

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Transfemoral carotid artery stent placement for asymptomatic extracranial carotid stenosis

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'). If the carotid stenosis is not causing any health problems it is asymptomatic.

In this procedure, a metal mesh called a stent is used to widen the narrowed carotid artery. A fine wire is inserted into an artery in the leg (transfemoral) and passed up into the carotid artery. The stent is then moved into place along the wire.

NICE is looking at transfemoral carotid artery stent placement for asymptomatic extracranial carotid stenosis. This is a review of NICE's interventional procedures guidance on carotid artery stent placement for asymptomatic extracranial carotid stenosis.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

NICE interventional procedures consultation document, May 2023

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 22 June 2023

Target date for publication of guidance: October 2023

1 Draft recommendations

- 1.1 Transfemoral 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 transfemoral 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 NICE's advice on [shared decision making](#), including [NICE's 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 [National Vascular Registry](#).
- 1.7 Further research should include details of patient selection and report longer-term 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 beyond 10 years is needed. It is also uncertain how well the procedure works compared with current standard medical therapy. 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

- 2.1 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. [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. It involves passing a guidewire into the carotid artery. The usual access point is the common femoral artery. 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.
- 3.2 The professional experts and the committee considered the key efficacy outcome to be: stroke prevention.
- 3.3 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 stents and cerebral protection devices, have changed over time.

- 3.8 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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Chair, interventional procedures advisory committee

May 2023

ISBN: