



Percutaneous transarterial carotid artery stent placement for asymptomatic extracranial carotid stenosis

Interventional procedures guidance Published: 22 November 2023

www.nice.org.uk/guidance/ipg777

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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

This guidance replaces IPG388.

1 Recommendations

- 1.1 Percutaneous transarterial carotid artery stent placement for asymptomatic extracranial carotid stenosis should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Clinicians wanting to do percutaneous transarterial carotid artery stent placement for asymptomatic extracranial carotid stenosis should:
 - Tell the clinical governance leads in their healthcare organisation.
 - Make sure that people (and their families and carers as appropriate)
 understand the procedure's safety and efficacy, and any uncertainties about
 these.
 - Consider <u>NICE's advice on shared decision making</u>, including <u>NICE's</u> information for the public.
 - Audit and review clinical outcomes of everyone having the procedure. The
 main efficacy and safety outcomes identified in this guidance can be entered
 into NICE's interventional procedure outcomes audit tool (for use at local
 discretion).

- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.
- 1.3 Healthcare organisations should:
 - Make sure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
 - Regularly review data on outcomes and safety for this procedure.
- 1.4 Patient selection should be done by a multidisciplinary team that should include an interventional radiologist or a neuroradiologist, a vascular surgeon, and a stroke physician or neurologist.
- 1.5 The procedure should only be done by clinicians with specific training and expertise in this technique.
- 1.6 NICE encourages clinicians to submit data to the <u>National Vascular Registry</u>.
- 1.7 Further research should include details of patient selection and report longerterm outcomes.

Why the committee made these recommendations

This guidance considers additional evidence that has been collected since the original NICE interventional procedures guidance on carotid artery stent placement for asymptomatic extracranial carotid stenosis.

There is still uncertainty about this procedure's use in asymptomatic extracranial carotid stenosis. Short-term evidence suggests that the risk of disabling stroke is similar in people who have this procedure compared with people who have conventional surgery. But more long-term evidence is needed. More research is also needed to identify which people might benefit most from this procedure. So, it is recommended only with special arrangements.

2 The condition, current treatments and procedure

The condition

The main arteries in the neck (the carotid arteries) can become narrowed by fatty deposits (extracranial carotid stenosis). Blood clots can form on these fatty deposits. Fragments can then detach, and lodge in thinner arteries that supply blood to parts of the brain. This can cause a stroke or a transient ischaemic attack (sometimes called a 'mini stroke'). In some people, the carotid stenosis is asymptomatic. It may be identified incidentally during imaging and investigations for other conditions, or during health screening.

Current treatments

2.2 For people with asymptomatic extracranial carotid stenosis, management includes lifestyle modification (diet, exercise and smoking cessation) and pharmacological therapy (antithrombotics, lipid-lowering agents, blood pressure reduction and glycaemic control). Some people with severe stenosis may be offered revascularisation and the conventional surgical approach used is carotid endarterectomy (CEA). This involves making an incision in the side of the neck to access the narrowed section of artery to remove the fatty deposits. A newer alternative approach is transcervical carotid artery revascularisation, which uses a transcarotid neuroprotection system. The common carotid artery is accessed directly, through a smaller incision than in CEA. This procedure is not being considered in this guidance. <a href="NICE's interventional procedures guidance on transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting was published in 2016.

The procedure

2.3 Carotid artery stent placement is usually done under local anaesthetic, after

imaging. It involves passing a guidewire into the carotid artery. The usual access point is the common femoral artery, but radial access has also been used. The carotid stenosis is then usually predilated using a balloon catheter. A metal mesh (stent) is inserted, which keeps the artery open to maintain blood flow and prevent restenosis and embolism.

- 2.4 Embolic protection devices are often used during the procedure to reduce the risk of procedural cerebral emboli.
- 2.5 Carotid stenting is a less invasive percutaneous alternative to CEA. Potential advantages include the avoidance of general anaesthesia and the need for a neck incision that may result in cranial and cutaneous nerve damage. The rate of general surgical complications such as myocardial infarction may also be reduced.

3 Committee considerations

The evidence

- 3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 9 sources, which was discussed by the committee. The evidence included 3 systematic reviews, 2 randomised controlled trials, 1 prospective cohort study, 2 retrospective cohort studies and 1 retrospective international administrative dataset. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in table 5 of the overview.
- The professional experts and the committee considered the key efficacy outcome to be: stroke prevention.
- The professional experts and the committee considered the key safety outcomes to be: stroke, infection, haemorrhage, restenosis.
- 3.4 One commentary from a person who had this procedure was discussed by the

committee.

Committee comments

- 3.5 The committee was informed that simulation training for the procedure is available.
- 3.6 The committee noted that there are several ongoing clinical trials.
- 3.7 The committee noted that technical aspects of the procedure, such as stent design and cerebral protection devices, have changed over time.
- The committee were informed that the use of a transradial approach is increasing, but noted that most of the published evidence that was considered used a transfemoral approach.
- The committee noted that although there is new information, there is still uncertainty about the role of this intervention in people with asymptomatic carotid stenosis.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

