NHS
National Institute for
Health and Clinical Excellence

Surgical repair of the valves in the deep veins of the legs

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 surgical repair can be used to treat people with persistent, poorly functioning valves in the deep veins of the legs 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 patients 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 poorly functioning valves 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 page 6.

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?

There are still uncertainties over the safety of this procedure and how well it works. If a doctor wants to use surgical repair to treat persistent, poorly functioning valves in the deep veins of the legs, he or she should make sure that extra steps are taken to explain the uncertainty and the likely benefits and 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 as part of the discussion. There should also be special arrangements for monitoring what happens after the procedure.

Other comments from NICE

There was not much evidence on how the procedure works in patients whose deep vein valves were damaged by a blood clot.

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

Surgical repair of valves in the deep veins of the legs

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

Blood flows into the legs through arteries and returns back to the heart in veins. Veins have valves inside them to stop the blood from travelling the wrong way and collecting in the legs. If these valves stop working properly it can cause swelling, skin changes and ulcers. If this happens in the deep veins of the legs it is called deep vein incompetence.

There are a number of different ways in which surgery can be used to repair the valves in the deep veins of the legs. Valvuloplasty is the most common method of valve repair. In this procedure the surgeon uses stitches to repair the valve. These stitches can be applied in two ways. Stitches can be used on the inside of the valve to tighten it or stitches can be used on the outside of the vein to make the vein narrower. The procedure is usually carried out under a general anaesthetic.

Superficial venous surgery, which usually involves stripping or tying off the affected veins, is sometimes performed at the same time as deep vein repair. Superficial veins are close to the surface of the body and carry less blood than deep veins.

What does this mean for me?

If your doctor has offered you surgical repair of the valves in the deep veins of the legs, he or she should tell you that NICE has decided that the benefits and risks are uncertain. 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 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 below. NICE looked at nine studies on this procedure.

How well does the procedure work?

All studies compared superficial venous surgery (SVS) and valvuloplasty with SVS alone. Using stitches to tighten the inside of the valve was the most common method.

In one study, SVS with valve repair prevented worsening of disease severity in 54 out of 63 patients, compared with 40 out of 62 patients who received SVS alone. In this study, 45 of the 63 patients treated with valvuloplasty had competent valves and did not require a second procedure within 7–8 years. In a smaller study of 11 patients, 9 had competent valves at 2 years post-valvuloplasty. In another study, 16 out of 17 patients treated with valvuloplasty had competent valves after an average of 25 months, compared with 4 out of 14 patients treated with SVS alone.

In a study of 169 legs, ulcers did not recur in 64% and 47% of patients with primary and secondary valvular incompetence, respectively, following valvuloplasty. A study of 141 legs reported that 76 out of 84 ulcers healed within 3 months of valvuloplasty, 13 of which recurred within the study period (up to 42 months).

A 10-year study in 44 patients found that valvuloplasty led to a better quality of life than SVS alone. This study also showed that in 35 of the legs that were followed up for 10 years the average blood pressure in the veins was significantly lower following SVS and valvuloplasty than with SVS alone.

The expert advisers expressed some uncertainty about how well the procedure works, particularly with regard to deciding which valve(s) to repair and which patients may benefit.

Risks and possible problems

In four studies, deep vein thrombosis occurred in 5 out of 141 legs, 8 out of 107 legs, 21 out of 169 legs and 11 out of 85 legs, respectively, following deep vein valve repair. There was a single report of pulmonary embolism (a blockage of the artery carrying blood from the heart to the lungs). Wound infections occurred in 1–7% of patients across all four studies, while internal bleeding occurred in 3–10% of patients. Two studies reported postoperative bleeding in 2 out of 144 and 8 out of 51 valve reconstructions.

The expert advisers stated that deep vein thrombosis, pulmonary embolism and bleeding were the main potential risks of the procedure.

More information about poorly functioning deep vein valves

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/IPG219

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1260).

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