Informing Drug Labeling and Practice
Guidelines: Transradial PCI, Antithrombotic
Safety and Potency: What Do We Know, What Do We Need to Know?

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Impact of Transradial PCI on Anti-Thrombotic Safety

Key Issue – Balance of ischemic events versus bleeding events post PCI

- Post PCI ischemia (at some level) is associated with increased mortality
  - Large MI
  - MI after major PCI complication
  - Reinfarction in ACS

- Bleeding is bad and possibly worse than ischemia
Anti-thrombotic Rx and Reducing Post PCI Ischemia

• GP IIb/IIIa Trials (EPISTENT and ESPRIT)
  • Reduce PPMI - including large MI
  • Mortality reduction at 1 year

• ISAR-REACT II
  • Abciximab in ACS pts pretreated with clopidogrel
    600mg reduced ischemic events

K Anderson et al. JACC 2001;37:2059-65
A Kastrati et al. JAMA 2006;295:1531-38
Bleeding Kills

- Pooled analysis of OASIS and CURE showed association of major bleeding and mortality at 30 days and 6 months
- Pts with MI or major bleed w/in 30 days of PCI in 4 RCTs had comparably increased mortality at 1 year
- In ACUITY, relative impact of MI or bleeding on subsequent mortality similar
- In HORIZONS-AMI, bivalirudin vs heparin + GPIIb/IIIa reduced bleeding and associated with lower 1-year mortality

J Eikelboom et al. Circulation 2006;114;774-82
K Anderson et al. JACC 2001;37:2059-65
Vascular Access and Bleeding

• Access complications and procedure bleeding account for most non-CABG bleeding events within 30 days
  • In ACUITY, access complications (3% vs 1%) for heparin/IIb/IIIa vs bivalirudin

• GI bleeding in ACUITY occurred in 1.3% and was associated with increased 30-day and 1-year mortality (anti-thrombotic regimen not a predictor)

E Nikolsky JACC;2009:54:1293-302
Identifying Risk for Ischemia vs Bleeding

• Risk factors for MI or reinfarction include elevated biomarkers, + FH CAD, older age, ST deviation, and prior MI

• Risk factors for non CABG major bleeding include female sex, baseline anemia, older age, heparin + GP IIb/IIIa, elevated baseline creatinine, elevated WBC, no prior PCI, prior CVA, ST deviation, upstream IIb/IIIa

S Pocock et al. Circulation 2010;121;43-51
Key Questions

- Can we select anti-thrombotic strategy based on relative risk for ischemia vs bleeding?
- Will avoidance of access site related bleeding via transradial access change the risk benefit ratio and anti-thrombotic strategy recommendations? (Is this risk group specific?)
- Does transradial access have an impact on bleeding beyond access-related complications?
- Do we need new RCTs that incorporate transradial access to assess risk benefit for potent and new anti-thrombotic treatments?