

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

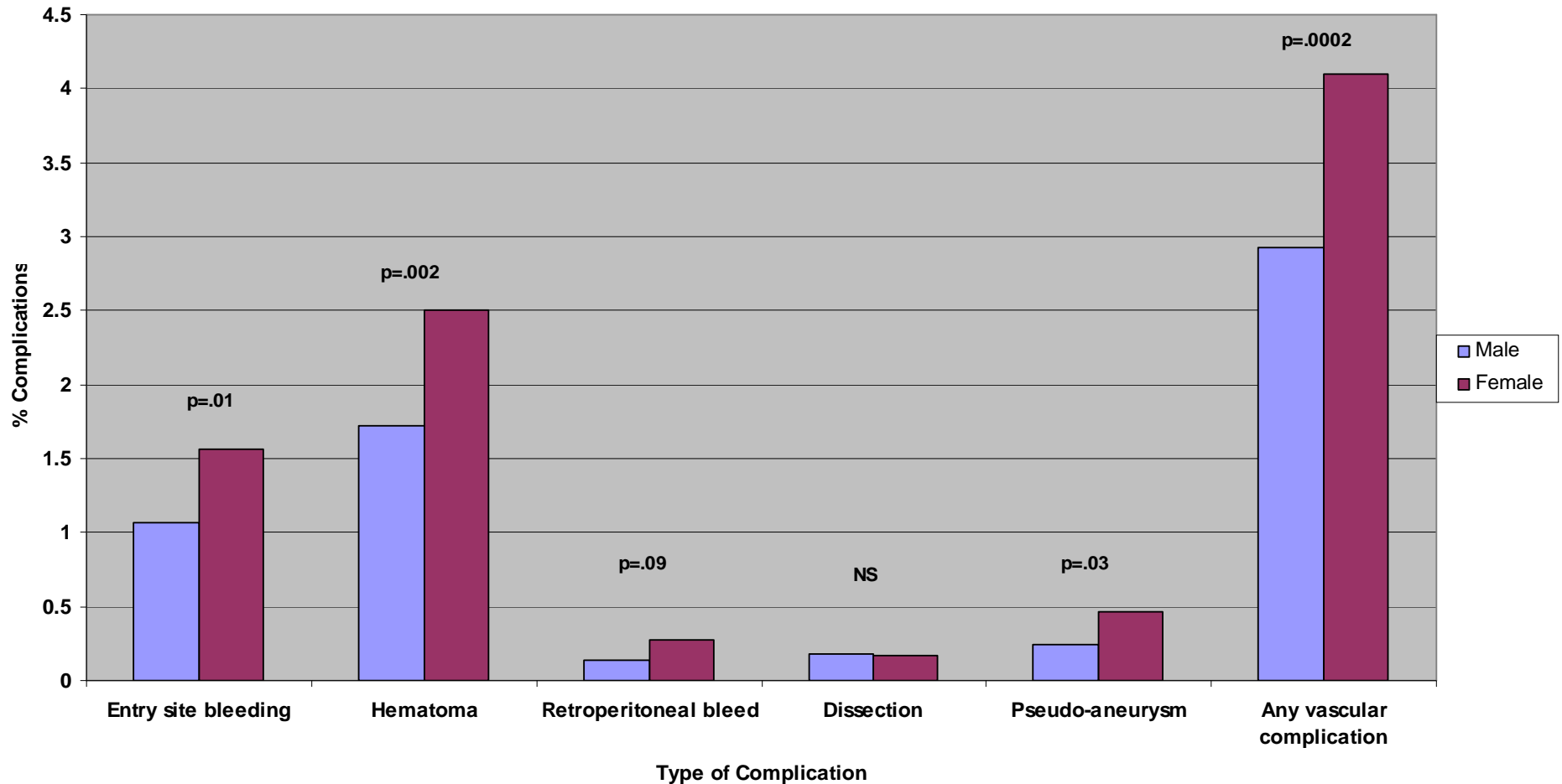
- Hemorrhage (entry site, retroperitoneal, hematoma > 10 cm)
- Arterial occlusion
- Arterial dissection
- A-V fistula
- Pseudo aneurysm
- Surgical device removal
- Infection

Multiple Logistic Regression Analysis

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

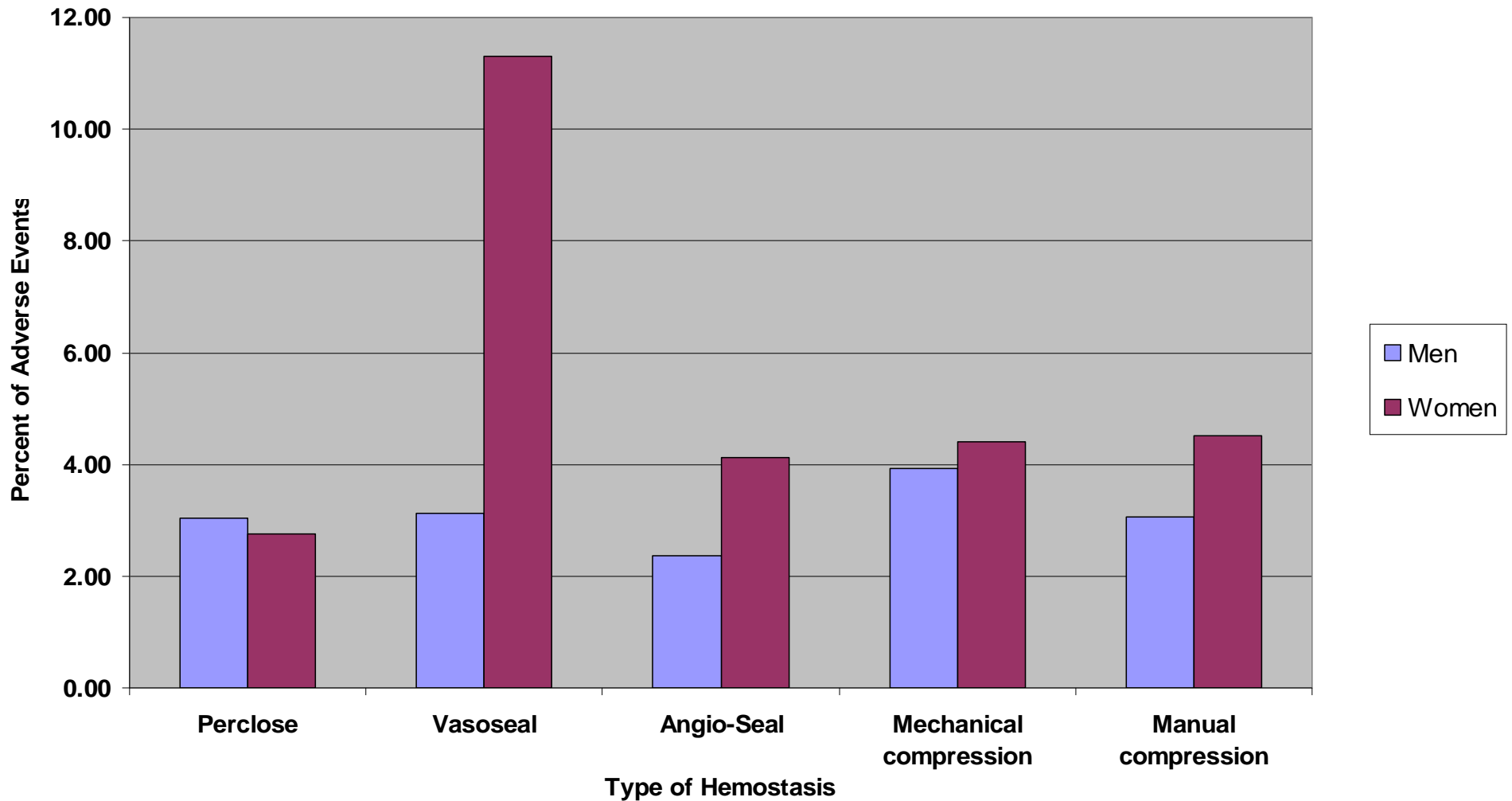
Local Vascular Complications Following Cardiac Catheterization by Gender

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



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)



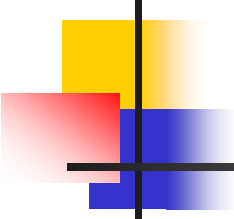
Conclusion

- 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



Difference Between Clinical Trials vs. Epidemiology

- 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