

Laser-assisted cerebral vascular anastomosis without temporary arterial occlusion

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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 the Institute's <u>information for patients</u> ('Understanding NICE guidance') 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. The Institute 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, refer to the Sources of evidence.

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% (75/77) of cases. A patent anastomosis was not achieved in 3% (2/77) 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% (10/11) of them.
- 2.3.3 In two case series of 77 and 34 patients, 68% (52/77) and 79% (27/34) of patients were independent (using the modified Rankin scale) at 2–4-month and 3.3-year follow-up, respectively. In the first study, functional health improved in 14% (11/77) of patients, was unchanged in 65% (50/77) and had decreased in 21% (16/77) at 2–4-month follow-up. In the second study, Rankin score (a measure of functional capacity) had improved in 71% (24/34) of patients at discharge and 74% (25/34) at 3.3-year follow-up. Of the 27 patients who had pre-existing cranial nerve compression in the second study, 30% (10/27) 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% (1/15), 6% (2/34), 4% (3/77) and 0% (0/1), 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% (16/77), by haemorrhage in 5% (4/77) and by other intracranial events in 3% (2/77) of patients. Procedure-related complications resulting in a Rankin score of 3–5 occurred in 9% (7/77) of patients.
- 2.4.3 The case series of 15 patients with carotid artery occlusion reported that ischaemic stroke occurred in 20% (3/15) of patients and dysphasia with right-sided weakness occurred in 13% (2/15).
- 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. The Institute has identified relevant audit criteria and developed an <u>audit tool</u> (which is for use at local discretion).
- 3.2 The Institute has produced interventional procedures guidance on <u>extracranial</u> to intracranial bypass for intracranial atherosclerosis.

Andrew Dillon Chief Executive February 2008

Sources of evidence

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

'Interventional procedure overview of laser-assisted cerebral vascular anastomosis without temporary arterial occlusion', June 2007.

Information for patients

NICE has produced <u>information describing its guidance on this procedure for patients and their carers</u> ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE <u>interventional procedure guidance</u> process.

We have produced a <u>summary of this guidance for patients and carers</u>. Tools to help you put the guidance into practice and information about the evidence it is based on are also <u>available</u>.

Changes since publication

14 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and 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.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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