

Carotid angioplasty and stenting: current status

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Abstract

CAROTID ANGIOPLASTY AND STENTING HAS RECENTLY EMERGED as a popular alternative to endarterectomy for the treatment of carotid atherosclerosis. Carotid endarterectomy has been scientifically validated, but many believe carotid angioplasty and stenting to be a less invasive, less expensive and equally safe and effective method of treatment. The evidence for and against the use of each procedure will be discussed.

Stroke is one of the leading causes of morbidity and mortality in North America, affecting over half a million patients at a cost of over 30 billion dollars a year.¹ Carotid endarterectomy (CEA), the surgical removal of atherosclerotic plaque from the cervical carotid bifurcation, provides effective stroke prophylaxis in symptomatic and asymptomatic patients, with 70% or greater stenosis of the internal carotid artery.²⁻⁵ The North American Symptomatic Carotid Endarterectomy Trial (NASCET), a randomized trial conducted at 50 clinical centers throughout the United States and Canada, found that CEA was highly beneficial for symptomatic patients with high-grade carotid stenosis.² Carotid angioplasty and stenting (CAS)⁶⁻⁸ is currently being used by some as an alternative method of treatment; this practice is controversial, however.

Transluminal angioplasty is a percutaneous interventional technique in which an endovascular balloon catheter is used to dilate a vessel mechanically. The procedure has been used successfully since the early 1970s to treat peripheral vessel atherosclerotic disease. Metallic stents can be deployed following angioplasty to maintain vascular patency and to reduce restenosis rates. The first carotid balloon angioplasty was reported in 1980;⁹ since then there has been an exponential growth in the number of carotid angioplasties performed worldwide.¹⁰ These procedures were initially performed by cardiologists, who found it an easy progression from the coronary to the carotid vessels.^{6,10,11} Despite widespread use, there has been no scientific validation of its utility.

We review the benefits and risks associated with CEA and CAS and summarize the debate over which treatment is optimal.

Carotid endarterectomy

The benefits of CEA for stroke prevention have been definitively shown in NASCET.² In this prospective study 659 symptomatic patients with severe carotid stenosis were randomized to a medical or surgical group. All patients received optimal medical management, including antiplatelet medication, and the surgical group underwent CEA. The absolute risk reduction of any ipsilateral stroke at 2 years was 17% for patients in the surgical group ($p < 0.001$). For the 1415 patients who underwent CEA the overall rate of perioperative stroke or death was 6.5%,¹² and perioperative medical complications, most of them cardiovascular, were seen in less than 10% of patients.¹³ The benefits have been confirmed in at least 2 other randomized controlled trials of CEA for patients with symptomatic carotid stenosis,^{3,5} in a study of 1662 patients with asymptomatic carotid artery stenosis⁴ and among symptomatic patients with moderate (58%–69%) stenosis.¹⁴

These clinical trials have shown the unequivocal benefits of CEA. The benefits would, however, be lost if complication rates higher than those reported are experienced. In addition, there are concerns that inappropriate overutilization of CEA

Review

Synthèse

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[Return to May 16, 2000 Table of Contents](#)

could occur and that complication rates may be higher outside academic centres.¹⁵

Carotid angioplasty and stenting

The first series of CAS reports appeared in the 1980s.^{16–18} Indications for CAS initially included restenosis after prior CEA, radiation-induced disease and medical conditions precluding surgery (e.g., coronary artery or chronic pulmonary disease). Although patient populations and disease conditions were often heterogeneous, retrospective reviews suggested that CAS could be a safe and less invasive alternative to CEA (Fig. 1).

Enthusiasm for CAS increased in the 1990s. A group at the University of Alabama who performed 271 procedures in 231 patients, 79% of whom were ineligible for surgery, reported a technical success rate of 99%, with a major stroke and death rate at 30 days of 1.4% and a minor stroke rate of 7.4%.^{11,19,20} In their latest 100 cases the complication rate was under 2%.²⁰

The North American Cerebral Percutaneous Transluminal Angioplasty Registry (NACPTAR) documented an 83% success rate in 165 nonsurgical patients, with a 30-day combined stroke and death rate from all causes of 9%.²¹ A

major prospective trial of CAS versus CEA is currently under way in Europe; the Carotid and Vertebral Transluminal Angioplasty Study (CAVATAS)²² has enrolled 504 patients and has reported a CAS success rate of 96% and complication rates of 6% in each of the treatment groups.

The debate

For years cardiologists and interventional neuroradiologists have emphasized the lower patient risk and cost of angioplasty when compared with surgery.⁸ Among the several technical issues that still must be resolved is whether cerebral protection using a downstream balloon is needed during angioplasty. This is advocated by some investigators as an essential precaution to decrease cerebral emboli,^{23,24} while others see it as a needless additional intervention that may actually increase risk.²⁵

There is also debate over whether stenting is always necessary after angioplasty. Serruys and colleagues²⁶ reported that clinical and angiographic outcomes were better in patients who received a stent than in those who received standard coronary angioplasty. In addition, the rates of symptomatic restenosis following CAS (7%–16%)²⁷ compared with rates following coronary angioplasty are generally low.

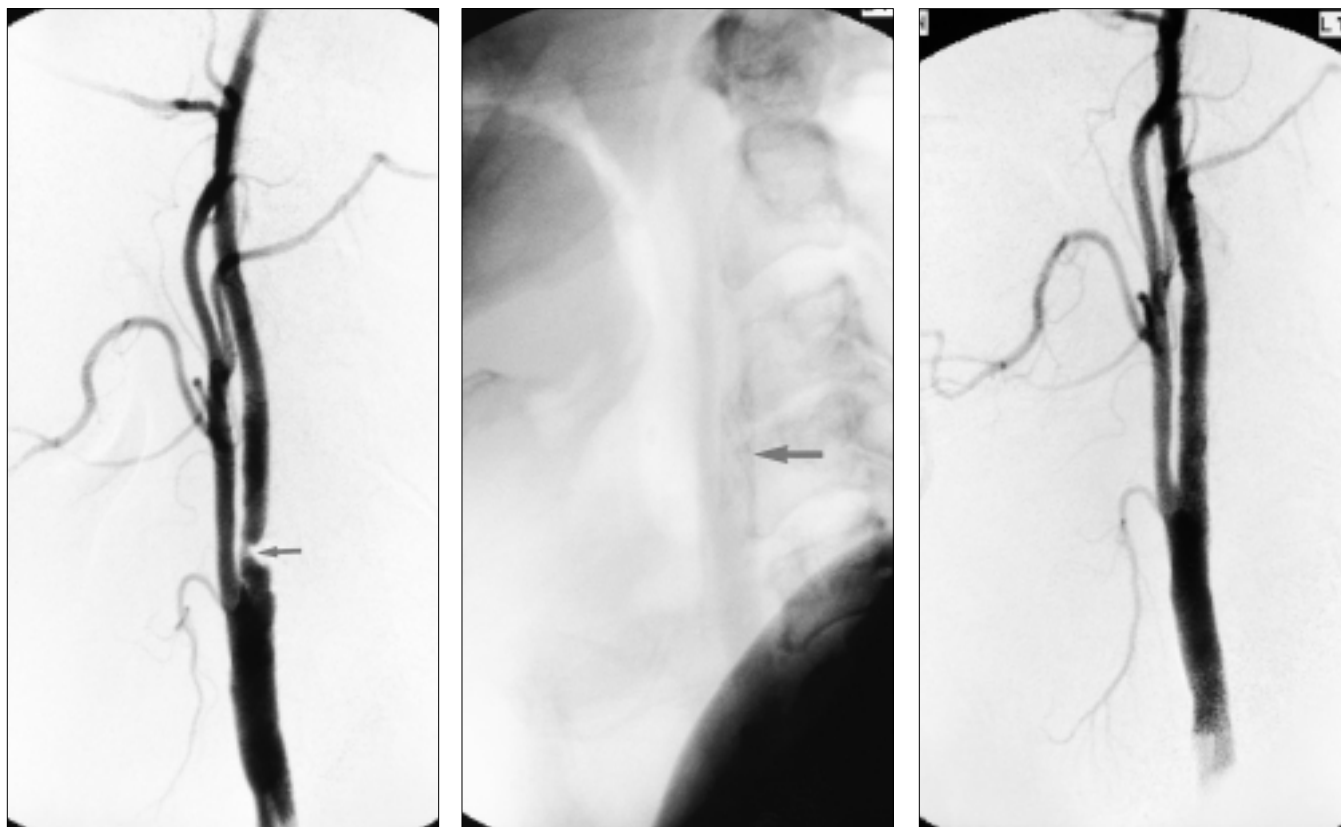


Fig. 1: Left: left common carotid digital subtraction arteriogram (lateral neck view) showing severe stenosis of the internal carotid artery (arrow). Centre: unsubtracted lateral view of the neck, showing stent deployment (arrow). Right: left common carotid digital subtraction arteriogram (lateral view) post-angioplasty and stenting, showing excellent re-expansion of the internal carotid artery.

This may relate to differences in surface exposure and tissue response between elastic (i.e., carotid) and muscular (i.e., coronary) arteries after balloon dilatation. Acute platelet deposition and chronic neointimal proliferation have been shown to be much greater in coronary vessels.²⁸

Surgeons have recommended caution be exercised when CAS is being considered.²⁹⁻³³ The quality of many of the CAS studies has been criticized, in that they are uncontrolled retrospective case series from single institutions. There is also concern that a very heterogeneous group of individuals unfamiliar with the management of cerebrovascular disease might be attracted to this relatively simple procedure.³³ The theoretical appeal of easily dilating the carotid artery has been tempered by the idea that "it simply does not seem safe to balloon [dilate] a lesion containing hemorrhagic, ulcerative or necrotic components because thromboembolic events may be inevitable and complications devastating."³⁴ Long-term patency rates and effects of stent fatigue are still unknown, and the difficulties of surgical repair of restenosis after CAS have only recently been described.³⁵

The true incidence of embolic events during angioplasty may be underestimated. Using transcranial Doppler monitoring during carotid procedures Jordan and colleagues detected numerous microemboli during catheter and balloon manipulation^{36,37} and estimated that the rate of microemboli with CAS may be up to 8 times the rate associated with CEA³⁶ (Fig. 2). A recent review of 53 CAS procedures performed in a group of high-risk patients ineligible for surgery reported a 15% perioperative rate of stroke and death.³⁸

The safety of CAS over that of CEA has thus been challenged by Jordan and colleagues,^{39,40} who retrospectively analyzed outcomes of 312 patients who underwent CAS and 121 who had CEA performed under local or regional anesthesia. The stroke and death rate for the CAS group was 9.7%, and 32.6% of the patients needed additional monitoring for cardiopulmonary complications. In the CEA group the stroke and death rate was 0.9%, and 17.4% re-

quired additional monitoring.³⁹ The cost advantage of CAS over CEA was also challenged after hospital charges for the 2 procedures were compared (average total charges for CAS patients, US\$24 848 and for CEA patients, US\$19 247).⁴¹

The design of the CAVATAS trial, the largest prospective comparison of CAS and CEA, has been criticized because patient entry appeared to be selective and nonconsecutive.⁴² Patients were included or excluded on the basis of angiographic stenosis morphology, associated medical conditions or local experience with each procedure. However, results of the trial to date²² indicate that carotid surgery and angioplasty are equivalent in safety and efficacy but that angioplasty has advantages with respect to nerve injury and cardiac complications.

The future

Answers to the questions surrounding the benefits of CAS lie in prospective, multicentre, randomized controlled trials. These has long been called for,^{7,15,30,43} and some believe that, until the trials are conducted, the procedure should only be performed as part of a rigid research protocol.^{29,31,44,45} Accordingly, the US Food and Drug Administration is withholding approval for the use of stents in carotid arteries, and the US Health Care Finance Administration does not currently provide reimbursement for CAS.

The Carotid Revascularization Endarterectomy versus Stent Trial (CREST) comparing CEA and CAS has recently been funded by the US National Institutes of Health.⁴⁶ The primary goal of this trial is to assess the relative clinical efficacy of the 2 procedures. In addition, the following will be assessed:

- differential efficacy among men and women
- preprocedural and postprocedural morbidity
- restenosis rates
- differences in quality of life and cost effectiveness
- subgroups of patients at differential risk

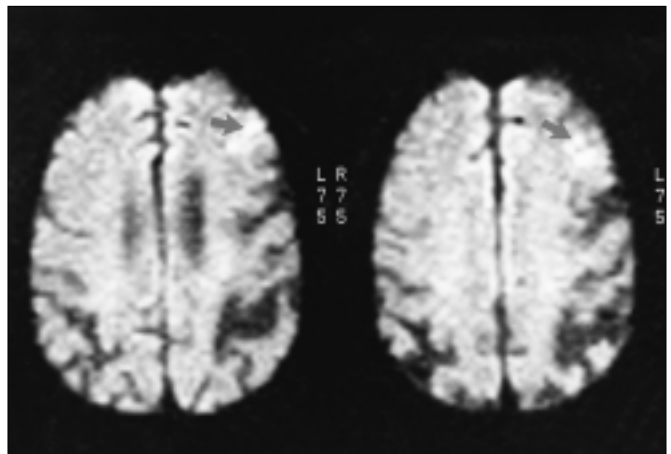
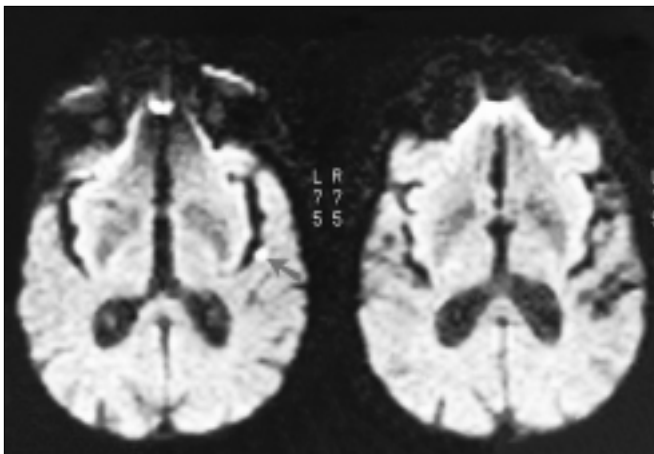


Fig. 2: Perfusion-weighted MRI, post-angioplasty and stenting, showing focal high-signal abnormalities consistent with acute infarcts in the left hemisphere (arrows). The patient was asymptomatic.

Approximately 2200 patients with symptomatic neurologic events and severe (> 70%) carotid stenosis will be randomized to either CAS or CEA over 3 years; 40 North American centres have agreed to participate to date, and it is anticipated that the study will take 5 years to complete. Until the results of this and other trials become available, CAS should be reserved for patients with significant medical contraindications to surgery. CEA is still the only procedure that has been clearly shown to reduce the risk of stroke in symptomatic patients with severe carotid stenosis.

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