

# SAFE PCI: Possible Substudies

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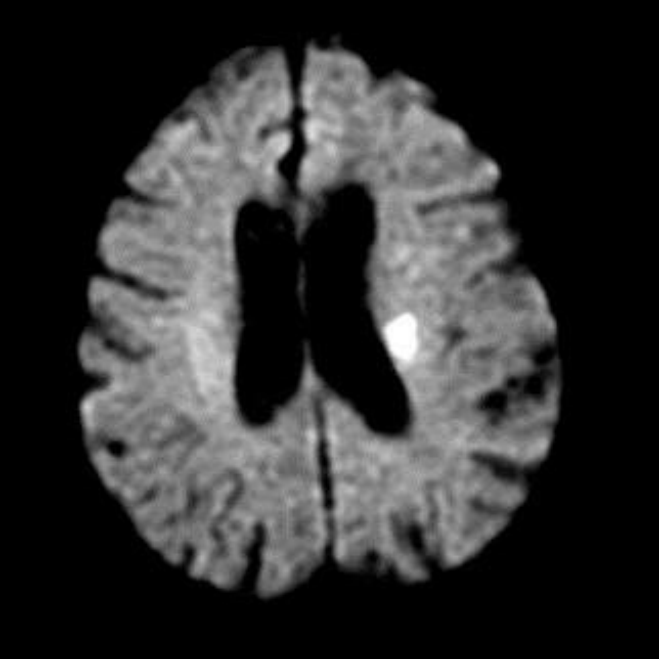
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- Many obvious substudies will be incorporated into the overall study design
  - Effect of BMI and age
  - Patient radiation exposure
  - Predictors of access/procedural failure
  - Pharmacologic/anticoagulant regimens
  - Clinical indication: ACS versus elective
  - Pain and discomfort assessment
  - Economic



# Embolization

- Stroke---big issue eg. TAVI, CAS, aortic valve stenosis---multiple studies with surrogate endpoints
  - Diffusion weighted MRI imaging of the brain pre and post TFI and TRI
    - (Hamon et al. SCIPION Trial---Silent Cerebral Infarction and PCI Evaluation n = 161 AS patients undergoing cardiac catheterization)
      - 12.6% TFI versus 18.6% TRI
  - Intraprocedural Transcranial Doppler
  - Neuro-psychological testing
- Renal infarction

# Radial Artery Injury/Patency

- OCT imaging of radial artery---intimal injury
- Vasoreactivity studies
- Radial artery occlusion post TRI
  - Predictors
  - Techniques
    - Sheaths, cocktails, hemostasis device
  - Clinical significance

# Post-Procedural Management

- Nursing management issues
- Femoral: closure device versus manual compression compared to TRI
- Same day discharge
- Patient satisfaction assessment
  - “I'm feeling very well and have resumed my normal activities. The recovery using the radial artery approach was far more rapid and comfortable than that from the femoral.”
    - Email from patient on 3/2/11 comparing TRI to TFI in 2002