NICE National Institute for Health and Care Excellence

NICE guidance

Transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting

HealthTech guidance
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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 Yellow Card Scheme.

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG561.

1 Recommendations

1.1 Current evidence on the safety of transcervical extracorporeal reverse flow neuroprotection for reducing the risk of stroke during carotid artery stenting shows well-documented risks. The evidence on efficacy is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.

1.2 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.

1.3 This procedure should only be carried out by clinicians with specific training and expertise in the technique who regularly perform complex endovascular interventions.

2 Indications and current treatments

2.1 Narrowing of the carotid arteries by atherosclerosis may lead to transient ischaemic attack (TIA) or stroke. Treatment includes managing cardiovascular risk factors (stopping smoking, taking antithrombotic medication and statins). In some people, surgical revascularisation (carotid endarterectomy) or carotid artery angioplasty and stenting may be considered. Debris dislodged during carotid artery stenting can embolise to the cerebral circulation and cause a TIA or stroke.

2.2 The risk of an embolic stroke during carotid artery stenting may be reduced either by using filters to capture any embolic debris (distal neuroprotection) or by temporarily reversing the blood flow through the stenotic lesion and away from the brain by blocking the flow in the carotid artery (proximal neuroprotection).

2.3 Neuroprotection devices may be introduced via the femoral or carotid artery.

3 The procedure

3.1 Transcervical extracorporeal reverse flow neuroprotection is an approach to providing proximal neuroprotection during carotid artery angioplasty and stenting. By directly accessing the carotid artery, it aims to avoid the risks of endovascular manipulation within the aortic arch that occur with a transfemoral approach, and make access possible if there is unfavourable aortic arch anatomy or iliac artery disease.

3.2 With the patient under local, regional or general anaesthesia, a small incision is made in the neck and a catheter introduced into the common carotid artery. A catheter is then placed in the femoral or jugular vein. The common carotid artery is temporarily blocked and retrograde flow is established through the stenosis in the internal carotid artery. The blood is passed through a filtering system outside the body to remove any dislodged debris. It is then returned through the femoral or jugular vein. Once blood flow is reversed, carotid artery angioplasty and stenting are done. After the stent has been successfully placed, normal blood flow to the brain is allowed to resume and the catheters are removed.

4 Efficacy

This section describes efficacy 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 interventional procedure overview.

4.1 In a comparative study of 64 patients treated by transcervical carotid artery stenting with flow reversal (n=31) or transfemoral carotid artery stenting with distal filter protection (n=33), there were no reports of stroke after stenting in either group. In a comparative study of 55 patients treated by transcervical carotid artery stenting with flow reversal or transfemoral carotid artery stenting with distal filter protection, 6% (2/31) of patients had a transient ischaemic attack (TIA) and none had a stroke in the transcervical carotid artery stenting group. In the transfemoral carotid artery stenting group, 4% (1/24) of patients had a TIA and 4% (1/24) had a stroke (timing not reported). In a prospective case series of 212 patients treated by transcervical carotid artery stenting with flow reversal, stroke occurred in 2% (4/212) of patients within 30 days of the procedure; there was 1 TIA and 3 major strokes.

4.2 In the comparative study of 64 patients treated by transcervical carotid artery stenting or transfemoral carotid artery stenting, there were no significant changes in the Rankin stroke scale after the procedure in either group.

4.3 In the same study of 64 patients, asymptomatic new ischaemic cerebral lesions were diagnosed on diffusion-weighted MRI in 13% (4/31) of patients in the transcervical group compared against 33% (11/33) in the transfemoral group (p=0.03). In a case series of 48 patients treated by transcervical carotid artery stenting with flow reversal, there were 16 new ischaemic lesions (diagnosed on diffusion-weighted MRI 3 days after the procedure) in 14% (6/43) of patients (mean of 2.7 lesions per patient, range 2 to 4). All lesions were ipsilateral to the operated carotid artery. In 4 out of 6 patients, the new lesions remained asymptomatic.

4.4 In a case series of 97 patients treated by transcervical carotid artery stenting with flow reversal, 3% (3/103) of procedures were converted to endarterectomy. The reasons for the conversions were common carotid dissection with the entry

sheath, inability to cross the lesion in the internal carotid artery with the guide wire and severe agitation in 1 patient who needed conversion to general anaesthesia. In the patient with severe agitation the surgeon chose to proceed with an endarterectomy rather than stenting.

4.5 In a comparative study of 81 patients treated by transcervical carotid artery stenting with flow reversal (n=36) or carotid endarterectomy (n=45), there were high-intensity transient signals detected by transcranial Doppler sonography during the procedure in 3% (1/36) of patients treated by transcervical carotid artery stenting (not reported for the carotid endarterectomy group). In a prospective case series of 62 patients treated by transcervical carotid artery stenting with flow reversal, there were perioperative high-intensity transient signals reported in 6% (2/62) of patients.

4.6 In the comparative study of 81 patients treated by transcervical carotid artery stenting or carotid endarterectomy, there was an increase in mean cerebral artery flow velocity (measured by transcranial Doppler) after completion of the procedure in 100% (36/36) of patients treated by transcervical carotid artery stenting. In the prospective case series of 62 patients treated by transcervical carotid artery stenting with flow reversal, there was a significant improvement in the middle cerebral artery mean flow velocity and pulsatility index on completion of the procedure.

4.7 The specialist advisers listed the following key efficacy outcomes: reduced incidence of clinical neuro-embolic events and a decreased rate of new ischaemic lesions on brain MRI post-procedure (a surrogate marker).

5 Safety

This section describes 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 interventional procedure overview.

5.1 Death from myocardial infarction 48 hours after the procedure was reported in 1 patient in a prospective case series of 212 patients treated by transcervical carotid artery stenting with flow reversal. Death was reported in 2 patients in a case series of 141 patients treated by transcervical carotid artery stenting with flow reversal. One patient died from respiratory failure within 30 days of the procedure and another patient died from myocardial infarction 15 days after the procedure after readmission with pneumonia and diabetic ketoacidosis.

5.2 Transient intolerance to flow reversal was reported in 1 patient treated by transcervical carotid artery stenting in a comparative study of 81 patients treated by transcervical carotid artery stenting (n=36) or carotid endarterectomy (n=45). Clamping of the common carotid artery was maintained only during the key steps of the procedure. Intolerance to flow reversal was reported in 1% (3/219) of procedures in the case series of 212 patients; this was treated by declamping the common carotid artery and rapidly completing the procedure.

5.3 Major dissection of the common carotid artery was reported in 1 patient treated by transcervical carotid artery stenting in the comparative study of 81 patients. This was treated by a bypass from the common carotid artery to the distal internal carotid artery. Arterial dissection was reported in 6% (8/141) of patients in the case series of 141 patients. For 5 dissections, no treatment was needed; they were at the site of the arterial sheath or between the sheath and the carotid bifurcation. For the 3 dissections that needed treatment, 1 procedure was converted to carotid endarterectomy at the original procedure, 1 needed the placement of a second stent during the original procedure and 1 was repaired surgically during the original procedure. One of the patients with a dissection had a minor ipsilateral stroke 8 hours after the procedure. This was judged to be unrelated to the dissection because the second stent had adequately managed the intimal flap.

5.4 Severe spasm of the distal carotid artery was reported in 1 patient treated by transcervical carotid artery stenting in the comparative study of 81 patients. Severe distal internal carotid spasm was reported in 2% (4/212) of patients in the case series of 212 patients; this was treated with intra-arterial nitroglycerin in 1 patient and it resolved spontaneously after guide wire withdrawal in 3 patients. Severe distal internal carotid spasm was reported in 2 patients in a case series of 62 patients treated by transcervical carotid artery stenting with flow reversal; this was treated with intra-arterial nitroglycerin. Distal internal carotid artery spasm was reported in 13% (6/48) of patients in a case series of 48 patients treated by carotid artery stenting with flow reversal. This was treated with intra-arterial nitroglycerin.

5.5 Bradycardia and hypotension related to balloon inflation was reported in 6% (2/36) of patients treated by transcervical carotid artery stenting in the comparative study of 81 patients. This was successfully treated with atropine. Bradycardia was reported in 13% (4/31) of patients in the transcervical carotid artery stenting with flow reversal group and in none of the patients in the transfemoral carotid artery stenting group with distal filter neuroprotection (n=24) in a comparative study of 55 patients.

5.6 Extensive cerebral haematoma was reported in 1 patient in the case series of 62 patients; this was identified on a CT scan after the patient returned with hemiplegia and aphasia after an episode of intense headache 48 hours after hospital discharge. It was treated by surgical drainage.

5.7 Transient laryngeal nerve palsy was reported in 1% (2/212) of patients in the case series of 212 patients; this was secondary to impregnation of the nerve with local anaesthesia. Cranial nerve injury affecting the 10th nerve was reported in 1 patient in the case series of 141 patients; this caused hoarseness, which fully resolved at 6 months.

5.8 Cervical haematoma was reported in 6% (2/31) of patients treated by transcervical carotid artery stenting in the comparative study of 55 patients; one of the 2 patients was treated by surgical drainage and had no neurological sequelae. Cervical haematoma was reported in 1 patient in the case series of 212 patients; this was treated by surgical drainage.

5.9 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers did not list any anecdotal adverse events. They considered that the following were theoretical adverse events: false aneurysm at the site of puncture, potential risk to the brain of reversing the flow in the internal carotid artery for the duration of the procedure and potential risk of re-establishing antegrade flow (reperfusion injury).

6 Further information

6.1 The committee noted that NICE has issued guidance on carotid stenting in symptomatic patients and carotid stenting in asymptomatic patients.

6.2 The committee was advised that the evidence for the clinical benefits of cerebral protection devices was not conclusive.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 561 has been migrated to HealthTech guidance 415. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.