Results of the International Extracranial/Intracranial Arterial Bypass: Implications for Radiologists

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The Cooperative International EC/IC Bypass Study Group has designed, carried out [1], and analyzed [2] a randomized clinical trial to determine if extracranial to intracranial (EC/IC) bypass surgery would benefit patients with appropriate symptomatic atherosclerotic lesions. A total of 1377 patients were assigned randomly to either best medical therapy, or to best medical therapy with surgical bypass, and then were followed for an average of 5 years. Remarkably, not one patient was lost in this follow-up. The results are statistically unequivocal: there is no reduction of stroke or death from stroke by EC/IC bypass surgery in symptomatic patients with internal carotid occlusion, internal carotid stenosis not accessible to endarterectomy, or stenosis or occlusion of the middle cerebral trunk [2-4]. The only real effect of EC/IC bypass in the patients studied was that strokes and death from stroke occurred earlier in the surgical group than in the medical group [2], a result that makes it difficult for surgeons to continue performing this surgery.

The trial design and results have been called an "exemplary" [3] and "remarkable" [4] piece of clinical investigation. This "landmark trial" [3] in the assessment of a surgical procedure must be considered by radiologists, especially neuroradiologists, for its far-reaching implications. First, in the study of patients with ischemic diseases, fine-detail angiography of intracranial vessels as part of standard investigations may not be as important as previously thought since the EC/IC bypass surgery has been discredited. For those of us who have spent time and energy to make such studies safer or who have contributed to the development of new investigative techniques to find potential candidates for EC/IC bypass surgery, there must now be the acceptance of a new reality. Physiologic tests, such as blood flow studies, PET scans, or other anatomic tests such as angiography in postoperative patients, have little meaning as a measurement of treatment—it is the clinical outcome that must be looked at in comparison with identical medical controls.

The gold standard of the efficacy of a diagnostic test should be the clinical outcome of a treatment chosen on the basis of information provided by that test. Many radiologists consider that providing a diagnostic study for the responsible physician to decide on a particular treatment is synonymous with providing good patient care. Now we must accept that this will not always be true. Presumably, the EC/IC bypass, a procedure that deals with inadequate hemodynamics, has failed to have its role verified, because most strokes are caused by emboli rather than inadequate hemodynamics.

We should now expect new clinical trials that will attempt to verify the indications for and efficacy of other treatments that have never been validated. For example, a protocol for a randomized trial to study the clinical results of carotid endarterectomy is being developed. Such a study, if carried out to a definitive result, would have enormous implications for radiologists. If positive, many patients currently being denied surgery by skeptical neurologists will ultimately be treated surgically and need many radiologic studies. If negative, many patients now being studied radiologically for surgical evaluation will no longer need extensive evaluation. Another area concerns the various treatments for back pain syndromes, especially those without definitive neurologic root signs. There is probably as much unverified surgery going on in that area, with diagnostic information provided by a plethora of radiologic studies, as in the treatment of stroke disease.

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This scientific approach to evaluate treatment efficacy should also be embraced by radiologists doing interventional work. This is especially true for controversial treatments. For example, embolization of brain arteriovenous malformations to prevent future hemorrhage and angioplasty of neck vessels to prevent stroke are two controversial areas in interventional neuroradiology that would benefit from a randomized clinical trial organized by involved radiologists. Comparing results of new treatments to aptly chosen historical studies is inaccurate, misleading, and self-serving. We hope that the model of randomized trial will be carried out more often to pinpoint the level of patient outcome in these areas.

REFERENCES