HERZZENTRUM LEIPZIG

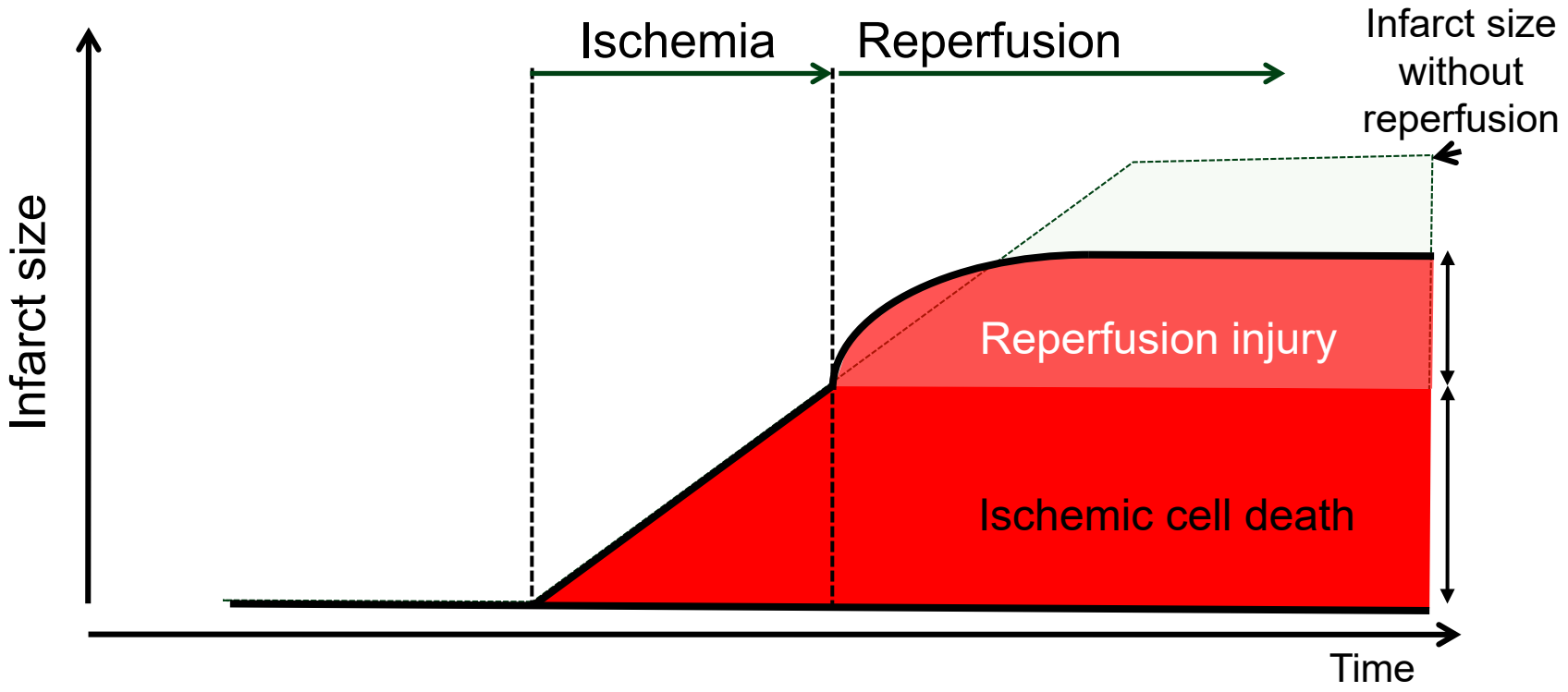
Leipzig Heart Institute LHI

UNIVERSITÄT LEIPZIG

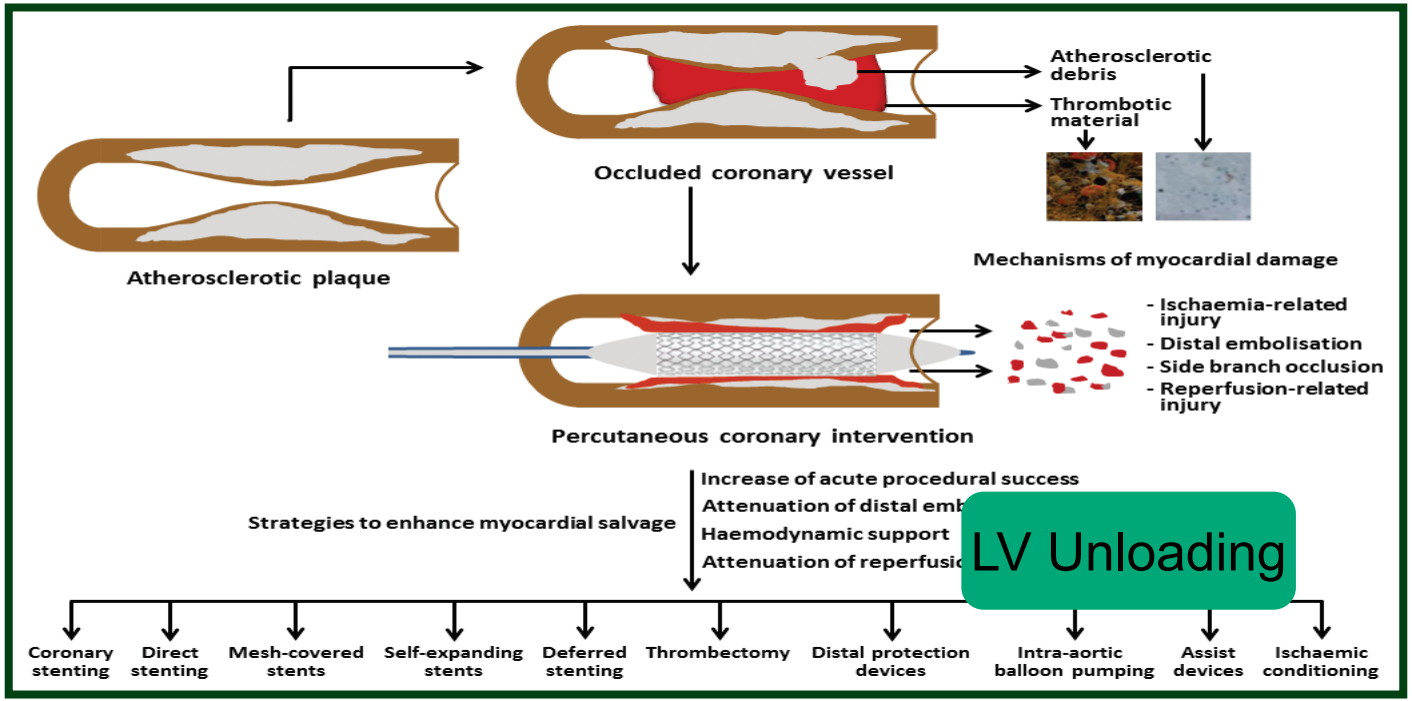
Discussion
Door-to-Unload (DTU) STEMI IMPELLA

Holger Thiele

Effects of Reperfusion



Mechanical Strategies – Reperfusion Injury



Ndrepepa et al. EuroIntervention 2016;12:319-328

CRISP am counterpulsation reduces infarct size pre pci in acute myocardial infarction

Previous Unloading Trial

Anterior MI without Shock

Randomized
Open Label
(n = 337)

Inclusion criteria
- Anterior STEMI
  2 mm in 2 contiguous leads or
  > 4 mm in anterior leads
- Planned primary PCI < 6 h

IABP pre PCI

Min. 12 h IABP post PCI

Standard-PCI

Routine Post PCI Treatment

Cardiac MRI Day 3-5 post PCI

Primary Endpoint: Infarct size by CMR

1. All Patients with CMR data
2. Patients with prox. LAD-occlusion TIMI 0/1 flow

Patel et al. JAMA 2011;306:1329-1337

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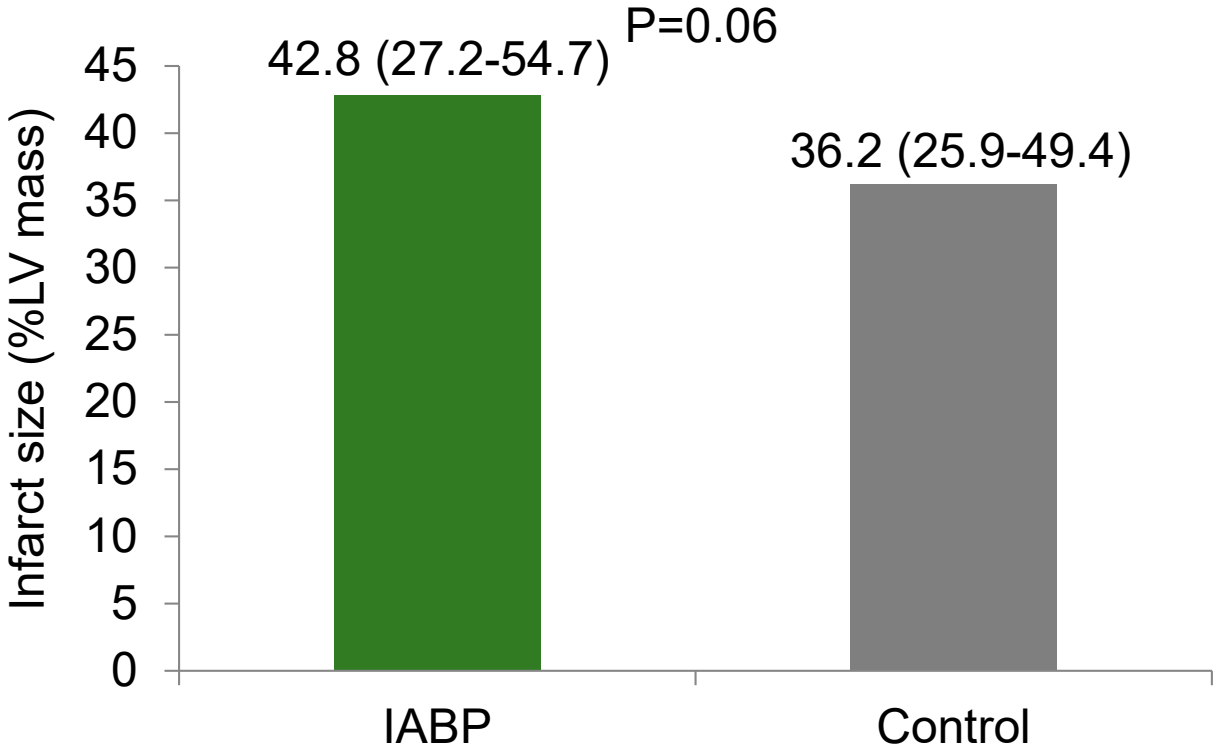
Previous Unloading Trial



Patel et al. JAMA 2011;306:1329-1337

DTU-STEMI – Trial Design Issues

Anterior STEMI referred for primary PCI

- Unload Immediate Reperfusion
- 
- Unload Delayed Reperfusion
- Standard PCI Radial access ?

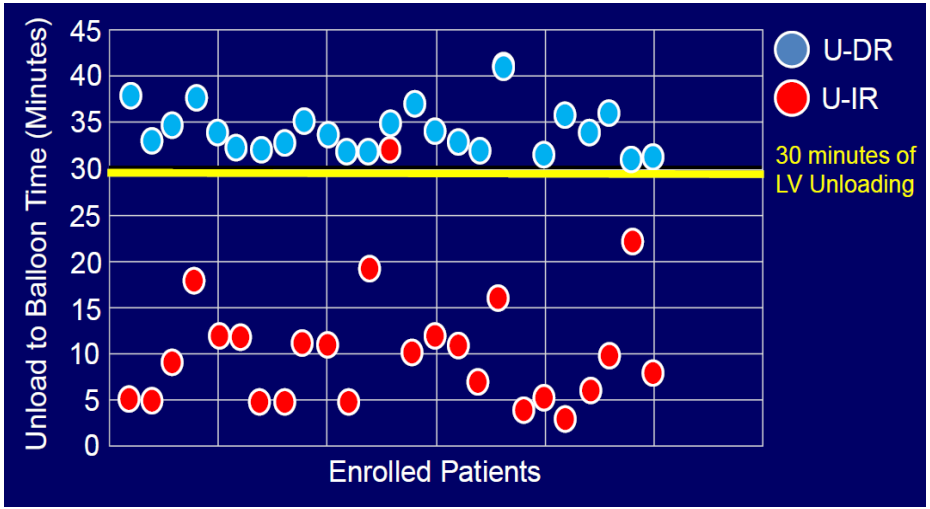
Primary efficacy endpoint: Infarct size at 30 days by CMR
Power analysis: Power = 88%, alpha = 0.05 to detect **absolute** difference in infarct size of 10% ±10% → 2 x 25 patients
No adjustment for losses in follow-up and missing CMR
Actually: 20% without CMR!

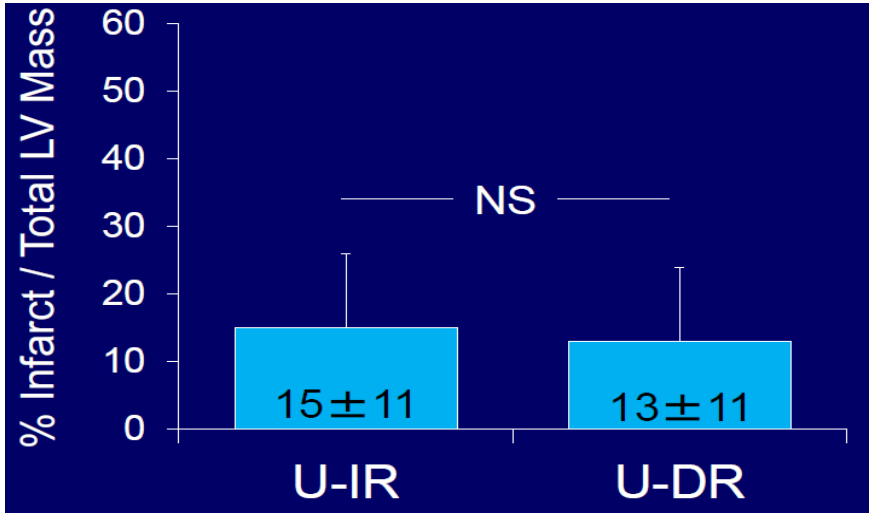
CRISP-AMI: Infarct size at day 3-5
Power analysis: Power = 81%, alpha = 0.025 to detect **relative** difference in infarct size of 25% → 2 x 150 patients

Adjustment for 10% missing data

Primary safety endpoint: MACCE at 30 days

Infarct Size – Primary Efficacy Endpoint





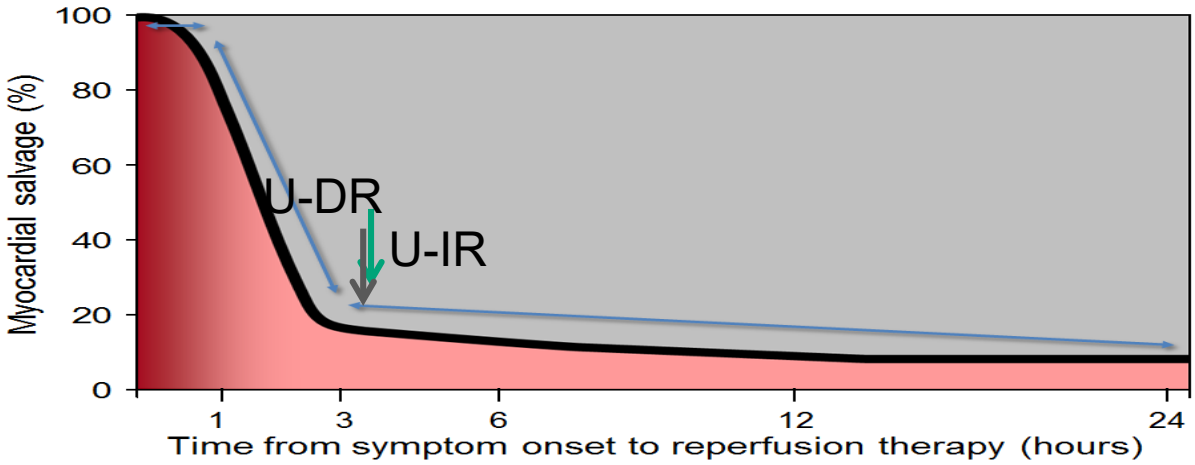
Conclusion:

Compared to U-IR, unloading first then delaying reperfusion for 30 min did not increase infarct size

True?

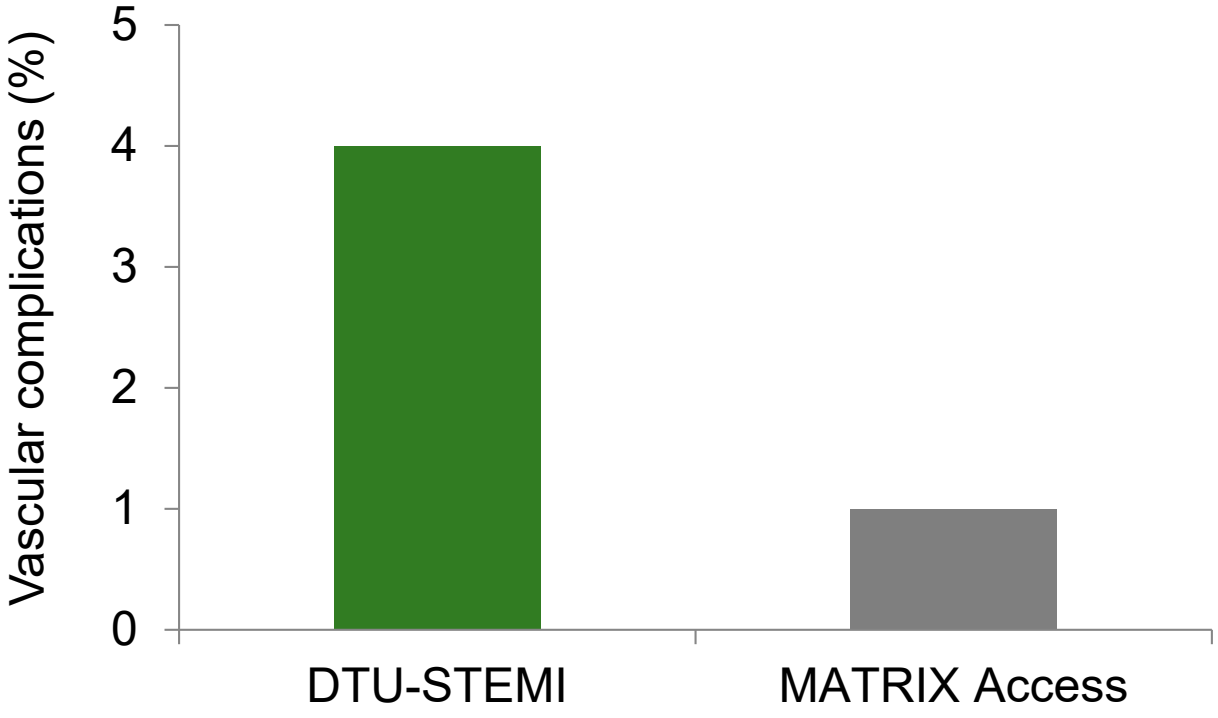
Infarct Size – Primary Efficacy Endpoint

U-IR	Symptom to unload time: 200 min	Unload to PCI: 11 min	**Total ischemic time: 211 min**
U-DR	Symptom to unload time: 176 min	Unload to PCI: 34 min	**Total ischemic time: 210 min**



Adapted from Gersh et al. JAMA 2005;293:979-986

Primary Safety Endpoint – Vascular Events



Valgimigli et al. Lancet 2015;385:2465–2476

Summary and Conclusions

- This small DTU-STEMI trial showed that unloading with Impella in anterior STEMI is feasible.
- Unloading leads to a delay in reperfusion by approximately 15 min.
- Based on the same total ischemic time there is no difference in infarct size between the U-IR and U-DR group.
- There is a lack of standard-of-care control group.
  Thus, the primary efficacy endpoint infarct size cannot reliably compared.
- Based on the small sample-size no reliable information is available for safety. Standard of care would also be the radial approach.

Thank you!