Assessment of short-term outcomes for protected carotid angioplasty with stents using recent evidence

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CRD summary
This review concluded that protected carotid angioplasty with stenting is associated with a low risk of peri-operative adverse outcomes and is appropriate for selective use in patients with a higher risk for surgical complications. The authors' conclusions are partly supported by the evidence presented; however, they are based on a weak study design and need to be confirmed by randomised controlled trials.

Authors' objectives
To determine the short-term outcomes for protected carotid angioplasty with stents (PCAS) in patients with carotid artery stenosis.

Searching
PubMed, PREMEDLINE and the Cochrane CENTRAL Register were searched from 2002 until December 2004 without any language restrictions; the search terms were reported. The bibliographies of the included studies were checked and five journals were handsearched for additional studies.

Study selection
Study designs of evaluations included in the review
The study designs eligible for inclusion were not explicitly stated, although the studies were required to have more than 10 participants. The designs actually included were not stated, but they appeared to be case series. The duration of follow-up was 30 days.

Specific interventions included in the review
Studies reporting data on angioplasty with stents using cerebral protection devices for the treatment of common or internal carotid stenosis were eligible for inclusion. The included studies used a range of different stent types and cerebral protection devices.

Participants included in the review
Patients with carotid artery stenosis undergoing common or internal carotid angioplasty using PCAS techniques were eligible for inclusion. The mean age of the patients in the included studies was 70.3 years, 67% were female, and 55% (range: 13 to 100) had symptomatic carotid stenosis.

Outcomes assessed in the review
Studies reporting data on stroke or death within 30 days of the PCAS procedure were eligible for inclusion. The outcomes of interest in the review were minor stroke, major stroke, death, and stroke and death combined.

How were decisions on the relevance of primary studies made?
The authors stated that a standardised form was used for study selection, but did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

Data extraction
The authors did not state how the data were extracted for the review, or how many reviewers performed the data extraction. The number of events for each of the outcomes of interest was extracted.

**Methods of synthesis**

*How were the studies combined?*

The authors reported a weighted average with 95% confidence interval (CI) for combined stroke and death. They also used generalised estimating equations with 95% CI to derive a pooled estimate of the rate of major stroke, minor stroke, death, and stroke or death.

*How were differences between studies investigated?*

The chi-squared test was used to assess heterogeneity. The Spearman rank coefficient was used to assess correlation between potential prognostic variables and the primary outcomes.

**Results of the review**

Twenty-six studies (n=2,992) were included.

Thirty days after the PCAS procedure, the rate of minor stroke was 0 to 6%, the rate of major stroke was 0 to 3%, and the death rate was 0 to 7%.

The pooled estimate was 2.4% (95% CI: 1.8, 3.0) for the combined stroke and death rate, 1.1% (95% CI: 0.9, 1.3) for minor stroke, 0.6% (95% CI: 0.4, 0.8) for major stroke, and 0.9% (95% CI: 0.5, 1.3) for death. The weighted average for combined stroke and death was 1.1% (95% CI: 0.9, 1.3).

Studies with a higher proportion of men and a higher proportion of symptomatic patients did not show a higher proportion of stroke or death.

No evidence of statistically significant heterogeneity was found.

**Authors' conclusions**

The rate of peri-operative adverse events associated with the PCAS procedure is relatively low. Selective use of PCAS for the treatment of carotid artery stenosis in patients at a higher risk from carotid endarterectomy (CEA) is appropriate.

**CRD commentary**

The review question was clear, but the authors did not adequately describe how they performed the study selection, data extraction and quality assessment processes. In addition, the review considered evidence from case series, so the review findings may not be reliable. Although the databases searched were reasonably comprehensive, relevant studies might have been missed since the review only considered studies published between 2002 and 2004.

No statistically significant heterogeneity was detected, although the studies appeared to be clinically heterogeneous. The authors pointed out that they were unable to assess the effects of PCAS on subgroups of patients, thus the review findings may not be generalisable to all subgroups, particularly patients who were symptomatic, used different stents or protection devices, or had a different degree of stenosis.

Overall, the authors’ conclusion about the risk of peri-operative adverse outcomes associated with PCAS appears to be supported by the evidence presented, although it was not possible to verify that selective use of PCAS is appropriate for the treatment of carotid artery stenosis in patients at a higher risk of surgical complications from CEA, since the authors did not review studies that compared PCAS with CEA.

**Implications of the review for practice and research**

Practice: The authors stated that selective use of PCAS to treat carotid stenosis in patients at highest risk for surgical
complications is appropriate until data becomes available from randomised controlled trials comparing CEA and PCAS.

Research: The authors stated that randomised controlled trials are needed to provide short- and long-term data on the effects of PCAS for the treatment of carotid artery stenosis.

Bibliographic details

PubMedID
16376197

DOI
10.1016/j.jvs.2005.08.020

Indexing Status
Subject indexing assigned by NLM

MeSH
Angioplasty /methods; Blood Vessel Prosthesis; Blood Vessel Prosthesis Implantation /instrumentation; Carotid Stenosis /surgery; Humans; Stents; Treatment Outcome

AccessionNumber
12006000527

Date bibliographic record published
31/08/2006

Date abstract record published
31/08/2006

Record Status
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.