

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia

Chronic limb-threatening ischaemia happens when blocked arteries reduce blood flow to a limb (usually the leg). Symptoms include pain and ulcers. In severe cases the tissue dies because of the lack of blood supply and there is a high risk of losing the limb.

In this procedure, under general anaesthesia, 2 small tubes are inserted through the skin (percutaneous) and moved into the target artery and vein, deep in the leg. A needle is used to create a hole to allow blood to flow from the artery into the vein, into the part of the leg beyond the blockage (venous arterialisation). The valves inside the vein are removed, and stents (small tubes) are placed to keep the hole working. The aim is to improve symptoms and preserve the affected limb by restoring blood flow.

NICE is looking at percutaneous deep venous arterialisation for chronic limb-threatening ischaemia.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the [draft guidance for consultation](#). Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

NICE interventional procedures consultation document, March 2023

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a [resolution process](#) before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 24 April 2023

Target date for publication of guidance: August 2023

1 Draft recommendations

- 1.1 Percutaneous deep venous arterialisation for chronic limb-threatening ischaemia should be used only in research. Find out [what only in research means on the NICE interventional procedures guidance page](#).
- 1.2 Further research should report:
- details of patient selection
 - details of the procedure
 - 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 based on a small number of people and limited in quality. It 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, it is unclear who will benefit from the procedure. Overall, how well the procedure works and how safe it is are uncertain.

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 or 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 6 sources, which was discussed by the committee. The evidence included 1 feasibility study, 1 pilot study, and 4 case series. It is presented in the [summary of key evidence section in the interventional procedures overview](#). Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: improvement in limb perfusion, reduction in amputation and quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, infection, worsening of perfusion, steal syndrome and major adverse cardiovascular events.
- 3.4 Three commentaries from people who have had this procedure were discussed by the committee.

Committee comments

- 3.5 A significant number of patients needed both planned and unplanned reinterventions.
- 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.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

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