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PERIPHERAL

Proximal Versus Distal Embolic Protection for Carotid Artery Stenting

A National Cardiovascular Data Registry Analysis

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ABSTRACT

OBJECTIVES The aim of this study was to compare the stroke/death rates between proximal embolic protection devices (P-EPDs) and distal filter embolic protection devices (F-EPDs) in elective carotid artery stenting (CAS).

BACKGROUND P-EPDs have theoretical advantages that may make them superior to F-EPDs for stroke prevention during CAS.

METHODS We examined 10,246 consecutive elective CAS procedures performed with embolic protection in the NCDR CARE registry between January 2009 and March 2013. We analyzed crude and propensity-matched rates of in-hospital combined death/stroke in patients treated with P-EPDs versus F-EPDs. Secondary analyses included 30-day adverse event rates and stroke rates by the involved cerebrovascular territory.

RESULTS P-EPDs were used in 590 of 10,246 cases (5.8%). Patients treated with P-EPDs had higher rates of symptomatic lesion status (46.8% vs. 39.7%, $p < 0.001$), atrial fibrillation/flutter (16.1% vs. 13.0%, $p = 0.03$), and history of a neurological event (51.2% vs. 46.6%, $p = 0.03$). In unadjusted and propensity-matched analyses, differences in in-hospital stroke/death between P-EPD and F-EPD cohorts were nonsignificant (1.5% vs. 2.4%, $p = 0.16$ and 1.6% vs. 2.0%, $p = 0.56$, respectively). For patients with available data ($n = 7,693$, 75.1%), 30-day adverse events rates were similar for P-EPDs and F-EPDs before (2.5% vs. 4.2%, $p = 0.07$) and after (2.7% vs. 4.0%, $p = 0.22$) propensity matching.

CONCLUSIONS Use of a P-EPD during CAS was associated with low rates of in-hospital stroke/death similar to those with an F-EPD in the first comparative effectiveness study of the devices. An adequately powered randomized trial comparing clinical outcomes between these devices is unlikely to be feasible. (J Am Coll Cardiol Intv 2015;8:609–15)

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ABBREVIATIONS AND ACRONYMS

CAS = carotid artery stenting

dwMRI = diffusion-weighted magnetic resonance imaging

EPD = embolic protection device

F-EPD = distal filter embolic protection device

NIHSS = National Institutes of Health Stroke Scale

P-EPD = proximal embolic protection device

Carotid artery stenting (CAS) is a commonly used revascularization procedure for the treatment of asymptomatic and symptomatic carotid artery disease. Although CAS is performed to decrease a patient's long-term probability of stroke, periprocedural and 30-day strokes remain important procedural complications. Embolic protection devices (EPDs) provide a theoretical mechanism to reduce periprocedural strokes, although data regarding their effectiveness have been mixed (1,2). Nevertheless, EPDs are mandated for reimbursement by Medicare and used in more than 95% of all CAS cases in the United States (1). Two types of EPD are currently available, with different mechanisms for stroke prevention. Distal filter EPDs (F-EPDs) are small baskets deployed in the internal carotid artery distal to the lesion to catch any debris that may be produced by manipulation during angioplasty and stent placement. Proximal EPDs (P-EPDs) use balloons to arrest or reverse flow to the internal carotid artery so that angioplasty and stenting can be performed with less risk of antegrade embolization. Aspiration is performed either continuously or before balloon deflation, theoretically capturing any debris released by the procedure.

A P-EPD may be theoretically superior to an F-EPD for stroke prevention because the carotid lesion is never touched in an unprotected fashion when using a P-EPD. Three small single-center studies demonstrated significantly fewer surrogate events, such as transcranial Doppler-detected microembolic signals and diffusion-weighted magnetic resonance imaging (dwMRI) lesions with the use of P-EPDs (3–5). No large-scale analysis using the clinical outcomes of stroke and mortality has yet been performed to evaluate the potential utility of P-EPDs compared with F-EPDs. In the current study, we sought to compare outcomes of CAS using F-EPDs and P-EPDs in a large, nationally representative, multi-institutional registry.

METHODS

STUDY POPULATION. The CARE (Carotid Artery Revascularization and Endarterectomy) Registry is an initiative of the American College of Cardiology Foundation with partnering support from the Society for Cardiovascular Angiography and Interventions, the Society of Interventional Radiology, the American Academy of Neurology, the American Association of Neurological Surgeons/Congress of Neurological Surgeons, the Society for Vascular Medicine, and the Society of Vascular and Interventional Neurology. The registry enrolls U.S. patients with carotid stenosis who have undergone revascularization with either carotid endarterectomy or CAS (6). It was created to monitor clinical practice, assess patient outcomes, and provide a framework for quality improvement initiatives. As of July 2013, the registry included 17,064 CAS procedures performed at 184 hospitals.

All patients undergoing CAS from January 2009 through March 2013 were initially evaluated for inclusion in this analysis. Patients with acute evolving stroke (n = 378, 3.26%), spontaneous carotid artery dissection (n = 93, 0.8%), or fibromuscular dysplasia (n = 66, 0.6%) or requiring general anesthesia (n = 517, 4.5%) were excluded because these patients represented distinct, often nonelective, subgroups of patients with substantially higher procedural risk. Patients for whom no embolic protection was attempted were excluded as well (n = 278, 2.6%). Outcomes in these patients were reported previously and were not directly relevant to the present analysis (1).

OUTCOMES. The primary outcome of interest was the occurrence of in-hospital major adverse events, defined as the composite of stroke and death. Stroke was defined as a new neurological deficit persisting for more than 24 h. The occurrence of stroke was recorded by trained data abstracters. The Registry also collects National Institutes of Health Stroke Scale (NIHSS) scores before and after procedures, administered by a certified independent examiner. Formal independent adjudication of documented strokes by a board-certified neurologist was not routinely performed, and data regarding the proportion of patients who underwent this adjudication process were unavailable. To account for potential incomplete ascertainment of small strokes, we used a secondary expanded definition of stroke that included patients with documented changes in NIHSS score ≥2 as a result of the procedure, combined with those

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