

NEJM STUDY DEMONSTRATES CAROTID STENTING WITH EMBOLIC PROTECTION IS COMPARABLE TO SURGERY

SAPPHIRE Three-Year Study Demonstrates Equivalent Stroke and Repeat Procedure Outcomes

WARREN, N.J., April 9, 2008 – According to a study published in *The New England Journal of Medicine* this week, three-year data from the Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy (SAPPHIRE) study in patients with severe blocked carotid arteries, the main blood vessels in the neck leading to the brain, who underwent carotid artery stenting (CAS) with the PRECISE[®] Nitinol Stent and the ANGIOGUARD[®] Emboli Capture Guidewire were comparably protected from stroke, heart attack, death, and repeat revascularization procedures as patients who underwent surgery (endarterectomy).

SAPPHIRE is a multicenter, prospective, randomized study that evaluated the safety and performance of the PRECISE[®] Nitinol Stent and ANGIOGUARD[®] Emboli Capture Guidewire, compared with endarterectomy, in 334 patients with high-grade carotid artery stenosis. The prespecified major secondary endpoint at three years was a composite of death, stroke, or myocardial infarction within 30 days after the procedure or death or ipsilateral stroke (occurring on the same side) between 31 days and three years.

At three years, data were available for 260 patients, 85.6 percent of patients (143 of 167) in the stenting group and 70.1 percent of patients (117 of 167) in the surgery group. The pre-specified major secondary endpoint occurred in 41 of the 167 patients who underwent stenting (cumulative incidence, 24.6 percent) and in 45 of 167 patients who underwent endarterectomy (cumulative incidence, 26.9 percent). There was no statistical significance between these groups. A procedure to re-open the blocked arteries (target-vessel revascularization) was infrequent in both groups.

“It is important to know the protection of carotid revascularization against future stroke and other ischemic events was maintained at three years and there was no significant difference in the cumulative incidence of major cardiovascular events between carotid revascularization and carotid surgery,” said Donald E. Cutlip, M.D., Executive Director of Clinical Investigation, Harvard Clinical Research Institute, Harvard Medical School.” Dr. Cutlip currently serves as an investigator in the Cordis-sponsored SAPPHIRE study.

SAPPHIRE is the first, longest-term randomized study comparing the safety and efficacy of carotid stenting with embolic protection to those undergoing endarterectomy or surgery in patients considered at a high surgical risk. Carotid artery stenting is a minimally invasive procedure that involves placement of a stent, a wire mesh device used to open a narrowed artery, up to the neck through a catheter near the leg. To reduce the chances of small pieces of plaque breaking off and entering the bloodstream during this process, SAPPHIRE researchers used an emboli-protection device to catch these small particles. The PRECISE[®] Stent and ANGIOGUARD[®] Guidewire are

approved to treat carotid artery disease in patients at high risk for adverse events from carotid endarterectomy (CEA) -- a surgical treatment for removing arterial plaque from the carotid artery.

“These long-term study results are important to the approximately one-third of patients who have severe carotid artery stenosis and require a less invasive, but effective treatment option because they are poor candidates for surgery,” said Sidney Cohen, M.D., Ph.D., Vice President, Clinical Research, Cordis Corporation. “Results show that stenting with the PRECISE® Nitinol Stent combined with the ANGIOGUARD® distal protection device offers these patients a safe and effective alternative to carotid surgery.”

Carotid Artery Disease

Carotid artery disease is the buildup of atherosclerotic plaque in the major neck vessels delivering blood to the brain, a major cause of stroke. CAS is a non-invasive, non-surgical procedure intended to improve blood flow to the brain while helping prevent debris from entering cerebral circulation, and an important alternative for patients who are ineligible for CEA. Risk factors for carotid artery disease include advanced age, family history of stroke, plaque buildup in other areas of the body, high blood pressure, and diabetes.

The American Heart Association estimates that 20 to 30 percent of strokes are associated with carotid artery disease, caused by particles of atherosclerotic plaque traveling into the vessels that supply the brain with oxygen and vital nutrients. Stroke affects an estimated 700,000 Americans each year, making it the nation’s third leading cause of death, and a leading cause of serious, long-term disability.

Cordis Corporation

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