

Transmyocardial laser revascularisation for refractory angina pectoris

Interventional procedures guidance

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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, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

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. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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.

1 Guidance

- 1.1 Current evidence on transmyocardial laser revascularisation (TMLR) for refractory angina pectoris shows no efficacy, based on objective measurements of myocardial function and survival. Current evidence on safety suggests that the procedure may pose unacceptable 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 Transmyocardial laser revascularisation (TMLR) for refractory angina pectoris is carried out with the patient under general anaesthesia. Ischaemic areas are selected for treatment using echocardiography or myocardial perfusion scan and coronary angiography before surgery. A left thoracotomy is performed and the pericardium opened. A laser device is then used to create a number of channels in the myocardium. Transoesophageal echocardiography confirms complete passage across the myocardial wall by the laser.
- 2.2.2 A number of different types of laser can be used for this procedure.

2.3 Efficacy

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.

- 2.3.1 A meta-analysis of 10 randomised controlled trials (RCTs; total 1,359 patients) found no difference in 12-month mortality between TMLR-treated patients and controls treated either medically or with coronary artery bypass grafting (CABG; odds ratio [OR] 0.89; 95% confidence interval [CI] 0.5 to 1.8). Nor was there any difference in mortality when studies comparing TMLR plus CABG against CABG alone were excluded (OR 0.8; 95% CI 0.5 to 1.2).
- 2.3.2 An RCT of 100 patients treated either with TMLR or medically reported that myocardial contractility (assessed with stress echocardiography or single photon emission computed tomography [SPECT]; lower value indicating worse function) was significantly lower in TMLR-treated patients (1.49 ± 0.44) than those treated medically (1.56 ± 0.47) at 12-month follow-up ($p < 0.05$). Six other RCTs found no significant difference in myocardial perfusion (examined with stress testing or perfusion scanning) in TMLR-treated patients, compared with patients treated medically. A meta-analysis of 4 RCTs (total 323 patients) reported greater mean improvement (from baseline) in total exercise time in TMLR-treated patients compared with those treated medically at 6-month follow-up (pooled mean difference 120.1 seconds; 95% CI 4.5 to 235.7).

- 2.3.3 A meta-analysis of 3 studies (total 135 patients) reported an improvement from baseline in angina score (measured using four-point scales) in TMLR-treated patients compared with those treated medically, with a reduction in mean difference in angina score between TMLR and non-TMLR treatment groups of -1.8 (95% CI -2.4 to -1.1) at 6-month follow-up and -1.0 (95% CI -1.7 to -0.3) at 12-month follow-up.
- 2.3.4 Five RCTs measured quality of life with different instruments. One RCT showed no significant difference between TMLR-treated patients and patients treated with thoracic sympathectomy, while the other 4 RCTs found significant improvements in quality of life for TMLR-treated patients compared with those treated medically (significance not stated). None of the studies had blinded patients to their treatment.
- 2.3.5 Specialist Advisers listed key efficacy outcomes as angina severity reduction, exercise capacity improvement, reduced medicine use and increased quality of life.

2.4 Safety

- 2.4.1 A meta-analysis of 10 RCTs indicated no difference in postoperative mortality between TMLR-treated patients and controls treated medically or with CABG (pooled OR 0.78; 95% CI 0.34 to 1.7). However, when 2 trials comparing TMLR plus CABG against CABG alone were excluded, postoperative mortality was greater in TMLR-treated patients than controls (OR 0.35; 95% CI 0.13 to 0.93).
- 2.4.2 In 7 RCTs the subsequent myocardial infarction rate was higher in TMLR-treated patients than in controls (6% [41 of 633] compared with 2% [11 of 651]; follow-up period 12 months; significance not stated).
- 2.4.3 An RCT of 100 patients reported that postoperative heart failure occurred more frequently in TMLR-treated patients (34% [17 of 50]) than in medically treated patients (0% [0 of 50]), but significance was not stated. An RCT of 182 patients reported that thromboembolic events occurred more frequently in TMLR-treated patients (10% [9 of 92]) than those treated medically (3% [3 of 90]), but significance and follow-up were not stated.

- 2.4.4 A case series of 169 TMLR-treated patients reported that 14% (23 of 169) developed acute non-inflammatory pericarditis following the procedure (sequelae not reported). In a case series of 20 TMLR-treated patients, acute mitral regurgitation was reported in 5% (1 of 20). An international multicentre case series of 932 patients reported cardiac tamponade in less than 1% (5 of 932) of patients.
- 2.4.5 A retrospective non-randomised controlled trial of 255 patients reported that neurological complications occurred more frequently after TMLR plus CABG (3% [1 of 36]) than after CABG alone (1% [3 of 219]), but significance and follow-up were not stated.
- 2.4.6 Specialist advisers stated that adverse events reported in the literature included death, myocardial infarction, heart failure, arrhythmias, and wound and other infections.

2.5 Other comments

- 2.5.1 The committee noted that some studies showed improvements in symptoms and quality of life, but considered that these were likely to be placebo responses in the light of evidence that showed no objective benefits.
- 2.5.2 The committee considered evidence on TMLR alone for refractory angina pectoris, and also on TMLR performed concomitantly with CABG.

3 Further information

- 3.1 NICE has published [interventional procedures guidance on percutaneous laser revascularisation for refractory angina pectoris](#), [technology appraisal guidance on myocardial perfusion scintigraphy for the diagnosis and management of angina and myocardial infarction](#), and a [guideline on managing stable angina](#).

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [systematic review](#).

Information for patients

NICE has produced [information on this procedure for patients and carers](#). 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](#).