

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Superficial venous arterialisation and selective venous occlusion for chronic limb threatening ischaemia in people with no other option for revascularisation

Chronic limb threatening ischaemia happens when blocked arteries reduce the blood flow in the lower leg. Symptoms include pain and ulcers. In severe cases the leg tissue dies because of the lack of blood supply and there is a high risk of losing the limb. In this procedure, an artery in the lower leg is joined to a large vein to divert blood flow through the vein towards the foot, bypassing the blocked arteries. The valves inside the vein are removed (superficial venous arterialisation) and smaller veins are blocked off (selective venous occlusion). The aim is to improve symptoms and preserve the affected limb by restoring blood flow.

NICE is looking at superficial venous arterialisation and selective venous occlusion for chronic limb threatening ischaemia in people with no other option for revascularisation.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts, who are consultants 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This document contains the [draft guidance for consultation](#).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 The draft guidance may change after this consultation.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 2022

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance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: 14 April 2022

Target date for publication of guidance: August 2022

1 Draft recommendations

1.1 Evidence on the safety of superficial venous arterialisation and selective venous occlusion for chronic limb threatening ischaemia in people with no other option for revascularisation shows well-recognised complications. Evidence on its efficacy is inadequate in quantity and quality. However, because this guidance covers people who have no other treatment options, this procedure can be used with special arrangements for clinical governance, consent, and audit or research. Find out [what special arrangements mean on the NICE interventional procedures guidance page](#).

1.2 Clinicians wanting to do superficial venous arterialisation and selective venous occlusion for chronic limb threatening ischaemia in people with no other option for revascularisation should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers as appropriate) clear written information to support [shared decision making](#), including [NICE's information for the public](#).
- Ensure that people (and their families and carers as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- 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 interventional procedure outcomes 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:

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- 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 multidisciplinary team with specialist expertise in managing chronic limb threatening ischaemia.
- 1.5 The procedure should only be done in specialist centres by surgeons with specific training and experience in this procedure.

2 The condition, current treatments and procedure

The condition

- 2.1 Chronic limb threatening ischaemia (CLTI), also known as critical limb ischaemia, is a severe blockage in the arteries of the lower extremities. It is an advanced stage of peripheral arterial disease. CLTI is characterised by severely diminished circulation, 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 CLTI needs urgent 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, laser atherectomy and directional atherectomy) and surgical treatments (such as bypass). Management of CLTI is described in [NICE's clinical guideline on peripheral arterial disease](#).

The procedure

- 2.3 Preoperative investigation (such as angiography, arterial and venous duplex scan) is needed to assess the vascular system and its blood flow. During the operation, an arteriovenous fistula is created between the great saphenous vein (GSV) and the appropriate patent artery. The GSV is then anastomosed end-to-side to the artery below the knee. Side branches of the GSV to the ankle level are ligated and valvulotomy is done.
- 2.4 This procedure arterialises the venous arch of the foot, with GSV maintained in situ and without compromising the existing collateral circulation. The aim is to improve symptoms and salvage the affected lower extremity.

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 4 sources, which was discussed by the committee. The evidence included 3 cohort studies and 1 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: limb salvage, pain relief and improvement in quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: mortality, need for major amputation, pain, bleeding and infection.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee noted that this procedure is only used for people with no other treatment options for arterial reconstruction.

3.6 The committee noted that the primary aims of this procedure are to reduce ischaemic limb pain, and limb salvage rather than the restoration of limb function.

3.7 The committee noted there was little published literature on this procedure and would encourage clinicians to publish their experience of this procedure including case series.

Tom Clutton-Brock

Chair, interventional procedures advisory committee

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