Cerebral protection devices for use during carotid artery angioplasty with stenting: a health technology assessment

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CRD summary
This review assessed the effects of cerebral protection devices during carotid angioplasty and stenting (CAS) in high-risk patients with severe carotid artery disease. The authors concluded that CAS plus cerebral protection may be a safe and effective alternative to carotid endarterectomy. Most of the evidence came from non-randomised studies of apparently variable quality, which severely limits the reliability of the conclusions.

Authors' objectives
To assess the safety and efficacy of cerebral protection devices during carotid angioplasty and stenting (CAS) in high-risk patients with severe carotid artery disease.

Searching
MEDLINE, EMBASE, the Cochrane Library, Biological Abstracts, HealthSTAR, CINAHL, EconLit, Centre for Reviews and Dissemination databases, Dissertation Abstracts International and Web of Science were searched from January 1990 to January 2005. Unpublished and non-peer reviewed studies were sought from internet searches of conference proceedings, technical papers, government-sponsored reports, clinical newsletters, editorials, commentaries and promotional material from manufacturers. SIGLE, Cabot, AMICUS, NLM Gateway and NTIS were also searched for unpublished studies. In addition, the most recent issues of vascular, neurological, radiological and neurosurgical journals were searched and reference lists of selected studies were screened. Only studies that were reported in English were included. The search strategy was reported.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), non-randomised controlled trials, retrospective, prospective or concurrent cohort studies, and clinical series were eligible for inclusion.

Specific interventions included in the review
Studies that compared carotid endarterectomy (CEA) or CAS without protection to CAS with cerebral protection devices were eligible for inclusion. Studies were excluded if they did not mention the use of cerebral protection devices, discussed only non-filter cerebral protection systems, or involved angioplasty and stenting in vessels other than the carotid artery. Where specified, the cerebral protection devices evaluated were GuardWire, NeuroShield, GuardWire plus, AngioGuard, AngioGuard XP, FilterWire and Parodi AES.

Participants included in the review
Studies of high-risk patients with severe carotid artery disease were eligible for inclusion. Where reported, the primary studies included symptomatic and asymptomatic patients with at least 50% stenosis to at least 80% stenosis.

Outcomes assessed in the review
Inclusion criteria were not specified in terms of the outcomes. The review assessed the 30-day incidence of death and stroke (major or minor), 30-day incidence of death, major stroke, minor stroke or myocardial infarction, and adverse effects and procedural or technical success.

How were decisions on the relevance of primary studies made?
Two reviewers independently selected studies using a predefined checklist of inclusion criteria.
Assessment of study quality
Studies were assessed using criteria for specific types of study design that had been derived from peer-reviewed published guidelines (no details of these criteria were stated). The studies were rated as good, good to fair, fair or poor. The authors did not state how the validity assessment was performed.

Data extraction
The data were extracted using a data extraction form, but the authors did not state how many reviewers performed the data extraction. The proportion of patients in each treatment group with each outcome of interest was extracted for each study.

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative and the findings from each study were summarised in tables.

How were differences between studies investigated?
Differences between the studies were apparent from inspection of the tables.

Results of the review
Eight studies (n=3,237) were included in the review: one RCT (n=334), one non-randomised controlled study (n=397), one concurrent cohort study (n=148), two non-concurrent cohort studies (n=438) and three clinical series (n=1,920).

The RCT was rated as 'good' quality. The non-randomised trial was rated 'good to fair'. Two cohort studies were rated 'fair'; the other was rated 'poor'. The three clinical series were rated 'poor'.

Efficacy. Three (two clinical series and a concurrent cohort study) of four studies reported a statistically significantly higher 30-day incidence of death and stroke (major or minor) with CAS compared with CAS plus protection; the fourth study (a clinical series) reported a non-statistically significantly higher incidence with CAS without protection.

None of the three studies (a non-randomised controlled study, a non-concurrent cohort study and a clinical series) assessing the 30-day incidence of death, major stroke or myocardial infarction found any significant difference between CAS plus protection compared with CEA. One study (a non-concurrent cohort study) found a statistically significantly higher incidence of minor stroke with CAS plus protection.

Safety.
Six studies reported the rate at which the cerebral protection device was deployed and retrieved: this ranged from 95.6 to 100%. None of the reported procedural complications had lasting effects. Adverse effects included transient arterial spasm (2.9 to 7.9%), blood flow impairment (2.7 to 13) and arterial wall injury (1 patient).

Cost information
No economic analyses of cerebral protection devices were found. The reviewers estimated that per-case treatment costs for CAS plus protection were slightly higher than for CEA (US$582), primarily due to higher equipment-related costs.

Authors' conclusions
Evidence suggests that CAS plus cerebral protection may be a safe and effective alternative to CEA in high-risk patients with severe carotid artery disease.

CRD commentary
The review addressed a clear question that was defined in terms of the participants, intervention and study design;
inclusion criteria for the outcomes were not specified. The strategy undertaken to identify trials was extensive and included considerable efforts to identify unpublished material. No attempts were made to minimise language bias. Methods were used to minimise reviewer errors and bias in the selection of studies, but it was unclear whether similar steps were taken in the validity assessment and data extraction processes. Validity was assessed, but the criteria used to rate studies from good to fair were not reported.

Given the differences between studies, a narrative synthesis was appropriate. However study quality was not taken into account when reporting the results, thus evidence from higher quality studies was not explicitly highlighted. The lack of complete reporting of review methods and the reliance on predominantly non-randomised studies of apparently variable quality limit the reliability of the conclusions.

Implications of the review for practice and research
Practice: The authors stated that the introduction of filter protection devices into routine clinical practice should be controlled (i.e. limiting it to high-risk, high-grade patients; performing procedures at specific sites by experienced specialists adhering to predefined protocols).

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.