

Subfascial endoscopic perforator vein surgery (SEPS)

**Understanding NICE guidance –
information for people considering the
procedure, and for the public**

May 2004

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About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called subfascial endoscopic perforator vein surgery. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether subfascial endoscopic perforator vein surgery is safe enough and works well enough for it to be used routinely.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of subfascial endoscopic perforator vein surgery and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 11).

About subfascial endoscopic perforator vein surgery

A venous ulcer is an open sore that is caused by poor blood flow in the vessels that take blood away from the skin. This usually happens in the lower part of the leg. If a person gets a small cut or opening in the skin there, it does not heal properly and becomes an open sore.

The problem with the blood flow happens because one or more veins in the leg aren't working properly. Normally, the veins are the blood vessels that take the blood back to the heart. In the legs, the blood has to flow against gravity. To stop it from flowing backwards, there are 'gates' known as valves in the veins that only open one way – once blood has been pushed up through the valve, it can't go back the way it has come.

Sometimes, the valves become weak so they let blood flow backwards. The result is that the blood flow isn't as strong as it should be and blood tends to collect in the surface veins. This can cause varicose veins. And when the blood flow is very weak, venous ulcers can develop.

A perforator vein is a blood vessel that links a surface vein with a deeper vein. If blood isn't flowing through the perforator veins properly, it starts to build up in the surface veins. The procedure NICE has looked at, which is called

subfascial endoscopic perforator vein surgery (SEPS for short), can be used for people who have a venous ulcer on the lower part of their leg thought to be because blood isn't being pushed properly through the perforator veins in the calf. It can also be used for people who have had an ulcer that has healed. In particular, SEPS is used when other measures, such as elevating or using pressure on the leg to help improve blood flow, or using medicine to help 'thin' the blood, haven't worked.

Before a person has subfascial endoscopic perforator vein surgery, they have what's known as a duplex scan of the blood vessels in their leg to see what veins are causing the problem.

At the start of the procedure, the blood is drained from the leg. A small cut is made in the calf, and the surgeon then passes a special deflated balloon into the calf muscle so that it's in the narrow space between the muscle and the muscle covering. The balloon is then inflated so it makes this space wider – this makes it easier for the surgeon to get to the perforator veins. Carbon dioxide gas is also put into the area and this also makes it easier for the surgeon to work on the veins. The perforator veins lie across the space that has been made, so the surgeon either clips them off or uses a special piece of equipment called an ultrasonic coagulator (or harmonic scalpel) to heat and seal them. Either way, the end result is that blood cannot go

through the vein at all, so it cannot build up at the skin surface.

The other way of doing this operation is to make a larger opening in the calf to get to the perforator veins. This is called open subfascial perforator vein surgery.

How well it works

What the studies said

Some of the studies that NICE looked at compared how well the new procedure worked with how well the open operation worked. To do this, they looked at whether the ulcer healed after the procedure and whether the patient got another ulcer later.

With the new procedure:

- the ulcers healed in 17 to 18 patients out of 20
- 2 out of 17 patients in one study and 5 out of 18 patients in another study went on to have another ulcer.

With the open operation:

- the ulcers healed in all the patients

- 4 out of 18 patients in one study and 13 out of 19 patients in another study went on to have another ulcer.

The results of these studies had to be treated with caution because not all the information was clear in the reports and some did not give information on what happened to every patient who joined the study.

What the experts said

The experts thought that there hadn't been enough studies carried out to show that the procedure worked well. They also thought that it wasn't clear what types of vein problem would be most suitable for the procedure.

Risks and possible problems

What the studies said

Two of the studies showed that patients who had the new procedure were far less likely to get an infection in the wound compared with patients who had the open operation (the wound is the opening made in the calf by the surgeon). In one of the studies, no patients who had the new procedure had an infection, while just over a half of those who had the open operation had an infection afterwards. In the other study, 2 out of

27 patients who had the new procedure had an infection, while 13 out of 29 patients who had the open operation had an infection.

Other problems with the new procedure included nerve damage and deep vein thrombosis (a clot in a vein that lies deep in the leg). Nerve damage affected from 0 patients in one study to 2 out of 30 patients in another. Deep vein thrombosis went from 0 in one study to 21 cases in 146 treated legs in another.

What the experts said

The experts agreed that the main problems were the ones reported in the studies: wound infection, nerve damage and deep vein thrombosis. Another possible problem was that a blood-filled swelling could form in the area (this is called a haematoma).

What has NICE decided?

NICE has decided that, if a doctor wants to carry out subfascial endoscopic perforator vein surgery, he or she should make sure that the patient understands what is involved and that there are still uncertainties over the safety of the procedure and how well it works. There should be special arrangements in place so that the patient only agrees (consents) to the procedure after this discussion has taken place.

Other comments from NICE

NICE has also said that the groups of patients that may be suitable for this new procedure aren't yet clear. Doctors should be careful when deciding whether to offer it to a patient so that they don't try it in someone for whom it is likely to be unsuitable.

What the decision means for you

Your doctor may have offered you subfascial endoscopic perforator vein surgery. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the benefits and risks of subfascial endoscopic perforator vein surgery which you need to understand before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these benefits and risks may be described above.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on subfascial endoscopic perforator vein surgery is on the NICE website (www.nice.org.uk/IPG059guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0574. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you want more information on ulcers and varicose veins, a good starting point is NHS Direct, telephone 0845 4647, or NHS Direct Online (www.nhsdirect.nhs.uk).

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