NICE guidance

Percutaneous laser revascularisation for refractory angina pectoris

Interventional procedure guidance
Published: 27 May 2009
nice.org.uk/guidance/ipg302

1 Guidance

1.1 Current evidence on percutaneous laser revascularisation (PLR) for refractory angina pectoris shows no efficacy and suggests that the procedure may pose unacceptable safety risks. Therefore, this procedure should not be used.

2 The procedure

2.1 Indications and current treatments

2.1.1 Angina pectoris is chest discomfort, often described as pressure or pain, typically occurring on exertion. It is caused by inadequate delivery of oxygen to the heart muscle, usually because of coronary artery disease. Refractory angina is a severe angina form that cannot be controlled by normal medical or surgical treatment.

2.1.2 Angina treatment depends on symptoms, medical history and angiography findings. Treatments include anti-anginal medication and revascularisation interventions (percutaneous coronary intervention or coronary artery bypass surgery). For patients with refractory angina, these treatments have either failed or are not clinically suitable.

2.2 Outline of the procedure

2.2.1 Percutaneous laser revascularisation for refractory angina pectoris is carried out with the patient under local anaesthesia. A catheter is inserted through the femoral artery, and advanced to the heart under fluoroscopic guidance. Ischaemic areas are selected for treatment using echocardiography or myocardial perfusion scan and coronary angiography. A laser device is then used to create a number of channels in the myocardium.

2.2.2 A number of different types of laser can be used for this procedure.

> 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 detailed information on the evidence, see the overview.

2.3 Efficacy

2.3.1 A meta-analysis of six randomised controlled trials (RCTs) involving 1040 patients reported no difference in mortality at 12-month follow-up between PLR-treated patients and medically managed patients (three RCTs), spinal cord stimulation (one RCT) or sham therapy (two RCTs) (pooled odds ratio [OR] 0.74; 95% confidence interval [CI] 0.32 to 1.7).

2.3.2 An RCT of 298 patients reported no difference in mean myocardial perfusion test score (using single photon emission computed tomography [SPECT] imaging; scoring system not described) between patients treated with high-dose PLR (defined as 20–25 laser pulses), low-dose PLR (defined as 10–15 laser pulses) or sham therapy (17.7 points, 19.3 points and 17.3 points, respectively at 6-month follow-up [p = 0.35]).

2.3.3 An RCT of 221 patients comparing PLR with medical management reported no difference in mean left ventricular ejection fraction between PLR-treated patients (median 51%) and medically managed patients (median 50%) at 3-month follow-up (significance not stated). An RCT of 82 patients reported no difference in mean left ventricular ejection fraction between patients treated with PLR (64%) and sham therapy (63%) at 12-month follow-up (significance not stated).

2.3.4 A meta-analysis of three RCTs reported no difference in post-procedural exercise tolerance using the Bruce Protocol Stress Test (a treadmill test) in patients treated with PLR compared with other interventions. A meta-analysis of five RCTs reported that exercise tolerance for PLR-treated patients was 17.7 seconds greater than in patients treated with comparators at 12-month follow-up (95% CI 4.4 to 31.0). When only studies with adequate patient blinding to allocated treatment were included in the meta-analysis, exercise tolerance differences at either 6 or 12 months were not significant.

2.3.5 In the RCTs of 298 and 141 patients there was no difference in the proportion of patients whose Canadian Cardiac Society Angina (CCSA) score improved by two or more classes at 6-month follow-up ($p = 0.33$). In an RCT of 82 patients, the proportion of patients with an improved CCSA score of two or more classes compared with baseline was not significantly different from patients treated with sham therapy at 12-month follow-up (35% [14/40]; 14% [6/42], respectively) ($p = 0.04$).

2.3.6 Specialist Advisers listed the key efficacy outcome as reduction of angina, which may or not be associated with objective measures, including improvement of perfusion scans, angina status and exercise capacity.

2.4 Safety

2.4.1 A meta-analysis of five RCTs including 819 patients reported no difference in mortality (up to 30-day follow-up) between PLR-treated patients and medically managed patients (three RCTs), spinal cord stimulation (one RCT) or sham therapy (two RCTs) (OR 1.4; 95% CI 0.4 to 4.9).

2.4.2 In six RCTs including 938 patients, the pooled myocardial infarction rate was higher in PLR-treated patients (7% [34/515]) than in the control groups (4% [17/423]). One RCT of 221 patients reported higher left bundle branch block rates following PLR (5% [5/110]) compared with medical management (1% [1/111]) (significance and follow-up not stated).

2.4.3 Randomised controlled trials of 298 and 221 patients reported left ventricular perforation rates of 1% (2/196) and 3% (3/110), respectively, in PLR-treated patients (none were reported in patients treated with comparators; events occurring during 30-day follow-up or within 24 hours, respectively; significance

not stated for either). In a case series of 25 patients treated with PLR, the myocardial perforation rate was 4% (1/25). A case series of 30 patients treated with PLR reported that 3% (1/30) of patients had pericardial tamponade during the procedure.

2.4.4 Among four RCTs, cerebrovascular accident or transient ischaemic attack occurred more frequently in patients treated with PLR (4% [10/285]) than in patients in the control arms of the studies (2% [5/287]) (significance and follow-up not stated).

2.4.5 The Specialist Advisers listed adverse events reported in the literature as myocardial infarction, arrhythmias and puncture site complications. They considered theoretical adverse events to include death, perforation of the cardiac muscle, damage to coronary arteries or other important structures, stroke and pericardial effusion.

3 Further information

3.1 NICE has published interventional procedures guidance on transmyocardial laser revascularisation for refractory angina pectoris and technology appraisal guidance on myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction. NICE is developing a clinical guideline on the management of stable angina [Now published as 'The management of stable angina'].

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

7 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