ICU
MANAGEMENT & PRACTICE

Blood Flow Reversal System Used During Carotid Stenting Is Both Safe And Effective, Study Shows

L. Nelson Hopkins, MD, Professor and Chairman of Neurosurgery/Professor of Radiology and Director of the Toshiba Stroke Research Center, at the State University of New York at Buffalo presented the results of "EMPiRE: A Multi-center Registry Evaluating Neuroprotection During Carotid Stenting with a Novel Flow Reversal System." The objective of the study is to demonstrate the safety and efficacy of the GORE Flow Reversal System which provides embolic protection by reversing the flow of blood through the ICA, directing embolic particles away from the brain. System components include a balloon sheath and dilator, balloon wire and an external filter.

The study was a prospective, multicenter, single-arm study against objective performance criterion (OPC). The subject population included individuals who were diagnosed with carotid stenosis requiring revascularization and who are at high risk for AEs from CEA. The study included 245 subjects enrolled at 28 sites; the enrollment period was from July 2006 to July 2008.
The mean age for study participants was 70; 16% or 38 patients were octogenarians and 165 were male. Seventy-eight were symptomatic and 167 were asymptomatic. In terms of medical history, 31% were current tobacco users, 35% had diabetes, 38% had respiratory ailments, 42% had coronary disease, 82% had hyperlipidema and 87% suffered from hypertension.

The mean procedure time was 80 minutes (25 minimum and 345 maximum) with a mean flow reversal time of 15 minutes. The mean hospital stay was 1 day (24 maximum).

According to researchers, the EMPiRE study met its study primary endpoint with a low death rate of 0.8%, low death/stroke rate of 2.0% and low major adverse event (MAE) rate of 3.7%. The GORE Flow Reversal System itself had a technical success rate of 96.3% (236 patients). Just 6 subjects (2.4%) were unable to tolerate the procedure but there were no permanent neurological deficits and intolerance was resolved when the balloons were deflated. The failure rate of 3.7% (9 patients) was due to such factors as balloon sheath rupture, tortuous anatomy, inability to position the device and patient inability to tolerate flow reversal.

In summarizing the conclusions from EMPiRE, Dr. Hopkins said, "The GORE Flow Reversal System is safe and efficacious for embolic protection during carotid angioplasty and stenting. And, it offers potential advantages over other embolic protection devices in that embolic debris is directed away from the brain, it is not necessary to cross target lesions unprotected and it provides an option for patients with unsuitable anatomy for distal embolic protection (e.g., tortuous IC or limited landing zone)."

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