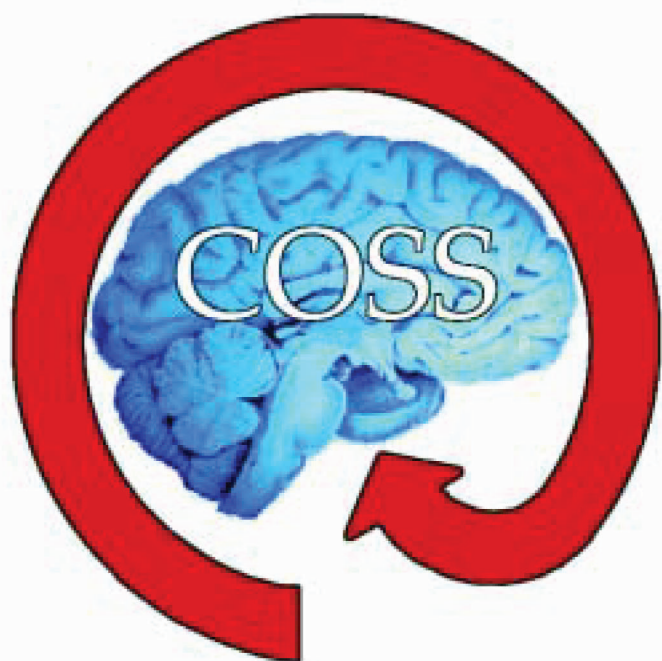


CAROTID OCCLUSION SURGERY STUDY



Funded by the National Institute of Neurological Disorders and Stroke

 Washington University in St. Louis
SCHOOL OF MEDICINE

UNIVERSITY OF IOWA, IOWA CITY, IA

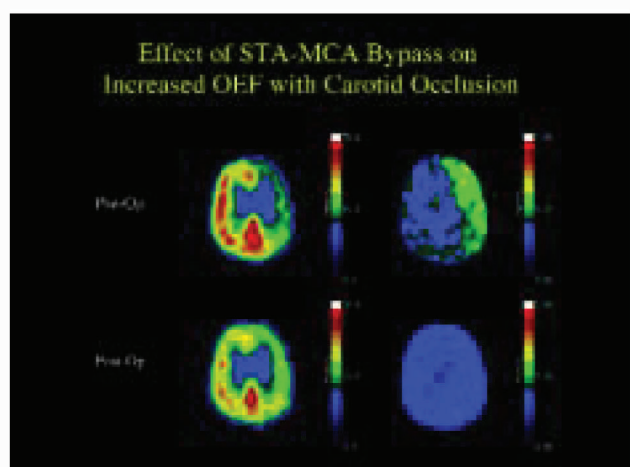
Physicians within the referral areas of the 20-30 participating centers are being asked for their help in identifying patients who meet the inclusion/exclusion factors. Patients who participate in this study will continue to receive care from their primary care physician.

BACKGROUND

Carotid artery occlusion accounts for 10-15% of carotid territory infarcts and TIAs, estimated at 80,000 per year in the United States. The risk of subsequent stroke is 5-7% per year on current medical treatment. Patients with symptomatic carotid artery occlusion who have increased oxygen extraction fraction (OEF) measured by PET have a 25-50% rate of subsequent stroke within the next two years if maintained on medical therapy. EC/IC bypass has the potential to reduce subsequent stroke by one-half in these patients, even taking into account the perioperative risk of 12%. It is appropriate at this time to perform a new trial of EC/IC bypass surgery in patients with symptomatic carotid occlusion and increased OEF identified by PET.

HYPOTHESIS

When added to best medical therapy, surgical anastomosis of the superficial temporal artery to the middle cerebral artery (STA-MCA) can reduce by 40%, despite perioperative stroke and death, subsequent ipsilateral ischemic stroke at two years in patients with recently symptomatic internal carotid artery occlusion and ipsilateral increased oxygen extraction fraction measured by positron emission tomography.

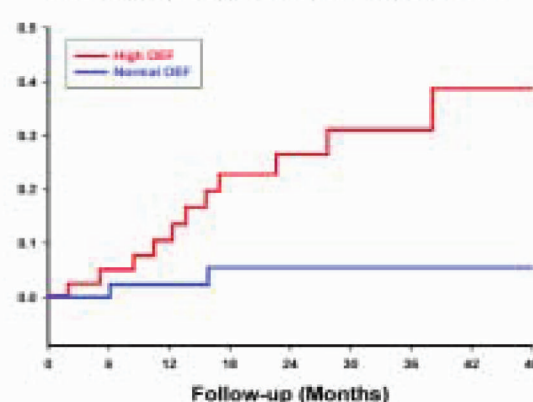


DESIGN

Multicenter, randomized, partially-blinded, controlled trial in 372 patients at 20-30 centers in North America. PET scans will be required of 903 clinically eligible patients.

We will offer both PET and EC/IC bypass free of charge to all eligible subjects provided that they agree to treatment randomization and follow-up if the PET shows increased OEF. Even for those who do not qualify for randomization into the trial because OEF is normal, the results of PET will provide useful information of good prognosis on medical therapy. Those with PET evidence of increased OEF will be randomized in equal numbers to receive or not receive EC/IC bypass.

IPSI LATERAL STROKE OCCURRENCE IN PATIENTS WITH SYMPTOMATIC CAROTID OCCLUSION



PRIMARY INCLUSION CRITERION

- Unilateral carotid artery occlusion symptomatic within the last 120 days

SELECTED EXCLUSION CRITERIA

- Known heart disease likely to cause cerebral embolism (Echocardiography is not required.)
- Subsequent cerebrovascular surgery planned which might alter cerebral hemodynamics
- Acute, progressing or unstable neurological deficit
- Medical indication for treatment with anticoagulant drugs, ticlopidine or clopidigrel such that aspirin cannot be substituted for 30-40 days

Further details and a list of participating sites may be found on the COSS web site at <http://dmchost.public-health.uiowa.edu/coss/>

For further information on the COSS study, please contact Carol Hess, project manager, at carol@npg.wustl.edu.

For further information from your local site, contact: