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Titel des Beitrags: Results of the Stent-Protected Angioplasty versus Carotid Endarterectomy (SPACE) study to treat symptomatic stenoses at 2 years: a multinational, prospective, randomised trial.

Abstract: BACKGROUND: The SPACE trial is a multinational, prospective, randomised study to test the hypothesis that carotid artery stenting is not inferior to carotid endarterectomy for treating patients with severe symptomatic carotid artery stenosis. We did not prove non-inferiority of carotid artery stenting compared with carotid endarterectomy for the 30-day complication rate, and we now report the results at 2 years. METHODS: Between March, 2001, and February, 2006, patients with symptomatic, severe (≥70%) carotid artery stenosis were recruited to this non-inferiority trial and randomly assigned with a block randomisation design to have carotid artery angioplasty with stenting or carotid artery endarterectomy. 2-year endpoints include several clinical endpoints and the incidence of recurrent carotid stenosis of at least 70%. Clinical and vascular follow-up was done by a certified neurologist. Analyses were by intention to treat and per protocol. This trial is registered with ISRCTN, number 57874028.12. FINDINGS: 1 214 patients were randomly assigned (613 were randomly assigned to carotid angioplasty with stenting and 601 were randomly assigned to carotid endarterectomy). In both the intention-to-treat and per-protocol
analyses the Kaplan-Meier estimates of ipsilateral ischaemic strokes up to 2 years after the procedure and any periprocedural stroke or death do not differ between the carotid artery stenting and the carotid endarterectomy groups (intention to treat 9.5% vs 8.8%; hazard ratio (HR) 1.10, 95%CI 0.75 to 1.61; log-rank p=0.62; per protocol 9.4% vs 7.8%; HR 1.23, 95%CI 0.82 to 1.83; log-rank p=0.31). In both the intention-to-treat and per-protocol populations, recurrent stenosis of 70% or more is significantly more frequent in the carotid artery stenting group compared with the carotid endarterectomy group, with a life-table estimate of 10.7% versus 4.6% (p=0.0009) and 11.1% versus 4.6% (p=0.0007), respectively. Only two incidences of recurrent stenoses after carotid artery stenting led to neurological symptoms. INTERPRETATION: After 2 years’ follow-up, the rate of recurrent ipsilateral ischaemic strokes reported in the SPACE trial is similar for both treatment groups. The incidence of recurrent carotid stenosis at 2 years, as defined by ultrasound, is significantly higher after carotid artery stenting. However, it cannot be excluded that the degree of in-stent stenosis is slightly overestimated by conventional ultrasound criteria.