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Contacts:

NINDS: Marian Emr or Margo Warren
301-496-5924
me20t@nih.gov; warrenm@ninds.nih.gov

Mayo: Kevin Punsky, 904-953-2299
punsky.kevin@mayo.edu
Nancy Jensen, 904-953-2299
jensen.nancy1@mayo.edu

**Landmark NIH Clinical Trial Comparing Two Stroke Prevention Procedures Shows Surgery and
Stenting Equally Safe and Effective**

Opportunities Exist to Target the Treatment to the Patient

A major new study of people at risk for stroke showed that two medical procedures designed to prevent future strokes are safe and effective overall. Physicians will now have more options in tailoring treatments for their patients at risk for stroke. In the trial of 2,502 participants, carotid endarterectomy (CEA), a surgical procedure to clear blocked blood flow and considered the gold standard prevention treatment, was compared to carotid artery stenting (CAS), a newer and less invasive procedure that involves threading a stent and expanding a small protective device in the artery to widen the blocked area and capture any dislodged plaque.

One of the largest randomized stroke prevention trials ever, the Carotid Revascularization Endarterectomy vs. Stenting Trial (CREST) took place at 117 centers in the United States and Canada over a nine-year period. CREST compared the safety and effectiveness of CEA and CAS in patients with or without a previous stroke. The trial was funded by the National Institute of Neurological Disorders and Stroke (NINDS), part of the National Institutes of Health, and led by investigators at Mayo Clinic, Jacksonville, Fla., and the University of Medicine and Dentistry of New Jersey in Newark.

The overall safety and efficacy of the two procedures was largely the same with equal benefits for both men and for women, and for patients who had previously had a stroke and for those who had not. However, when the investigators looked at the numbers of heart attacks and strokes, they found differences. The investigators found that there were more heart attacks in the surgical group, 2.3 percent compared to 1.1 percent in the stenting group; and more strokes in the stenting group, 4.1 percent versus 2.3 percent for the surgical group in the weeks following the procedure.

The study also found that the age of the patient made a difference. At approximately age 69 and younger, stenting results were slightly better, with a larger benefit for stenting, the younger the age of the patient. Conversely, for patients older than 70, surgical results were slightly superior to stenting, with larger benefits for surgery, the older the age of the patient.

“The CREST trial results show that we now have two safe and effective methods to treat carotid artery disease directly, the tried and true CEA, and the new kid on the block, CAS,” said Thomas G. Brott, M.D., professor of neurology and director for research at Mayo Clinic in Jacksonville, and the study’s national principal investigator. “There was evidence that people who were younger than 70 did better with stents while those over 70 had better results with the surgery, but the results for all men and women were excellent.”

“The CREST trial provides doctors and patients with much needed risk/benefit information to help choose the best carotid procedure based on an individual’s health history. This personalized decision making should translate into improved patient outcomes,” said Walter J. Koroshetz, M.D., deputy director of NINDS.

Stroke, the third leading cause of death in the United States, is caused by an interruption in blood flow to the brain by a clot or bleeding. The carotid arteries on each side of the neck are the major source of blood flow to the brain. The buildup of cholesterol in the wall of the carotid artery, called atherosclerotic plaque, is one cause of stroke. Because people with carotid atherosclerosis also usually have atherosclerosis in the coronary arteries that supply the heart, the CREST trial tracked the rate of heart attacks, in addition to stroke and death.

In CREST, approximately half the patients had recent symptoms due to carotid disease such as a minor stroke, or a transient ischemic attack (TIA), indicating a high risk for future stroke. The other half had no symptoms but were found to have narrowing of the carotid artery on one of a variety of tests assessing carotid narrowing and plaque. Such patients, termed asymptomatic, are at much lower risk of stroke than those with symptoms.

One of the strengths of the study, according to investigators, is that CREST was conducted in a variety of real world settings, including large and small public and private hospitals. Physicians had to demonstrate a high degree of proficiency and safety in order to participate in the trial. The study found no significant differences in the outcomes, no matter what type of medical specialist performed the stenting procedure, including cardiologists, neuroradiologists, interventional radiologists, vascular surgeons and neurosurgeons.

“Although the purpose of the study was to compare the two procedures, we were pleased to find that both CEA and stenting have become extraordinarily safe,” said Gary Roubin, M.D. Ph.D., chairman, department of cardiovascular medicine, of the Lenox Hill Hospital in New York City, a lead investigator for CREST and study co-principal investigator for stenting.

The researchers point out that the rate of stroke and death in the surgical group was the lowest ever reported in a large stroke prevention trial. “The rate for stroke and death in carotid stenting was also the lowest yet reported in any randomized trial, and significant advances in technology, technique and patient selection for stenting have continued over the eight-year enrollment in CREST,” said Dr. Roubin.

As a result, the pivotal differences were the lower rate of stroke following surgery and the lower rate of heart attack following stenting, according to the investigators. A year after the procedure, the

patients who had suffered a stroke reported that the effects of the stroke had a greater impact on their quality of life than was reported by those patients who had suffered a heart attack.

The average age of the patients in this trial was 69. “These patients have many good years ahead of them, and that’s why the lessons learned from CREST are so important. People have some very good options for stroke prevention that we hope will not only extend the length but also the quality of their lives,” said Dr. Brott.

“CAS may offer a reasonable alternative to CEA, particularly in patients who prefer a less invasive procedure, and in younger patients. However, it should be kept in mind that for the endpoint of stroke, CEA has been shown to be the safer procedure. It is when heart attacks are added that the results of the two procedures become similar,” said Wesley S. Moore, M.D., professor and chief, emeritus, division of vascular surgery of the University of California at Los Angeles, and co-principal investigator for surgery in the CREST trial. Dr. Moore went on to say that it is also important to point out that the complications from either procedure in this study are the lowest reported to date and are a tribute to the quality of the surgeons and interventionists who participated in this trial.

The CREST investigators concluded that while CEA has a proven record and long term durability, both CAS and CEA are safe and useful tools in the right setting for stroke prevention, and technology continues to improve each procedure.

“The CREST trial was a large, complex undertaking that will provide the medical community with important information on the comparative effectiveness of these two procedures. NINDS is committed to long-term follow up of this group of patients, which will help us learn even more about how best to prevent stroke,” said Story Landis, Ph.D., NINDS director.

Partial funding for the study was supplied by Abbott, of Abbott Park, Ill., the maker of the stents.

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The NINDS (www.ninds.nih.gov) is the nation’s leading funder of research on the brain and nervous system. The NINDS mission is to reduce the burden of neurological disease – a burden borne by every age group, by every segment of society, by people all over the world.

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