Further lessons from the EC/IC bypass study

H.J.M. Barnett
Professor: Department of Neurology, University of Western Ontario, Canada

Further study of the data from the EC/IC Bypass Trial has been pursued for three specific goals. Firstly, the issue of possible distortion of the conclusions by virtue of noncompliance in the centers with the obligation of randomization has been examined very closely. The thrice-yearly neurosurgical reports from the participating neurosurgeons in the 52 centers which entered 1191 patients (86.5% of the total study), reported that 1249 patients received bypass surgery outside the trial. Of these, 925 were medically ineligible by our protocol requirement, 258 refused to be placed in a trial which required randomization, and a mere 66 were deviated from the trial by a deliberate decision of the participating neurologists or neurosurgeons. The ratio of randomized and eligible to non-randomized and operated is 1191:1294, very close to 1:1. By contrast in the coronary artery study (CASS) this ratio, favoring non-randomization, was 25:1. Our participants in these key centers exhibited a disciplined approach to their commitments to the trial and they failed to randomize willing and eligible subjects on the average of 1.3 times per center every five years.

Secondly, a number of prognostic studies were carried out in the medically-treated groups to clarify the impact of certain important variables on the outcome. The differential outcome of the radiological subgroups of TIA and minor stroke patients were examined. In the medically-treated patients, fatal and non-fatal strokes occurred within 18 months in 20% of those with ICA occlusion and continuing symptoms after the diagnostic arteriogram, and in 18% of the patients with intracranial carotid stenosis. By contrast patients with ICA occlusion without new symptoms and the patients with middle cerebral artery stenosis and occlusion had fatal and non-fatal 18 months stroke rates of 14%. At 5 years the patients with ICA occlusion and new symptoms after arteriographic confirmation, and those with ICA intracranial stenosis patients had 35% rates of fatal and non-fatal stroke; the rates for those with ICA occlusion without new symptoms and for MCA stenosis both stand at 30% and for MCA occlusion at 20%.

Patients who entered the trial with minor stroke had a minimally worse prognosis than those who entered with TIA. The occurrence of recent events (less than 30 days prerandomization) portend greater risk of stroke than later events (30—91 days). Frequency of TIA in the 3 months prior to entry made a substantial difference, with the worst outlook for those having 3 or more compared with those having 2 or less ischemic events in this time-period. Except for those patients entering with recent stroke and having 2 or less TIA's in the 3 months pre-entry period, the highest rate of stroke and fatal stroke was in the 12 weeks period after entry.

Thirdly, further intensive search has been made for possible subgroups which might benefit in stroke-prevention from bypass surgery. None have surfaced including those with recent or frequent ischemic events, and in those without evidence of good collateral supply in the presence of occluded or stenosed MCA or similar occlusive or stenotic lesions of the ICA. It should be re-emphasized that this was not a trial to validate or deny benefit in ischemic recovery. Such a trial has never been conducted.

(Jpn. J. Stroke 9: 481, 1987)