

# Ultrasound-guided foam sclerotherapy for varicose veins

Interventional procedures guidance

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[www.nice.org.uk/guidance/ipg440](http://www.nice.org.uk/guidance/ipg440)

## 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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG314 and IPG217.

# 1 Guidance

- 1.1 Current evidence on the efficacy of ultrasound-guided foam sclerotherapy for varicose veins is adequate. The evidence on safety is adequate, and provided that patients are warned of the small but significant risks of foam embolisation (see section 1.2), this procedure may be used with normal arrangements for clinical governance, consent and audit.
- 1.2 During the consent process, clinicians should inform patients that there are reports of temporary chest tightness, dry cough, headaches and visual disturbance, and rare but significant complications including myocardial infarction, seizures, transient ischaemic attacks and stroke.

## 2 The procedure

### 2.1 Indications and current treatments

- 2.1.1 Varicose veins are enlarged tortuous veins with deficient valves. Venous insufficiency occurs when blood collects in them rather than being pumped back to the heart. 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 discolouration, inflammatory dermatitis and ulceration. Great saphenous vein insufficiency is the most common form of venous insufficiency in people presenting with symptoms.

2.1.2 Conservative methods such as compression hosiery (support stockings or tights) may help people with symptomatic varicose veins. If symptoms are severe the main treatment options include surgery (ligation and stripping of the great saphenous veins or ligation with or without stripping of the small saphenous veins, and phlebectomy), endovenous laser treatment and radiofrequency ablation.

## 2.2 Outline of the procedure

2.2.1 The aim of ultrasound-guided foam sclerotherapy for varicose veins is to damage the endothelial surface of the vein causing scarring and leading to blockage of the treated varicose veins. Sclerosant, in the form of a foam, is intended to have good surface area contact with the vein walls.

2.2.2 The procedure may be carried out with local anaesthesia. Sclerosant foam is injected into the affected veins using ultrasound guidance. The foam causes an inflammatory reaction in the vein wall, blocking the vein. Compression bandages are applied after the procedure and are typically worn for between a week and a month.

2.2.3 More than 1 vein may be treated during the same session. If any vein is incompletely treated, further injections may be given in the same or subsequent sessions.

## 2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and 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 [overview](#).

2.3.1 A randomised controlled trial (RCT) of 73 patients (82 legs), in which foam sclerotherapy plus saphenofemoral ligation (n=39) was compared with standard surgery (n=43), reported above-the-knee vein obliteration in 58% (19 out of 33) of legs in patients treated in the foam plus saphenofemoral ligation group and

54% (14 out of 26) of legs in patients treated by standard surgery alone at 5-year follow-up ( $p=0.19$ ). Below-the-knee vein obliteration was reported in 24% (8 out of 33) of legs in patients treated by foam plus saphenofemoral ligation and 39% (10 out of 26) of legs in patients treated by standard surgery alone at 5-year follow-up ( $p=0.34$ ).

- 2.3.2 A meta-analysis of 2 RCTs (included in a systematic review) with 340 patients reported that foam sclerotherapy was not significantly more efficacious ( $n=174$ ) than liquid ( $n=166$ ) in occluding the vein (relative risk [RR] 1.5; 95% confidence interval [CI] 0.6 to 3.6,  $I^2=95\%$ , indicating significant heterogeneity), with follow-up ranging from 1 to 10 years.
- 2.3.3 In a case series of 146 patients (203 limbs), the clinical recurrence rate (reported in 23 patients) with significant venous symptoms (visible or palpable varices, aching, oedema or venous skin changes) was 4%, the clinical recurrence rate with minimal venous symptoms was 22%, and recurrence with no venous symptoms was 74% at 5-year follow-up.
- 2.3.4 In the RCT of 73 patients the median Venous Clinical Severity scores (graded from 0 [absent] to 3 [severe]; maximum score 30) decreased from 5 to 1 in patients treated by foam sclerotherapy plus saphenofemoral ligation and decreased from 5 to 3 in patients treated by surgery alone at 5-year follow-up ( $p=0.35$  between groups;  $p$  values for change within groups not reported).
- 2.3.5 The RCT of 73 patients reported that the median Aberdeen Varicose Vein Questionnaire scores (range 0 to 100, with higher scores indicating more severe effects) decreased from 12 at baseline to 7 in patients treated by foam sclerotherapy plus saphenofemoral ligation, and from 16 at baseline to 6 in patients treated by surgery. The difference between the groups was statistically significant but not considered 'clinically significant' at 5-year follow-up ( $p=0.02$ ).
- 2.3.6 The Specialist Advisers listed additional key efficacy outcomes as mobility and recurrence of leg ulceration.

## 2.4 Safety

- 2.4.1 Stroke was reported in a case report of 3 patients, all of whom were subsequently diagnosed with a patent foramen ovale. In 1 patient treated by foam sclerotherapy and ambulatory phlebectomy, middle cerebral arterial bubbles were detected immediately after the procedure (treated with tissue plasminogen activator), and in the other 2 patients middle cerebral arterial ischaemic change was confirmed (1 day after the procedure in 1 patient and 2 days after the procedure in the other patient). All 3 patients recovered completely with no further neurological or thrombotic events reported at follow-up ranging from 3 months to 2 years. A transient ischaemic attack after injection was reported in 1 patient in a case series of 1,025 patients. Complete clinical recovery occurred in 30 minutes.
- 2.4.2 Myocardial infarction was reported in 1 patient 30 minutes after injection (unpublished report included in the systematic review; no further details available).
- 2.4.3 A grand mal epileptic seizure was reported in 1 patient 40 minutes after injection (based on an unpublished report included in the systematic review; no further details available).
- 2.4.4 Bubble embolisation was reported in 73% (60 out of 82) of patients in a case series of 82 patients with right-to-left shunts. 'Most' bubbles were detected within 15 minutes of the foam injection and no new neurological symptoms were detected at follow-up (assessed at 1, 7 and/or 28 days).
- 2.4.5 Transient visual disturbance was reported in 5 patients, during or shortly after treatment, in a case series of 977 patients treated by foam sclerotherapy.
- 2.4.6 Headache was reported in 3 patients immediately after the procedure in the case series of 977 patients (resolved in 24 hours after treatment by analgesia).
- 2.4.7 Pulmonary embolism (treated by an anticoagulant) was reported in 1 patient in the case series of 977 patients 5 weeks after the procedure.
- 2.4.8 Thrombophlebitis was reported in 7% (17 out of 230) of patients treated by foam

sclerotherapy within 1 week of the procedure compared with 0% of 200 patients treated by surgery in an RCT of 430 patients ( $p < 0.001$ ).

- 2.4.9 Skin pigmentation was reported in 6% (12 out of 213) of patients treated by foam sclerotherapy compared with 1% (2 out of 177) of patients treated by surgery in the RCT of 430 patients at 2-year follow-up.
- 2.4.10 Complications including coughing, chest tightness or heaviness, panic attack, malaise and vasovagal fainting occurred at a rate of 0% to 3% across the studies in the systematic review (follow-up ranged between 1 month and 5 years).
- 2.4.11 The Specialist Advisers listed an additional theoretical adverse event to be extravasation.

## 3 Further information

### Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

### Information for patients

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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### Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).