Title **Endovascular Treatment of Carotid Stenosis**

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Aim

To evaluate the clinical effectiveness and cost effectiveness of protected carotid stenting (PCAS) as compared to carotid endarterectomy (CEA) for patients with carotid stenosis.

Conclusions and results

Evidence on the performance of PCAS in the short term and long term is insufficient to make any other statement than that PCAS is a promising emerging technology, and more expensive than CEA. Most published literature is based on clinical trials or observational studies in centers of clinical excellence. Surgeons in clinical trials are usually rigorously screened before they can participate in the trial and usually have an above-average level of experience with the procedure. Patients also are carefully selected for trials and are generally not representative of the entire patient population for whom the technology is likely to be used. If the procedure becomes widely available without clear guidance or conditions for its use, the outcomes will deteriorate. The economic literature review showed that PCAS is not cost effective relative to CEA. Additional costs for the stents and cerebral protection devices do not outweigh the short-term savings associated with shorter lengths of stay nor the slightly fewer short-term complications. However, outcomes and costs will inevitably change if the technology becomes more widely used as the technology advances and operators gain experience with the procedure. Both changes have implications for the effectiveness and costs of the technology.

Recommendations

- PCAS should be made available to patients that are at high risk for stroke, but are poor candidates for surgery. Information on these interventions should be registered prospectively.
- Experimental use of PCAS in other patients should be limited to ongoing randomized clinical trials (RCTs) comparing PCAS with CEA, eg, the ICSS trial.
- Experimentation with PCAS outside clinical trials is ethically and economically difficult to justify.
- Treatment decisions should be made by vascular teams, consisting of at least one surgeon, radiologist, or neurologist (or a geriatrician replacing the neurologist). Centers should have sufficient experience (sufficient number of carotid interventions) and maintain sufficient experience.
- Registration of the outcomes of all carotid interventions should be improved.
- CEA remains the standard treatment. Exceptions should be motivated.

Methods

A literature search on the clinical and cost effectiveness of PCAS is supplemented with information from experts. Rapidly evolving technology is less amenable to the standard methodology of systematic literature review. Besides technological changes, the clinical conditions are important for the outcome of the intervention, ie, skill of the interventionist, preference of the surgeon or radiologist for one intervention or another, excellence of the center, and the choice of device. These considerations guide the interpretation of the literature on PCAS. Three external validators with international expertise in this domain validated the scientific report.

Further research/reviews required

This report will need to be updated after publication of the results of the major RCTs comparing CEA with PCAS. Ethical committees should define the conditions for introducing expensive emerging technology.

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