

# Pressure-controlled Intermittent Coronary Sinus Occlusion

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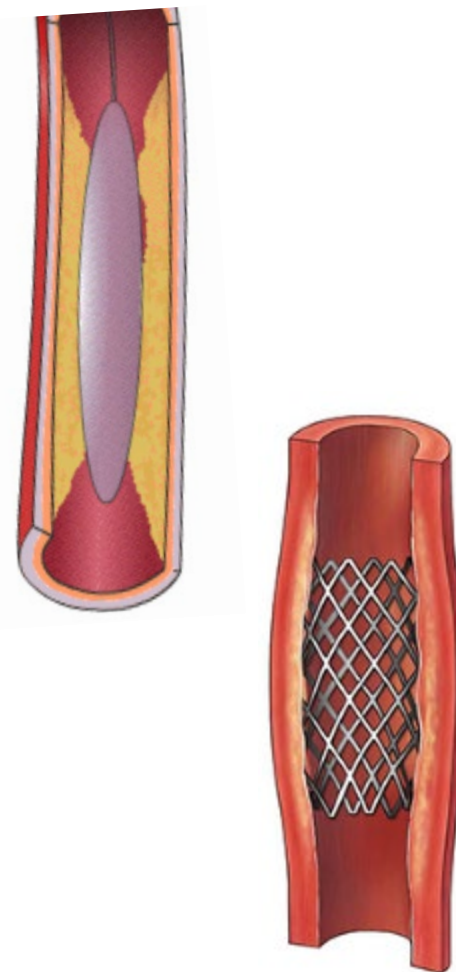
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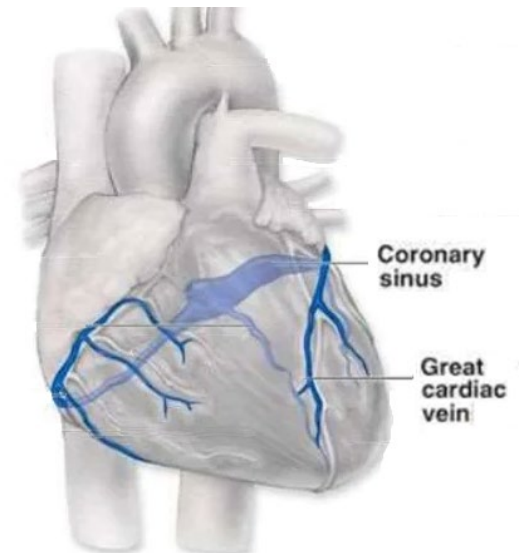
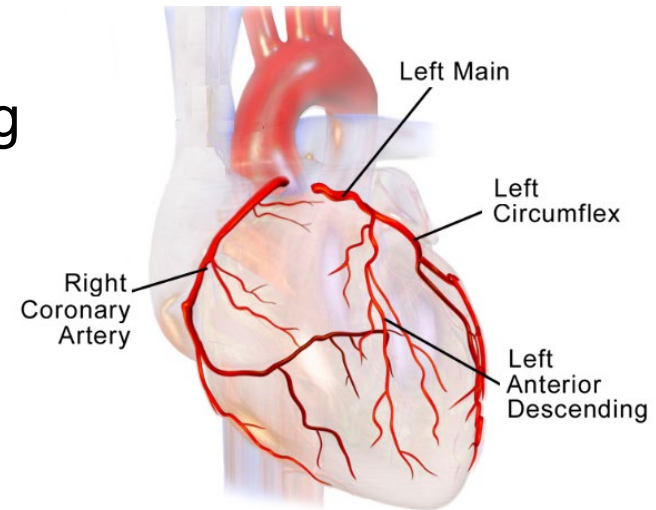
# PCI and its Limits

- Percutaneous coronary interventions have greatly advanced treatment of acute myocardial infarction.
- Despite best practices in PCI, favorable clinical outcomes post-AMI have plateaued in the last 10 years.
  - 30 day post-AMI mortality following PCI persists at 3-4%
  - De novo heart failure is diagnosed in 13% of patients 30 days post-AMI, increasing to 20-30% at one year



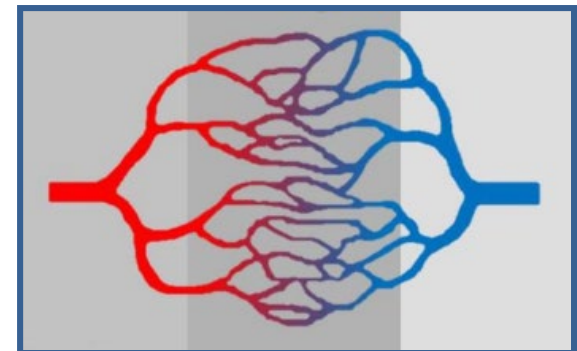
# Myocardial Circulation

- The heart's myocardial cells, like all living muscle, require circulation of blood.
- The large coronary arteries supply oxygenated blood to the heart muscle.
  - Left main
  - Left circumflex
  - LAD
  - RCA
- The large coronary veins remove deoxygenated blood.
  - Coronary sinus
- These large coronary vessels are visible on the epicardial surface of the heart.



# Microvasculature of the Heart

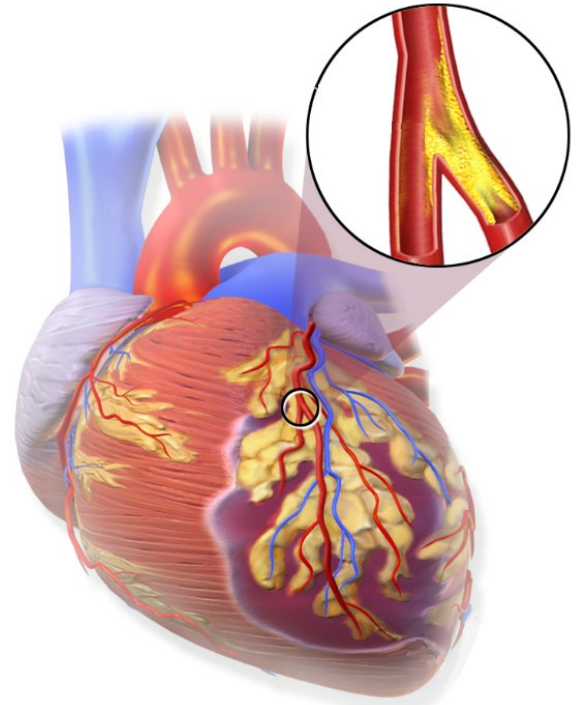
- Myocardial cells deep within the heart also require circulation of blood.
- The microvasculature involves a complex network of smaller and smaller branches.
- Ultimately, coronary arterioles and venules interface at the capillary beds.



# Microvasculature

## Role in AMI

- Obstruction of a coronary artery on the heart's surface is the most common cause of AMI, but not the sole factor contributing to adverse outcomes.
- Reduced perfusion from obstruction of the microvasculature contributes to the size of the infarction.
- Opening the coronary artery on the heart's surface with PCI is often not enough.

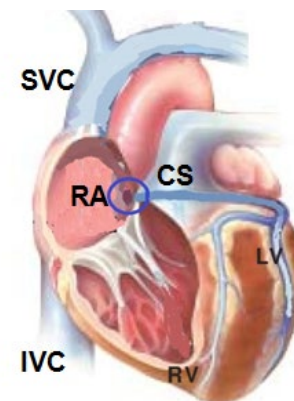


*\* Reduced perfusion from obstruction within the heart's microvasculature is associated with poor outcomes in the treatment of AMI \**

# PiCSO Procedure

- Pressure-controlled intermittent coronary sinus occlusion is performed in conjunction with coronary artery stenting in AMI.

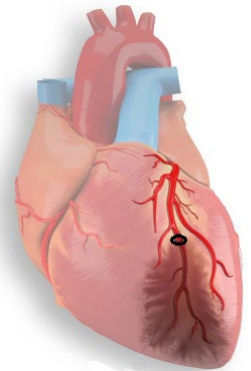
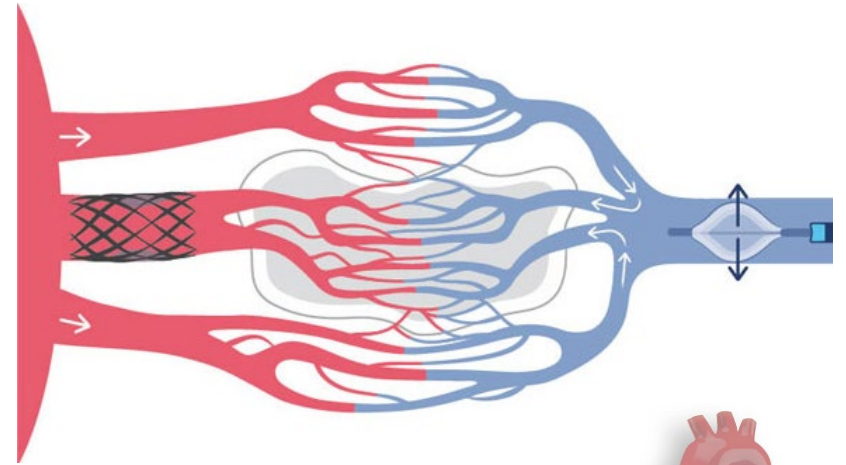
- ① Flow Restoration: The culprit coronary artery is re-opened, eg, by angioplasty.
- ② Coronary Sinus Cannulation: After femoral vein access, the PiCSO catheter is advanced to the right atrium with its balloon in the coronary sinus, and inflation/deflation cycles are initiated.
- ③ Stent Placement: The stent is placed through the area of obstruction in the coronary artery.
- ④ PiCSO Completion: PiCSO inflation/deflation continues during stenting and for a time after.



balloon in coronary sinus

# Balloon Inflation

- Balloon inflation blocks drainage of blood out of the coronary sinus.
- The increased pressure forces blood to be pushed back to reperfuse the infarct zone.
- Reperfusion can save the tissue beyond the central infarct core, reducing the size of the infarct.

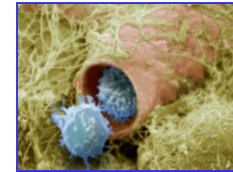
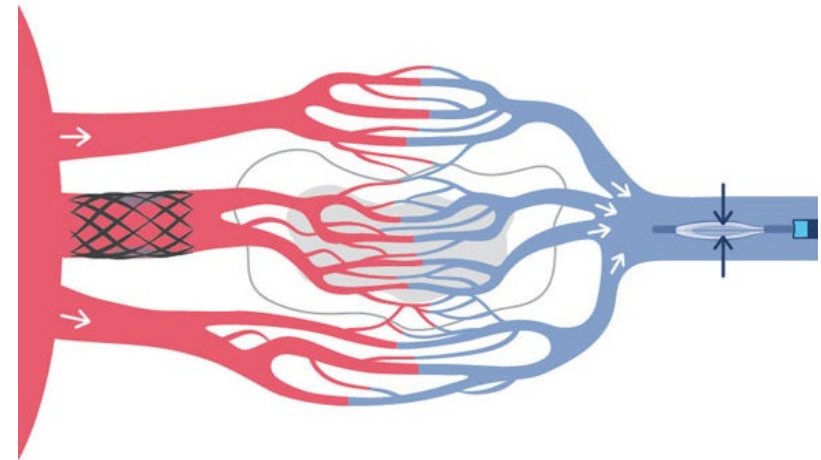


*\* Size of infarct is strongly linked to both mortality and hospitalization for heart failure \**



# Balloon Deflation

- After an AMI, the blood contains noxious byproducts of cell death.
- Stent placement may release microdebris which can obstruct the microvasculature.
- The sudden drop in pressure during balloon deflation creates a suction effect:
  - washes out noxious agents
  - clears microdebris



*\* Improved viability of the microcirculation is strongly linked to improved outcomes post-AMI \**



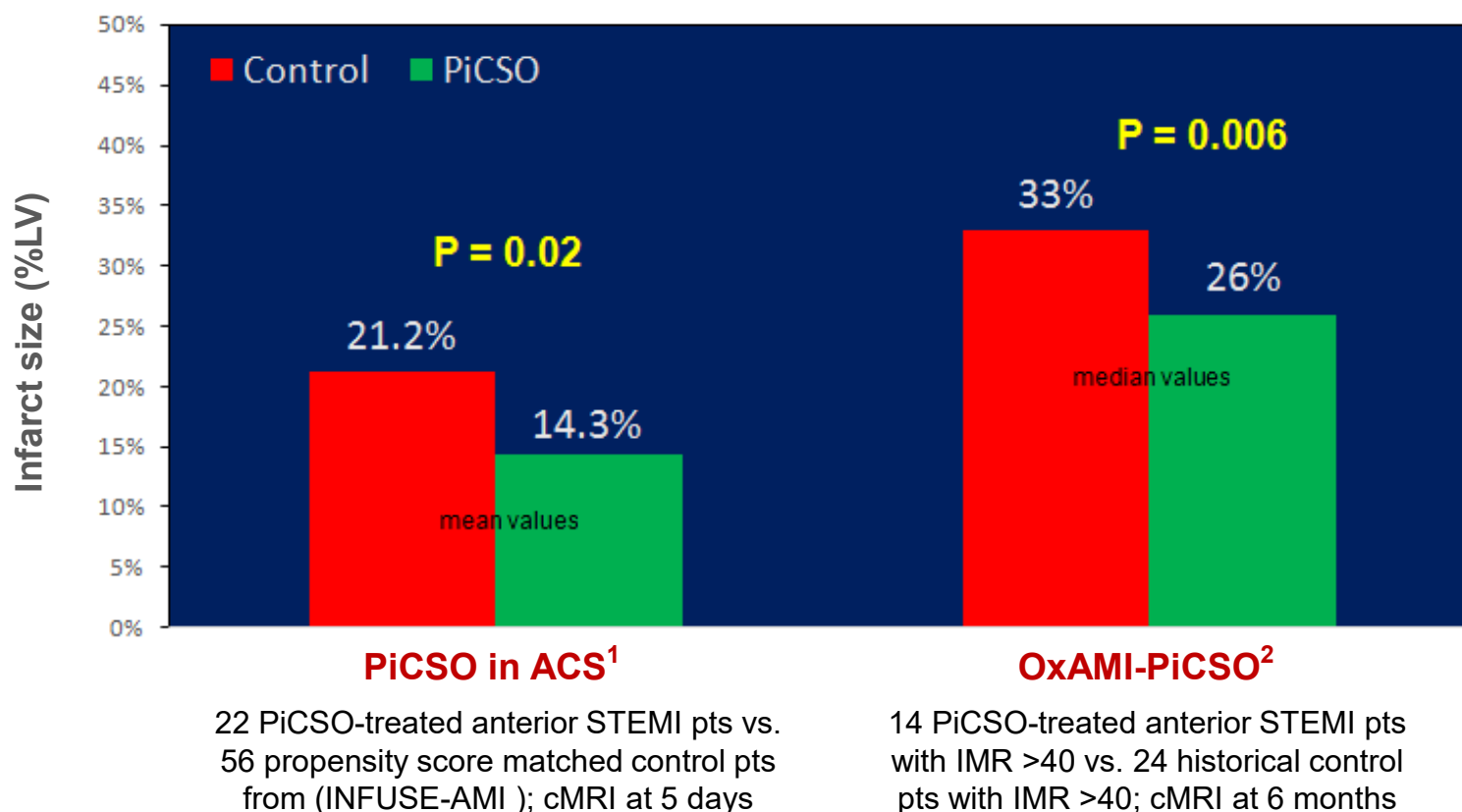
# Patient Population

- ✓ ST-segment elevation myocardial infarction (STEMI)
  - ✓ Anterior wall MI involving the left anterior descending coronary artery
  - ✓ Presentation within 12 hours
  - ✓ Absence of cardiogenic shock
- 
- This comprises an estimated 25-30% of STEMI patients and about 10% of all AMI patients.



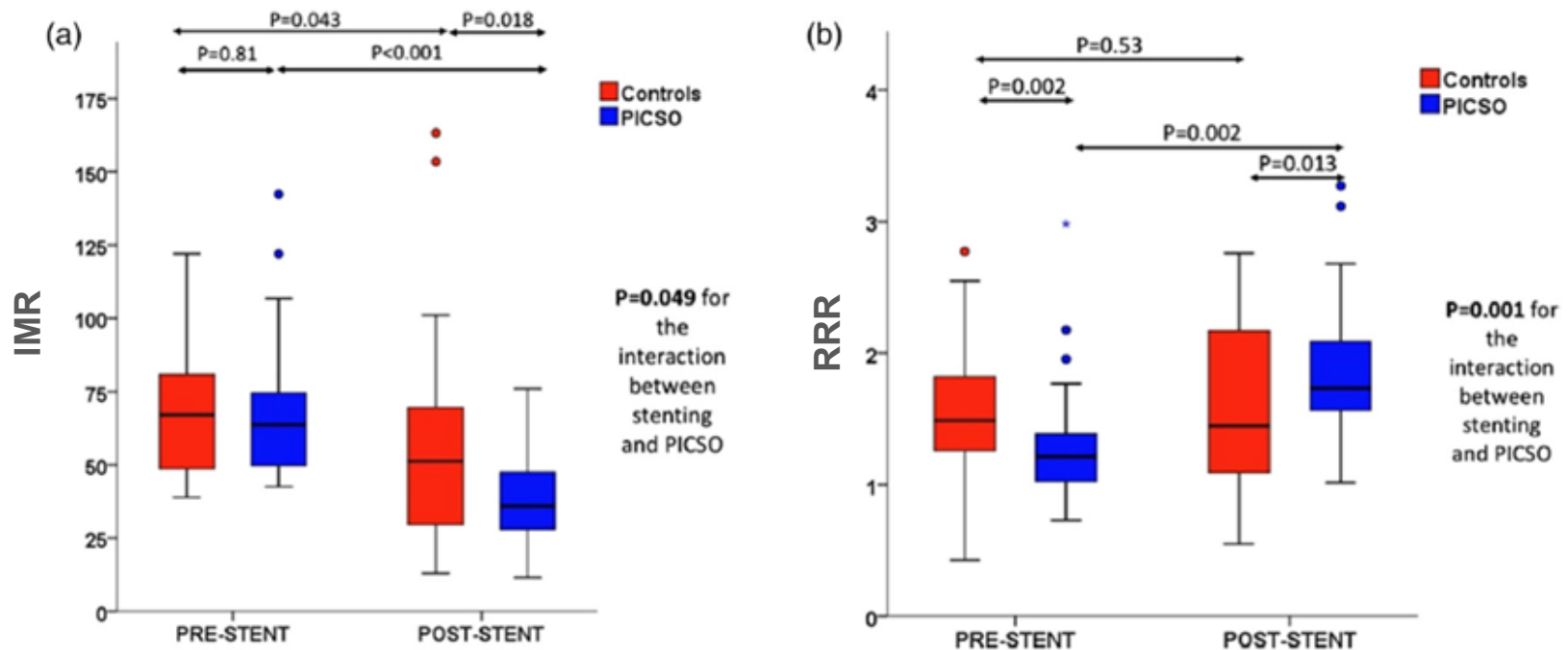
# Preliminary Data: Reducing Infarct Size

- At 6 months, PiCSO patients maintained a 7% reduction in absolute infarct size (26% vs 33%).



# Preliminary Data: Improving Microcirculation

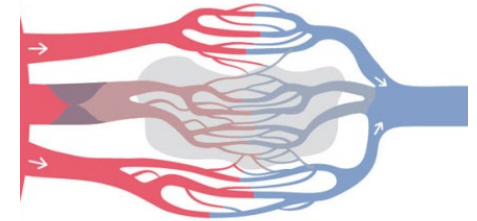
- Microvascular perfusion (IMR) and vasodilation (RRR) improved significantly in PiCSO-treated patients vs control STEMI patients.
- PiCSO was associated with a lower rate of microvascular obstruction (66.6% vs 86.1%).



**OxAMI-PiCSO Latest Data**

# Documentation

- The procedure takes place in a cath lab.
- Each stage is documented in the procedure report.
  - initial angioplasty of the coronary artery
  - positioning the balloon in the coronary sinus and starting cycles of balloon inflation and deflation
  - stent placement in the coronary artery
  - continued cycles of balloon inflation and deflation
- At completion, the interventionalist records the duration of coronary sinus balloon inflation and deflation cycling.
- The abbreviation “PiCSO” is commonly used.
- The catheter model name “PiCSO Impulse” may also be used.



# Questions?

