NICE National Institute for Health and Care Excellence

NICE guidance

Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia

HealthTech guidance

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www.nice.org.uk/guidance/htg698

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 IPG773.

1 Recommendations

1.1 Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia in people with limited treatment options 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 percutaneous deep venous arterialisation for chronic limb-threatening ischaemia 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 Further research should report:

- details of patient selection (including number of patients dependent on dialysis)

- details of the procedure technique
- duration of anticoagulation
- patient outcomes (including planned and unplanned reintervention rate, major amputation rate, and quality of life).

Why the committee made these recommendations

The evidence is limited in quality and quantity; in particular, long-term data and quality of life data are lacking. The evidence includes different procedure techniques and different ways of selecting patients who have no other options for arterial revascularisation (restoring blood flow to a body part in which the blood vessels have become blocked). So, in people who have limited treatment options, this procedure can be used with special arrangements.

2 The condition, current treatments and procedure

The condition

2.1 Chronic limb-threatening ischaemia of the lower extremities is caused by severely narrowed or blocked arteries. It is an advanced stage of peripheral arterial disease. The severely reduced blood supply causes ischaemic pain, ulceration, tissue loss and gangrene. It is associated with high amputation and mortality rates, and poor quality of life.

Current treatments

2.2 Chronic limb-threatening ischaemia usually needs treatment to re-establish blood flow to the affected area and to prevent major amputation. Treatment options include medications, endovascular interventions (such as angioplasty, stents and directional atherectomy) and surgical treatments (such as bypass). Management of chronic limb-threatening ischaemia is described in NICE's clinical guideline on peripheral arterial disease.

The procedure

2.3 The procedure uses an endovascular, minimally invasive approach. An arteriovenous fistula is created to allow venous arterialisation in the below-the-knee vasculature. The aim is to restore blood flow to the ischaemic foot.

2.4 Preoperative investigation is needed to confirm adequate pedal venous anatomy and identify a suitable crossover point between the vessels.

2.5 The procedure is usually done using general anaesthesia, and with ultrasound guidance. Antegrade arterial access is established through the common femoral

artery, and retrograde venous access is established through the tibial vein. Arterial and venous catheters are inserted and advanced to the target artery and vein (most frequently the posterior tibial artery and vein). Once both catheters are positioned with a crossover point, a needle is used to create an arteriovenous fistula. Valvulotomy of the vein is then done, usually from the crossover point to the midfoot. Multiple stents are placed in the vein from the level of the calcaneus to the arteriovenous crossover point, and a crossing stent is inserted to maintain the arteriovenous fistula. This establishes retrograde blood flow down the veins, which become arterialised.

2.6 Arteriography is done at the end of the procedure to visualise blood flow into the deep venous arch.

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 7 sources, which was discussed by the committee. The evidence included 1 single-arm pivotal study, 2 single-arm pilot studies, and 4 case series. It is presented in the summary of key evidence section in the overview. Other relevant literature is in the appendix of the overview. Additional documentation in confidence provided by a company was also considered by the committee.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: improvement in limb perfusion and wound healing, reduction in major amputation, and improvement in quality of life.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, infection, worsening of perfusion, and steal syndrome.

3.4 Three commentaries from people who have had this procedure were discussed by the committee.

Committee comments

3.5 Some patients needed both planned and unplanned reinterventions. The reinterventions might not have been related to this procedure.

3.6 The committee was informed that patient selection and postprocedural surveillance are important, and that patients should be followed up for life.

3.7 The committee was informed that this is a challenging procedure, and that it should only be done by clinicians with specific training and experience in this

technique.

3.8 There are different techniques and devices used, which might have different efficacy and safety profiles. The committee was informed that there is currently only 1 device with regulatory approval for use in the UK.

3.9 The committee encourages data entry into a registry that captures the technique used.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 773 has been migrated to HealthTech guidance 698. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.