
To the Editor:

We appreciated the editorial by Stabile and Esposito,1 where the authors made an extensive discussion on conflicting results between our trial and others previously published.2,4 The authors’ conjectures on these studies suggest that operator experience with carotid artery stenting procedures seems to be the best brain embolic protective factor. We agree with the authors in most of their comments and here address additional points with the aim of expanding available knowledge of the subject in focus.

Stabile and Esposito considered that a lower experience of operator with flow-reversal device (12 cases versus >400 cases with filters) was the major factor associated with the poorer results obtained by the flow-reversal group of our trial.2 In fact, operator experience imbalances are usually an inherent limitation of interventional trials assessing new devices. Nevertheless, we are not completely convinced that it could definitively explain disparities among results. Indeed, the authors reported that both the European studies come from centers with large experience in carotid artery stenting.1 However, in a recent Brazilian study, that compared filter protection against the same proximal blockage device used in previous trials,3,4 Cano et al5 showed best results with the proximal blockage device, even with a lower operator’s experience of the technique (13 cases).

Furthermore, Stabile and Esposito1 conclude that the operator’s experience imbalance of our study largely explain our final outcomes. The authors argued that our reported differences between flow-reversal and filter procedure times (22.41 versus 16.78 minutes; P<0.001) were in accordance with the lower operator’s experience with the flow-reversal device.1 However, in previous trials, the mean procedure times were also significantly longer with proximal than with distal protection devices 30 versus 22 minutes (P<0.001) reported by Bijuklic et al4 and Cano et al, respectively, whereas Montorsi et al3 did not report procedure times with the proximal protection group. Moreover, it is noteworthy that our mean procedure time with flow-reversal (22.41 minutes) was the shortest, which clearly contradicts Stabile’s opinion.

Another interesting finding that could influence discrepancies among studies was the premedication protocols of antiplatelet and heparin regimens. Although other studies used aspirin (300 mg/d), clopidogrel (75 mg/d), and unfractionated heparin (5000 UI bolus),3–5 we indicated aspirin (300 mg/d), clopidogrel (75 mg/d), and unfractionated heparin (5000 UI bolus).3,4 Although we cannot prove that these differences among premedication protocols explain conflicting results, different premedication protocols have been suggested as a significant factor influencing outcomes.5

Finally, small sample trials using a highly sensitive surrogate outcome measure tool may be associated with a high number of confounder factors and we think that the operator’s experience is one of the most efficient embolic protection factors. However, we cannot forget other variables that could also influence outcomes, such as the embolic protection devices and premedication protocols. We strongly agree with the authors that well-designed randomized trials are necessary to provide more definitive answers.

Disclosures

None.

References

Letter by de Castro-Afonso et al Regarding Article, "Operator's Experience Is the Most Efficient Embolic Protection Device for Carotid Artery Stenting"