

Treating peripheral arterial disease using a laser and a balloon catheter to unblock arteries

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 laser treatment and a balloon catheter (with or without stenting) can be used in the NHS for people with peripheral arterial disease. 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.

NICE has produced this guidance because 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 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 peripheral arterial disease or the procedure in detail – a member of your healthcare team should also 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 7.

What has NICE said?

This procedure can be offered routinely as a treatment option for people with peripheral arterial disease 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 team of healthcare professionals who are experienced in managing diseases of the circulation should decide who should have this procedure. The team should include a vascular surgeon and a vascular interventional radiologist, who both specialise in blood vessels. The team should think carefully about whether this procedure would benefit the patient more than conventional balloon angioplasty.

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

The medical name for this procedure is ‘percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease’.

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

The main arteries in the legs can become narrowed and blocked by fatty deposits (plaques). This is called peripheral arterial disease (sometimes shortened to PAD). Symptoms range from leg pain to ulcers or gangrene, in which case amputation may be needed.

Lifestyle changes (for example, exercise and giving up smoking) are the main treatments for peripheral arterial disease. People with severe symptoms may be offered procedures to clear the blocked artery. These include balloon angioplasty (temporarily inserting and expanding a small balloon in the artery to widen it) and inserting a stent (an expandable mesh tube).

This procedure – a combination of laser treatment and balloon angioplasty – may be offered to patients with peripheral arterial disease if balloon angioplasty or stenting on their own are not practical or could be unsafe.

The patient is first given a local anaesthetic. A laser attached to a catheter (flexible tube) is inserted into an artery in the leg. Then, using an X-ray imaging technique called fluoroscopy, the laser is moved to the site of the blockage to burn away the deposits. A balloon is then inserted using a catheter, and inflated. A stent may be inserted to prevent the artery blocking or narrowing again.

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 using a laser and a balloon catheter to unblock arteries 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 9 studies on this procedure.

How well does the procedure work?

Three studies looked at how well laser treatment combined with balloon angioplasty worked.

In the first study, 116 patients were treated with 1 of 2 types of laser as well as balloon angioplasty, or with balloon angioplasty on its own. One year after the procedure, arteries were still unblocked in 45% and 36% of patients who had laser treatment and balloon angioplasty, depending on which type of laser treatment they had, and in 50% of patients who only had balloon angioplasty.

The second study looked at 318 patients who had laser treatment plus balloon angioplasty. After 1 year, arteries were still unblocked in 34% of these patients.

The third study used a 4-point scale from the American Heart Association to record how well patients were doing 3 years after laser treatment. Out of 127 patients in the study who had laser treatment and balloon angioplasty, 24 had improved by 1 point, 25 by 2 points and 13 by 3 points.

This study also used a test called an ankle-brachial index to measure improvements in blood flow. Patients treated successfully with balloon angioplasty with or without laser treatment all had a significant improvement when they were checked at 3 years.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that the main things that showed the procedure had worked were the treated arteries becoming wider, increased blood

flow, tissue healing, symptom relief, better quality of life, and avoiding the need for amputation or another procedure.

Risks and possible problems

In a study of 40 patients who had laser treatment, 2 died within 30 days from causes unrelated to the procedure.

In another study, an artery was damaged during the procedure in 21 of 77 patients who had laser treatment plus balloon angioplasty, and 6 of 39 patients who had balloon angioplasty only.

In another study a blood vessel tore in 4 of the 127 patients who had laser treatment plus balloon angioplasty.

In a study of 215 patients, when they were checked after 3 years, some had a blockage in the artery in their leg caused by material that had come from elsewhere in the body. This happened to 4 out of 127 patients who had laser treatment plus balloon angioplasty (3 needed treatment) and 5 out of 88 patients who had balloon angioplasty only (4 needed treatment).

In 2 studies with a total of 378 patients, an abnormal passage (fistula) formed between an artery and a vein in 3 patients.

In 2 studies with a total of 352 patients, 11 patients had treatment for a balloon-like swelling in the artery at the site where the catheter was inserted during the procedure.

In nearly two-thirds of patients in a study of 338, the tissue that was being treated warmed up – this was thought to be because of heat from the laser.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that complications at the site where the catheter is inserted had been reported. They also said that burns could be a problem in theory.

More information about peripheral arterial disease

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

For details of all NICE guidance on peripheral arterial disease 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 ‘percutaneous laser atherectomy as an adjunct to balloon angioplasty (with or without stenting) for peripheral arterial disease’. This leaflet and the full guidance aimed at healthcare professionals are available at <http://guidance.nice.org.uk/HTG294>

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on Accessibility at the bottom of the NICE homepage 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.

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