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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating angina using a laser applied to the inside of the heart wall via a catheter inserted through an artery

NICE 'HealthTech 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 applied to the heart wall via a catheter (thin tube) inserted through the groin 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).

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 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 page 6.

Information about NICE HealthTech guidance 193

What has NICE said?

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

Treating angina using a laser applied to the inside of the heart wall via a catheter inserted through an artery

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 'Percutaneous laser revascularisation for refractory angina pectoris'. 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 local anaesthesia. Areas of the heart are selected for treatment by scanning. A thin tube called a catheter is inserted into an artery in the groin and moved up towards the heart. X-rays may be used to make sure it is in the right place. Small channels which the blood can flow through are then made in the heart wall using laser beams.

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.

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 11 studies on this procedure.

How well does the procedure work?

An analysis of six studies involving 1040 patients reported that death rates after 1 year were no different in those who had laser treatment and those treated with drugs, spinal cord stimulation or sham therapy ('dummy' laser treatment that has no effect).

A study of 298 patients looked at blood flow to the wall of the heart. After 6 months blood flow in patients who had the laser treatment was no better than in those who had sham therapy.

Two studies looked at how well the heart pumped blood. In a study of 221 patients there was on average no difference after 3 months between patients who had the laser treatment and those who were treated with drugs. Another study of 82 patients also found no difference between patients who had the laser treatment and those who had sham therapy after 1 year.

Analysis of three small studies showed that patients who had the laser treatment did not have better exercise tolerance (measured on a treadmill) after the procedure than those who had other treatments. In

an analysis of five small studies, patients who knew they had had the laser treatment could exercise for about 18 seconds longer than patients who had other treatments, after 1 year. But in studies of patients who didn't know which treatment they were getting there was no difference after 6 months or 12 months.

In three studies involving 521 patients, angina severity was no different in patients who had laser treatment and those who had other treatments, after 6 months or 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 key success factors include reduction of angina, severity of angina and exercise capacity.

Risks and possible problems

In an analysis of five studies involving 819 patients there was no difference in death rate immediately after the operation between patients who had the laser treatment and those who had drug treatment, spinal cord stimulation or sham therapy.

Six studies involving 938 patients showed that more patients who had the laser treatment had a heart attack (34 out of 515 patients) than those who didn't (17 out of 423 patients). In a study of 221 patients, more patients who had the laser treatment had problems with the nerves that cause the heart muscle to contract (5 out of 110 patients) than those treated with drugs (1 out of 111 patients).

Perforation of the heart wall was another problem. The left ventricle (lower chamber of the heart) was found to be perforated in 2 out of 196 patients (up to 30 days after the procedure) and in 3 out of 110 patients (within 24 hours) who had the laser treatment. In another study 1 out of 25 patients had a perforated heart wall muscle. One out of 30 patients had a large collection of fluid in the space around the heart.

Out of four studies, more patients who had the laser treatment had a stroke or temporary lack of oxygen to the brain (10 out of 285) than patients who didn't (5 out of 287).

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 heart attack, irregular heartbeat and complications where the catheter was inserted. Theoretical problems include death, perforation of the heart muscle, damage to the arteries that supply blood to the heart or to other important structures, stroke, and the build-up of fluid in the space around the heart.

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. This 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 'Percutaneous laser revascularisation for refractory angina pectoris'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG193

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N1874). 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.

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