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***It's Minimally Invasive, But Is It Better?***

***Mayfield Neurosurgeons Compare New Strategy to the "Gold Standard"***

***For Treating Carotid Stenosis and Preventing Strokes***

CINCINNATI, Ohio – Mayfield Clinic neurosurgeons are playing an important role in a federally funded investigation into whether minimally invasive treatment of narrowed carotid arteries is superior to the proven surgical method that requires an incision. Officially named the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST), the multi-site study compares the traditional surgical procedure of carotid endarterectomy to stent-assisted carotid angioplasty.

The trial is for patients who have stenosis (a narrowing or blockage) of the carotid artery and have recently suffered a transient ischemic attack (TIA), a non-disabling mini-stroke. 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. Patients may be included in the CREST study if they have more than 50 percent blockage of the carotid artery, as determined by an angiogram, or more than 70 percent blockage, as determined by ultrasound.

"We're following the same logic that the cardiac sciences followed 20 years ago, which is to find a path of less invasive therapy to achieve the same end that had proven clinically beneficial through surgery," said Dr. Andrew Ringer, a Mayfield Clinic neurosurgeon and Principal Investigator of the Cincinnati portion of the trial. "It's a trend throughout medicine to seek less invasive ways of treating disease, particularly when you're talking about preventive treatment, like this. We want the treatment to be less morbid than the risk of the disease itself."

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Dr. Ringer, Director of the Endovascular Laboratory at the University of Cincinnati (UC) College of Medicine, is performing the stent-assisted carotid angioplasty procedures in the CREST trial, while Dr. Mario Zuccarello, a Mayfield neurosurgeon and Director of the Division of Cerebrovascular Surgery at UC, is performing the carotid endarterectomies. About 50 qualifying patients will be treated in the Cincinnati portion of the study, all at The Neuroscience Institute at University Hospital. Each patient's treatment – whether by stenting or endarterectomy – will be randomly determined.

While the endarterectomy has a proven track record and remains the “gold standard” for patients who can tolerate surgery, many physicians believe the stenting procedure has advantages because it is less invasive and does not pose risks associated with surgical intervention and anesthesia. During an endarterectomy, a surgeon makes an incision in the neck and physically removes plaque from the inside of the artery. During stenting, the physician inserts a catheter or tube into an artery in the groin and then threads the catheter through the arteries to the location of the plaque within the carotid artery. A balloon dilates the artery, and the stent is placed so that it covers the plaque and holds the artery open.

Dr. Ringer cautioned, however, that less invasive does not always mean better. “The concern with carotid, or cerebrovascular intervention, is that the potential risks are much different than with angioplasty anywhere else in the body, including the heart or the kidney,” he said. “In those organs, if you have a small amount of embolus – blood clot or plaque – that breaks free and plugs up a distal artery, the patient may not become symptomatic. But if you have that same small amount of embolus that goes to the brain, the patient has a stroke and you know about it. A physician who performs cerebrovascular intervention must be prepared to manage this rare, but very real, complication.”

Dr. Ringer, a member of the Greater Cincinnati/Northern Kentucky Stroke Team, is the only physician in the region approved to perform stenting in the CREST trial. Over the last four years Dr. Ringer performed more than 100 of the procedures in patients for whom endarterectomy would have posed a high risk. Those patients suffered from complicating factors, such as complete occlusion of the other carotid artery, prior endarterectomy, significant coronary artery disease, or presence of scar tissue from radiation treatment. As a result of the trials involving high-risk patients like these, carotid angioplasty and stenting gained FDA approval earlier this month as a therapy for high-risk carotid stenosis.

“These high-risk patients constituted the first patients who gave us experience with carotid angioplasty stenting,” Dr. Ringer said. “They demonstrated that stenting, when appropriately applied by

someone with proper training, is very safe. That was borne out in our own data: we have treated more than 100 patients and experienced a stroke rate of less than 1 percent. That compared very favorably to surgical treatment. Our goal now is to find out whether this also applies to the standard patient who is at risk of stroke.”

CREST, which began in 2000, is supported by the National Institute of Neurological Disorders and Stroke, a division of the National Institutes of Health. The investigational stent being used in CREST is the ACCULINK(TM) Carotid Stent System, an elastic-like metal scaffold.

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.

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 CREST, including details about eligibility, visit:  
<http://www.clinicaltrials.gov/ct/gui/show/NCT00004732> or  
[http://www.mayfieldclinic.com/CT\\_CREAST.htm](http://www.mayfieldclinic.com/CT_CREAST.htm)

Patients or families wishing to enroll in CREST in Cincinnati can contact Suzanne Kempisty-Cliver of the Mayfield Clinic at (513) 558-5387 or [suzanne.kempisty-cliver@uc.edu](mailto:suzanne.kempisty-cliver@uc.edu)

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