EPIC study finds new embolic protection device had 97.5 percent success rate during carotid artery stenting

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A multicenter EPIC (FiberNet Embolic Protection System in Carotid Artery Stenting Trial) study found that the FiberNet Embolic Protection System (EPS) had a 97.5% success rate when used in patients undergoing carotid artery stenting (CAS). Full findings are published early online in *Catheterization and Cardiovascular Interventions*, the official journal of The Society for Cardiovascular Angiography and Interventions.

Carotid artery stenosis or carotid artery disease occurs when plaque forms in the carotid artery, causing it to narrow and increasing risk for ischemic stroke. According to the National Institutes of Health, a blockage of a blood vessel is the most frequent cause of stroke, responsible for 80% of the estimated 700,000 strokes in the U.S. annually. Carotid artery stenosis is often treated with CAS, the placement of a tiny flexible tube in the diseased vessel.

Unfortunately, stenting procedures carry the risk of embolism, where plaque breaks away from the site of formation and blocks another artery downstream. Embolic protection devices have emerged to prevent strokes by catching the debris that may break away during CAS surgery. Over the past decade, several protection systems have emerged with varying degrees of success.

A research team led by Subbarao Myla, M.D, FSCAI, evaluated the

safety and efficacy of this new design concept for embolic protection during CAS. The study was designed to demonstrate that the 30-day major adverse event (MAE) rate of all death, stroke, and myocardial infarction (MI) is significantly less than the performance goal of 8.3% from the ARCHeR 3 results.

The trial enrolled 237 patients with a mean age of 74 years from 26 centers across the U.S. and Europe. Study participants were 64% male and 20% had symptomatic carotid artery disease (CAD). Results indicate the combined MAE rate at 30 days following carotid endarterectomy (CEA) for all death, stroke and heart attack was 3.0%.

"The 30-day death, stroke, and MI rate of 3.0% is encouraging," says Dr. Myla. The researchers concluded that the FiberNet EPS, when used with commercially available stents, produced low stroke rates following CAS in high surgical risk patients with CAD.

Dr. Myla describes the team's experience with the new embolic protection device: "The low crossing profile and integration of a primary guidewire shortened procedure time, and facilitated lesion crossing and filter placement, especially in the presence of tortuous anatomy. The 0.014" guidewire tip demonstrated good torque response and the guidewire provided excellent support…it was ideal for procedures in which tortuosity would preclude placement of a more structured DPD with a stiff delivery catheter. Conformability of the expanded fiber network to the vessel wall and the short landing zone of the device made it ideal for challenging anatomy distal to the lesion. Anecdotally, investigators have commented the FiberNet EPS resulted in fewer vessel spasms."

More information: "Carotid Artery Stenting in High Surgical Risk Patients using the FiberNet® Embolic Protection System: The EPIC Trial Results." Subbarao Myla, J. Michael Bacharach, Gary M. Ansel,

Eric J. Dippel, Daniel J. McCormick, Jeffrey J. Popma. Catheterization and Cardiovascular Interventions; Published Online: March 1, 2010 (DOI: 10.1002/ccd.22386).