

# Ultrasound-guided foam sclerotherapy for varicose veins

This document replaces previous guidance on ultrasound-guided foam sclerotherapy for varicose veins (interventional procedure guidance 217).

## 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 includes systemic side effects in some patients. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit.
- 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.
  - Ensure that patients understand the potential side effects of the procedure, including those thought to be associated with foam embolisation, and provide them with clear written information, which should include other treatment options. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from [www.nice.org.uk/IPG314publicinfo](http://www.nice.org.uk/IPG314publicinfo)).
  - Audit and review clinical outcomes of all patients having ultrasound-guided foam sclerotherapy for varicose veins (see section 3.1).
- 1.3 The procedure should only be undertaken using sclerosants licensed for varicose veins. The practice of mixing liquid sclerosant with air or other gas 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.

## 2 The procedure

### 2.1 Indications and current treatments

- 2.1.1 Varicose veins are enlarged tortuous veins with deficient valves such that blood collects in the veins rather than being pumped back to the heart (venous insufficiency). The superficial saphenous veins of the leg are the veins most commonly affected, and often the most symptomatic. Varicose veins affect 20–30% of adults.
- 2.1.2 Varicose saphenous veins may be associated with heaviness, aching, throbbing, itching and cramps or fatigue in the legs. In the long term, some patients may develop skin discolouration, inflammatory dermatitis and skin ulceration.
- 2.1.3 Compression hosiery may improve symptomatic varicose veins. If symptoms persist, the treatment options to abolish truncal varicose veins include surgery (usually stripping and ligation of the long or short saphenous veins and phlebectomies), foam sclerotherapy and laser or radiofrequency ablation.

### 2.2 Outline of the procedure

- 2.2.1 Ultrasound-guided foam sclerotherapy for varicose veins is carried out with the patient under local anaesthesia. Sclerosant foam is injected into the affected veins using ultrasound monitoring. The foam causes an inflammatory reaction in the vein wall, destroying the vein's lumen and blocking the vein. Compression bandages are applied postprocedurally.

## Interventional procedure guidance 314

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

2.2.2 More than one 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.

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, available at [www.nice.org.uk/IP244boverview](http://www.nice.org.uk/IP244boverview)

## 2.3 Efficacy

2.3.1 A systematic review of the published evidence on these procedures included a total of 67 studies: 9 randomised controlled trials (RCTs), 1 registry report, 8 non-randomised comparative studies, 43 case series and 6 case reports.

2.3.2 Across 5 RCTs including 640 patients, the median rate of complete venous occlusion was 84% following foam sclerotherapy (range 67–94%) (follow-up ranged from 3 months to 10 years). A meta-analysis of 3 RCTs including 540 patients reported that foam was not significantly more efficacious in occluding the vein compared with liquid sclerotherapy (relative risk [RR] 1.4, 95% confidence interval [CI] 0.9 to 2.1) (follow-up 1–10 years). A meta-analysis of 2 RCTs including 324 patients reported that surgery was not significantly more efficacious than foam in achieving venous occlusion (RR 0.9, 95% CI 0.7 to 1.1) (follow-up 3 months to 1 year).

2.3.3 The rates of varicose vein recurrence and development of new veins varied across the studies, ranging from less than 1% to 51% of patients at follow-up ranging from 6 weeks to 10 years. In 1 RCT of 129 patients, 51% (66/129) of patients had recurrence of varicose veins after foam, and varicose veins recurred at a higher rate in patients treated with foam compared with both surgery (ligation) and surgery combined with liquid sclerotherapy (RR 1.4, 95% CI 1.1 to 1.9) (duration of follow-up 10 years).

2.3.4 An RCT of 148 patients treated by either 3% or 1% polidocanol foam reported successful elimination of venous reflux in 69% and 68% of patients, respectively, at 2-year follow-up. In patients treated with 3% or 1% polidocanol foam, recurrence was reported in 36% and 37% of saphenous veins of patients, respectively (2-year follow-up). No significant difference in immediate injection response or rate of recurrence was reported between the 2 groups at 2-year follow-up (significance not stated).

2.3.5 An RCT of 95 patients treated with either foam or liquid sclerotherapy reported success rates of 53% (25/47) and 12% (4) (denominator not stated), respectively, at 2-year follow-up (significance not stated).

2.3.6 The RCT of 95 patients reported venous spasm immediately after injection in 31% (15) and 66% (31) of those treated with liquid and foam, respectively ( $p < 0.0001$ ) (denominators not stated). In the foam group, venous spasm predicted success of the procedure in 100% of patients, but the absence of venous spasm did not predict failure (there was no association with success in the liquid group).

2.3.7 The Specialist Advisers listed key efficacy outcomes as absence of varicose veins; vessel occlusion at 1 week, 6 months and 5 years; abolition of venous reflux; recurrence; number of treatments required; and disease-specific and general quality-of-life improvements.

## 2.4 Safety

2.4.1 A case report of 2 patients described major neurological events after foam sclerotherapy in both patients. The first was found slumped in her chair 25 minutes after the injection. The second patient had a transient loss of consciousness 20 minutes after the procedure; air was detected in the right venous circulation on computed tomography scan (and an air bubble in the middle cerebral artery), although the results of a neurological exam 2 weeks after the incident

were mostly normal (despite a persistent, mild numbness). In a case series of 89 patients there was 1 report of a patient having a stroke following foam sclerotherapy. One epileptic event was also reported (unpublished). In the survey of 70 UK surgeons using foam sclerotherapy, 2 surgeons reported a stroke and 1 surgeon reported a transient ischaemic attack (timing of events not stated). In the systematic review, headache occurred at various rates across the studies ranging from 0% to 23% at 60-day follow-up. Transient confusion occurred at a median rate of 0.5% (range 0–1.2%).

- 2.4.2 In the systematic review including 67 studies, rates of visual disturbance following foam sclerotherapy ranged from 0% to 6%. None lasted for longer than 2 hours and no long-term or permanent visual impairment was reported. Clinical audit data of ultrasound-guided foam sclerotherapy in 7027 patients reported visual disturbance in 1% (67/7027) of patients (follow-up not stated). A journal commentary of 33 patients reported transient scotoma and migraine in 1 patient each, immediately after an injection of 1% polidocanol foam (both were otherwise asymptomatic and 'healthy').
- 2.4.3 A case series of 89 patients reported development of myocardial infarction in a patient approximately 30 minutes after injection of foam (unpublished).
- 2.4.4 The systematic review reported complications including coughing, chest tightness/heaviness, panic attack, malaise and vasovagal fainting occurring at a rate of 0–3% across the studies (follow-up ranged from 1 month to 5 years).
- 2.4.5 Foam microemboli in the right atrium and ventricle were reported in all 33 patients, although none were reported to have had neurological symptoms. Emboli were also discovered in the left atrium and ventricle in 5 patients later detected to have right-to-left shunts through a patent foramen ovale.
- Preliminary RCT results for 11 patients reported right-to-left shunts in one third of patients. These preliminary results also reported that 90% of patients had bubbles in their cerebral circulation during the procedure (exact figures not stated). A case series of 20 patients with suspected patent foramen ovale or describing respiratory or cerebral symptoms (migraine and visual disturbance, among others) after foam sclerotherapy reported that transthoracic echocardiography showed bubbles in the left side of the heart in 65% of patients (13/20) immediately after the procedure. Transcranial Doppler tests were positive for bubbles in the middle cerebral artery in 5 of the patients with bubbles in the left side of the heart. The 7/20 patients without bubbles in the left side of the heart reported visual disturbance, migraine, shortness of breath, dizziness and numbness.
- 2.4.6 Lower back pain was reported at a median of 4% in 4 RCTs including 511 patients (follow-up ranged from 3 months to 1 year).
- 2.4.7 In 13 case series including a total of 2828 patients, there were 11 reports of deep vein thrombosis (DVT) (median rate 0.4%). In a case series of 290 patients, there was a single report of a patient developing a pulmonary embolism 4 months after treatment. Clinical audit data of foam sclerotherapy in 7027 patients reported DVT in less than 1% (36/7027) of patients (follow-up not stated).
- 2.4.8 There were 2 case reports, of 1 patient each, of allergic reaction to the sclerosant. The first described a patient treated twice within 6 months; within 20 minutes of the second treatment the patient had developed tachycardia and became hypotensive (they were resuscitated, treated by intravenous drugs and hydrocortisone and discharged from hospital after 24 hours). The second case report described 1 patient treated once with foam; after 10 minutes they had an anaphylactoid reaction (with a weak pulse and

tachycardia) but retained consciousness (treated by epinephrine, hydrocortisone, phenazoline and intravenous fluids; duration of treatment not stated; patient made a full recovery).

2.4.9 Four RCTs including a total of 517 patients reported skin pigmentation after the procedure at a median rate of 32% at a maximum of 1-year follow-up. Four case series including 781 patients reported a median cutaneous necrosis rate of 1% at a maximum of 1-year follow-up.

2.4.10 The Specialist Advisers listed anecdotal adverse events as skin ulceration and superficial thrombophlebitis. The Specialist Advisers considered a theoretical adverse event to be arterial thrombosis.

## 2.5 Other comments

2.5.1 The Committee noted that there was considerable variability in foam preparation such that there was insufficient evidence to draw conclusions on the relative safety of different types and strengths of sclerosing agents, volume of foam and foam-producing techniques.

2.5.2 The Committee also noted that some recent publications addressed the systemic events following foam sclerotherapy, indicating evolving techniques and postprocedural care to reduce side effects.

## 3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion) available from [www.nice.org.uk/IPG314](http://www.nice.org.uk/IPG314)

3.2 The National Patient Safety Agency runs the National Reporting and Learning System (NRLS), and clinicians should report any serious adverse events relating to the use of this procedure to the NRLS ([www.npsa.nhs.uk/nrls](http://www.npsa.nhs.uk/nrls)).

3.3 NICE has published interventional procedures guidance on the safety and efficacy of radiofrequency ablation of varicose veins ([www.nice.org.uk/IPG8](http://www.nice.org.uk/IPG8)), transilluminated powered phlebectomy for varicose veins ([www.nice.org.uk/IPG37](http://www.nice.org.uk/IPG37)) and endovenous laser treatment of the long saphenous vein ([www.nice.org.uk/IPG52](http://www.nice.org.uk/IPG52)).

## Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind. See [www.nice.org.uk/IPG314publicinfo](http://www.nice.org.uk/IPG314publicinfo)

## Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email [publications@nice.org.uk](mailto:publications@nice.org.uk)) and quote reference number N1977 for this guidance or N1978 for the 'Understanding NICE guidance'.

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