

Carotid artery stent placement for asymptomatic extracranial carotid stenosis

Interventional procedures guidance

Published: 27 April 2011

www.nice.org.uk/guidance/ipg388

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. However, 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.

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.

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.

1 Guidance

This document replaces previous guidance on carotid artery stent placement for carotid stenosis (interventional procedure guidance 191).

- 1.1 Current evidence on the safety of carotid artery stent placement for asymptomatic extracranial carotid stenosis shows well-documented risks, in particular the risk of stroke. The evidence on efficacy is inadequate in quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake carotid artery stent placement for asymptomatic extracranial carotid stenosis should take the following actions.
- Ensure that patients and their carers understand the uncertainty about the procedure's efficacy, the risk of stroke and other complications, and the reasons for advising stenting rather than endarterectomy or best medical treatment alone in their particular case. Patients should be provided with clear written information. In addition, the use of NICE's [information for patients](#) ('Understanding NICE guidance') is recommended.
- 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 specialist interest in stroke. Cardiac surgeons and cardiologists should liaise with the multidisciplinary team in relation to patients being considered for this procedure as a prelude to cardiac surgery.
- 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.
- 1.5 NICE encourages clinicians either to enter patients into the [ACST-2 trial](#) (Asymptomatic Carotid Artery Surgery Trial 2) or to submit data to the Endovascular Carotid Register, run by the [British Society of Interventional Radiology](#) and the [Vascular Society of Great Britain and Ireland](#). NICE may review this procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Asymptomatic stenosis of the extracranial carotid arteries may be identified incidentally through imaging – for example, before cardiac surgery. Patients with carotid stenosis are at an increased risk of transient ischaemic attack (TIA) or stroke; but the risk is lower compared with patients with symptomatic stenosis.
- 2.1.2 Good medical control of cardiovascular risk factors is essential. Severe asymptomatic stenoses are sometimes treated by carotid endarterectomy.

2.2 Outline of the procedure

- 2.2.1 Carotid stenting is 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.

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 Efficacy

- 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 randomised controlled trial (RCT) of 2522 patients reported that among asymptomatic patients there was no significant difference in the rate of stroke or death following stenting or endarterectomy (5% vs 3%; hazard ratio [HR] 1.86, 95% confidence interval [CI] 0.95 to 3.66; $p = 0.07$) at a median 2.5-year follow-up (absolute figures not stated). A non-randomised controlled study including 8706 asymptomatic patients reported no significant difference in stroke or death rate following carotid stenting (2%) and endarterectomy (2%) in asymptomatic patients ($p = 0.16$) (absolute figures and follow-up not stated).
- 2.3.3 A UK national register of 291 asymptomatic patients reported 5-year event rates as follows: stroke 4%; stroke or TIA 8%; mortality or disabling stroke 19%; and mortality 18%.
- 2.3.4 The Specialist Advisers listed key efficacy outcomes as long-term patency and freedom from stroke or death.

2.4 Safety

- 2.4.1 The UK national register of 291 asymptomatic patients reported a mortality rate of < 1% (1/181) at 30-day follow-up.
- 2.4.2 A meta-analysis of 2 studies including 140 asymptomatic patients reported no significant difference in stroke or death rate at 30-day follow-up between the stenting group (4% [3/73]) and the endarterectomy group (3% [2/63]) (odds ratio 1.06, 95% CI 0.16 to 6.94; $p = 0.96$). The UK national register of 291 asymptomatic patients reported death or disabling stroke rate of 1% (2/181) by 30-day follow-up.
- 2.4.3 The UK national register of 291 asymptomatic patients reported the following event rates: disabling stroke < 1% (1/181), non-disabling stroke 1% (2/181), TIA 2% (4/181) and myocardial infarction < 1% (1/181) at 30-day follow-up. The RCT of 85 asymptomatic patients reported no perioperative strokes or TIAs in either the stenting group or the endarterectomy group.
- 2.4.4 The RCT of 2252 patients with either symptomatic or asymptomatic stenosis reported that there was a significantly lower incidence of perioperative myocardial infarction following carotid stenting (1% [14/1262]) than following endarterectomy (2% [28/1240]) (HR 0.50, 95% CI 0.26 to 0.94; $p = 0.03$).

- 2.4.5 The Specialist Advisers listed anecdotal or reported adverse events related to this procedure as femoral artery damage and renal failure. They considered theoretical adverse events to be dissection, restenosis or contrast allergy/nephrotoxicity.

2.5 Committee comments

- 2.5.1 The Committee noted that the case mix in recent observational studies from the US is substantially different to that in the UK.
- 2.5.2 The Committee noted uncertainties about the benefits of carotid stenting before cardiac surgery.

3 Further information

- 3.1 For related NICE guidance see our [website](#).

Information for patients

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

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

It updates and replaces NICE interventional procedure guidance 191.

We have produced a [summary of this guidance for patients and carers](#). Information about the

evidence it is based on is also [available](#).

Changes since publication

20 December 2011: minor maintenance

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Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

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

Accreditation

