Carotid artery stenting (CAS) is a reputable and safe alternative therapeutic option to surgical endarterectomy for treatment of obstructive extracranial carotid atherosclerosis. Because of the routine use of cerebral embolic protection devices (EPDs), post-CAS neurological complications have decreased substantially during the past years, and it is now accepted that the use of EPDs abates postprocedural stroke risk.1

It has been speculated that a proximal EPD may offer more efficient neuroprotection because it is active before target lesion crossing, whereas distal EPDs must cross the lesion to establish neuroprotection.2

As of today, because of the small incidence of post-CAS neurological events, it is difficult to prove the superiority of one EPD compared with another on the basis of the ability to reduce clinically relevant neurological events.

Diffusion-weighted MRI (DW-MRI) is the most sensitive method to diagnose brain infarction at the early phase and is a major improvement compared with computed tomography.3,4

The use of DW-MRI has disclosed that besides clinically apparent postprocedural strokes, CAS, as any other cardiovascular intervention, is associated with the occurrence of new small clinically silent brain lesions on post-treatment DW-MRI.5 In past years, DW-MRI lesions have been valued as surrogate markers of brain embolism to evaluate the relative efficacy of EPDs.

In this issue of Circulation: Cardiovascular Interventions, de Castro-Afonso et al6 reported the results of a single center trial in which the authors evaluated the relative efficacy of proximal (n=21) and distal EPD (n=19) for CAS. They reported a significant reduction in the incidence (15.8% versus 47.6%; P=0.03), number (0.73 versus 2.6; P=0.05), and size (0.81 versus 2.23 mm; P=0.05) of new DW-MRI brain lesions when distal EPDs were used. These results are different and in contrast from what have been reported in the literature to date.

A subcohort analysis from a randomized trial (n=53) that compared proximal versus distal EPD for the treatment of lipid-rich carotid stenosis showed robust reduction in the occurrence of new DW-MRI brain lesions when proximal protection was used (42.8% [9/21] rate in the distal EPD group and 14.3% [2/14] in the proximal EPD).7 Another similar randomized trial reported a robust difference in the proportion of patients with post-CAS new DW-MRI brain lesions (45.2% proximal EPD versus 87.1% distal EPD; P<0.001).8

Looking at these data, it is clear that there is a lack or reproducibility among them. The proportion of patients with new DW-MRI brain lesions varies too much among the studies, even when the same type of protection system is adopted.

How can we explain this data variability? Are these studies comparable according to protocol design, patient selection, lesion characteristics, and operator experience?

Patients’ characteristics were quite similar among the studies. The only notable difference, the rate of symptomatic patients, depicts the specific laboratory clinical practice. In the study by de Castro-Afonso et al8 =80% of the patients were symptomatic. Only one fifth of the patients were symptomatic in the other 2 studies. This can affect the overall incidence of DWI lesion and cannot have a selective effect on a specific EPD and cannot justify the data variability.

Plaque echogenicity can affect the occurrence of post-CAS silent ischemic lesions: hard plaques produce less embolization than soft ones.9 Unfortunately, plaque characteristics have not been described in these studies. This paucity of data precludes a possible comparison and does not help us to justify the data variability.

Of note, there are some minimal differences in carotid stent use. In this study by de Castro-Afonso et al,4 the investigator adopted a stainless steel stent with a closed cell design, similarly the same stent was used by Montorsi et al7 in their study. Bijuklic et al8 adopted a nitinol stent with and hybrid cell design in their randomized trial. These stents have been demonstrated to perform equally in a large prospective registry (E. Stabile et al, personal communication, 2013), and the difference in their use in the cited studies cannot justify opposite findings.

Concerning the specific EPD, it is true that all the studies compared distal with proximal EPDs, but there are some differences among them. Montorsi et al7 and Bijuklic et al8 adopted the endovascular clamping system in their studies for proximal protection, contrarily de Castro-Afonso et al used the flow-reversal system.8 If this difference can justify the disconcerting difference in the results is hard to tell, we could speculate that the endovascular clamping system is smaller and more flexible than the flow reversal one. Consequently it should be less traumatic when it is removed from the carotid artery at the end of the procedure when neuroprotection is not in place any more.

Similarly, even the distal EPD used are different among the studies. The investigators used 2 different types of filter. They
reported a large unpredictability of data (the incidence of new postprocedural DW-MRI detected lesions ranged from 15.8% to 87.1%). Recent bench work evaluation of these 2 different filters demonstrated that they have a comparable ability to capture embolic particle and makes really difficult to explain that data variability.10

CAS outcomes are influenced by operators experience on the procedure itself and on the use of specific EPD.11,12 Both the European studies are coming from catheterization laboratories with robust experience in carotid stenting performed with both proximal and distal EPDs. de Castro-Afonso et al6 stated that they do have a good experience in distal protected CAS (450 CAS procedures in 10 years). This means ≈50 procedures per year, a number that is in accordance with current guidelines and should provide outcomes similar to those of high volume centers with well-experienced operators.13 They also stated that they performed only 12 proximal protected procedures before starting randomization. It is clear that the amount of experience they have with the specific EPDs is not equal and is testified by the fact that the mean procedure time was longer when they used proximal protection. The authors explain this difference stating that flow-reversal device is more complex and requires more technical steps.

Dissecting a CAS procedure, it becomes clear that there is a comparable complexity between a proximal protected and a distal protected one. A proximal protected CAS has 5 procedural steps (external carotid artery selective engagement, protection system placement, wiring of the lesion, stenting, and retrieval of the protection system). Comparably, a distal protected CAS also has 5 procedural steps (guiding catheter placement, wiring of the lesion with protection system, stenting, retrieval of the protection system, and retrieval of the guiding catheter).

If we consider the authors’ experience level on the use of proximal protection, it is clear that they are at the beginning of their learning curve on the use of proximal protection for CAS (<50 cases),11 alternatively they have robust experience in performing distal protected CAS (>400 cases).12 From this difference of experience on the use of specific EPDs, it is sufficient to justify the discrepancy between their reported data and those available in the literature, coming from operators with bulky and similar experience on the use of both proximal and distal EPDs.

At the end of our discussion, we have to conclude that de Castro-Afonso et al6 presented interesting data and reminded us that it is still not clear at all which kind of EPD can provide the best cerebral protection. Looking at their data, operator’s experience seems still to be the best protective factor for the brain of a patient undergoing CAS.

A true randomized trial is needed now more than ever. This amount of conflicting results should be of stimulus for all physicians, scientists, and industry members involved in the field of EPD to make an effort in producing a well-designed randomized clinical trial that will provide a definitive answer on the relative efficacy of each EPD.

Disclosures

None.

References


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