Drs. Sackett and Oczkowski commented on 2 pivotal trials comparing carotid artery stenting (CAS) with carotid endarterectomy for symptomatic carotid stenosis (1).

While they have described very important basic concepts of evidence-based medicine in relation to noninferiority trials, we felt that an important aspect of trial methodology is of concern. Previous studies have shown that patients undergoing CAS have a higher risk for postprocedural stroke if cerebral protection devices (CPDs) are not used (2). In the EVA-3S study (3), the operators used various CPDs as per the trial protocol, whereas in the SPACE trial (4), these devices were not used in most cases. This very important technical difference impacts outcomes of such high-risk procedures. Differences in methodology always need to be carefully considered when evaluating device trials and when practicing evidence-based medicine.

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