

# TREAT Today and Tomorrow: Pilot program & Potential Nested Studies

Sunil V. Rao MD

*Assistant Professor of Medicine*

*Duke University Medical Center*

*Durham VA Medical Center*

*Duke Clinical Research Institute*



Duke Clinical Research Institute  
DUKE UNIVERSITY MEDICAL CENTER

# Rationale

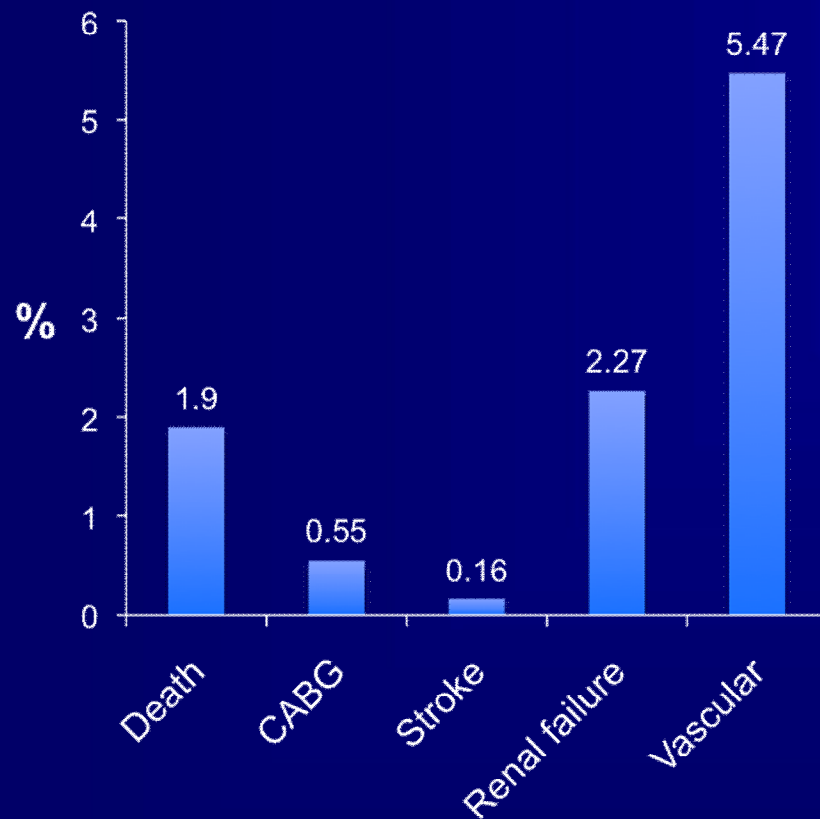
- ✓ **Bleeding is a common complication**
- ✓ **Bleeding is associated with short- and long-term morbidity and mortality**
- ✓ **Bleeding most commonly occurs at the vascular access site in pts undergoing PCI**
- ✓ **Bleeding limits the clinical use of certain antithrombotic therapies**



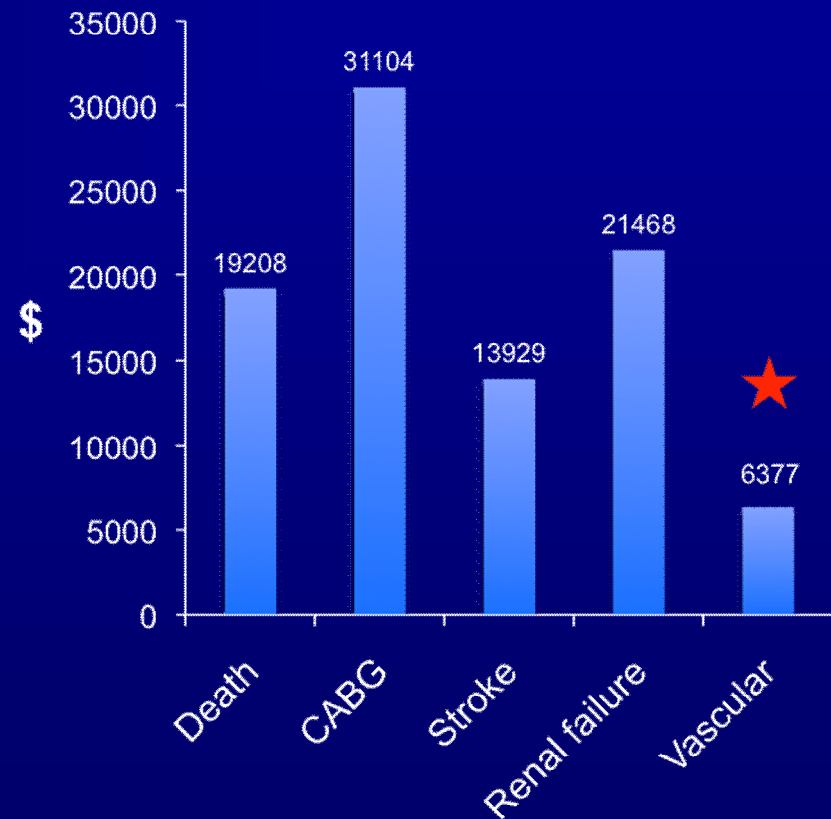
# PCI-related complications and costs

*N=335,477 Medicare pts undergoing PCI in 2002*

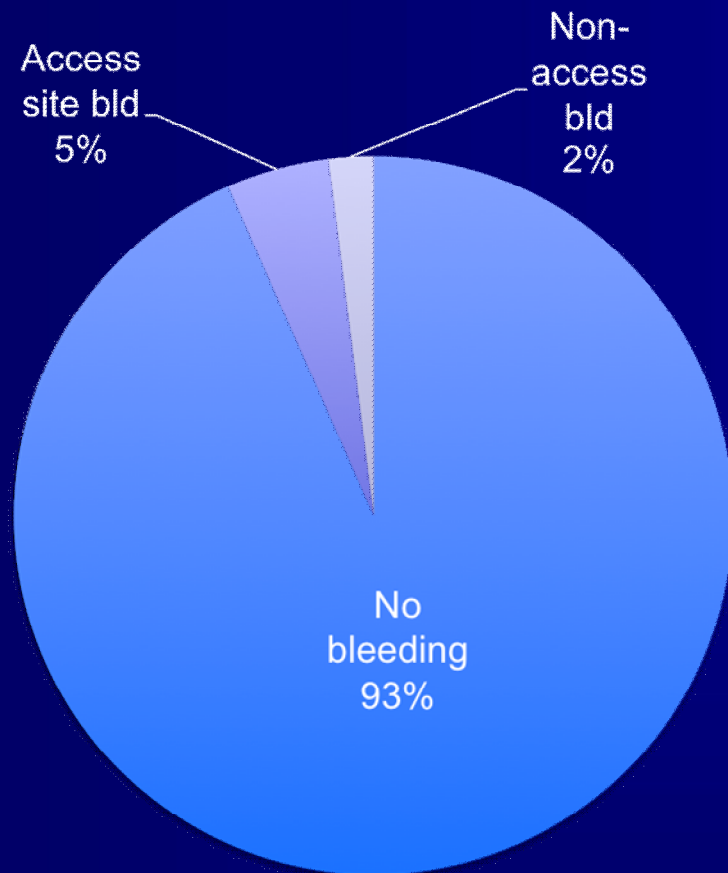
### Incidence of Complications



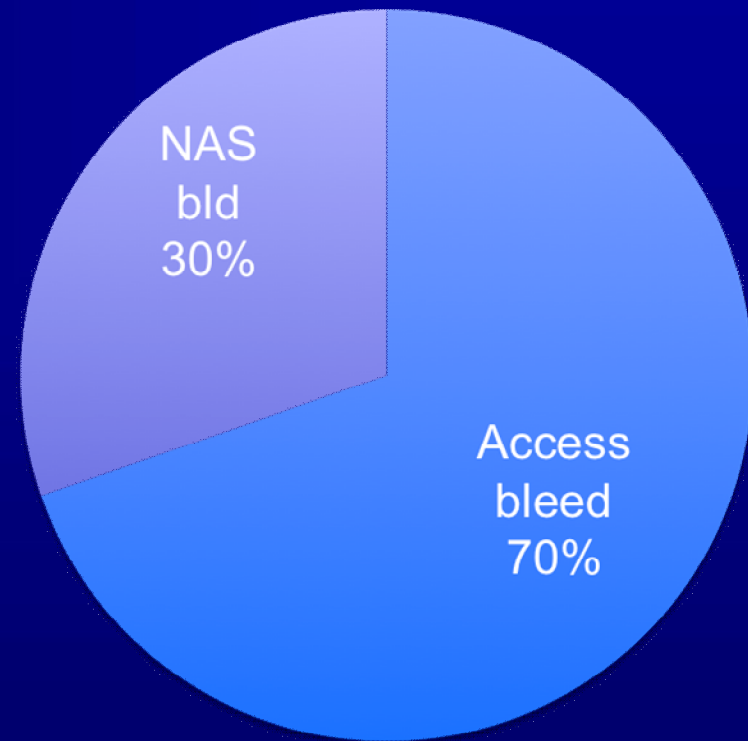
### Incremental Cost



# Bleeding in PCI Trials: Frequency and site\*



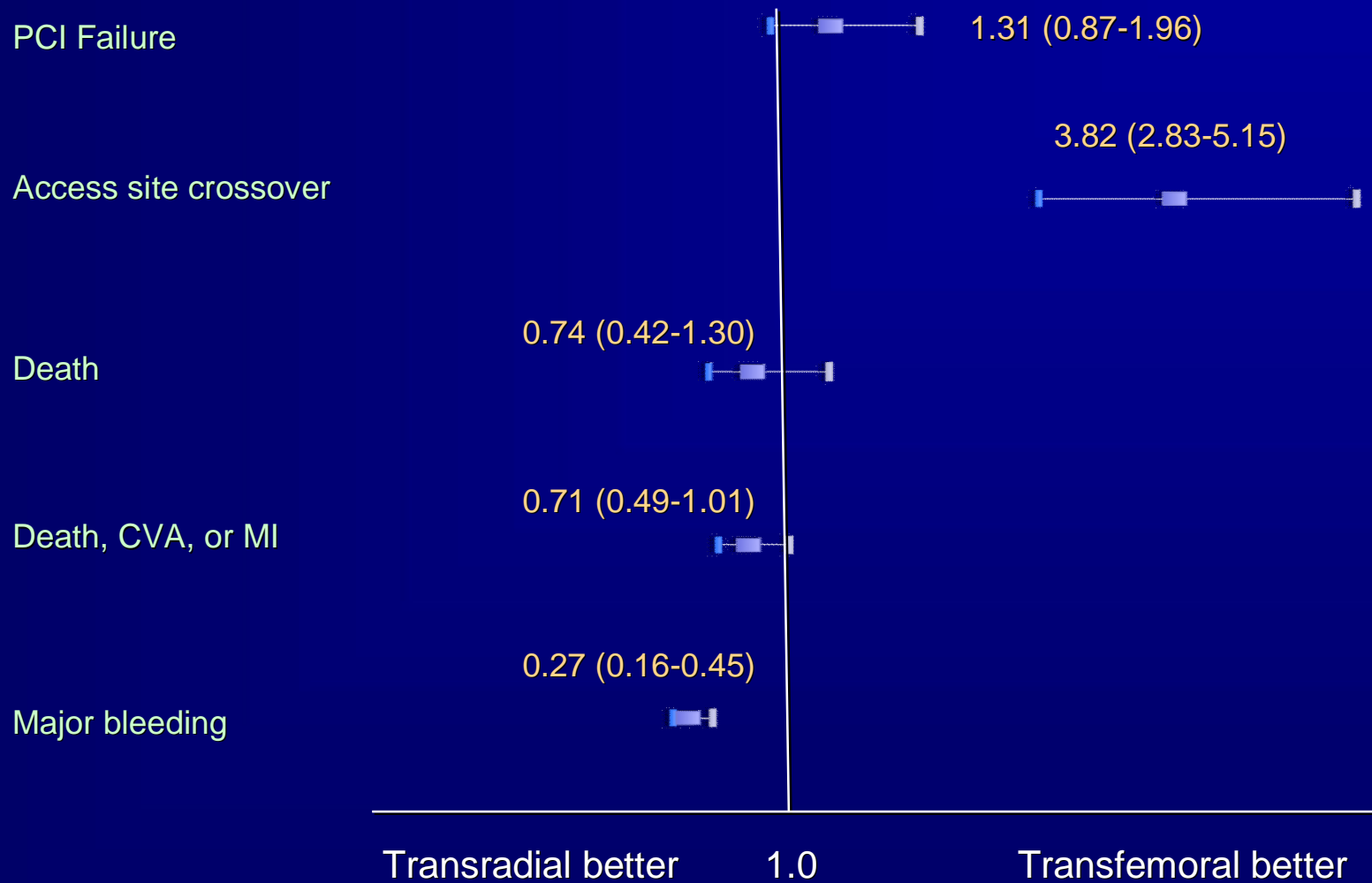
## Among bleeders



\*All transfemoral access

# Transradial access and outcomes

*N=21 studies, 5600 patients*



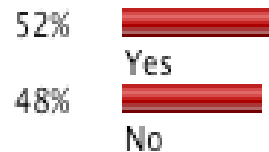
Poll

Should radial access become the default choice for PCI?

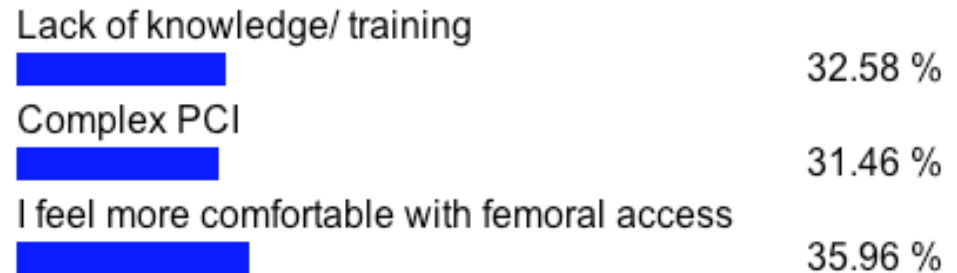
See: Radial-access PCI safe and successful in high-risk patients and complex lesions

Results

Respondents: 672



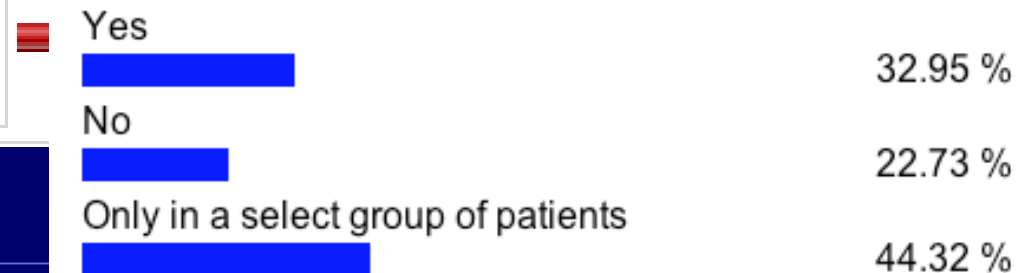
What is the main reason not to use the radial approach?



How frequently should radial access for PCI be used?



Is there any advantage to the radial approach over the femoral approach for PCI access?



## The design

- ✓ **The goal: Can transradial reduce bleeding with accepted/approved antithrombotics and INFORM THE LABEL?**
- ✓ **TransRadial Education And Therapy (TREAT) Program**
  - λ A series of programs that includes both prospective clinical investigations, educational programs, nested studies
  - λ Prospective registry
    - Uses NCDR CathPCI as a backbone*
    - Site identification*
    - Data collection with 1-2 unique pages*



# TREAT Pilot Program Design Assumptions

- ✓ **Broad sampling of clinical practice**
  - λ No exclusion criteria
  - λ Multiple anticoagulant/antiplatelet strategies
- ✓ **Concomitant femoral procedures**
- ✓ **Collect complications – “costs” of the radial approach**





## Potential for nested studies

- ✓ **Collect resource use**
- ✓ **Evaluate new devices whether designed specifically for radial approach or not**
  - λ Catheters, Guides
  - λ Hemostasis devices
  - λ Access kits
- ✓ **Incorporate new antithrombotic strategies as commercially available**
  - λ Ticagrelor, Vorapaxar
  - λ Xa inhibitors, oral DTIs



## TREAT - Challenges

- ✓ **Low penetration of transradial in the US**
  - ✓ “E” part of the TREAT
- ✓ **Sampling of various antithrombotic agents and class effect of radial?**
  - ✓ Does an effect in one agent translate to an effect in another in the same class?
- ✓ **Is it reasonable to expect that data from a registry is sufficient to inform drug labeling?**

