



Superficial venous arterialisation for chronic limb threatening ischaemia

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www.nice.org.uk/guidance/ipg736

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 <u>assess and reduce the environmental</u> impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 Evidence on the safety of superficial venous arterialisation for chronic limb threatening ischaemia shows well-recognised complications. Evidence on its efficacy is inadequate in quantity and quality. However, in people with no other option for revascularisation, 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 for chronic limb threatening ischaemia should:
 - Inform the clinical governance leads in their healthcare organisation.
 - Give people (and their families and carers as appropriate) clear written information to support <u>shared decision making</u>, including <u>NICE's information</u> 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 procedures 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:
 - 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.
- 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 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.
- 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.
- The professional experts and the committee considered the key efficacy outcomes to be: limb salvage, pain relief and improvement in quality of life.
- The professional experts and the committee considered the key safety outcomes to be: mortality, need for major amputation, pain, bleeding and infection.
- Patient commentary was sought but none was received.

Committee comments

- 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.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.