Abstract:

BACKGROUND: Results from randomised controlled trials have shown a higher short-term risk of stroke associated with carotid stenting than with carotid endarterectomy for the treatment of symptomatic carotid stenosis. However, these trials were underpowered for investigation of whether carotid artery stenting might be a safe alternative to endarterectomy in specific patient subgroups. We therefore did a preplanned meta-analysis of individual patient data from three randomised controlled trials.

METHODS: Data from all 3433 patients with symptomatic carotid stenosis who were randomly assigned and analysed in the Endarterectomy versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) trial, the Stent-Protected Angioplasty versus Carotid Endarterectomy (SPACE) trial, and the International Carotid Stenting Study (ICSS) were pooled and analysed with fixed-effect binomial regression models adjusted for source trial. The primary outcome event was any stroke or death. The intention-to-treat (ITT) analysis included all patients and outcome events occurring between randomisation and 120 days thereafter. The per-protocol (PP) analysis was restricted to patients...
receiving the allocated treatment and events occurring within 30 days after treatment. FINDINGS: In
the first 120 days after randomisation (ITT analysis), any stroke or death occurred significantly more
often in the carotid stenting group (153 [8·8%] of 1725) than in the carotid endarterectomy group (99
[5·8%] of 1708, risk ratio [RR] 1·53, [95% CI 1·20-1·95], p=0·0006; absolute risk difference 3·2
[1·4-4·9]). Of all subgroup variables assessed, only age significantly modified the treatment effect: in
patients younger than 70 years (median age), the estimated 120-day risk of stroke or death was 50
(5·8%) of 869 patients in the carotid stenting group and 48 (5·7%) of 843 in the carotid
endarterectomy group (RR 1·00 [0·68-1·47]); in patients 70 years or older, the estimated risk with
carotid stenting was twice that with carotid endarterectomy (103 [12·0%] of 856 vs 51 [5·9%] of 865,
2·04 [1·48-2·82], interaction p=0·0053, p=0·0014 for trend). In the PP analysis, risk estimates of
stroke or death within 30 days of treatment among patients younger than 70 years were 43 (5·1%) of
851 patients in the stenting group and 37 (4·5%) of 821 in the endarterectomy group (1·11
[0·73-1·71]); in patients 70 years or older, the estimates were 87 (10·5%) of 828 patients and 36
(4·4%) of 824, respectively (2·41 [1·65-3·51]; categorical interaction p=0·0078, trend interaction
p=0·0013). INTERPRETATION: Stenting for symptomatic carotid stenosis should be avoided in older
patients (age>=70 years), but might be as safe as endarterectomy in younger patients. FUNDING:
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