Bleeding, Procedural Outcomes and Other Key Endpoints/Variables

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Epidemiologic Perspective

- Epidemiological study of major bleeding associated with transfemoral approach
- Differences in safety profile between transfemoral vs. transradial approach
Background

- Reports to FDA associated with hemostasis devices: 1996-2000
  - 1880 serious injuries
  - 36 deaths
- Female preponderance
Purpose

- Understand excess risk in women
- Identify risk factors – especially type of hemostasis device
American College of Cardiology National Cardiovascular Disease Registry (ACC-NCDR)

- Cath lab admissions from ACC-NCDR registry
- 13,878 subjects
- 59 institutions
- Fourth quarter 2003
Outcomes

- Hemorrhage (entry site, retroperitoneal, hematoma > 10 cm)
- Arterial occlusion
- Arterial dissection
- A-V fistula
- Pseudo aneurysm
- Surgical device removal
- Infection
Multiple Logistic Regression Analysis

- Type of hemostasis
- Sheath size
- Demographics (Age, race, gender)
- Diagnostic vs. interventional cath.
- BMI
- # caths performed by institution
- Elective vs. emergency status
- Comorbidities (NYHA class, diabetes, hypertension, PVD, shock, recent PCI, ARF, hx of CHF, LMCA stenosis)
Local Vascular Complications Following Cardiac Catheterization by Gender

Source: American College of Cardiology - National Cardiovascular Disease Registry Year 2003, 4th Quarter

- Entry site bleeding: Male 1.5%, Female 1.5%, p=.01
- Hematoma: Male 3.0%, Female 4.0%, p=.002
- Retroperitoneal bleed: Male 0.5%, Female 0.5%, NS
- Dissection: Male 0.3%, Female 0.3%, p=.09
- Pseudo-aneurysm: Male 0.2%, Female 0.2%, p=.03
- Any vascular complication: Male 3.0%, Female 4.0%, p=.0002
Relative Risk of Any Vascular Complications Following Cardiac Catheterization by Gender

Source: National Cardiovascular Disease Registry Year 2003, 4th Quarter
Other Risk Factors

- Positive association with vascular events
  - Sheath size
  - Renal failure
  - Emergency indication
  - Interventional cardiac catheterization (PCI)
Conclusion

- Most important finding: Excess risk for Vasoseal
- Vasoseal removed from market
  - FDA presentations at conferences
  - Vasoseal mfg. objects to our analysis
  - First article published January 2006
  - Market share for Vasoseal declines
  - Second article published on-line 9-18-06
  - 31 days later, manufacturer announces plans to cease marketing Vasoseal
Transfemoral vs. Transradial approach

- Meta-analysis – 13 clinical trials
- Superior safety profile for transradial
  - Major bleeding: OR = 0.27, p < .001
  - Trend towards reduced MI, stroke, death
Transradial approach widely recommended as procedure of choice

Yet < 3% cardiac catheterizations performed with transradial approach

Transradial approach more difficult

Clinical trials use highly experienced and skilled practitioners compared to real world settings

Not known if superior safety profile can be carried over to real world settings