

Understanding NICE guidance

Information for people who use NHS services

Treating varicose veins with foam injections using ultrasound guidance

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how foam injections (known as foam sclerotherapy) using ultrasound guidance can be used in the NHS to treat people with varicose veins. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. 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.

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.

What has NICE said?

Although there is good evidence about how well this procedure works in the short term, some patients have had problems with circulation, which could affect other parts of the body. If a doctor wants to use foam injections for varicose veins, they should make sure that extra steps are taken to explain the potential risks of the procedure. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information (including information about other treatments) as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

NICE has said that only chemicals approved to treat varicose veins should be used for this procedure.

NICE has also encouraged the collection of long-term evidence about this procedure.

Other comments from NICE

The way the foam is prepared varies considerably so it was impossible to decide on the safety of different types and strengths of the chemical, how much is used, or how it is produced.

Recent publications show how the techniques and care needed after the procedure to reduce side effects affecting other parts of the body are developing.

Treating varicose veins with foam injections using ultrasound guidance

The medical name for this procedure is 'ultrasound-guided foam sclerotherapy for varicose veins'.

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

Varicose veins are wider than normal, so their valves do not close and they can't transport the blood properly. The long vein that runs from the foot up to the thigh is most commonly affected. They affect 20–30% of adults.

Symptoms of varicose veins can include heaviness, aching, throbbing, itching and cramps or fatigue in the legs. Some patients may develop skin discolouration, inflammation or ulcers.

Compression tights or stockings may improve symptoms. People with persistent symptoms may be offered surgery to strip out the affected veins, or the veins may be removed using laser or heat energy.

The procedure is carried out using a local anaesthetic. Sclerotherapy involves injecting a chemical (called a sclerosant) into the affected vein, inflaming it so it becomes blocked. The procedure is monitored using ultrasound imaging. Standard sclerotherapy uses a liquid sclerosant. In foam sclerotherapy the liquid is mixed with air or another gas to produce a foam, which is thought to be more effective than liquid sclerotherapy.

After the vein has been blocked with the foam, a compression bandage is put on the leg. More than one vein can be treated at a time. Further injections may be needed.

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.

What does this mean for me?

If your doctor has offered you foam injections for varicose veins, he or she should tell you that NICE has decided that although the procedure works in the short term there are uncertainties about how safe it is. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. 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 should also be given information about other treatment options.

NICE has also decided that more information is needed about this procedure, especially about how it works in the long term. Your doctor may ask you if details of your procedure can be used in this way. Your doctor will give you more information.

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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 82 studies on this procedure.

How well does the procedure work?

In five studies including 640 patients, the average rate of veins being successfully blocked was 84%. For blocking veins, foam sclerotherapy was no more effective than liquid sclerotherapy in an analysis of three studies with 540 patients, and surgery was no more effective than foam sclerotherapy in an analysis of two studies with 324 patients.

The rate at which patients' varicose veins returned or at which they developed new ones varied across the studies, from less than 1% to 51%. The studies followed patients' progress for a minimum of 6 weeks, up to 10 years. In one study of 129 patients, 66 patients treated with foam sclerotherapy saw their varicose veins return after 10 years. The same study found that varicose veins were more likely to return after foam sclerotherapy than after surgery or after surgery plus liquid sclerotherapy.

Venous reflux (a common problem linked to varicose veins, in which the blood flows backwards into the legs instead of travelling towards the heart) was successfully treated in around 70% of patients after 2 years in a study of 148. However, the problem returned in just over 35% of patients after 2 years.

In a study of 95 patients, the procedure was successful in 53% of patients who had foam sclerotherapy and 12% of patients who had liquid sclerotherapy, when their progress was checked after 2 years.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. They said that the aims of the procedure include eliminating varicose veins and venous reflux, reducing the recurrence of varicose veins, and improving quality of life.

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

Risks and possible problems

Serious complications have been reported after foam sclerotherapy in a small number of patients. One patient collapsed and another temporarily lost consciousness around 20 minutes after treatment. Both recovered but one was left with mild numbness. In a survey of 70 UK surgeons who have used foam sclerotherapy to treat varicose veins there were two reports of strokes and one of a transient ischaemic attack (a 'mini-stroke'). In a study of 89 patients, one had a heart attack half an hour after the foam injection, there was one epileptic event, and one patient had a stroke.

In an analysis of 67 studies, between 0% and 23% of patients had headaches and up to 1.2% had confusion for a short time after the procedure. In the same analysis, between 0% and 6% of patients had vision problems but none lasted for longer than 2 hours. Other problems affecting between 0% and 3% of patients included coughing, chest tightness or heaviness, panic attack, feeling generally unwell, and fainting.

Foam was found in the hearts of 33 patients in one study, although none had symptoms as a result. Bubbles were also detected in the blood vessels in the brain in most patients in a study of 11 patients and in 5 out of 20 patients in another study.

Out of 9855 patients, 47 developed deep vein thrombosis (DVT). One patient out of 290 developed a blockage in the artery to the lungs 4 months after the procedure.

Other problems included an allergy to the foam sclerosant in 2 patients, low back pain in 4% of 511 patients, and skin discolouration in 32% of 517 patients.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. They said that possible problems include skin ulceration, vein inflammation and blocking of an artery.

More information about varicose veins

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on varicose veins, visit our website at www.nice.org.uk

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. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. 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 is about 'ultrasound-guided foam sclerotherapy for varicose veins'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG314

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1978. The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.