Carotid angioplasty with or without stent placement versus carotid endarterectomy for
treatment of carotid stenosis: a meta-analysis
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CRD summary
This review compared carotid angioplasty with or without stent placement (CAS) with carotid endarterectomy for carotid stenosis. The authors concluded there was no significant difference between treatments for 30-day stroke or death, but CAS reduced myocardial infarction and cranial nerve injury. Incomplete reporting of the review methods and differences in outcomes between studies weaken the robustness of the conclusions.

Authors' objectives
To compare carotid angioplasty with or without stent placement (CAS) with carotid endarterectomy (CEA) for the treatment of carotid stenosis.

Searching
MEDLINE and the Cochrane Library were searched from 1990 to 2003; the search terms were reported. Searches were also conducted of the Stroke Trials database and the Cardiovascular Trials database (references were given). Reviews and proceedings of cardiovascular, neurology and neurosurgery-related conferences and reference lists were screened, and personal files were searched. The manufacturers of stents and the investigators of identified trials were also contacted.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion.

Specific interventions included in the review
Studies that compared CAS with CEA were eligible for inclusion. In all but one of the included studies, stent placement was attempted; one study required the use of a distal protection device.

Participants included in the review
Studies of patients of any age and either gender, with symptomatic or asymptomatic carotid stenosis of any severity, were eligible for inclusion. The carotid stenosis had to be confirmed by either noninvasive imaging or conventional angiography. Most of the studies included 100% of patients with symptomatic carotid stenosis; in one study approximately 30% of the patients were symptomatic.

Outcomes assessed in the review
Inclusion criteria were not specified in terms of the outcomes. The main outcomes of interest were 1-month composite rates of stroke and death, all strokes, disabling strokes, myocardial infarction (MI), cranial nerve injury and major bleeding. The other outcomes assessed were 1-year ipsilateral stroke, major ipsilateral stroke and target lesion revascularisation. The reviewers accepted the definitions used for outcomes in the primary studies.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
Validity was assessed and scored using the Jadad scale, which considers the reporting and handling of randomisation, blinding and handling of withdrawals. The maximum possible score was 5 points. Additional aspects of methodological quality assessed included randomisation technique, independent ascertainment of outcomes, method used to determine
eligibility, inclusion and exclusion criteria, definition of outcomes, and the reporting of adequate data for intention-to-treat analysis. Two reviewers independently assessed validity using the Jadad scale. Additional aspects of methodological quality were extracted by one reviewer and assessed by all four reviewers.

Data extraction
One reviewer extracted some specified data, but the review did not state how many reviewers performed the remaining data extraction. Data were extracted on the occurrence of each outcome of interest, and were used to calculate a relative risk (RR) with 95% confidence intervals (CIs).

Methods of synthesis
How were the studies combined?
The results from the individual studies were combined using a random-effects Mantel-Haenszel meta-analysis. A pooled RR with 95% CI was calculated separately for each outcome of interest. Publication bias was visually assessed using a funnel plot and explored using the methods proposed by Begg and Egger.

How were differences between studies investigated?
Statistical heterogeneity was assessed using the chi-squared statistic (P<0.1 indicated statistical heterogeneity). The meta-analyses were also performed using a fixed-effect model and using a pooled estimate from both fixed-effect and random-effects models. Data for the composite rate of stroke and death were also analysed after omitting 2 studies with the largest number of patients (each in turn and together), after excluding the RCT using distal protection devices, and after only including data from symptomatic patients.

Results of the review
Six RCTs (n=1,177) met the inclusion criteria of the review. Five trials were included in the meta-analysis (n=1,154); one (n=23) was excluded as the sample size and number of events were too small to be included in a valid analysis.

The median quality score according to the Jadad scale was 3 (range: 1 to 3).

No statistically significant difference was observed between CAS and CEA for the 1-month composite stroke or death rate (RR 1.3, 95% CI: 0.6, 2.8, P=0.5), based on 1,154 participants in 5 RCTs. There was evidence of statistical heterogeneity (P=0.07). The sensitivity analyses found that the results were similar when using a fixed-effect model, when excluding 2 RCTs accounting for most patients, and when excluding 1 RCT using distal protection devices. A subgroup analysis of studies of symptomatic patients also found no statistically significant difference. There was no evidence of publication bias from the funnel plot, Begg's test (P=0.62) or Egger's test (P=0.69).

No statistically significant difference was observed between CAS and CEA for the 1-month stroke rate (RR 1.3, 95% CI: 0.4, 3.6, P=0.4) or disabling stroke (RR 0.9, 95% CI: 0.2, 3.5, P=0.9), based on 831 participants in 3 RCTs.

CAS was associated with a statistically significant reduction in 1-month MI rates (RR 0.3, 95% CI: 0.1, 0.8, P=0.02; 814 patients in 2 RCTs) and cranial nerve injury (RR 0.05, 95% CI: 0.01, 0.3, P<0.001; 918 patients in 3 RCTs) compared with CEA.

No statistically significant difference was observed between CAS and CEA for major bleeding (RR 0.6, 95% CI: 0.2, 2.1; 918 patients in 3 RCTs), 1-year or more rates of ipsilateral stroke (RR 0.8, 95% CI: 0.5, 1.2, P=0.2; 814 patients in 2 RCTs) or for revasculisation (RR 0.9, 95% CI: 0.1, 19.4, P=0.9; 657 patients in 2 RCTs).

Authors' conclusions
There was no significant difference between CAS and CEA for 30-day stroke or death, but CAS was associated with a reduced rate of MI and cranial nerve injury.

CRD commentary
The review addressed a clear question defined in terms of the participants, intervention, outcomes and study design. Several relevant sources were searched and attempts were made to locate unpublished studies, thus limiting the possibility of publication bias. Furthermore, a formal assessment of publication bias suggested that this was not present in the review. It was unclear whether any language limitations had been applied. The methods used to select studies were not described and those used to extract the data were not described in full, so it is not known whether any efforts were made to reduce reviewer error and bias. Two reviewers independently assessed validity using the Jadad criteria, thus reducing the potential for bias and errors, but other validity criteria were not extracted in duplicate.

Adequate information on the included studies was presented, and this highlighted differences in terms of risk factors, symptoms and techniques used across studies. In addition, the finding of significant heterogeneity for the meta-analysis of the primary composite outcome suggested that pooling may not have been appropriate. However, the sensitivity analyses and subgroup analysis examining relevant differences did not change the results. Statistical heterogeneity was not reported for the other outcomes, thus it was not possible to assess the appropriateness of pooling these outcomes. In summary, the incomplete reporting of review methods and the uncertainty about differences between the studies mean that the reliability of the authors' conclusions is uncertain.

Implications of the review for practice and research
Practice: The authors stated that the results of large randomised trials such as the Carotid Revascularization Endarterectomy versus Stent trial should provide data to support the use of one method over the other in clinical practice.

Research: The authors did not state any implications for further research.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.