NICE guidance

Extracranial to intracranial bypass for intracranial atherosclerosis

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg596

This guidance replaces IPG348.

1 Recommendations

This document replaces previous guidance on extracranial to intracranial bypass for intracranial atherosclerosis (interventional procedures guidance 348).

1.1 Current evidence on the safety and efficacy of extracranial to intracranial bypass for intracranial atherosclerosis shows that there is no benefit to the patient from the intervention. There are major concerns around its safety, therefore this procedure should not be used to treat this condition.

2 Indications and current treatments

2.1 Intracranial atherosclerosis is usually a progressive condition which narrows and hardens the blood vessels supplying the brain, limiting its blood supply. This can cause transient ischaemic attacks or permanent neurological damage (stroke).

2.2 Conservative management of atherosclerosis includes smoking cessation, and antiplatelet, lipid-lowering and antihypertensive medication. Endovascular techniques (angioplasty or stenting) may be used to dilate an arterial narrowing.

3 The procedure

3.1 The aim of extracranial to intracranial bypass for intracranial atherosclerosis is to increase blood flow in intracranial arteries to relieve symptoms of cerebral hypoperfusion or reduce the risk of stroke. 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) through a mini-craniotomy. Typically, an end-to-side anastomosis is used. A graft (for example a radial artery or a saphenous vein graft) may be needed to allow higher flow.

3.2 Careful pre-operative planning involving ultrasound, angiography, computed tomography (CT), single-photon emission CT scanning or brain reserve testing is needed.

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 A systematic review of 2,591 patients (2 randomised controlled trials [RCTs] with follow-up intervals of 56 and 25 months, and 19 non-randomised studies with follow-up not stated) reported no difference in

stroke rates (any type) between patients having extracranial to intracranial (EC-IC) bypass (plus best medical treatment) and those having medical treatment only (in the RCTs n=1,691; odds ratio [OR] 0.99, 95% confidence interval [CI] 0.79 to 1.23, p=0.91 and in the non-randomised studies [18 studies], n=881; OR 0.80, 95% CI 0.54 to1.18, p=0.25). In the same systematic review, ischaemic stroke rate was not statistically significantly different between patients having EC-IC bypass and those having medical treatment only (in the RCTs n=1,573; OR 0.69, 95% CI 0.44 to 1.08, p=0.11 and in the non-randomised studies [13 studies], n=640; OR 0.72, 95% CI 0.44 to 1.18, p=0.19). Two RCTs reported a statistically significantly smaller probability of stroke, vascular event or vascular death among the patients having EC-IC bypass when compared with patients having medical treatment only (n=1,573; OR 0.68, 95% CI 0.51 to 0.91, p=0.009). No statistically significant difference in ischaemic stroke rate was seen in the systematic review of 2,591 patients (13 non-randomised studies; n=673; OR 0.69, 95% CI 0.45 to 1.04, p=0.079). Two non-randomised studies (n=361) reported no statistically significant difference in intracranial haemorrhage rates between patients having EC-IC bypass when compared with patients having medical treatment only (OR 1.14, 95% CI 0.44 to 2.93, p=0.79) in the same systematic review. A systematic review of 506 patients reported a statistically significantly lower rate of stroke 12 months after surgery in patients with severe stage I failure (loss of autoregulatory vasodilation) who had EC-IC bypass (1%) than in patients having medical treatment only (19%, 95% CI 1.17 to 4.08, p=0.015). In the same systematic review, stroke rate was not statistically significantly different in patients with stage II failure (autoregulatory failure characterised by decreases of cerebral blood flow and increases of oxygen extraction fraction) who had EC-IC bypass (0%) when compared with patients having medical treatment only (13%, 95% CI 0.89 to 3.63, p=0.10). In an RCT of 1,377 patients, EC-IC bypass surgery was associated with a 14% (90% CI 3 to 34) increased relative risk of fatal and non-fatal stroke (Mantel-Haenszel chi-squared =1.72) at a mean follow-up of 56 months (p value not reported). In an RCT (n=195) comparing 97 patients having EC-IC bypass with 98 patients who had medical treatment only, ipsilateral ischaemic stroke rate was not statistically significantly different between groups (rate difference 2%, 95% CI −10 to 14, p=0.81) at 2-year follow-up. A case series of 204 patients who had EC-IC bypass

reported the rate of patients free of stroke or fatal stroke to be 92% (138/150) at 1-year follow-up and 87% (86/99) at 5-year follow-up.

4.2 In the systematic review of 2,591 patients, 11 non-randomised studies reported a statistically significantly smaller risk of transient ischaemic attack or amaurosis in patients who had EC-IC bypass when compared with patients who had medical treatment only (n=524; OR, 0.34, 95% CI 0.16 to 0.69, p=0.003). Three non-randomised studies from the same systematic review reported no statistically significant difference in normalisation of cerebral haemodynamics between patients who had EC-IC bypass and those having medical treatment only (n=56; OR 6.63, 95% CI 1.85 to 23.78).

4.3 The RCT of 1,377 patients reported a graft patency rate, assessed by angiography, of 96% (576/600) in patients who had EC-IC bypass, at a median of 32 days post-procedure. In the RCT of 195 patients, graft failure rate at 2-year follow-up was 2% (2/97) in patients who had EC-IC bypass.

4.4 In an RCT of 43 patients there was no statistically significant difference in neurocognitive function (measured by 14 standardised neuropsychological tests and the Centre for Epidemiological Studies depression scale), at 2-year follow-up, between patients who had EC-IC bypass and patients who had medical treatment only (point estimate 0.02, 95% CI, 20.50 to 0.54, p=0.93).

4.5 The specialist advisers listed reduction in stroke rate compared with medical treatment only as the key efficacy outcome.

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 In a randomised controlled trial (RCT; n=1,377) comparing 663 patients who had extracranial to intracranial (EC-IC) bypass with 714 patients who had medical treatment only, the rate of cerebral and retinal

ischaemic events was higher in the EC-IC-bypass group (12% [81/663]) than in the medical group (3% [24/714]) within 30 days of surgery (or 39 days of randomisation for the medical group), no p value reported. The same RCT reported a higher rate of major stroke, defined as an 'inability to function without assistance', in the group who had EC-IC bypass (3% [20/663]) compared with the medical-treatment-only group (1% [9/714]), within 30 days of surgery or 39 days of randomisation, p value not reported. A case series of 876 patients with occlusive cerebrovascular disease reported no statistically significant difference in the rate of post-procedure stroke in asymptomatic patients who had EC-IC bypass (2% [2/123]) when compared with asymptomatic patients who had intracranial stenting (4% [10/243], p=0.341). The same case series reported a statistically significantly higher rate of post-procedure stroke in symptomatic patients who had EC-IC bypass (25% [32/126]) than in symptomatic patients who had intracranial stenting (10% [40/384], p<0.001).

5.2 In the case series of 876 patients with occlusive cerebrovascular disease, asymptomatic patients were no more likely to be transferred to another care facility, rather than home, if they had EC-IC bypass (16% [19/121]) when compared with patients who had intracranial stenting (9% [21/237], p=0.08). Symptomatic patients were statistically significantly more likely to be transferred to another care facility, rather than home, if they had EC-IC bypass (66% [80/121]) when compared with patients who had intracranial stenting (53% [180/338], p=0.08). In a case series of 415 patients who had EC-IC bypass, destination at discharge for patients with post-procedure stroke was home (59% [41/69]), short-term facility (25% [17/69]) and long-term facility (9% [6/69]).

5.3 The following adverse events were reported in the RCT of 195 patients who had EC-IC bypass: epidural or subdural haematoma (2% [2/97]), seizures (2% [2/97]), respiratory disorder (1% [1/97]), hypotension (1% [1/97]), and wound infection (1% [1/97]). The following adverse events happened to the same patient (1% [1/97]): deep vein thrombosis, atrial flutter, cardiac tamponade and pulmonary embolus. Haemorrhage, haematoma complicating the procedure, hydrocephalus, ventriculostomy, mechanical ventilation, deep vein thrombosis, pulmonary embolism and placement of an inferior vena cava filter were reported in the case series

of 415 patients who had EC-IC bypass (no frequencies were reported).

5.4 Reperfusion injury with cerebral oedema was reported in 1 patient in a case series of 85 patients who had EC-IC bypass.

5.5 Temporary dysesthesia on the graft harvest site (1/13) and haematoma at the graft harvest site (1/13) was reported in a case series of 13 patients who had EC-IC bypass.

5.6 As well as 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 happen, even if they have never done so). For this procedure, specialist advisers listed no anecdotal adverse events. They did not identify any theoretical adverse events that had not previously been reported.

6 Committee comments

6.1 This guidance only covers the use of this procedure for the indication of intracranial atherosclerosis. This procedure is used for other indications, for which it may have different safety and efficacy profiles, and this guidance does not apply to those indications.

7 Further information

7.1 For related NICE guidance, see the NICE website.

7.2 Patient commentaries were sought but none was received.

Information for patients

NICE has produced information on this procedure for patients and carers (information for the public). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation