

Treating varicose veins with foam injections using ultrasound guidance

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

This document is about when and how foam injections (known as foam sclerotherapy) 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).

This HealthTech 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 document 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 give you full information and advice about these. The document 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 page 6.

What has NICE said?

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

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

The risks of the treatment include temporary chest tightness, dry cough, headaches, problems with vision, and rare but serious problems such as heart attack, fits and stroke (including transient ischaemic attacks, known as ‘mini-strokes’).

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.

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.

Small valves inside the veins help blood flow properly through them. Varicose veins develop when these valves do not work properly, allowing blood to collect in the veins. This enlarges the veins and causes the valves to deteriorate further. Varicose veins commonly occur in the legs. Many people have no symptoms, but if they do, these can include heaviness, aching, throbbing, itching, cramps or tiredness in the legs.

If needed, compression tights or stockings may improve the symptoms of varicose veins. If the symptoms become severe (with skin discolouration, inflammation or skin ulcers) people may be offered surgery to strip out or tie off the affected veins or both, or procedures to remove the veins using lasers or heat energy.

The procedure may be carried out using local anaesthetic.

Foam sclerotherapy uses a chemical (called a sclerosant, which causes scarring of the inside of the vein so that it becomes blocked) mixed with air or another gas to produce a foam. The foam is injected into the affected veins using ultrasound imaging to monitor its progress. More than 1 vein can be treated at a time. If any varicose veins need more treatment, further injections can be given at the same time or in a later procedure. Compression bandages are normally worn for between a week and a month after the procedure.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks that treating varicose veins with foam injections using ultrasound guidance is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

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?

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 below. NICE looked at 22 studies on this procedure.

How well does the procedure work?

A study of 73 patients (procedures were carried out on 82 legs) looked at how well veins were blocked by foam injections combined with tying off the long vein running from the foot to the thigh, compared with surgery alone. When patients were followed up at 5 years, there was little difference between foam injection plus surgery and surgery alone. In 33 patients treated with foam injections plus surgery, the varicose vein blocked above the knee in 19, and blocked below the knee in 8. In 26 patients who had surgery only, the varicose vein blocked above the knee in 14, and blocked below the knee in 10. In both groups the severity of patients' varicose veins reduced and their quality of life was improved 5 years after treatment.

For blocking veins, foam injections were no more effective than a liquid formulation in 2 studies (involving a total of 340 patients, with follow-up ranging from 1 to 10 years).

Varicose veins did not remain blocked in 23 out of 146 patients who had foam injections (procedures were carried out on 203 legs). Of those patients, 4% had varicose veins with serious symptoms such as skin colour changes, aching or swelling within 5 years of treatment. A further 22% of patients had symptoms that weren't serious, and 74% of patients whose varicose veins did not remain blocked after foam injections had no symptoms at 5 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. The advisers said that the main aims of treatment are to improve patients' ability to move around and to avoid leg ulcers.

Risks and possible problems

Serious complications have been reported after foam injections in some patients. One study reported on 3 patients who had strokes after the procedure. All had a kind of heart defect called a patent foramen ovale. All 3 patients recovered completely and had no further symptoms of stroke. In a study of 1025 patients treated with foam injections, 1 patient had a type of 'mini-stroke' called a transient ischaemic attack. This patient recovered in half an hour.

In a review of studies including 6856 patients, 1 patient had a heart attack within 30 minutes and another patient had an epileptic fit within 40 minutes of foam injection (no further details about these patients were reported). In the same study up to 3% of patients experienced coughing, chest tightness, feelings of panic, discomfort or fainting, between 1 month and 5 years after the procedure.

A study involving 82 patients with the heart defect patent foramen ovale noted bubbles in the blood vessels to the brain in 60 patients shortly after foam injection. These patients were each monitored for 1, 7 or 28 days, and no new symptoms affecting their brain or nervous system were reported. In a study of 977 patients, 5 patients had temporary disturbance of their vision during the procedure or shortly after it, and 3 patients had headaches immediately after the procedure.

In the study of 977 patients, blockage of a lung artery (known as a pulmonary embolism) was reported in 1 patient, 5 weeks after foam injection. The blockage was treated with a drug that stops blood from clotting.

Other problems were reported in a study of 430 patients. Inflammation of veins in the leg was reported in 17 patients out of 230 who had the

foam injection, compared with none of the 200 patients who had surgery. At 2-year follow-up, darkening of the skin was found in 12 out of 213 patients treated by foam injection compared with 2 out of 177 patients treated by surgery.

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. The advisers said that a possible problem caused by the procedure would be the leaking of foam into the tissue around the varicose vein.

More information about varicose veins

NHS Choices (www.nhs.uk) may be a good place to find out more.

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. HealthTech 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 document is about 'ultrasound-guided foam sclerotherapy for varicose veins'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG301

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 document in their own information about this procedure.

National Institute for Health and Clinical Excellence

Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT; www.nice.org.uk

ISBN 978-1-4731-8719-1

Feb 13

© National Institute for Health and Clinical Excellence, 2013. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of NICE.