NICE National Institute for Health and Care Excellence

NICE guidance

Percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices

HealthTech 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.

Contents

This guidance replaces IPG380.

1 Recommendations

1.1 Current evidence on the efficacy of percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices is inadequate in quality. Evidence on safety is inadequate, specifically with regard to the risk of distal embolisation. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices (see section 3.1).

1.3 Further research into percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices should take the form of well-conducted trials, which should define patient selection, treatment protocols and location and types of arterial lesions treated, and report long-term patency outcomes. NICE may review this procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Femoropopliteal arterial lesions are common in patients with symptomatic peripheral arterial disease (PAD) of the lower limbs, usually presenting with intermittent claudication.

2.1.2 Cardiovascular risk factor modification is fundamental to management. For patients with severely impaired walking distance or with critical limb ischaemia, revascularisation procedures such as balloon angioplasty, stenting or bypass grafting can be used.

2.2 Outline of the procedure

2.2.1 Percutaneous atherectomy of femoropopliteal arterial lesions with plaque excision devices aims to improve arterial flow by removing atheromatous plaque that is restricting blood flow.

2.2.2 With the patient under local anaesthesia, a guidewire is inserted percutaneously into the femoral artery, and the atherectomy catheter is introduced. Catheters of various diameters are available to suit the arterial diameter at the site of the lesion. After appropriately positioning the device, a high-speed rotating cutting blade excises the plaque. Plaque debris is usually collected in a distal nosecone and removed on device withdrawal. Alternatively, depending on the catheter design, the sheathed cutting blade may be advanced over the guidewire beyond the lesion and then exposed so that excision can be undertaken while the device is being withdrawn. Several passes of the catheter may be required. A distal embolic protection device is sometimes used. Adjunctive balloon angioplasty or stenting of the atherectomised segment may be done before removal of the sheath.

2.2.3 Various devices can be used 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 case series of 601 patients reported that procedural success (≤50% residual stenosis with no death, myocardial infarction, amputation, revascularisation, or major bleeding) was achieved in 95% (778 out of 822) of lesions at 30-day follow-up.

2.3.2 A case series of 275 patients reported that limb amputation was avoided in 93% of patients at 12-month follow-up and 92% of patients at 18-month follow-up (absolute figures not stated). A case series of 60 patients reported that amputation was required in 7% (4 out of 60) of patients at a mean 5-month follow-up. Of these patients, 2 had a patent atherectomy site but continuing ischaemia.

2.3.3 The case series of 601 patients reported that no further target lesion revascularisation was required in 90% of patients at 6-month follow-up (n=248), and in 80% of patients at 12-month follow-up (n=87; absolute figures not stated).

2.3.4 A case series of 34 patients reported clinical PAD improvement of 1 or more grades (on the Trans-Atlantic Inter-Society Consensus [TASC] II grading system) in 75% (27 out of 36) of procedures at 1-month follow-up and 55% (12 out of 22) of procedures at 12-month follow-up. A case series of 16 patients (17 limbs) with TASC grade C lesions reported that 71% (12 out of 17) had improved symptoms at 1-month follow-up, and 41% (7 out of 17) of limbs remained symptom-free at 6-month follow-up.

2.3.5 The case series of 275 patients reported that for all primary percutaneous atherectomy procedures (without adjunctive balloon angioplasty) the primary patency rate (arterial duplex ratio between proximal adjacent artery and the arterial lesion in question greater than 5.0) was 53% at 18-month follow-up (absolute figures not stated).

2.3.6 The Specialist Advisers listed key efficacy outcomes as adequate luminal channel

and long-term patency, limb salvage, improvement in claudication, quality of life and ulcer healing.

2.4 Safety

2.4.1 Periprocedural embolism was reported in 1 out of 1,258 procedures in the case series of 601 patients (clinical sequelae were not described) and in 7% (5 out of 70) of procedures in the case series of 60 patients (treated with suction embolectomy or tissue plasminogen activator). Embolism (treated by atherectomy) was reported in 5% (1 out of 18) of procedures in a case series of 16 patients.

2.4.2 Intraoperative arterial wall perforation occurred in 1% (10 out of 1,258) of procedures in the case series of 601 patients (clinical sequelae not described). No arterial wall perforation was reported in case series of 60 and 131 procedures.

2.4.3 Graft thrombosis (requiring surgery) following atherectomy at the inflow end of a femorofemoral crossover graft was reported in 1 patient in the case series of 34 patients. Pseudoaneurysm formation (requiring surgery) was reported in 1 patient in the same case series.

2.4.4 The Specialist Advisers considered theoretical adverse events to include distal embolisation, limb loss, puncture site bleeding or haematoma and device-related complications.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 380 has been migrated to HealthTech guidance 251. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.