NICE guidance

Percutaneous laser coronary angioplasty

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg378

1 Guidance

1.1 Current evidence on the safety and efficacy of percutaneous laser coronary angioplasty is adequate to support the use of this procedure in carefully selected patients for whom conventional angioplasty would otherwise be technically difficult, provided that normal arrangements are in place for clinical governance, consent and audit.

2 The procedure

2.1 Indications and current treatments

2.1.1 Coronary artery disease (CAD) refers to the narrowing and occlusion of the coronary arteries as a result of atherosclerosis. This can cause angina, myocardial infarction and heart failure.

2.1.2 Treatment options for patients with CAD with severe stenosis or occlusion include thrombolysis, percutaneous balloon angioplasty, stent placement, percutaneous cutting balloon or coronary artery bypass grafting.

2.1.3 Percutaneous laser coronary angioplasty has been used for CAD with severe stenosis or atherosclerotic occlusion, when standard techniques for recannalisation are unlikely to succeed or have failed.

2.2 Outline of the procedure

2.2.1 Percutaneous laser coronary angioplasty aims to penetrate plaque within coronary arteries that is not amenable to standard techniques such as balloon angioplasty or stenting alone.

2.2.2 A thin, flexible fibre-optic catheter connected to a laser-generating source outside the body is introduced via the femoral artery. The catheter is advanced over a guidewire through the artery to the blockage in the coronary artery, under fluoroscopic guidance. The tip of the catheter system emits pulses of laser light to vaporise the plaque while being slowly advanced across the lesion.

2.2.3 Percutaneous laser coronary angioplasty has also been done using a laser guidewire system but that method is not now in regular use.

2.2.4 This procedure is often used with adjunctive balloon angioplasty and followed by angiography to document the results.

> 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 303 patients treated with laser guidewire or mechanical guidewire reported procedural success (defined

as the ability to cross the target lesion at the first attempt) in 53% (76/144) and 47% (75/159) of patients respectively (p = 0.33). A non-randomised controlled study of 3733 procedures reported that 'lesion success' assessed angiographically was achieved in 89% and 94% of native vessels treated with laser angioplasty using 2 different laser devices, and in 91% and 95% of saphenous vein grafts for which laser treatment was attempted (absolute figures not stated). A case series of 958 patients reported that among 55 patients who underwent immediate postoperative angiographic assessment, coronary stenosis (assessed by the percentage of artery diameter blocked) decreased from 83% at baseline to 49% following laser angioplasty and to 38% following adjunctive balloon angioplasty (absolute figures not stated).

2.3.2 The RCT of 303 patients treated with laser guidewire or mechanical guidewire reported no major adverse cardiac events in 54% (78/144) and 67% (106/159) of patients respectively at 400-day follow-up (p = 0.026).

2.3.3 Major adverse cardiac events (death, myocardial infarction or revascularisation) were more frequent after laser angioplasty compared with balloon angioplasty in the meta-analysis of 9222 patients at up to 1-year follow-up (odds ratio [OR] 1.32; 95% confidence interval [CI] 1.01 to 1.73).

2.3.4 A case series of 1862 patients reported that 71% of patients had an improvement in their angina symptoms, 13% had unchanged symptoms and 16% had worse symptoms at 6-month median follow-up (absolute figures not stated).

2.3.5 A meta-analysis of 16 studies including a total of 9222 patients reported that angiographically measured restenosis occurred more frequently after laser angioplasty than after balloon angioplasty (OR 1.55; 95% CI 1.09 to 2.20) at follow-up of between 3 months and 1 year. An RCT of 96 patients treated by laser angioplasty and adjunctive balloon angioplasty or by balloon angioplasty alone reported restenosis in 52% and 47% of patients respectively at 163 days median follow-up (p = not significant; absolute figures not stated).

2.3.6 The case series of 1862 patients reported restenosis greater than 50% of

the artery diameter in 54% (434/797) of eligible patients undergoing angiographic assessment at 6-month median follow-up. A case series of 495 stenosed saphenous vein grafts treated by laser angioplasty reported restenosis in 55% of the 161 patients who had angiographic assessment at 6-month follow-up (absolute figures not stated).

2.3.7 The Specialist Advisers listed key efficacy outcomes as procedural success, angiographic success, quality-of-life scores, target vessel revascularisation and cardiac enzyme level post procedure.

2.4 Safety

2.4.1 The meta-analysis of 9222 patients treated by laser angioplasty or balloon angioplasty reported no difference between the groups in the rate of myocardial infarction at 30-day follow-up (OR 1.39; 95% CI 0.69 to 2.82). A meta-analysis of 3012 patients being treated for in-stent restenosis reported that the pooled mean rate of major adverse cardiac events was 35% for laser angioplasty, 29% for balloon angioplasty and 31% for stent-in-stent treatment (absolute figures not stated).

2.4.2 A non-randomised controlled study of 8932 procedures reported that the rate of arterial perforation was 2% (5/242) for laser angioplasty, less than 1% (11/7905) for balloon angioplasty and 0% (0/116) for mechanical rotational atherectomy.

2.4.3 The Specialist Advisers listed theoretical adverse events as death, coronary dissection, abrupt vessel closure, thermal damage to the vessel and restenosis.

3 Further information

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.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.

Changes since publication

2 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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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation