

# Meeting of the Circulatory System Devices Advisory Panel

October 11, 2007

## Representing SCAI & ACC

- Financial conflicts: None
- Travel expenses reimbursed by SCAI/ACC.

Christopher J. White, MD, FSCAI, FACC, FAHA, FESC  
Chairman, Department of Cardiovascular Diseases  
Ochsner Clinic Foundation  
New Orleans, LA

# BIAS

Representing SCAI and ACC

- Interventional cardiologist.
- Practicing carotid stenting since 1994.
- National PI for BEACH (high risk registry).
- Participating in 2 RCT's (CREST and ACT-1).
- **Can alternative carotid trials get a fair hearing ?**
  - Panel make-up unbalanced: surgeon vs cardiologist.
  - Absent cardiologist carotid stenting advocate.

# Randomized Controlled Trials

- RCT's are an excellent, but NOT EXCLUSIVE source of comparative clinical trial information.
- There are MANY precedents for FDA device approval with alternative, non-randomized, trial designs.
- Are average risk carotid patients SPECIAL in some way, as to require only RCT's for device approval ?

# Faults of Randomized Trials

- Patients are highly selected. NASCET and ACAS never described the outcomes in the average Medicare population undergoing CEA (Wennberg et al.)
- The trials take too long (> 5 yrs) to complete and the equipment and techniques evolve over time.
- Investigators are highly selected and their results may not be reproducible in the community.

# Alternative Trial Designs



- **Concurrent controls:**
  - Non-randomized matched concurrent control patients. The COAST trial proposed different sites for as “surgery sites” and “carotid stent sites”.
- **Cohort controls:**
  - Use data from a “matched” group to develop a comparator group for carotid stents.
- **Registry OPC trials:**
  - Use predetermined OPC’s as comparator endpoints for carotid stent trials in defined populations.

# PRECEDENT FOR DEVICE APPROVALS

- The FDA established a pathway for endovascular alternatives for open surgery by approving:
  - AAA stent-grafts (Gore, Medtronic, and Guidant devices) as safe and effective based upon concurrent control, non-randomized trial designs.
  - Why is it different for carotid disease ?
- It is INCONSISTENT to not allow non-RCT's for carotid patients ?

# Unique Outcome Guidance

Carotid Artery Disease is **Unique** in Having Guideline Recommendations

30 day Death and MI

- Symptomatic patients  $\leq 6\%$
- Asymptomatic patients  $\leq 3\%$

No other revascularization procedure has defined “threshold” outcomes.  
Why not use these OPC’s for device approval ?

# What If ?

- A RCT shows that CAS is as good or better than CEA... BUT the 30 day death and MI rate exceeds the Guideline recommendations ?
  - CAVATAS RCT comparing Carotid angioplasty and Carotid surgery in symptomatic patients had a 30 day stroke & death rate of **10%** in both.
- Wouldn't you rather rely on CAS meeting a THRESHOLD of  $\leq 6\%$  in symptomatic patients and  $\leq 3\%$  in asymptomatic patients, in a broad population of real-world patients ?

# CONCLUSION

- Carotid stenting is currently an FDA approved alternative to CEA for patients at increased risk for carotid surgery and... will likely become an option for average surgery risk patients.
- Any attempt to gather more information, in a broader sample of patients, from a more inclusive operator sample, will be of value when considered in the context of the RCT's.
- Carotid stenting is a less morbid option that our patients deserve. We should be aggressively seeking to define the population that benefits, not restricting access to RCT's.