

Carotid artery stent placement for symptomatic extracranial carotid stenosis

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg389

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG191.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of carotid artery stent placement for symptomatic extracranial carotid stenosis is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and audit or research.
- 1.2 During the consent process, clinicians should ensure that patients understand the risk of stroke and other complications associated with this procedure. Clinicians should also ensure that patients understand the reasons for advising carotid artery stent placement rather than endarterectomy in their particular case.
- 1.3 Patient selection should be carried out by a multidisciplinary team, which should include an interventional radiologist or a neuroradiologist, a vascular surgeon and a physician with a specialist interest in stroke.
- 1.4 This procedure should only be carried out by clinicians with specific training and expertise in the technique who regularly perform complex endovascular interventions. The Royal College of Radiologists has produced training standards.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Stenosis of the extracranial carotid arteries due to atherosclerosis can cause transient ischaemic attacks (TIAs) or stroke. Patients with symptomatic carotid stenosis are at increased risk of stroke.
- 2.1.2 Good medical control of cardiovascular risk factors is essential. Prompt treatment of the carotid stenosis is carried out in selected patients: carotid endarterectomy is the standard treatment.

2.2 Outline of the procedure

- 2.2.1 Carotid stenting is usually carried out with the patient under local anaesthesia using a percutaneous transfemoral approach. A guidewire is passed into the carotid artery, commonly with a cerebral protection device at its tip, which is designed to prevent any debris from passing into the cerebral circulation during the procedure. The carotid stenosis is then usually pre-dilated using a balloon catheter. A metal mesh (stent) is inserted to treat the stenosis, with the aim of preventing both embolism and restenosis.
- 2.2.2 Carotid stenting is a less invasive percutaneous procedure than carotid endarterectomy which aims to avoid wound complications associated with that procedure.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 2.3.1 The efficacy outcomes described below include stroke or death that occurred

more than 30 days after the procedure (unless specified otherwise). Stroke or death occurring on or before 30 days were considered to represent safety outcomes.

- 2.3.2 A meta-analysis of 3,433 symptomatic patients reported no significant difference in mortality between patients treated by stenting (2% [32 out of 1,725]) and endarterectomy (1% [22 out of 1,708]; relative risk [RR] 1.44, 95% confidence interval [CI] 0.84 to 2.47; $p=0.18$) at 120-day follow-up. A randomised controlled trial (RCT) of 2,522 patients reported no significant difference in mortality between patients treated by stenting (11%) and those treated by endarterectomy (13%; hazard ratio [HR] 1.12, 95% CI 0.83 to 1.51; $p=0.45$) at median 2.5-year follow-up (absolute figures not stated).
- 2.3.3 A UK national register of 953 symptomatic patients treated by stenting reported a 5-year rate of mortality, disabling stroke or mortality, and stroke of 19%, 21% and 7% respectively (data on 173, 167 and 156 patients respectively were available for analysis).
- 2.3.4 An RCT of 1,713 symptomatic patients reported no significant difference in the rate of disabling stroke or death between the stenting group (5% [43 out of 853]) and the endarterectomy group (3% [27 out of 857]; HR 1.28, 95% CI 0.77 to 2.11) at 120-day follow-up.
- 2.3.5 The RCT of 2,522 patients reported that among symptomatic patients there was no significant difference in the rate of stroke or death following stenting (8%) and endarterectomy (6%; HR 1.37, 95% CI 0.90 to 2.00; $p=0.14$) at 2.5-year follow-up (absolute figures not stated). A non-randomised controlled study including 1,086 symptomatic patients reported a significant difference in the rate of stroke or death following carotid stenting (8%) and endarterectomy (5%) in symptomatic patients ($p=0.01$; absolute figures and follow-up not stated).
- 2.3.6 An RCT of 1,214 symptomatic patients treated by stenting or endarterectomy reported that both groups had a 2% rate of ipsilateral stroke during 31-day to 2-year follow-up (HR 1.17, 95% CI 0.51 to 2.70; p =not significant).
- 2.3.7 The Specialist Advisers listed a key efficacy outcome as long-term stroke prevention.

2.4 Safety

- 2.4.1 The meta-analysis of 3,433 symptomatic patients reported no significant difference in mortality at 30-day follow-up between patients treated by stenting (1% [19 out of 1,679]) and those treated by endarterectomy (<1% [10 out of 1,645]; RR 1.86, 95% CI 0.87 to 4.00; $p=0.10$). In the UK national register of 953 symptomatic patients treated by stenting, 30-day post-procedural mortality was 2%.
- 2.4.2 The meta-analysis of 3,433 symptomatic patients reported that the rate of stroke at 30-day follow-up was significantly higher following stenting (7% [125 out of 1,679]) than following endarterectomy (4% [70 out of 1,645]; RR 1.74, 95% CI 1.31 to 2.32; $p=0.0001$): this excess was attributable largely to patients older than 70 years. The UK national register of 953 symptomatic patients treated by stenting reported disabling stroke in 1% (8 out of 829) of patients, non-disabling stroke in 3% (26 out of 829) and TIA in 4% (32 out of 829) at 30-day follow-up.
- 2.4.3 An RCT of 2,252 patients reported that there was a significantly lower incidence of perioperative myocardial infarction following carotid stenting (1% [14 out of 1,262]) than following endarterectomy (2% [28 out of 1,240]; HR 0.50, 95% CI 0.26 to 0.94, $p=0.03$).
- 2.4.4 The Specialist Advisers listed known adverse events as access site complications, peripheral emboli, carotid artery rupture, femoral catheter access site damage and reactions to contrast material. They considered radiation-induced neoplasia to be a theoretical adverse event.

2.5 Committee comments

- 2.5.1 The Committee noted recent observational studies were from the US where case mix is different from the UK.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).