Response to Letter by Naggara et al

Regarding Article, “Are Distal Protection Devices ‘Protective’ During Carotid Angioplasty and Stenting?”

Response:

Embolic protection devices (EPD) are currently considered the standard of care during both angioplasty and stenting for carotid stenosis. However, there are limitations associated with the use of these devices, including their relative stiffness; the need for some to cross the lesion before protection is achieved; relative prolonged occlusion time for some; and the recatching phase with crossing of a freshly stented segment, with potential risk to generate distal emboli. In their systematic review of mostly single-institution observational studies, Naggara et al found that the pooled relative risk of stroke or death in patients treated with EPDs (EPD+) compared with those undergoing unprotected carotid artery stenting (EPD−) was 0.55 (95% CI, 0.41−0.73), and they cite methodological shortcomings in our own single-institution study.2 We routinely use protection devices during angioplasty and stenting because we believe their use makes sense despite the lack of strong evidence supporting routine use. However, we also believe there are situations where the EPD itself is the most problematic part of the procedure; in such cases, it is reasonable to perform portions of the procedure or the entire procedure without this protection. Most studies in the analysis of Naggara et al were single-institution series just like our own, with all the methodological shortcomings associated with such studies. Moreover, Naggara and colleagues ignored that most series reported in their updated systematic review (and our own is no exception) included historical EPD− controls for comparison. These patients were treated in the first phase of the learning curve for most operators, and with devices not quite as sophisticated as are ones used in more recent years. In addition, as it is common in the early phases of new technology, such as angioplasty and stenting at that time, patients considered for this treatment were true high-risk surgical candidates with significant comorbidities. This was also reflected in our series where patients treated without an EPD had significantly higher rates of hypertension, symptomatic lesions, and history of myocardial infarction, all factors shown to be associated with higher risk of periprocedural complications after angioplasty and stenting.2 The statement by Naggara et al that in our series the relative risk of stroke, myocardial infarction, or death was 0.42 in EPD+ patients is highly misleading because it does not take into account that these patients were healthier, and were treated by much more experienced operators and with much better devices than were patients who underwent EPD−.

Although the evidence for EPDs comes mostly from observational, single-institution studies, there is strong evidence against them from randomized studies like in International Carotid Stenting Study (ICSS),4 and these high-quality data cannot be ignored. In conclusion, although we support the use of embolic devices in most cases, we do not feel that their use is absolutely necessary, and there may be situations where it is better to go unprotected; this is especially the case when placement of the protection device itself is the riskiest portion of the procedure. The main aim of our article was to trigger a healthy debate on this topic in light of ICSS data.

Disclosures

None.

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