

Laser-assisted cerebral vascular anastomosis without temporary arterial occlusion

Interventional procedures 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.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of laser-assisted cerebral vascular anastomosis without temporary arterial occlusion is based on very limited numbers of patients. Therefore, the procedure should only be used with special arrangements for clinical governance, consent, and audit or research.
- 1.2 Clinicians wishing to undertake laser-assisted cerebral vascular anastomosis without temporary arterial occlusion should take the following actions.
 - Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, use of NICE's information for the public is recommended.
 - Audit and review clinical outcomes of all patients having laser-assisted cerebral vascular anastomosis without temporary arterial occlusion (see section 3.1).
- 1.3 Selection of patients for this procedure should be carried out in the context of a multidisciplinary team including a neurosurgeon and an interventional neuroradiologist.
- 1.4 Publication of safety and efficacy outcomes will be useful. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Aneurysms and other abnormalities of arteries supplying the brain may be suitable for treatment by open surgery or endovascular techniques, such as insertion of coils or stents. In some cases, arterial bypass of an abnormality may be necessary. This is achieved either by direct anastomosis between branches of the external carotid and internal carotid arteries or by an interposition saphenous vein or radial artery graft. In both techniques there is a risk of stroke as the cerebral blood supply is temporarily occluded while the anastomosis to the intracranial artery is performed.

2.2 Outline of the procedure

- 2.2.1 The laser-assisted non-occlusive anastomosis technique aims to achieve cerebral arterial bypass without the need for temporary arterial occlusion, thus maintaining cerebral blood flow throughout the procedure.
- 2.2.2 The procedure is performed under general anaesthesia. The distal (cerebral) anastomosis site is prepared by stitching a platinum ring onto the wall of the recipient vessel. The bypass graft is sutured end-to-side to the recipient vessel outside the ring. A combined laser–vacuum suction catheter is introduced through the bypass graft into the platinum ring on the wall of the recipient vessel. Using vacuum suction and laser pulses, a disc-shaped area is resected in the wall of the recipient vessel. This punched-out disc is withdrawn while still attached to the vacuum catheter, completing the anastomosis without interrupting cerebral blood flow. The graft is then temporarily clipped to prevent backflow while the resected wall is closed (in direct extracranial/ intracranial bypass) or the proximal anastomosis is formed (in indirect interposition extracranial/intracranial bypass). When interposition grafts are used, the proximal anastomosis is performed using a standard end-to-end or end-to-side anastomosis.

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more details, see the [overview](#).

2.3 Efficacy

- 2.3.1 In a case series of 77 patients with intracranial aneurysms undergoing bypass using laser-assisted cerebral vascular anastomosis without temporary arterial occlusion, a patent high-flow bypass was successfully created in 97% (75 out of 77) of cases. A patent anastomosis was not achieved in 3% (2 out of 77) of cases because the excised section of the targeted artery wall did not attach to the laser tip on withdrawal. A second procedure was required in 8 patients (10%), usually because of postoperative graft thrombosis.
- 2.3.2 In a second case series of 15 patients with carotid artery occlusion and recurrent ischaemic symptoms, transcranial Doppler ultrasound of 11 patients who survived to 6 months showed that a patent bypass was maintained in 91% (10 out of 11) of them.
- 2.3.3 In two case series of 77 and 34 patients, 68% (52 out of 77) and 79% (27 out of 34) of patients were independent (using the modified Rankin scale) at 2 to 4-month and 3.3-year follow-up, respectively. In the first study, functional health improved in 14% (11 out of 77) of patients, was unchanged in 65% (50 out of 77) and had decreased in 21% (16 out of 77) at 2 to 4-month follow-up. In the second study, Rankin score (a measure of functional capacity) had improved in 71% (24 out of 34) of patients at discharge and 74% (25 out of 34) at 3.3-year follow-up. Of the 27 patients who had pre-existing cranial nerve compression in the second study, 30% (10 out of 27) resolved at the same follow-up.
- 2.3.4 The Specialist Advisers considered key efficacy outcomes to be graft patency (including angiographic assessment) without further stenosis and lack of haemorrhage during the procedure.

2.4 Safety

- 2.4.1 In four studies, postoperative mortality (up to 30-day follow-up) following laser-assisted cerebral vascular anastomosis without temporary arterial occlusion was reported to be 7% (1 out of 15), 6% (2 out of 34), 4% (3 out of 77) and 0% (0 out of 1), respectively. The indication for the procedure varied between studies.

- 2.4.2 The case series of 77 patients with intracranial artery aneurysms in whom the procedure was used reported persistent deficit caused by ischaemia in 21% (16 out of 77), by haemorrhage in 5% (4 out of 77) and by other intracranial events in 3% (2 out of 77) of patients. Procedure-related complications resulting in a Rankin score of 3 to 5 occurred in 9% (7 out of 77) of patients.
- 2.4.3 The case series of 15 patients with carotid artery occlusion reported that ischaemic stroke occurred in 20% (3 out of 15) of patients and dysphasia with right-sided weakness occurred in 13% (2 out of 15).
- 2.4.4 The Specialist Advisers considered the theoretical adverse events of the procedure to include leakage of the anastomosis and laser damage to the bypass vessel wall leading to late stenosis.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant [audit criteria](#) and developed an [audit tool](#) (which is for use at local discretion).
- 3.2 NICE has produced [interventional procedures guidance on extracranial to intracranial bypass for intracranial atherosclerosis](#).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).