Extracranial to intracranial bypass for intracranial atherosclerosis

Interventional procedures guidance
Published: 23 June 2010
nice.org.uk/guidance/ipg348

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. However, 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.

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.

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.

This guidance replaces IPG73.
1 Guidance

This guidance replaces previous guidance on high-flow interposition extracranial to intracranial bypass (interventional procedure guidance 73).

1.1 Current evidence on the efficacy and safety of extracranial to intracranial (EC–IC) bypass for intracranial atherosclerosis is inconsistent and remains limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake EC–IC bypass for intracranial atherosclerosis should take the following actions.

- Inform the clinical governance leads in their Trusts.

- Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy in relation to symptom reduction and stroke prevention, and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended.

- Audit and review clinical outcomes of all patients having EC–IC bypass for intracranial atherosclerosis (see section 3.1).

1.3 Patient selection for EC–IC bypass for intracranial atherosclerosis should be carried out by a multidisciplinary team with experience of managing patients with cerebral hypoperfusion syndromes who are undergoing this procedure. The team should include a neuroradiologist, neurologist/stroke physician and vascular neurosurgeon. The procedure should be done only by surgeons with specific training.

1.4 NICE encourages further research into EC–IC bypass for intracranial atherosclerosis. Research studies should clearly define patient selection criteria and report symptomatic and quality of life outcomes. NICE is aware of current clinical trials involving this procedure and may review the procedure on publication of further evidence.
2 The procedure

2.1 Indications and current treatments

2.1.1 Intracranial atherosclerosis is a progressive degenerative condition that can cause transient ischaemic attacks, reversible neurological deficit associated with hypoperfusion syndromes or permanent neurological damage (stroke).

2.1.2 Management is usually conservative, including smoking cessation interventions, and antiplatelet, lipid-lowering and antihypertensive medication.

2.2 Outline of the procedure

2.2.1 The aim of EC–IC bypass for intracranial atherosclerosis is to bypass severe stenoses in intracranial arteries to relieve hypoperfusion symptoms and/or reduce stroke risk. Patient selection and operative planning involve imaging techniques including ultrasound, angiography, computed tomography (CT) or single-photon emission CT scanning. Careful consideration of the clinical benefits and risks is important.

2.2.2 With the patient under general anaesthesia, the extracranial donor artery (usually the superficial temporal artery) is anastomosed to a superficial cerebral artery (usually a subpial middle cerebral artery branch) using a mini-craniotomy. Typically, an end-to-side anastomosis is used. Use of a graft (for example a radial artery or a saphenous vein graft) may be required when more distant vessels are anastomosed.

Sections 2.3 and 2.4 describe efficacy and 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 overview.

2.3 Efficacy

2.3.1 A randomised controlled trial (RCT) of 1377 patients treated by EC–IC bypass (n = 663) or best medical care (n = 714) reported a 14% increase in the relative risk of fatal and non-fatal stroke after EC–IC bypass at a mean 55.8-month follow-up.
2.3.2 A systematic review of 506 patients treated by EC–IC bypass (23 studies with follow-up intervals of 14 days to 16.7 months) reported annual stroke rates of 0–16.7%.

2.3.3 A systematic review of 2591 patients including 2 RCTs with follow-up intervals of 55.8 and 25 months, and 19 non-randomised controlled trials (no follow-up stated) reported no stroke rate differences between the procedure and best medical care (for the RCTs: odds ratio [OR] 0.99, 95% confidence interval [CI] 0.79 to 1.23; p = 0.91) (for the non-randomised controlled trials: OR 0.80, 95% CI 0.54 to 1.18; p = 0.25).

2.3.4 A non-randomised comparative study of 42 patients reported a stroke rate of 0% in the 12 patients treated by EC–IC bypass at 5-month follow-up and 30% in the 30 patients treated by best medical care at 18-month follow-up (p = 0.041).

2.3.5 The systematic review of 2591 patients reported no difference in mortality rates between those treated by the procedure and those treated by best medical care in the 2 RCTs (OR 0.81, 95% CI 0.62 to 1.05; p = 0.11) and 19 non-randomised controlled trials (OR 1.00, 95% CI 0.62 to 1.62; p = 0.99).

2.3.6 The RCT of 1377 patients treated by EC–IC bypass or best medical care reported mortality rates of 17% (112/663) and 20% (140/714) respectively (mean follow-up 58.8 months).

2.3.7 The RCT of 1377 patients treated by EC–IC bypass or best medical care reported major functional impairment (inability to function without assistance) in 7% (46/663) and 5% (36/714) of patients respectively after a mean 55.8-month follow-up.

2.3.8 The Specialist Advisers listed key efficacy outcomes as graft patency and improvement of blood supply to the brain.

2.4 Safety

2.4.1 Case series of 415 and 201 patients treated by EC–IC bypass reported mortality rates of 2% (10/412) at hospital discharge and 14.9% (30/201) within 30 days respectively.
2.4.2 The Specialist Advisers listed anecdotal adverse events of death, stroke or intracerebral haemorrhage.

2.5 Other comments

2.5.1 The Committee noted that symptoms of cerebral hypoperfusion were the usual indication for use of this procedure, but that the published evidence failed to include relevant endpoints such as relief of such symptoms and quality of life measures.

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 For related NICE guidance see our website.

Information for patients

NICE has produced information on this procedure for patients and carers (‘Understanding NICE guidance’). It explains the nature of the procedure and the guidance issued by NICE, 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 interventional procedure guidance process.

It updates and replaces NICE interventional procedure guidance 73.
We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

Changes since publication

29 November 2011: 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.

Copyright

© National Institute for Health and Clinical Excellence 2010. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

Contact NICE

National Institute for Health and Clinical Excellence
Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT

www.nice.org.uk
nice@nice.org.uk
0845 033 7780
Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

NICE accredited

www.nice.org.uk/accreditation