

EDITORIAL COMMENT

## Embolic Protection Devices in the Spotlight\*



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Carotid artery stenting (CAS) is a valid alternative to carotid endarterectomy provided that specific criteria are fulfilled (1-3). These include asymptomatic patients if the procedure is performed with perioperative stroke and death complication rates <3% and symptomatic patients with perioperative stroke and death complication rates <6%. Embolic protection devices (EPDs) are used in CAS for distal embolic event reduction, with a view to improving clinical outcomes. Studies and meta-analyses have pointed out the importance of EPDs mainly in the context of comparisons between CAS and carotid endarterectomy (4,5).

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In a study reported in this issue of *JACC: Cardiovascular Interventions*, Knappich et al. (6) analyzed data from 13,086 CAS procedures (8,360 asymptomatic cases and 4,726 symptomatic ones) performed in Germany over a period of 3 years (2012 to 2014). Data were available and collected from a nationwide quality assurance registry databank operated by the Institute for Applied Quality Improvement and Research in Health. The study's primary outcome measure was in-hospital rates of stroke or death. Secondary outcome measures included major stroke or death and any stroke or death until hospital discharge. Intraprocedural and periprocedural variables included in the analysis were intraprocedural

neurophysiological monitoring, type of procedure (angioplasty, stenting, or both), stent design and stent type, duration of the procedure, antiplatelet medication, and use of EPDs.

Angioplasty and stenting with an EPD was used in 60.4% of cases. In most of the cases, dual antiplatelet therapy was prescribed. The primary outcome event occurred in 2.4% of the patients (317 of 13,086 [1.7%] in asymptomatic and 3.7% in symptomatic patients). Relatively low periprocedural major adverse event rates relative to those reported in randomized controlled trials were noted (4). Univariate analysis demonstrated that the only factor associated with significantly lower primary outcome was EPD use. When multivariate regression analysis was performed, EPD use was associated with a significantly lower rate of any in-hospital stroke and also a lower rate of the secondary outcome of combined in-hospital stroke or death. No other factors independently influenced outcome measures.

Although the clinical benefit of EPDs during CAS has been previously reported, and their use is recommended in current international guidelines, the findings of this study are a valuable addition to the published research. The main reason randomized controlled trials have failed to uncover the significance of EPD use is their design, which is aimed mainly at detecting significant differences between CAS and carotid endarterectomy in hard clinical endpoints rather than in specific technical considerations. In contrast, studies analyzing larger collections of data (e.g., retrospective analysis of registries or meta-analyses statistics) are able to highlight technical details that improve clinical outcomes (7,8). Although multicenter registries lack randomization, they do offer the possibility of investigating a broader range of patients in an everyday clinical practice setting. Therefore, the conclusions are closer to real-world scenarios. In

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contrast, this study suffers from several limitations due to its retrospective, observational character, and outcomes should be interpreted with caution. Data from a national databank may be biased because of the heterogeneous patient population and the possibility of underreporting periprocedural clinical events. This analysis highlights the valuable contribution of EPDs in reducing major adverse events. The use of embolic protection with CAS further complicates a procedure that demands highly developed endovascular skills. Thus, the

improvement of endovascular devices and technical specifications are important factors that could certainly improve outcomes. This study provides significant evidence for CAS procedures and brings the clinical impact of EPDs into the spotlight.

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