NICE National Institute for Health and Care Excellence

NICE guidance

Percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease

HealthTech guidance

Published: 27 November 2012

www.nice.org.uk/guidance/htg294

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.

Contents

This guidance replaces IPG433.

1 Recommendations

1.1 Current evidence on the efficacy and safety of percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection should be carried out by a vascular multidisciplinary team including a vascular surgeon and a vascular interventional radiologist. The multidisciplinary team should consider carefully whether using percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease is likely to have any benefits over conventional recanalisation by balloon angioplasty (with or without stenting) alone.

2 The procedure

2.1 Indications and current treatments

2.1.1 Chronic atherosclerotic peripheral arterial disease commonly causes narrowing or blockage of lower limb arteries. Symptoms include intermittent claudication, ischaemic rest pain, ulceration and gangrene.

2.1.2 Cardiovascular risk factor modification is fundamental to the management of peripheral arterial disease. For patients with severely reduced walking distance or critical limb ischaemia, revascularisation procedures such as balloon angioplasty, stenting or surgery (bypass grafts or endarterectomy) can be used.

2.2 Outline of the procedure

2.2.1 The aim of percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease is to achieve recanalisation when balloon angioplasty and/or stenting alone are considered not to be technically feasible or sufficiently safe.

2.2.2 Using local anaesthesia and fluoroscopy, a laser device (with or without a guidewire) is advanced through the artery to the narrowing or blockage. The laser emits pulses of laser light to vaporise the blockage. This is carried out as an adjunct to recanalisation using balloon angioplasty. A stent may then be inserted to treat any stenosis and/or to prevent embolism and restenosis.

2.2.3 Several types of laser are available for this procedure.

2.3 Efficacy

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.

2.3.1 A randomised controlled trial of 116 patients treated by pulsed laser atherectomy plus balloon angioplasty, by continuous-wave laser atherectomy plus balloon angioplasty, or by balloon angioplasty alone, reported that treated arterial segments were patent on angiography at 1-year follow-up in 45%, 36% and 50% of patients respectively (patient numbers and level of significance not stated).

2.3.2 A case series of 318 patients (411 lesions) treated by laser atherectomy plus balloon angioplasty reported primary patency (defined as uninterrupted patency with no procedures performed on the treated segment or at its margins) in 34% of patients (patient numbers not reported) at 1-year follow-up.

2.3.3 A non-randomised controlled study of 215 patients reported that there was improvement in American Heart Association limb status grade classification of 1 grade in 19% (24 of 127) of patients, 2 grades in 20% (25 of 127) of patients, and 3 grades in 10% (13 of 127) of patients after laser atherectomy plus balloon angioplasty at 36-month follow-up.

2.3.4 The non-randomised controlled study of 215 patients reported significantly improved mean ankle brachial index at rest for the 167 patients in whom technical success had been achieved (105 patients treated by laser atherectomy plus balloon angioplasty and in 62 patients treated by balloon angioplasty alone). Pressure indices increased significantly from baseline to 36-month follow-up in both the laser atherectomy plus balloon angioplasty group (0.34±0.16 to 0.55±0.16; $p<0.001$) and the balloon angioplasty alone group (0.33±0.18 to 0.52±0.13; $p<0.001$); significance between groups not reported.

2.3.5 The specialist advisers listed key efficacy outcomes as an increase in arterial diameter and blood flow, tissue healing, symptom relief, improvement in quality of life, amputation-free survival and reintervention rates.

2.4 Safety

2.4.1 A case series of 40 patients who had laser atherectomy (with or without balloon angioplasty or stenting) reported that 5% (2 of 40) of patients died within 30 days of the procedure but stated that neither death was related to the revascularisation procedure (no further details reported).

2.4.2 Dissection of the arterial wall occurred in 35% (13 of 37) of patients treated by pulsed laser atherectomy plus balloon angioplasty, in 20% (8 of 40) of patients treated by continuous-wave laser atherectomy plus balloon angioplasty, and in 15% (6 of 39) of patients treated by balloon angioplasty alone in the randomised controlled trial of 116 patients (p=0.005).

2.4.3 Vessel perforation occurred in 3% (4 of 127) of patients treated by laser atherectomy plus balloon angioplasty in the non-randomised controlled study of 215 patients (no further details given).

2.4.4 Complete or partial embolic occlusion of a proximal lower limb artery was reported in 3% (4 of 127) of patients treated by laser atherectomy plus balloon angioplasty (3 were symptomatic and were treated by local lysis or dilatation) and in 6% (5 of 88) of patients treated by balloon angioplasty alone (4 were symptomatic and were treated by local lysis or dilatation) in the non-randomised controlled study of 215 patients at mean 36-month follow-up.

2.4.5 Arteriovenous fistula was reported in less than 1% (2 of 338) of patients in a case series of 338 patients treated by laser atherectomy (alone or plus balloon angioplasty; 'during or after the procedure'; no further details reported). Arteriovenous fistula was reported in 3% (1 of 40) of patients within 30 days of the procedure in the case series of 40 patients ('treated conservatively'; no further details reported).

2.4.6 Pseudoaneurysms at the puncture site were reported in 10 patients in a case series of 312 patients treated by laser atherectomy (with stenting if indicated). These were treated using ultrasound-guided compression. Pseudoaneurysms were reported in 3% (1 of 40) of patients within 30 days of the procedure in the case series of 40 patients (treated conservatively; no further details reported).

2.4.7 Warming of tissues at the treatment site, thought to be caused by direct thermal effect of the laser treatment ('during or after' the procedure), was reported in 64% (215 of 338) of patients in the case series of 338 patients.

2.4.8 In addition to the above, specialist advisers stated that the adverse events reported in the literature were access site complications. They considered thermal injury to be a theoretical adverse event.

2.5 Other comments

2.5.1 The committee noted that much of the evidence on this procedure is not recent. A limited amount of the older evidence described using laser alone for atherectomy but more recent evidence focused on its use as an adjunct to balloon angioplasty (with or without stenting). This more recent evidence and the advice of specialists underpinned the decision to evaluate laser recanalisation as an adjunctive procedure.

2.5.2 While the committee considered the evidence adequate to recommend normal arrangements for the use of percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting), it remained uncertain about whether its use confers any advantages over balloon angioplasty alone and, if so, in which patients: this underpinned the recommendation in section 1.2.

2.5.3 The committee was advised that the application of laser technology in percutaneous atherectomy has evolved during the period covered by the published evidence and may continue to do so.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 433 has been migrated to HealthTech guidance 294. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8675-0

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.