

## The CREST Trial:

### Expanding Treatment Options for Patients with Carotid Artery Stenosis

Carotid stenosis is responsible for a substantial burden of ischemic stroke in the United States. In appropriate candidates, carotid revascularization affords an incremental stroke risk reduction beyond that provided by medical therapy and therapeutic lifestyle change alone.

The SAPPHIRE (Stenting and Angioplasty with Protection of Patients with High Risk for Endarterectomy) trial demonstrated that among symptomatic (> 50% stenosis) and asymptomatic (>80% stenosis) patients at *high surgical risk* for carotid endarterectomy (CEA) [e.g., age over 80 years, recent acute coronary syndrome, unrevascularized coronary artery disease, heart failure, severe COPD, end stage renal disease, planned major surgery, prior ipsilateral neck dissection, endarterectomy or neck irradiation], carotid artery stenting (CAS) and CEA are equivalent at reducing long-term stroke risk, and equally safe. At MHVI, we continue to enroll patients in 2 post-marketing registries of *high surgical risk* patients with carotid stenosis, CHOICE (Carotid Stenting For High Surgical-Risk Patients; Evaluating Outcomes Through The Collection Of Clinical Evidence) and SAPPHIRE Worldwide. By collecting real-world data on these patients, and pooling these data with those from other Centers around the world, we are better able to evaluate and hone this novel, minimally invasive procedure and as a consequence, improve its associated outcomes. If you have questions about whether your patients might be suitable candidates for participation in either of these registry trials, please contact the Michigan Heart Research Hotline at 734-712-7787 or site Principal Investigator, Dr. Herbert Aronow (670-1452).

Until recently, the relative efficacy and safety of carotid stenting and endarterectomy were unknown for patients with carotid stenosis at *low surgical risk* (i.e., who lacked the high-risk characteristics listed above). Published online in the May 26, 2010 issue of the New England Journal of Medicine, NIH-sponsored CREST (Carotid Revascularization Endarterectomy vs. Stenting Trial) randomized 2,502 *low surgical risk* symptomatic (> 50% stenosis) or asymptomatic (>60% stenosis) patients with carotid stenosis to CAS or CEA and followed them for up to 4 years. Conducted at 117 North American sites, CREST is the largest completed randomized trial to date comparing these two revascularization strategies. The incidence of the primary endpoint, death, myocardial infarction or stroke up to 30 days or ipsilateral stroke up to 4 years was similar in both groups (CAS 7.2% vs. CEA 6.8%, p=NS). The risk of ipsilateral stroke after the first 30 days was also similar (2.0% for CAS and 2.4% for CEA, P=NS). Interestingly, the risk of minor stroke was greater after CAS, while the risk of MI was greater

after CEA. Women and men fared similarly in the trial, however age appeared to play an important role such that older patients had better outcomes with surgery and younger patients with stenting. At the Michigan Heart & Vascular Institute (MHVI), CREST was led by Site Principal Investigator, Dr. Herbert Aronow, from Cardiovascular Medicine and Michigan Heart Research Coordinator, Jennifer Piper. Sub-Investigators included Drs. Walter Whitehouse, Brian Halloran and Michael Heidenreich from Vascular Surgery and Dr. Susan Hickenbottom from Neurology.

At MHVI, we have undertaken a multidisciplinary, collaborative approach to the care of patients with carotid stenosis. Leadership from Cardiovascular Medicine, Interventional Radiology and Vascular Surgery meet regularly to formulate and update privileging requirements for performance of carotid revascularization procedures, design best practice protocols to standardize the medical care of these patients and benchmark our Institution's carotid stenting and endarterectomy outcome data against other sites from around the United States through the ACC NCDR CARE (American College of Cardiology National Cardiovascular Data Registry Carotid Artery Revascularization and Endarterectomy) Registry.