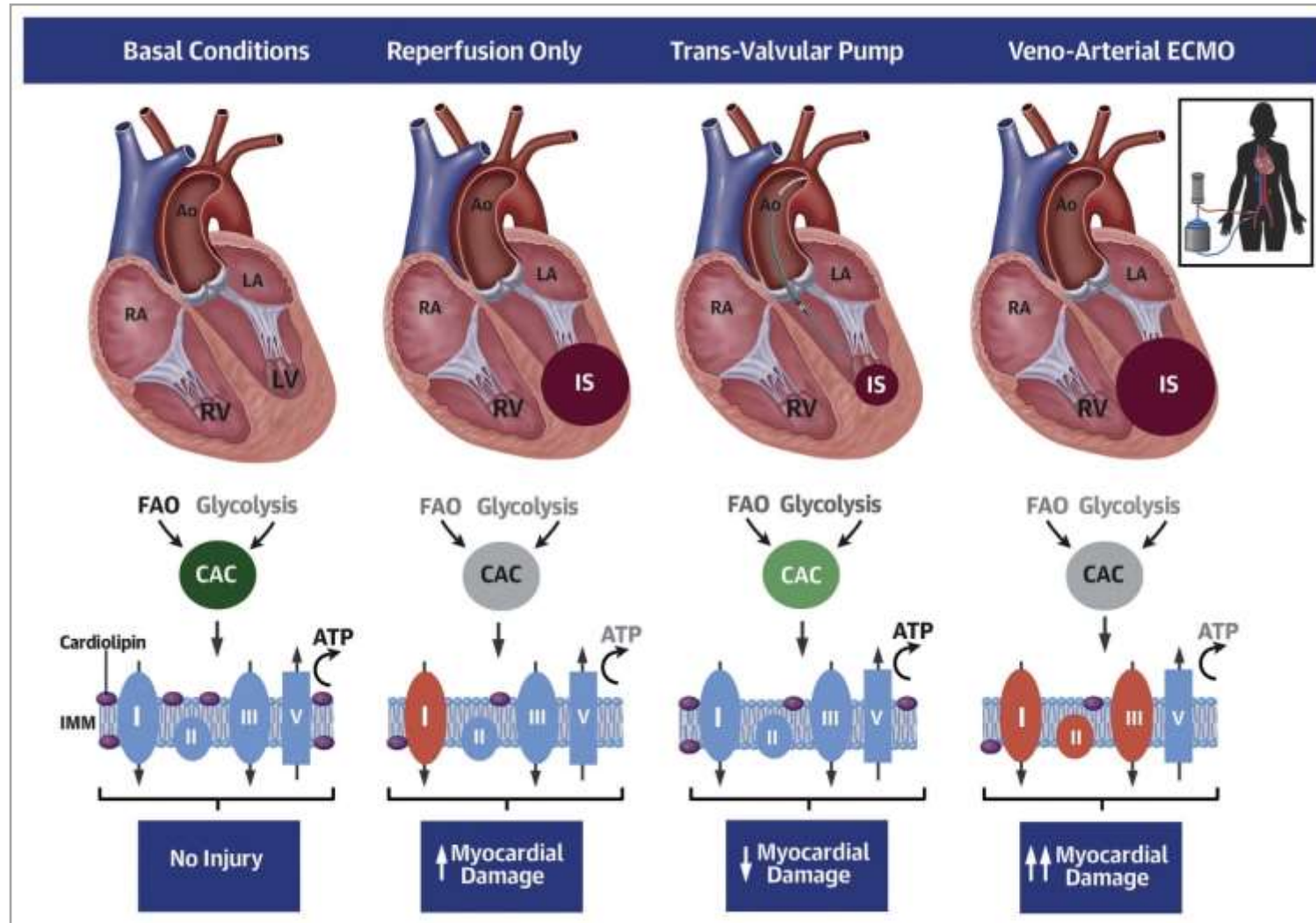
What about unloading?

UNLOADING – THE SCIENCE



- Decreased myocardial oxygen consumption
- Activation of cardioprotective signaling
- Increased cardiac microvascular perfusion into infarct zone
- Hemodynamic stabilization through reperfusion-dependent arrhythmia
- Bridge through reperfusion-induced myocardial stunning
- Reduced acute infarct size and subsequent scar size

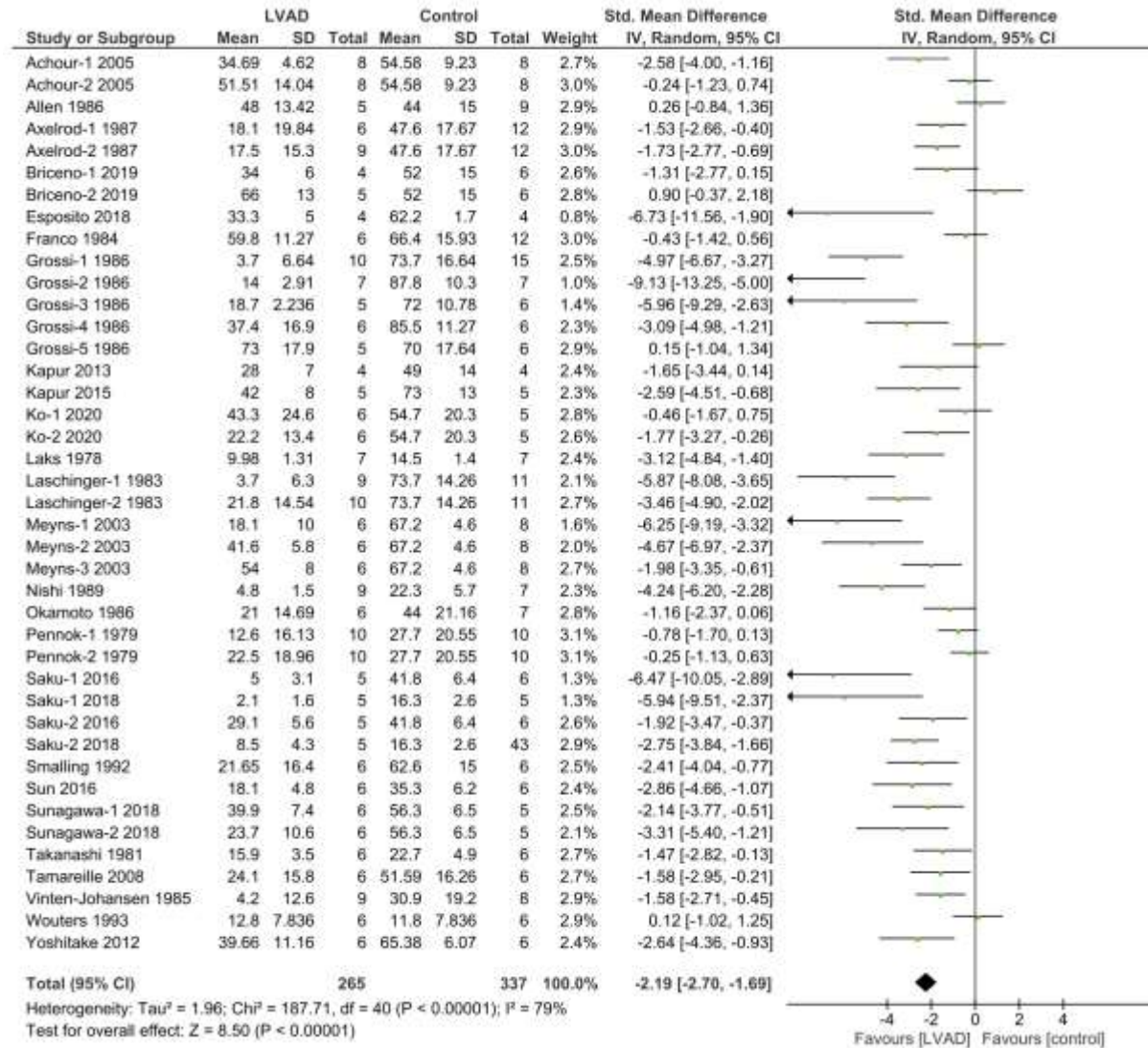
CHOICES



Is there evidence for unloading?

But that's just basic science...

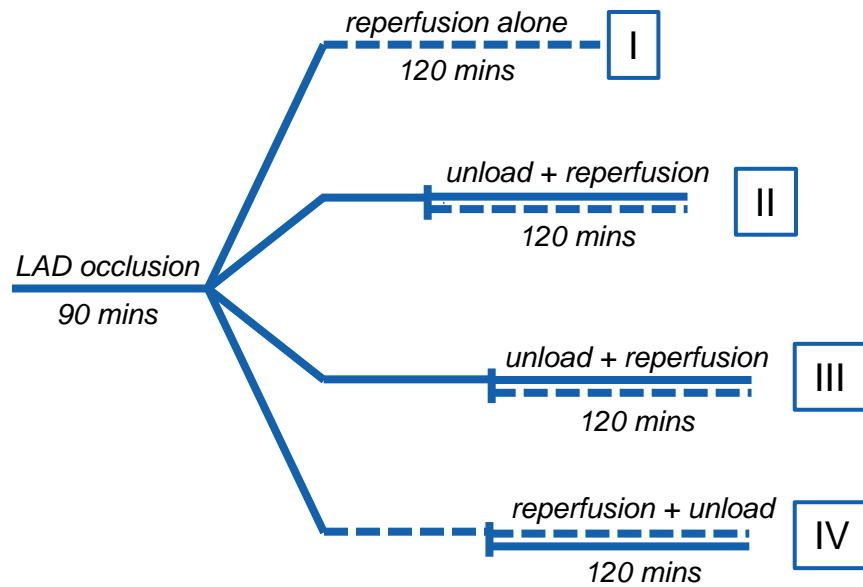
LV Unloading has Data to Support it?



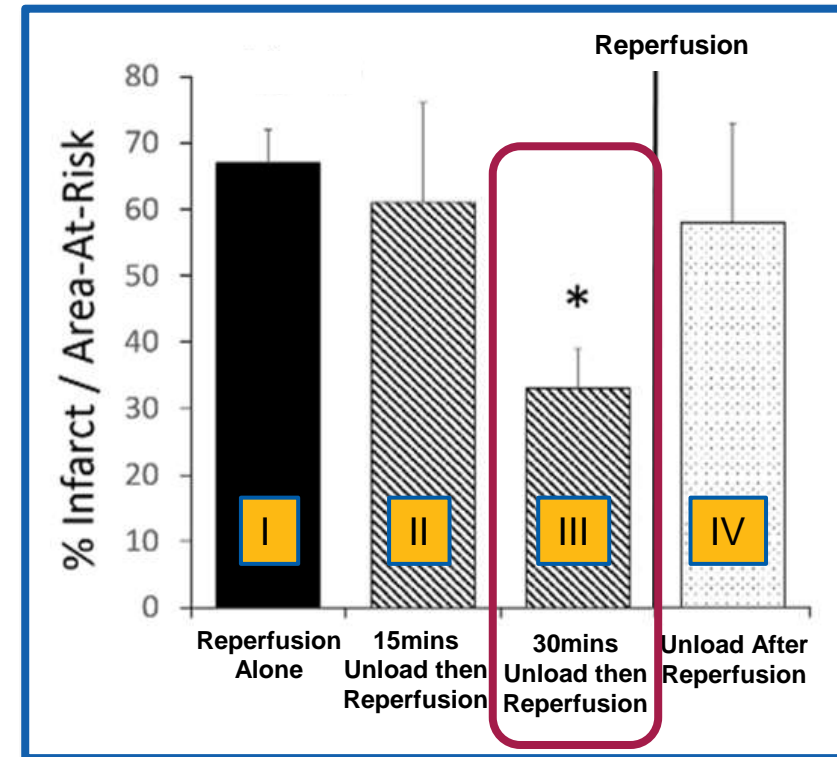
What's next?

UNLOADING 30MINS BEFORE REPERFUSION DEMONSTRATED STRONGEST CARDIOPROTECTIVE EFFECT

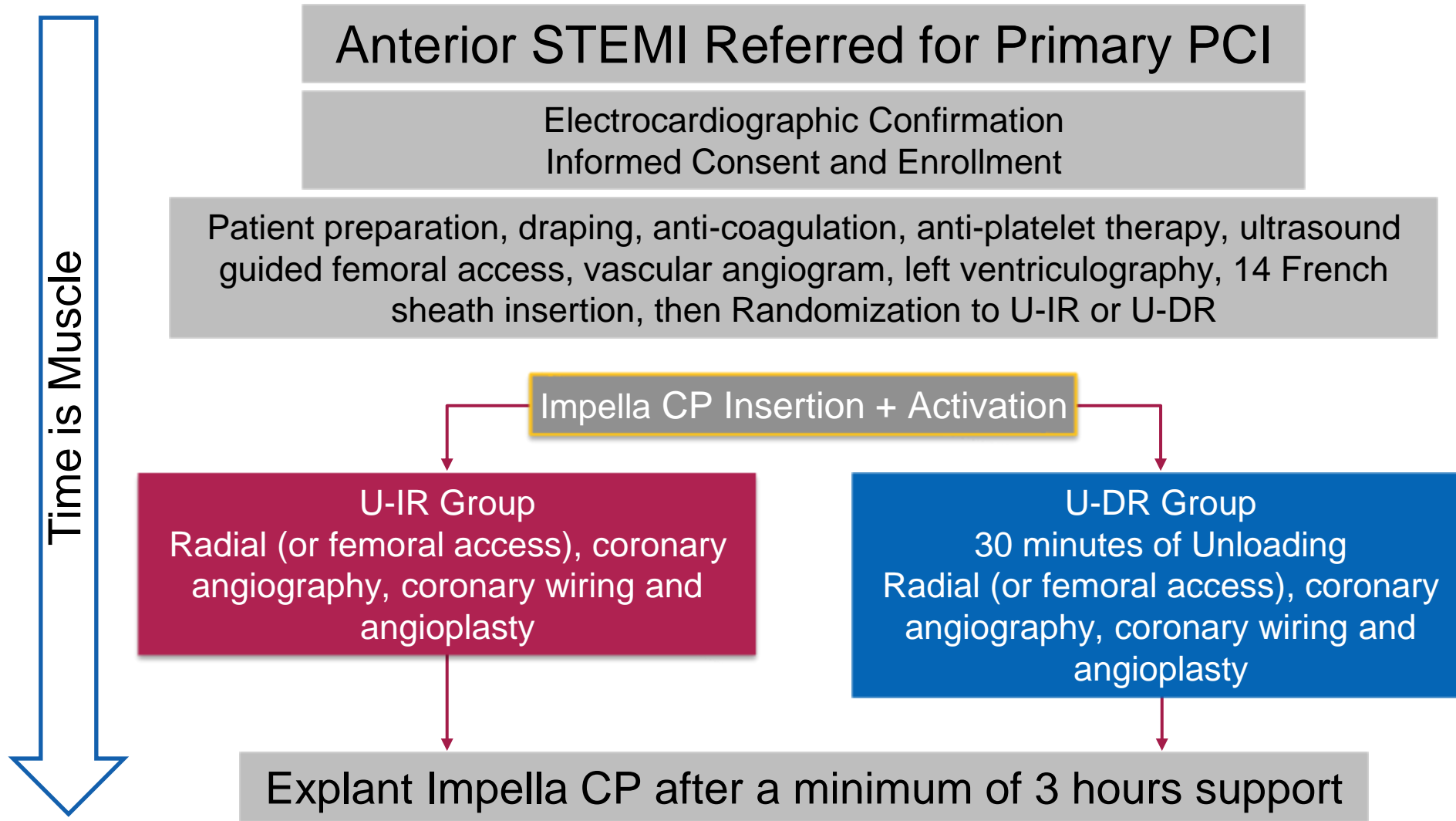
Experimental Design



Results: Infarct Size / Area-at-Risk (AAR)

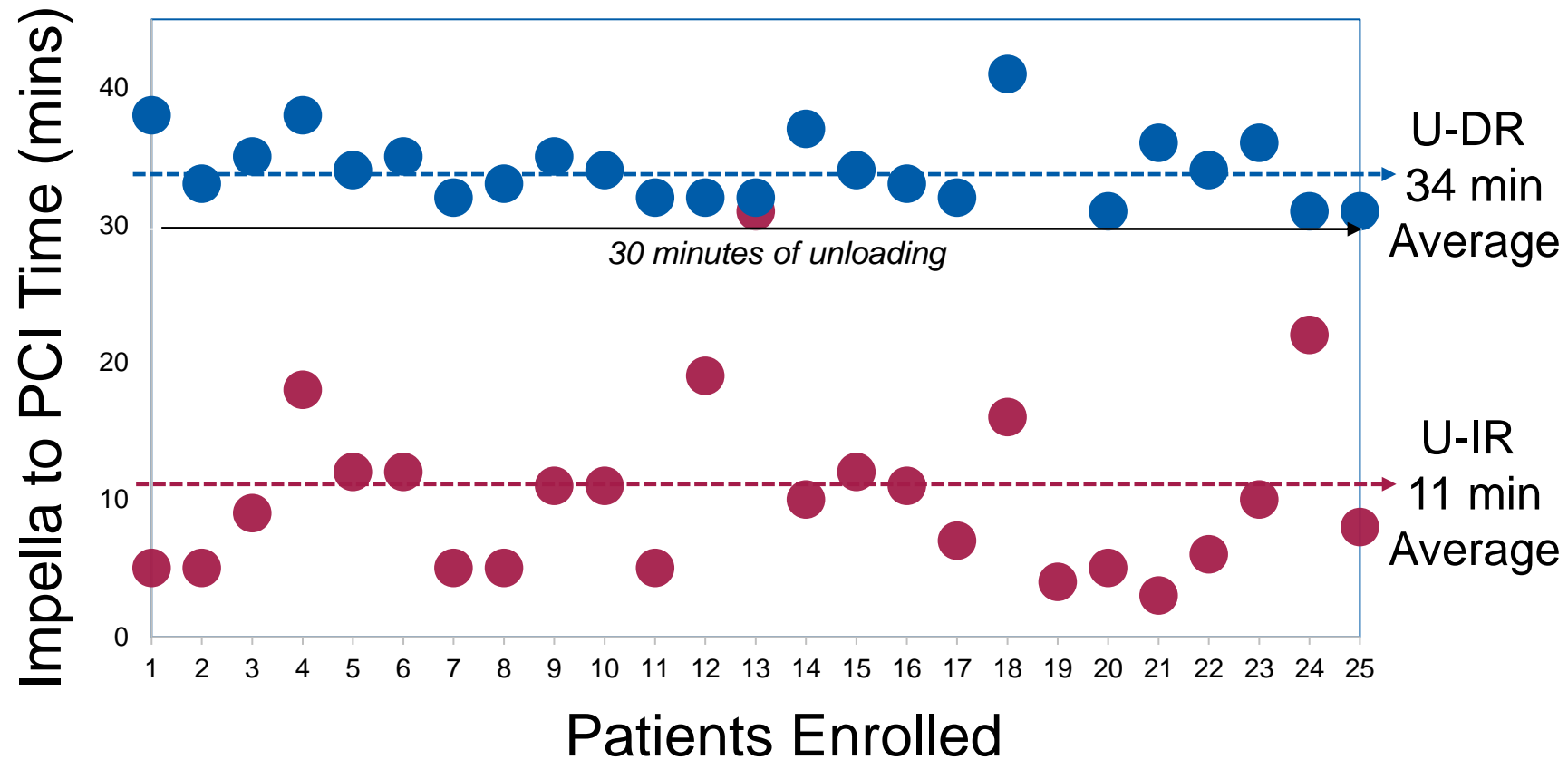


DOOR-TO-UNLOAD: STEMI PILOT TRIAL STUDY DESIGN



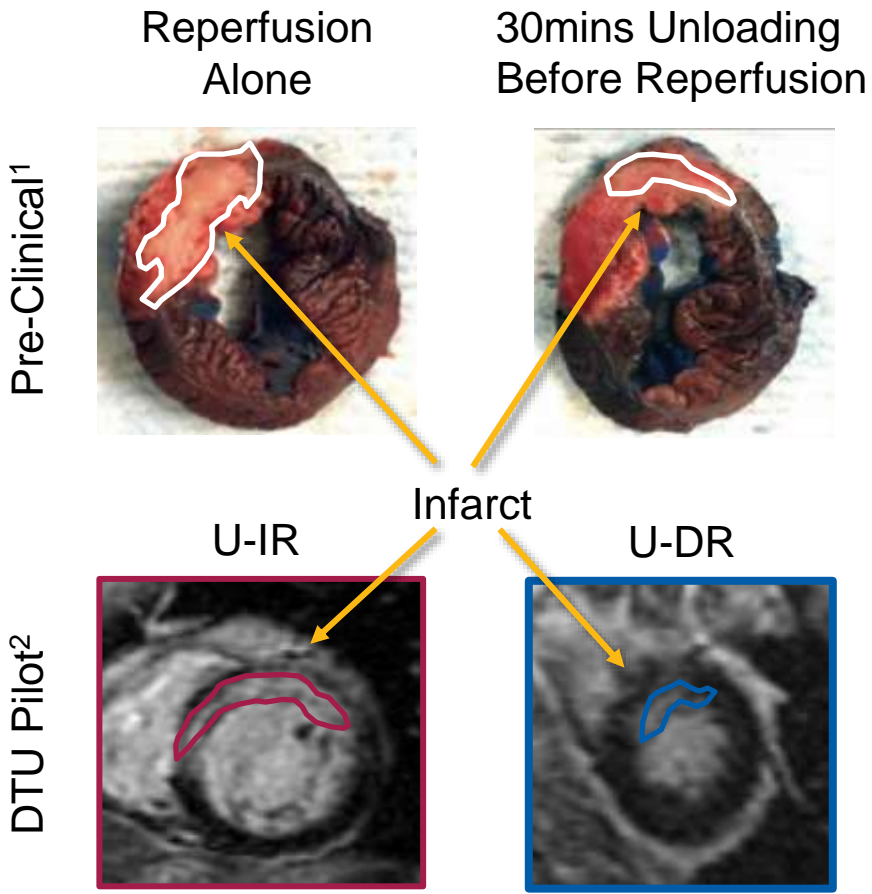
Independent Data Safety Monitor, Electrocardiographic, Angiographic and Cardiac Magnetic Resonance Imaging Core Labs

SUCCESSFUL ENROLLMENT & PROTOCOL COMPLETION ZERO BAIL-OUT PCI IN THE U-DR GROUP

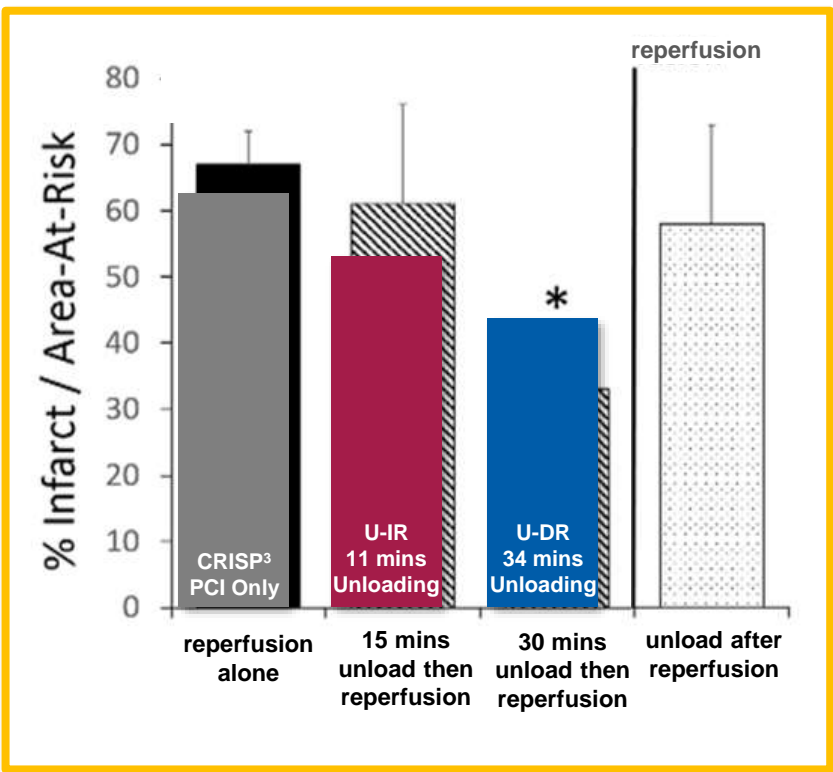


U-IR Unloading followed by Immediate Reperfusion
U-DR Unloading for 30 minutes with Delayed Reperfusion

SUCCESSFUL TRANSLATION FROM PRE-CLINICAL TO PATIENTS



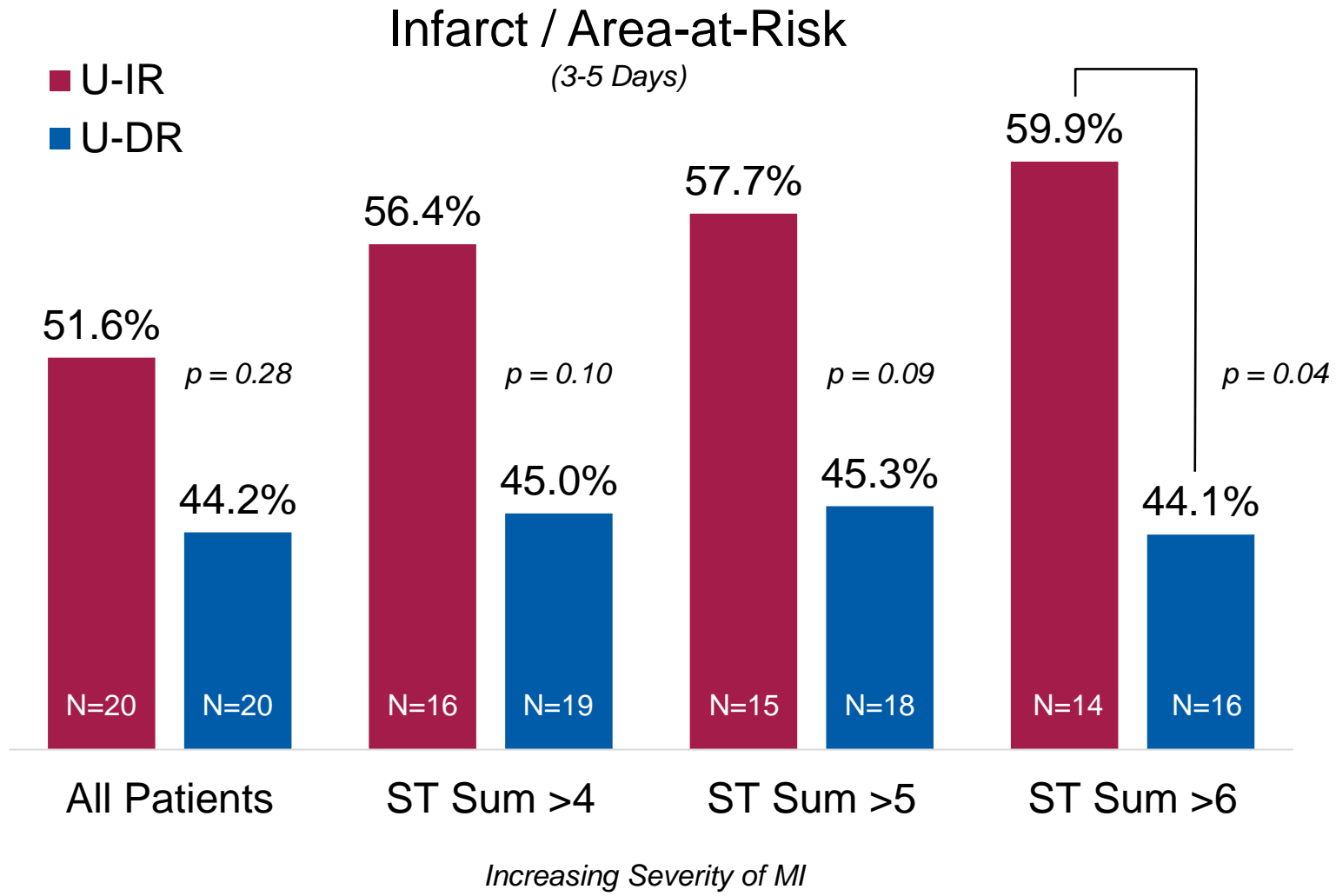
Infarct Size / Area at Risk (AAR)



U-IR Unloading followed by Immediate Reperfusion
U-DR Unloading for 30 minutes with Delayed Reperfusion

1. Esposito M, et al. *JACC*; 2018
2. Kapur N, et al. *Circulation Ahead of Print*; 2018, 10.1161
3. Patel M, et al. *JAMA*; 2011

30MINS UNLOADING DECOUPLES INFARCT SIZE FROM SEVERITY OF MI



SAFETY OUTCOMES

Clinical Variable	U-IR (n=25)	U-DR (n=25)	p-value
CV Mortality, n (%)	1 (4%)	1 (4%)	NS
Reinfarction, n (%)	0	0	NS
Stroke or TIA, n (%)	1 (4%)	0	NS
Traditional 30-Day MACCE, n (%)	2 (8%)	1 (4%)	NS
Major Vascular Events, n (%)	0	2 (8%)	NS
Bleeding (BARC \geq 2)	3 (12%)	4 (16%)	NS
Bleeding Requiring Transfusion	2 (8%)	1 (4%)	NS
Aortic Valve Injury	0	0	NS
Acute Renal Dysfunction	1 (4%)	1 (4%)	NS
Hemolysis	1 (4%)	0	NS

U-IR Unloading followed by Immediate Reperfusion

U-DR Unloading for 30 minutes with Delayed Reperfusion

Clinical Variable	U-IR (n=25)	U-DR (n=25)	p-value
CV Mortality, n (%)	1 (4%)	1 (4%)	NS
Reinfarction, n (%)	0	0	NS
Stroke or TIA, n (%)	1 (4%)	0	NS
Traditional 30-Day MACCE, n (%)	2 (8%)	1 (4%)	NS
Major Vascular Events, n (%)	0	2 (8%)	NS
Total 30-Day Composite MACCE, n (%)	2 (8%)	3 (12%)	NS

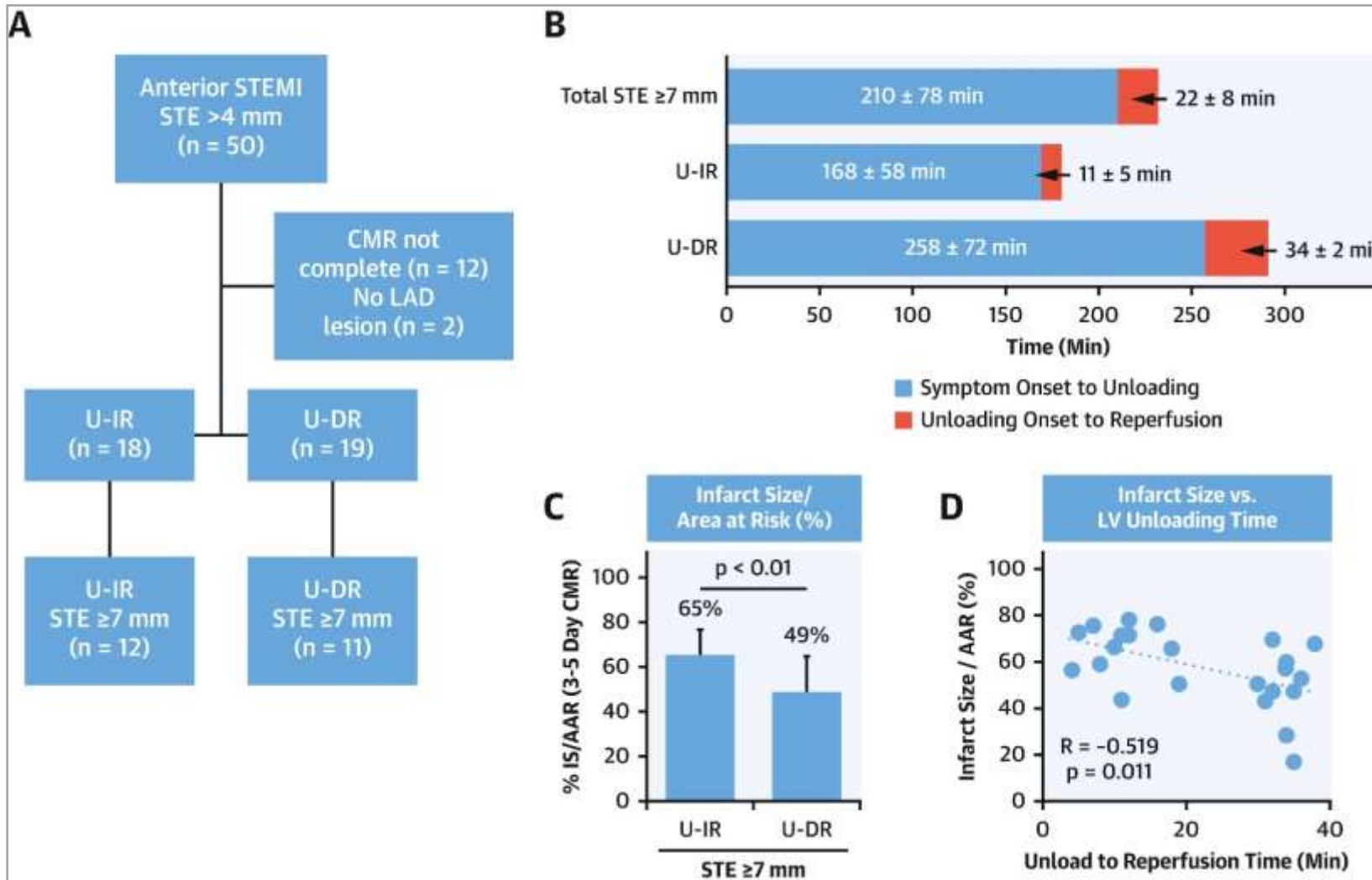
CV Mortality → POOR PATIENT SELECTION

- One mortality on POD 24 due to chronic lung disease
- One mortality due to shock on admission

Major Vascular Events → PREVENTABLE VASCULAR INJURY

- Two iliofemoral dissection at the time of device removal

LARGE ANTERIOR MI'S BENEFIT FROM UNLOADING IRRESPECTIVE OF DTB TIME



DTU PILOT PER-PROTOCOL ANALYSIS

