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***Bypass Surgery Isn't Only for the Heart;
NIH-Funded Neurosurgical Study Explores Bypass of the Carotid Artery
As a Strategy for Preventing Recurrent Strokes***

CINCINNATI, Ohio – Just as a blocked artery in the chest can lead to a potentially fatal heart attack, a blocked artery in the neck can lead to a lethal or disabling stroke. Neurosurgeons at the Mayfield Clinic and The Neuroscience Institute, in a process bearing similarities to lifesaving coronary bypass surgery, are exploring the use of carotid artery bypass surgery as a strategy for preventing recurrent strokes in patients with complete blockage of this primary artery in the neck.

The delicate surgical procedure, called “extracranial-intracranial bypass,” involves connecting an artery from the scalp outside the skull to a brain artery inside the skull, thereby bypassing a blocked carotid artery. The body’s two carotid arteries, one on the right side and one on the left, run through the neck and supply oxygen-rich blood to the brain.

Officially named the Carotid Occlusion Surgery Study (COSS), the federally funded research trial involves patients who: (1) have complete blockage of one of these critical arteries; (2) have already suffered a stroke or transient ischemic attack (TIA), sometimes referred to as a mini-stroke; and (3) have not developed natural bypass arteries of their own, a life-saving mechanism that enables some individuals with blocked carotid arteries to continue getting adequate blood flow to the brain. Patients who qualify for the COSS trial would face a 25 to 50 percent risk of suffering a stroke during the next two years if they were treated with medications alone.

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“The COSS study is designed to find a long-term treatment to lower the risk of stroke or death in patients with blocked carotid arteries,” said Dr. Mario Zuccarello, a neurosurgeon with the Mayfield Clinic and The Neuroscience Institute and director of the Division of Cerebrovascular Surgery at the University of Cincinnati (UC) College of Medicine. “The carotid bypass is considered experimental, however, because it has not been generally performed for this condition. We also do not yet have scientific proof that it will reduce the incidence of stroke in these patients.”

Extracranial-intracranial bypass is not risk-free. The risk of stroke is 7.6 percent, and the risk of death is 1 percent, with most untoward incidents occurring during surgery or in the first month after surgery.

Dr. Zuccarello is the principal investigator for the Cincinnati portion of the multiple-site study, which began in April 2003 and runs through 2008. The study is sponsored by the National Institutes of Health. About 90 patients are expected to participate in the study at The Neuroscience Institute at UC and University Hospital.

Most of the 700,000 strokes that strike Americans each year occur when a blood clot suddenly cuts off the flow of oxygen to the brain. An estimated 61,000 strokes in patients who had not previously experienced a stroke, and 19,000 TIAs, are associated with carotid occlusion. Stroke is the third leading cause of death and the leading cause of disability in the United States.

Major eligibility requirements for participation in COSS are:

- occlusion of one or both carotid arteries;
- hemispheric TIA or mild to moderate stroke in the territory of an occluded carotid artery within 120 days;
- reduced flow of blood to the brain and reduced oxygen use by the brain, as measured by PET neuroimaging;
- arteries that can be surgically connected, as demonstrated by a cerebral arteriogram, a test that produces a map of arteries in the neck and brain.

Patients participating in COSS will be randomly assigned one of two treatment protocols. One group of patients will undergo extracranial-intracranial bypass surgery; the other group of patients will

remain on medications prescribed by their physicians. Participants will remain in the study for two to six years.

The Mayfield Clinic is recognized as one of the nation's leading physician organizations for clinical care, education, and research of the spine and brain. The group includes 16 neurosurgeons and treats 20,000 patients from 35 states and a dozen countries in a typical year. Mayfield's neurosurgeons are active participants in important clinical trials and have pioneered surgical procedures and instrumentation that have revolutionized the medical art of neurosurgery for brain tumors and neurovascular diseases and disorders.

The Neuroscience Institute is a regional center of excellence that embraces nine neuroscience specialties within the University Hospital, the Health Alliance and the UC College of Medicine. The Institute is dedicated to patient care, research, education, and the development of new medical technologies.

For more information about the COSS study, including details about eligibility, visit:

http://www.mayfieldclinic.com/CT_COSS.htm

<http://www.aans.org/library/Article.aspx?ArticleId=21861>

Patients or families wishing to enroll in COSS in Cincinnati can contact Suzanne Kempisty-Clover of the Mayfield Clinic at (513) 558-5387 or suzanne.kempisty-cliver@uc.edu

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