

Ultrasound-guided foam sclerotherapy for varicose veins

1 Guidance

- 1.1 Current evidence on ultrasound-guided foam sclerotherapy for varicose veins shows that it is efficacious in the short term. The evidence on safety indicates that there are transient side effects in a small number of patients such that the procedure should be used with special arrangements for consent, and for audit or research.
- 1.2 Clinicians wishing to undertake ultrasound-guided foam sclerotherapy for varicose veins should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Patients should be fully informed of the potential side effects associated with the procedure. Clinicians should provide patients with clear written information. In addition, use of the Institute's 'Understanding NICE guidance' is recommended (available from www.nice.org.uk/IPG182publicinfo).
 - Audit and review clinical outcomes of all patients having ultrasound-guided foam sclerotherapy for varicose veins.
- 1.3 The procedure should only be undertaken using pharmaceuticals licensed for sclerotherapy of varicose veins. Current practice includes mixing liquid sclerosant with air with the intention of improving efficacy, and this constitutes off-label use.
- 1.4 Current evidence of long-term efficacy is limited and clinicians are encouraged to collect longer-term follow-up data.
- 1.5 The procedure has been referred to the Review Body for Interventional Procedures for a systematic review.

2 The procedure

2.1 Indications

- 2.1.1 Varicose veins affect 20–30% of adults. The long saphenous vein is the most commonly affected vein among people presenting with symptoms.

- 2.1.2 People with venous insufficiency may suffer from heaviness, aching, throbbing, itching and cramps or fatigue in the legs. Chronic venous insufficiency can, in some patients, lead to skin discoloration, inflammatory dermatitis and skin ulceration.
- 2.1.3 Conservative methods such as compression hosiery (support stockings or tights) may help patients with symptomatic varicose veins. If symptoms are sufficiently troublesome, the main treatment options are sclerotherapy and/or surgery (usually stripping and ligation of the long or short saphenous veins, and phlebectomies). Ultrasound-guided foam sclerotherapy for varicose veins is a variation of sclerotherapy techniques that use liquid injection. It uses a sclerosant solution that has been transformed into foam by being mixed with air or other gas.

2.2 Outline of the procedure

- 2.2.1 A needle is inserted into the main affected superficial vein, usually under ultrasound guidance. Sclerosant foam is then injected and monitored using ultrasound. Once the foam has filled the main superficial vein, the upper end of the vein may be compressed to prevent entry of foam into the deeper veins. The foam causes inflammation of the vein wall, obliteration of the vein's lumen and vein occlusion.
- 2.2.2 Further injections may be given during the same session to make sure that all the varicose veins have been completely filled. If any vein is incompletely treated, further injections can be given in subsequent sessions.

2.3 Efficacy

- 2.3.1 In a randomised controlled trial comparing liquid and foam sclerotherapy using polidocanol, elimination of reflux in the long saphenous vein at 3 weeks was noted in 84% (38/45) of patients in the foam group compared with 40% (17/43) of patients in the liquid group. At 6 months, 4% (2/45) of patients in the foam group developed re-canalisation of the treated veins compared with 14% (6/43) of patients in the liquid group.

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This guidance is written in the following context

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales and Scotland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

2.3.2 In a non-randomised study comparing liquid and foam sclerotherapy with up to 12 months follow-up, complete occlusion was demonstrated in the long saphenous vein in 68% (25/37) of patients treated with foam compared with 18% (7/40) of patients in the liquid group. Recurrent varicose veins were found in 8% (3/37) of patients in the foam group and 25% (10/40) of patients in the liquid group.

2.3.3 In another comparative study, using sodium tetradecyl sulphate (STD), reflux disappeared in 67% of limbs treated with foam compared with 47% of limbs in the liquid group at 6 months' follow-up. In two other studies evaluating foam sclerotherapy using STD, successful treatment was reported in 97% (109/112) of treated veins at a mean follow-up of 22.5 months, and 93% of patients at follow-up ranging from 20 to 180 days (n = 170). It is difficult to interpret and compare this evidence because of the variation in delivery of foam sclerotherapy between trials. For more details, refer to the 'Sources of evidence' section.

2.3.4 The Specialist Advisers expressed uncertainty regarding the efficacy of this procedure. They thought that the current published evidence did not provide clear evidence of benefit, particularly in the long term.

2.4 Safety

2.4.1 Complications reported after foam sclerotherapy included the development of superficial thrombophlebitis, thrombosis in deep calf veins and skin pigmentation. A number of studies also report that approximately 2% of patients experience transient side-effects including chest tightness, dry cough, headache, paraesthesia, or visual disturbance following the procedure. In a further report of 12,173 sclerotherapy sessions of which 6395 were with foam, there were 37 (0.6%) adverse events following foam sclerotherapy. These included: 8 cases of isolated transient visual disturbances; 8 cases of visual disturbances combined with headache, nausea or vasovagal fainting (all 16 cases spontaneously regressed with no after effects); 6 cases of vasovagal fainting; 3 cases of thrombosis of the perforating veins; and 1 case of deep venous thrombosis (less than 1% each). There is a single case report of a patient developing stroke shortly following foam sclerotherapy. For more details, refer to the 'Sources of evidence' section.

2.4.2 The Specialist Advisers listed the potential complications of this procedure as deep vein thrombosis, thrombophlebitis and allergy. One Adviser stated that

the risks associated with this procedure were comparable to those of liquid sclerotherapy.

2.5 Other comments

2.5.1 The volume and concentration of foam varied among the studies, and it is unclear whether these may influence efficacy outcomes and/or the rate of reported complications.

2.5.2 Currently, only liquid sclerosants (not mixed with air or gas) are licensed for the treatment of varicose veins. It was noted that the method used to mix the liquid sclerosant with air and the size of the foam bubbles used may influence safety.

2.5.3 It was also noted that there had been one episode of myocardial infarction shortly after this procedure. Whether this event relates to foam sclerotherapy treatment is uncertain.

3 Further information

3.1 The Institute has issued guidance on radiofrequency ablation of varicose veins (www.nice.org.uk/IPG008), transilluminated powered phlebectomy for varicose veins (www.nice.org.uk/IPG037) and endovenous laser treatment of the long saphenous vein (www.nice.org.uk/IPG052).

Andrew Dillon
Chief Executive
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Understanding NICE guidance

NICE has produced information describing its guidance on this procedure for patients and their carers. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG182publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of ultrasound-guided foam sclerotherapy for varicose veins', March 2004.

Available from: www.nice.org.uk/IP244overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1068. *Information for the public* can be obtained by quoting reference number N1069.

The distribution list for this guidance is available at www.nice.org.uk/IPG182distributionlist

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