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Letter by Naggara et al Regarding Article, “Are Distal Protection Devices ‘Protective’ During Carotid Angioplasty and Stenting?”

To the Editor:

The usefulness of embolic brain protection (EBP) devices in patients treated by carotid artery stenting is a matter of continuous debate. To date, as all available evidence comes from observational studies, no definite conclusions can be established. Tallarita et al published their experience with 357 patients treated with carotid artery stenting, including 252 patients treated with EBP. The observed risks of stroke, myocardial infarction, or death were 5/252 (2.0%) and 5/105 (4.8%) in patients treated with and without EBP, respectively. As there were no significant differences between protected and unprotected carotid artery stenting, they concluded that the real efficacy of EBP must be questioned. However, they missed some important previous data and, more importantly, misinterpreted the nonsignificant result of their study.

Several meta-analyses of observational studies have shown that EBP is associated with reduced risk of stroke and new, mostly asymptomatic, ischemic lesions on diffusion-weighted magnetic resonance imaging after carotid artery stenting. In our recent systematic review, the pooled relative risk of stroke or death was 0.52 (95% CI 0.30-0.89; I² = 0%) in patients treated with and without EBP, respectively. As there were no significant differences between protected and unprotected carotid artery stenting, they concluded that the real efficacy of EBP must be questioned. However, they missed some important previous data and, more importantly, misinterpreted the nonsignificant result of their study.

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Figure. Pooled relative risks of 30-day stroke or death (A) or stroke (B) according to protected or unprotected CAS status (random-effects models). The systematic review has been updated until June 2011. RR indicates relative risk; CI, confidence interval; I², percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance); P-value associated to Cochran chi-squared statistical test for heterogeneity. Tallarita’s study corresponds to ROCHESTER, 2011.
death in EBP-treated compared with non-EBP-treated patients was 0.55 (95% CI, 0.41–0.73). Based on Tallarita et al data, the relative risk of stroke, myocardial infarction, or death is 0.42 (95% CI, 0.13–1.33) and thus totally in agreement with the pooled relative risk from our systematic review. The direction and magnitude are exactly the same when looking at stroke, myocardial infarction, and death separately. Although advances in technique and patient selection over time may have confounded the apparent protective effect of devices observed in these analyses, the results of the meta-analyses can be considered the most reliable available evidence. Moreover, the potential methodological limitations of previous studies also apply to Tallarita’s study.

The conclusion drawn by the authors illustrates the problem of misinterpreting nonsignificant findings. Studies that do not demonstrate a significant difference between 2 options are often called negative. This term may wrongly imply that the study has shown that there is no difference, whereas the only way that a large probability value can be interpreted is that the study does not provide sufficient evidence for an effect; ie, “absence of evidence is not evidence of absence.” In particular, the sample size of this study was inadequate to address the issue. Including data from Tallarita et al, assuming that deaths were not caused by fatal stroke, the results of the updated meta-analysis (until June 2011) are unchanged, with EBP being strongly associated with a lower risk of 30-day stroke or death (combined relative risk, 0.57; 95% CI, 0.43–0.74; Figure A) or stroke only (combined relative risk, 0.55; 95% CI, 0.41–0.72; Figure B).

Disclosures

None.

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