

Trial Designs of Carotid Artery Stenting in Conventional Risk Patients

Stroke Systems Work Group of the
Practice Committee

American Academy of Neurology

Irene Katzan, MD
October 11, 2007

Overview

- AAN supports need for well-designed trials to evaluate use of Carotid Artery Stenting (CAS) in conventional risk patients
- Consideration of alternative designs may be appropriate in situations where successful completion of RCTs is not feasible.
- Alternative designs to RCTs should avoid interfering with recruitment of current trials: CREST and ACT-1
- Off label use of devices impedes enrollment

Overview of Need

Stent trials published in 2006 were not positive:

- SPACE failed to demonstrate the periprocedural noninferiority of carotid-artery stenting to CEA
- EVA-3S stopped for safety and futility with stenting demonstrating a greater 30-day risk than CEA.

. For now, carotid stenting seems prudent only for symptomatic patients with high surgical risk

Desired Elements

Study Populations:

- Both symptomatic and asymptomatic subjects
- Atherosclerotic extracranial internal carotid stenoses, 70% - 99% stenoses
- No upper age limit
- Patients eligible and at reasonable risk for both carotid endarterectomy and CAS

Endpoints: total stroke, ipsilateral stroke, all-cause mortality, and myocardial infarction (include event severity)

Follow-up:

- 30-day and 1-year
- longer times for trials that include medical management arm
 - 2-year follow-up for those involving symptomatic disease
 - 5-year follow-up for those involving asymptomatic disease

Concluding Thoughts

- There should be a multi-disciplinary approach in the conduction of clinical trials
- Avoid designs that interfere with recruitment of current trials: CREST and ACT-1
- Off label use of devices impedes enrollment
- Linking reimbursement with clinical trials may be a timely and cost efficient method to gather additional evidence regarding the efficacy of CAS