

Understanding NICE guidance

Information for people who use NHS services

Treating angina using a laser device inserted through a cut in the chest and applied to the outside of the heart wall

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 using a laser device inserted through a cut in the chest and applied to the outside of the heart wall can be used in the NHS to treat people with angina. 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.

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 angina 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?

The evidence on how safe this procedure is and how well it works shows that it doesn't work, based on measurements of heart function and survival, and may pose unacceptable risks. Therefore, NICE has said that this procedure should not be used.

Other comments from NICE

Some studies showed improvements in symptoms and quality of life, but NICE thought they were probably placebo responses.

NICE looked at evidence on the procedure alone and when it was performed at the same time as coronary artery bypass surgery.

Treating angina using a laser device inserted through a cut in the chest and applied to the outside of the heart wall

This procedure may not be the only possible treatment for angina. Your healthcare team should talk to you about any other treatment options available.

The medical name for this procedure is 'Transmyocardial laser revascularisation for refractory angina pectoris' (often referred to as TMLR). Refractory means that the angina cannot be controlled by normal medical or surgical treatment.

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

Angina occurs when the heart muscle doesn't get enough oxygen because not enough blood is getting to the heart, usually because of coronary heart disease. Symptoms include pain or tightness in the chest, usually brought on by physical activity.

Conventional treatments include drugs and surgery. But in people with refractory angina, these either haven't worked or aren't suitable.

The procedure is done with the patient under a general anaesthetic. Areas of the heart are selected for treatment by scanning. The surgeon makes a cut in the left side of the chest and small channels which the blood can flow through are then made in the heart wall using laser beams.

Summary of possible benefits and risks

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

What does this mean for me?

Your doctor should not offer you this procedure because there is not enough evidence to say that it works, and it may pose unacceptable risks.

How well does the procedure work?

Analysis of ten studies involving 1359 patients showed death rates were no different in patients who had laser treatment (TMLR) and those who had been treated with drugs or with coronary artery bypass surgery.

A study of 100 patients that looked at how well the heart pumps blood found that it was worse in patients who had laser treatment than in patients who were treated with drugs, 1 year later. Six other studies found there was no difference in blood supply to the heart wall between those who had laser treatment and those who were treated with drugs.

Analysis of four studies involving 323 patients reported that those who had laser treatment showed a greater improvement in how long they were able to exercise than those who were treated with drugs, 6 months after treatment. Five studies measured quality of life. In four of them, patients who had laser treatment had a greater improvement in quality of life than those treated with drugs. The other study found that there was no difference between patients who had laser treatment and those who had surgery on heart muscle nerves.

An analysis of three small studies involving 135 patients looked at how severe their angina was after treatment. Patients who had laser treatment showed an improvement over those who had drug treatment. But this improvement got less after 6 months and even smaller after 1 year.

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 success factors were less severe angina, patients being able to exercise more and better quality of life, and reduced medication use.

Risks and possible problems

Analysis of seven small studies showed that overall more patients treated with laser had heart attacks (41 out of 633) than patients in the control groups (11 out of 651) 1 year later. In another study, 17 of 50 patients who had laser treatment had heart failure but none of the 50 patients treated with drugs did.

In a study of 255 patients, a greater proportion of those who had laser treatment and coronary artery bypass surgery had nerve problems (3%) than those who only had bypass surgery (1%). In another study, more patients who had laser treatment had blocked blood vessels caused by clots (9 out of 92) than those who were treated with drugs (3 out of 90).

Overall, in 10 studies the death rate immediately after the operation was no different between patients who had laser treatment and those who had other treatments. But when two studies (comparing the laser treatment plus coronary artery bypass surgery with the bypass surgery only) were removed from the analysis, the overall death rate was higher in patients who had the laser treatment.

Other complications included a reaction in the sac surrounding the heart (23 out of 169 patients) and abnormal blood flow from the lower to the upper chamber of the heart (1 out of 20 patients). In another study fluid collected in the sac around the heart in 5 out of 923 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. The advisers said that problems include death, heart attack, heart failure, arrhythmias (problems with the heart beat) and infections.

More information about angina

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.

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 'Transmyocardial laser revascularisation for refractory angina pectoris'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG301

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1872). 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.