NICE National Institute for Health and Care Excellence

NICE guidance

# Intravascular lithotripsy for calcified arteries in peripheral arterial disease

HealthTech guidance

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www.nice.org.uk/guidance/htg707

# 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 IPG780.

# 1 Recommendations

1.1 Intravascular lithotripsy for calcified arteries in peripheral arterial disease should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE guidance page.

1.2 Clinicians wanting to do intravascular lithotripsy for calcified arteries in peripheral arterial disease should:

- Inform the clinical governance leads in their healthcare organisation.
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Take account of NICE's advice on shared decision making, including NICE's information for the public.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by a vascular multidisciplinary team including interventional radiologists and vascular surgeons.

1.5 NICE encourages further research into intravascular lithotripsy for calcified arteries in peripheral arterial disease. Research should include:

- details of patient selection, including the location and degree of stenosis
- details of additional interventions
- longer-term outcomes, including mortality and amputation
- patient-reported outcomes including quality of life
- the need for revascularisation and amputation.

**Why the committee made these recommendations**

There is a moderate amount of evidence, including data from a randomised controlled trial, which suggests the procedure is safe. The evidence shows that blood vessel diameter is increased after the procedure, but because intravascular lithotripsy is sometimes done alongside other procedures it is difficult to know whether this is directly because of the intravascular lithotripsy procedure. The evidence suggests that the procedure is associated with a reduced need for a stent to keep the vessel open. But there is not enough long-term evidence, or evidence about how many amputations will be prevented by having this procedure. More evidence is also needed on patients' quality of life.

There may be groups of people who would particularly benefit from this procedure. These could include people with smaller vessels or with calcified arteries in a location unsuitable for a stent, but more evidence is needed.

# 2 The condition, current treatments and procedure

## The condition

2.1 Peripheral arterial disease (PAD) is caused when a build-up of fatty substances (plaque) in the arteries restricts blood supply to the limbs, usually the legs. The plaque can calcify and become like bone. This is known as intravascular calcification, and it is particularly common in people with diabetes mellitus or chronic kidney disease. The most common initial symptom of PAD is leg pain while walking, known as intermittent claudication. If blood flow is severely restricted, chronic limb-threatening ischaemia (CLTI, also known as critical limb ischaemia) can develop. Symptoms include severe pain at rest, ulceration or gangrene. CLTI is associated with a high risk of amputation and death, and the presence of arterial calcification increases these risks.

## Current treatments

2.2 Management of PAD is described in NICE's clinical guideline on peripheral arterial disease. For CTLI, revascularisation using percutaneous transluminal angioplasty (with or without stent placement) or a bypass graft is recommended. Atherectomy devices that vaporise, cut or grind away plaque within the artery are sometimes used alongside balloon angioplasty. If revascularisation is not an option, major amputation may be offered.

## The procedure

2.3 Arterial access is established as for a standard angioplasty, usually through the femoral artery in the groin. An angioplasty balloon with a source of acoustic pressure waves (lithotripsy emitters) is introduced and inflated next to the heavily calcified arterial plaques. The pressure exerted by the balloon is too low to

expand the vessel but high enough to ensure good contact between the surface of the balloon and the arterial walls. Acoustic pressure waves are then transmitted from the balloon, fracturing superficial and deep calcium within the arterial wall. As with standard angioplasty, a stent is sometimes inserted after the lithotripsy to keep the artery patent. The procedure is used as a preparatory treatment for balloon angioplasty or as an alternative to standard angioplasty.

2.4 The aim of intravascular lithotripsy is to improve the blood flow in the affected limb and prevent the need for amputation.

# 3 Committee considerations

## The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 10 sources, which was discussed by the committee. The evidence included 1 systematic review and meta-analysis, 1 randomised controlled trial (reported in 2 papers), 1 prospective single-arm trial, 2 retrospective cohort studies, 1 prospective single centre registry and 2 case reports. It is presented in the summary of key evidence section in the overview. Other relevant literature is in table 5 of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: quality of life, vessel patency, amputation rate, amputation-free survival, procedural success, revascularisation rate and need for a stent.

3.3 The professional experts and the committee considered the key safety outcomes to be: embolisation, perforation, dissection, worsening of pain and long-term procedure failure.

3.4 Patient commentary was sought but none was received.

## Committee comments

3.5 Most of the evidence was on femoropopliteal lesions, but there was some evidence on iliac lesions. There are several ongoing studies, including 1 on arteries below the knee.

3.6 Clinical experts explained that the procedure is only used for chronic limb ischaemia and would not be used in an acute setting.

3.7 The clinical experts advised that there is no clear consensus for assessing the

degree of calcification in a peripheral artery.

3.8 Studies that used intravascular lithotripsy to allow access for an endovascular cardiac procedure were not included in the evidence for this guidance.

3.9 There is a company-funded registry of people having the procedure in the UK. But this is no longer recruiting.

3.10 There is an unmet need for a safe and effective endovascular option for treating heavily calcified arterial lesions when surgery is unsuitable.

# Update information

**Minor changes since publication**

**January 2026:** Interventional procedures guidance 780 has been migrated to HealthTech guidance 707. The recommendations and accompanying content remain unchanged.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.