

Study reveals embolic neuroprotection system reduces risk of cardiac events

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Results of a study on the use of the FiberNet® Embolic Protection System in carotid artery stenting were reported today during the 20th annual Transcatheter Cardiovascular Therapeutics (TCT) scientific symposium, sponsored by the Cardiovascular Research Foundation (CRF). The research showed a low number of strokes and cardiac events in patients who had stents implanted utilizing a new embolic neuroprotection system during carotid stenting with commercial stents.

Subbarao Myla, MD, Medical Director CV Research and Vascular Intervention, Hoag Memorial Hospital, Newport Beach, Calif. presented the results of "EPIC: Evaluating the Use of the FiberNet® Embolic Protection System in Carotid Artery Stenting." The study looked at patients who were at high risk for CEA that were treated with the FiberNet® Embolic Protection System during carotid artery stenting procedures. The data was compiled into a registry that tracked 237 patients at 26 sites across the U.S.

The system uses a unique filter design with low porosity and, according to Dr. Myla, "Its easy-to-use features combined with aspiration prior to retrieval lead to low event rates. The FiberNet system allows blood flow during the procedure, a fiber-based filter captures particles as small as 40 µm and the stent is delivered for placement using a standard coronary guide wire."

In the study, patients at high-risk for CEA were treated in a prospective, multi-center, non-randomized trial. The demographic profile of study

participants included patients of mean age 73.9 ± 8.3 (ranging from 46-89), 21.1% were octogenarians, 62.4% were male, 20.3% were symptomatic, 39.7% had diabetes and 22.2% were current smokers.

Key exclusion criteria included planned treatment of contra-lateral carotid within 30 days, stroke within 48 hours, myocardial infarction (MI) within 14 days, total occlusion, stenosis unsuitable for carotid stenting and serial lesions that require more than one stent.

The EPIC study revealed very low stroke, MI and death rates using the FiberNet embolic protection system during carotid stenting. Further, the low porosity filter and ease of use combined with aspiration prior to retrieval led to low event rates. The 30-day event rates showed deaths constituted 0.4% of all strokes 2.1% (major stroke — 1.3% and minor stroke — 0.9%) and all myocardial infarctions at 0.9%. The 30 day composite primary endpoint for all events was 3.0%

Procedural results included a 97.5% technical success rate, 94.1% FiberNet device success, 100% two-wall vessel apposition and 90.9% visible debris captured.

Source: Cardiovascular Research Foundation

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