

# Carotid artery stent placement for carotid stenosis

## 1 Guidance

1.1 Current evidence suggests that stent placement for carotid artery stenosis is safe and efficacious in the short term. However, long-term efficacy in terms of prevention of stroke and restenosis is unknown, and there are uncertainties about the benefits for asymptomatic patients. Therefore, clinicians wishing to undertake this procedure should take the following actions.

- Ensure that patients understand the uncertainty about the long-term safety and efficacy of the procedure and provide them with clear written information. Use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from [www.nice.org.uk/IPG191publicinfo](http://www.nice.org.uk/IPG191publicinfo)).
- Audit and review clinical outcomes of all patients having carotid artery stent placement for carotid stenosis.

1.2 Clinicians undertaking this procedure should have adequate training before performing the technique. The Royal College of Radiologists have produced standards for training.

1.3 Selection of patients for this procedure should involve a multidisciplinary team, which could include a vascular surgeon, an interventional radiologist, a neuroradiologist, a neurologist, a stroke physician and a cardiologist.

1.4 Research is ongoing, and clinicians are strongly encouraged to enter symptomatic patients into the ongoing International Carotid Stenting Study (ICSS, [www.ion.ucl.ac.uk/cavatas\\_icss/index2.htm](http://www.ion.ucl.ac.uk/cavatas_icss/index2.htm)). Carotid stent procedures performed outside of the ICSS trial should be submitted to the Endovascular Carotid Registry held by the British Society for Interventional Radiology and the Vascular Society of Great Britain and Ireland ([www.bsir.org](http://www.bsir.org) and

[www.vascularsociety.org.uk](http://www.vascularsociety.org.uk)). The Institute may review the procedure upon publication of further evidence.

## 2 The procedure

### 2.1 Indications

2.1.1 Stroke secondary to carotid stenosis occurs when a major portion of one or both carotid arteries is narrowed or blocked. Carotid stenosis increases the risk of ischaemic stroke by acting as an embolic source.

2.1.2 People with asymptomatic carotid stenosis have a lower risk of stroke than those with symptomatic disease.

2.1.3 Carotid endarterectomy has been the standard treatment for patients with symptomatic stenosis. Carotid stenting is a less invasive percutaneous procedure than carotid endarterectomy for the treatment of carotid stenosis. It has evolved from percutaneous transluminal angioplasty and avoids the need for an incision in the neck.

### 2.2 Outline of the procedure

2.2.1 Carotid stenting is carried out under local anaesthesia and involves passing a fine wire into the carotid artery via the femoral artery in the groin. A small balloon catheter may be passed over the wire to pre-dilate the narrowed artery before inserting a metal mesh (stent), which keeps the artery open to maintain blood flow and prevent restenosis.

2.2.2 A cerebral protection device is usually used in this procedure to prevent particles that are dislodged during the stenting procedure from passing into the cerebral circulation. Once the stent has been implanted, the protection device is removed via the delivery catheter.

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### This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

## 2.3 Efficacy

- 2.3.1 Three meta-analyses have been published that compared stenting and endarterectomy for carotid artery stenosis. The most recent of these analyses reports the outcomes of five randomised controlled trials involving 1269 patients (both asymptomatic and symptomatic), 632 of whom were randomised to undergo carotid stenting. There was no significant difference between the two treatment groups in the rate of any stroke or death at 1 year after the procedure (odds ratio [OR] 1.01; 95% confidence interval [CI] 0.82 to 1.94). However, there was some evidence to suggest that restenosis may be more common after stenting than after endarterectomy.
- 2.3.2 Similar results were found in a non-randomised controlled study of 397 patients (both asymptomatic and symptomatic), 254 of whom underwent carotid stenting. At 12 months there was no significant difference in the combined death/stroke rate between the stent group (10%) and the endarterectomy group (14%). The incidence of restenosis was higher in the stent group, but the difference was not significant.
- 2.3.3 Studies on this procedure show substantial heterogeneity, making it difficult to interpret the evidence. In particular, there are differences between study populations (asymptomatic versus symptomatic patients), and earlier studies focused on balloon angioplasty rather than stenting. For more details, refer to the 'Sources of evidence' section.
- 2.3.4 The Specialist Advisers expressed uncertainty about the efficacy of this procedure in comparison with surgery. They considered that the long-term results were still unknown and that it is still unclear which patients were most likely to benefit from the procedure. One Specialist Adviser was of the opinion that efficacy in asymptomatic patients is not proven.

## 2.4 Safety

- 2.4.1 Analysis of 30-day safety data from five randomised controlled trials comparing stent with endarterectomy for carotid artery stenosis found no significant difference in the odds of any stroke or death (OR 1.33; 95% CI 0.86 to 2.04). The rate of stroke or death within 30 days reported in the non-randomised study series ranged from

5.3% (357/6753) to 10% (15/150) without cerebral protection, and from 1.8% (16/896) to 5.2% (5/97) with cerebral protection. For more details, refer to the 'Sources of evidence' section.

- 2.4.2 Data from a carotid artery stent registry shows mortality related to the procedure ranged from 0.3% (7/2110) for asymptomatic patients treated with cerebral protection to 1% (43/4282) for symptomatic patients treated without protection. For more details, refer to the 'Sources of evidence' section.
- 2.4.3 Carotid stenting does not involve incision in the neck, and the potential risk for cranial neuropathies is very low. The Cochrane review reports a significantly lower incidence of cranial neuropathy following stenting compared with endarterectomy (OR 0.12; 95% CI 0.06 to 0.25). For more details, refer to the 'Sources of evidence' section.
- 2.4.4 The Specialist Advisers listed potential complications as procedure-related stroke or death, groin haematoma, thrombosis, rupture and perforation. Some of the Specialist Advisers expressed uncertainty about the safety of the procedure in comparison with surgery.

Andrew Dillon  
Chief Executive  
September 2006

### 'Understanding NICE guidance'

NICE has produced information describing its guidance on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from [www.nice.org.uk/IPG191publicinfo](http://www.nice.org.uk/IPG191publicinfo)

### Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedures overview of carotid artery stent placement for carotid stenosis', July 2004.

Available from: [www.nice.org.uk/ip008overview](http://www.nice.org.uk/ip008overview)

### Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1120. 'Understanding NICE guidance' can be obtained by quoting reference number N1121.

The distribution list for this guidance is available at [www.nice.org.uk/IPG191distributionlist](http://www.nice.org.uk/IPG191distributionlist)

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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