30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomised non-inferiority trial.

BACKGROUND: Carotid endarterectomy is effective in stroke prevention for patients with severe symptomatic carotid-artery stenosis, and carotid-artery stenting has been widely used as alternative treatment. Since equivalence or superiority has not been convincingly shown for either treatment, we aimed to compare the two. METHODS: 1200 patients with symptomatic carotid-artery stenosis were randomly assigned within 180 days of transient ischaemic attack or moderate stroke (modified Rankin scale score of <3) carotid-artery stenting (n=605) or carotid endarterectomy (n=595). The primary endpoint of this hospital-based study was ipsilateral ischaemic stroke or death from time of randomisation to 30 days after the procedure. The non-inferiority margin was defined as less than 2.5% on the basis of an expected event rate of 5%. Analyses were on an intention-to-treat basis. This trial is registered at Current Controlled Trials with the international standard randomised controlled trial number ISRCTN57874028. FINDINGS: 1183 patients were included in the analysis. The rate of death or ipsilateral ischaemic stroke from randomisation to 30 days after the procedure was 6.84% with
carotid-artery stenting and 6.34% with carotid endarterectomy (absolute difference 0.51%, 90% CI -1.89% to 2.91%). The one-sided p value for non-inferiority is 0.09. INTERPRETATION: SPACE failed to prove non-inferiority of carotid-artery stenting compared with carotid endarterectomy for the periprocedural complication rate. The results of this trial do not justify the widespread use in the short-term of carotid-artery stenting for treatment of carotid-artery stenoses. Results at 6-24 months are awaited.

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