



# Carotid artery stent placement for symptomatic extracranial carotid stenosis

Interventional procedures guidance Published: 27 April 2011

www.nice.org.uk/guidance/ipg389

This guidance replaces IPG191.

#### 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 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.
- 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.

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, available at www.nice.org.uk/guidance/IP/8/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.
- A meta-analysis of 3433 symptomatic patients reported no significant difference in mortality between patients treated by stenting (2% [32/1725]) and endarterectomy (1% [22/1708]) (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 2522 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).
- 2.3.2 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).
- 2.3.3 An RCT of 1713 symptomatic patients reported no significant difference in the rate of disabling stroke or death between the stenting group (5% [43/853]) and the endarterectomy group (3% [27/857]) (HR 1.28, 95% CI 0.77 to 2.11) at 120-day follow-up.
- 2.3.4 The RCT of 2522 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 1086 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).
- 2.3.5 An RCT of 1214 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).
- 2.3.6 The Specialist Advisers listed a key efficacy outcome as long-term stroke prevention.

### 2.4 Safety

- 2.4.1 The meta-analysis of 3433 symptomatic patients reported no significant difference in mortality at 30-day follow-up between patients treated by stenting (1% [19/1679]) and those treated by endarterectomy (< 1% [10/1645]) (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 3433 symptomatic patients reported that the rate of stroke at 30-day follow-up was significantly higher following stenting (7% [125/1679]) than following endarterectomy (4% [70/1645]) (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% (8/829) of patients, non-disabling stroke in 3% (26/829) and TIA in 4% (32/829) at 30-day follow-up.
- 2.4.3 An RCT of 2252 patients 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).
- 2.4.4 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

3.1 For related NICE guidance see <u>www.nice.org.uk</u>

#### 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. See <a href="www.nice.org.uk/guidance/">www.nice.org.uk/guidance/</a> <a href="https://linearch.nice.org.uk/guidance/">IPG389/publicinfo</a>

## **Endorsing organisation**

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.

#### Accreditation

