



Cyanoacrylate glue occlusion for varicose veins

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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. However, 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.

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.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

1.1 Current evidence on the safety and efficacy of cyanoacrylate glue occlusion for

varicose veins is limited in quantity and quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

- 1.2 Clinicians wishing to use cyanoacrylate glue occlusion for varicose veins should:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
 - <u>Audit</u> and review clinical outcomes of all patients having cyanoacrylate glue occlusion for varicose veins (a national register is currently under development).
- 1.3 Patient selection should be done by clinicians who can offer a range of treatment options in addition to cyanoacrylate glue occlusion.
- 1.4 This procedure should only be done by clinicians with specific training in this technique.
- 1.5 NICE may update the guidance on publication of further evidence.

2 Indications and current treatments

- 2.1 Varicose veins are a sign of underlying venous insufficiency and affect 20–30% of adults. Most people with varicose veins have no symptoms but venous insufficiency may cause fatigue, heaviness, aching, throbbing, itching and cramps in the legs. Chronic venous insufficiency can lead to skin discoloration, inflammatory dermatitis and ulceration. Great saphenous vein insufficiency is the most common form of venous insufficiency in people presenting with symptoms.
- 2.2 Many people have varicose veins that do not cause any symptoms or need any treatment on medical grounds. However, some people will need treatment for the relief of symptoms, or if there is evidence of skin discoloration, inflammation or ulceration. Treatment options include endothermal ablation, ultrasound-guided foam sclerotherapy, and surgery (usually stripping and ligation of the great and small saphenous veins, and phlebectomies).

3 The procedure

- 3.1 Cyanoacrylate glue occlusion aims to close varicose veins by adherence then fibrosis of the lumen, without the need for tumescent anaesthesia (infusion of a large volume of dilute local anaesthetic around and along the entire length of the vein). The need for post-operative compression therapy is also reduced.
- 3.2 The procedure is done using local anaesthesia. An introducer sheath is inserted into the distal great saphenous vein in the affected leg and, using ultrasound guidance, a delivery catheter is advanced into position just before the saphenofemoral junction. The proximal vein is compressed and a measured dose of cyanoacrylate glue is delivered through the tip of the catheter to seal the vein. The catheter is withdrawn in stages and the steps repeated to close the vein (that is, proximal vein compression and further measured doses) using ultrasound imaging to monitor progress. The procedure may also be done in a similar fashion for the small saphenous vein.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>interventional procedure overview</u>.

- 4.1 A randomised controlled trial of 222 patients with varicose veins treated by cyanoacrylate glue occlusion or radiofrequency ablation reported closure rates of 100% and 86% respectively at 1-month follow-up (p<0.01; absolute numbers not reported). A case series of 38 patients treated by cyanoacrylate glue occlusion reported complete closure of the great saphenous vein in 100% (38/38) of patients at 48-hour follow-up (diagnosed by duplex ultrasound imaging). The closure rates at 12- and 24-month follow-up were 92%; there were 2 partial recanalisations and 1 complete recanalisation. A case series of 70 patients reported that 93% (63/68) of patients were free from recanalisation at 12-month follow-up. A case series of 65 saphenous vein procedures (43 great saphenous veins and 22 small saphenous veins) reported a closure rate of 99% at 3-month follow-up (absolute numbers not reported).
- 4.2 The randomised controlled trial of 222 patients reported an improvement in the

Venous Clinical Severity Score of approximately 3.5 points from baseline at 3-month follow-up (p<0.01), with no differences between the 2 treatment groups (cyanoacrylate glue occlusion or radiofrequency ablation). The case series of 38 patients treated by cyanoacrylate glue occlusion reported an improvement in the mean Venous Clinical Severity Score from 6.1 at baseline to 1.5 at 12-month follow-up (n=36, p<0.001). At 6- and 24-month follow-up, 84% and 65% of legs respectively had no oedema, compared with 39% of legs before treatment (absolute numbers not reported). Before treatment, all legs showed clinically relevant varicosities. At 12- and 24-month follow-up, 50% and 35% of legs were free from varicosities respectively (absolute numbers not reported). In the same study, the proportion of patients free from pain increased from 13% at baseline to 84% at 6-month follow-up and 64% at 24-month follow-up (absolute numbers not reported). The case series of 70 patients reported an improvement in the mean Venous Clinical Severity Score from 4.3 at baseline to 1.1 at 12-month follow-up (p<0.0001).

4.3 The specialist advisers listed key efficacy outcomes as complete closure of great/small saphenous vein (on duplex ultrasound), absence of long-term recanalisation, improvement in leg symptoms, improvement in quality of life and patient satisfaction.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the <u>interventional procedure overview</u>.

- Thread-like thrombus extensions across the saphenofemoral junction were reported in 21% (8/38) of patients in a case series of 38 patients (seen on ultrasound imaging at 48-hour follow-up). At 6-month follow-up, all thrombus extensions had resolved without clinical sequelae. Thrombus extension into the common femoral vein was reported in 1 patient in a case series of 70 patients; this resolved without progression.
- Phlebitis was reported in 16% (6/38) of patients in the case series of 38 patients; the patients had mild pain and erythema, which persisted for an average of 5 days. Superficial thrombophlebitis that resolved spontaneously was reported in 1 patient in the same case series. A mild phlebitic reaction was

reported in 11% (8/70) of patients in the case series of 70 patients, with a median duration of 6.5 days. Self-limited thrombophlebitis was reported after 40% (4/10) of procedures in a case series of 10 veins. 'Mild' phlebitis in the treatment zone was reported in 6% (6/108) of patients treated by cyanoacrylate glue occlusion in a randomised controlled trial of 222 patients. 'Moderate' phlebitis not in the treatment zone was reported in 1 patient treated by cyanoacrylate glue occlusion in the same study and 'mild' superficial vein thrombophlebitis was reported in 3% (3/108) of patients.

- 5.3 Low-grade cellulitis that resolved with oral antibiotics was reported in 1 patient in the case series of 38 patients. Moderate access site infection was reported in 1 patient treated by cyanoacrylate glue occlusion in the randomised controlled trial of 222 patients.
- A postoperative erysipeloid-phlebitic skin reaction was reported after 15% (10/65) of procedures in the case series of 65 patients; all resolved quickly after conservative compression therapy. A hypersensitivity reaction was reported in 1 patient in the case series of 10 veins; the patient had simultaneous occlusion of both incompetent anterior accessory saphenous veins and the reaction was thought to be caused by subcutaneous delivery of the adhesive.
- 5.5 Hyperpigmentation was reported in 1 patient in the case series of 38 patients: this was still visible at 24-month follow-up.
- 5.6 Moderate and mild paraesthesia were each reported in 1 patient treated by cyanoacrylate glue occlusion in the randomised controlled trial of 222 patients.
- In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers described the following anecdotal adverse events: nerve injury (no other details provided) and inadvertent injection into the subcutaneous space, muscle or perivenous space. They considered that the following were theoretical adverse events: embolisation of glue to the lungs; cerebrovascular complications giving rise to transient or permanent neurological sequelae; deep vein thrombosis; scarring; ulceration; haematoma; and pain.

6 Committee comments

- The committee noted that cyanoacrylate glue occlusion for varicose veins has the theoretical benefit of allowing people to have outpatient treatment for varicose veins, without the use of tumescent anaesthesia or compression hosiery.
- The committee noted that the published evidence is relatively small and that rare or uncommon risks may not yet be apparent.

7 Further information

7.1 For related NICE guidance, see the <u>NICE website</u>.

Information for patients

NICE has produced information on this procedure for patients and carers (<u>information for the public</u>). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

This guidance was developed using the NICE interventional procedures guidance process.

We have produced <u>information for the public</u> explaining this guidance. Information about the <u>evidence</u> the guidance is based on is also available.

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Changes after publication

October 2015: Minor maintenance.

August 2015: Minor maintenance.

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Endorsing organisation

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

Accreditation

