

Understanding NICE guidance

Information for people who use NHS services

Treating varicose veins with foam injections

NICE 'interventional procedures guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

This leaflet is about when and how foam injections can be used to treat people with varicose veins in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which people will benefit most from it.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe varicose veins or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on the back page.

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. 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 how well the procedure works and whether it represents value for money for the NHS.



What has NICE said?

This procedure can be offered as a treatment option for people with varicose veins provided that doctors are sure that:

- the patient understands what is involved and agrees to the treatment, and
- the results of the procedure are monitored.

A small number of patients may experience brief side effects. There should be special arrangements for monitoring what happens when a person has foam injections for varicose veins.

The procedure should only be done using liquid chemicals which have been approved to treat varicose veins. These liquids are not licensed in the UK for mixing with air or other gas to make a foam.

In addition, there is not a lot of information on how well the procedure works in the long term, and NICE has encouraged doctors to collect more long-term information.

Other comments from NICE

Mixing the liquid with air or another gas, and the size of the foam bubbles can both affect how safe the procedure is.

The amount and concentration of the foam varied among the studies and it is unclear whether this made a difference.

This procedure may not be the only possible treatment for varicose veins. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Foam injections for varicose veins

The procedure is not described in detail here – please talk to your specialist for a full description.

Varicose veins are veins that have become wider than normal, so that their valves do not close which means they can't transport the blood properly. The long saphenous vein, which runs from the foot up to the thigh, is the vein that is most commonly affected.

Symptoms of varicose veins can include heaviness, aching, throbbing, itching and cramps or fatigue in the legs. Some patients might have skin discoloration, skin inflammation or ulcers on the skin.

People with severe symptoms may be offered sclerotherapy. Sclerotherapy involves injecting a chemical into the affected vein which inflames the vein and causes it to block. The chemical used to fill the vein is called the sclerosant. In standard sclerotherapy, a liquid sclerosant is used. Foam sclerotherapy is slightly different because the liquid is mixed with air or another gas to produce a foam which is thought to be more effective than liquid sclerotherapy.

Doctors use ultrasound guidance to create an image of the vein so they can deliver and monitor the procedure. Several veins can be injected in the same session. After the vein has been blocked with the foam, a compression bandage is put on the leg.

Some patients may need more than one session if the veins have not been filled enough.

What does this mean for me?

NICE has said that this procedure works well enough for use in the NHS. If your doctor thinks it is a suitable treatment option for you, they should make sure you understand the benefits and risks before asking you to agree to it. A small number of people may experience brief side effects, so you should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described here. NICE conducted a review of all the published evidence, and looked at a total of 67 studies on this procedure.

How well does the procedure work?

Across the studies, the average rate of veins being successfully blocked was 84%. No study had a success rate of less than 60%. An analysis of five studies – three studies comparing foam with liquid sclerotherapy, and two comparing foam sclerotherapy with surgery to strip varicose veins, showed that foam was slightly better than liquid sclerotherapy but not quite as good as surgery. Overall there were no significant differences in efficacy between foam sclerotherapy and the two other treatments.

The average rate of varicose vein recurrence and development of new veins varied across the studies, ranging from 1–15% of patients at follow-up intervals ranging from 6 weeks to 6 years. In one study, the rate of vein recurrence was 51% at 10 years.

Risks and possible problems

Complications reported after foam sclerotherapy included darkening of the skin of the leg in 32% of patients in four studies that followed 517 patients for up to a year. Arterial events including deep vein thrombosis

(DVT) occurred in 0–6% of patients on average across the studies. In 13 studies of a total of 2828 patients, there were 11 reports of DVTs (an average rate of 0.4%).

Other complications included allergic reaction, bruising, leakage of the sclerosant into surrounding body tissues, and lower back pain. All these complications occurred at an average rate of 4.2% in four studies at up to a year follow-up. The incidence of damage to nerves was less than 1% across all studies.

Other complications included chest tightness, confusion, migraine and visual disturbance.

Rates of visual disturbance following foam sclerotherapy ranged from 0% to 6%. No visual disturbance was reported that lasted for longer than 2 hours and no long-term or permanent visual damage was reported. A short period of confusion occurred in an average of 0.5% of patients, while the rate of headaches reported varied between studies from 0% to 23% at 60 days. Other complications reported included coughing, chest tightness/heaviness, panic attack, a general feeling of being unwell and fainting which occurred in 0–3% of patients.

Serious complications have been reported after foam sclerotherapy, including stroke and heart attack. In one study of 89 patients, 1 patient suffered a stroke following foam sclerotherapy. One case of heart attack and an epileptic event were also reported.

In a study of 290 patients, 1 patient developed a pulmonary embolism (blood clot travelling to the lung) 4 months after treatment.

More information about varicose veins

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG217

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1256).