

Treating liver metastases using non-thermal high-energy pulses of electricity

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 non-thermal high-energy pulses of electricity can be used in the NHS to treat people with liver metastases. 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 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 liver metastases or the procedure in detail – a member of your healthcare team should 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 8.

What has NICE said?

The evidence that NICE looked at showed that there were risks with this procedure, and that there are still uncertainties about how well it works.

For this reason, NICE has said that this procedure should only be carried out as part of a research study. The research should look at how well the procedure works to prevent the liver tumour growing again, and patient survival after the procedure.

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Your healthcare team should talk to you about what treatment options are available.

The medical name for this procedure is irreversible electroporation for treating liver metastases.

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

Liver metastases is the medical term for secondary cancer of the liver. It means cancer that starts in one part of the body – most commonly the bowel – spreads to the liver. Treatment depends on how large the tumours are, how many there are, and where they are.

Treatments include surgery to cut away the cancerous parts of the liver, using heat or freezing to kill the cancer cells, chemotherapy, cutting off the tumour's blood supply, and radiotherapy.

The aim of this procedure (irreversible electroporation, or IRE for short) is to destroy cancer cells using short, repetitive, non-thermal high-energy pulses of electricity. It is claimed that this allows cancer cells to be destroyed with less damage to nearby healthy tissue, such as blood vessels and nerves, than other types of treatment.

Before the procedure the patient is given a general anaesthetic and a drug to prevent muscle contractions. Special needles are then inserted through the skin in and around the tumour. Sometimes open or keyhole surgery is used instead. Short pulses of electricity fire between the needles for several minutes. The needles may then be moved and the process repeated until the whole tumour and a small area of surrounding tissue is treated. To avoid the electrical pulses causing problems with the patient's heartbeat, a process called cardiac synchronisation should be used. This is when the heart is monitored using ECG (electrocardiography) so that the pulse of electricity is given during the heart's resting period (the period between heartbeats when it is least affected by shocks).

What does this mean for me?

Your doctor can only offer you this procedure as part of a research study.

NICE has recommended that some details should be collected about every patient who has this procedure in the UK. Your doctor may ask you if details of your procedure can be used in this way and will give you more information about this.

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?

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 8 studies on this procedure.

How well does the procedure work?

A study of 38 patients looked at how well the procedure worked. The patients had 69 procedures in total for tumours in the liver, lung or kidneys. The study reported a 50% response rate in 45 of the procedures aimed at destroying tumours in the liver, but the study did not explain what the response was or how long after the procedure the patients were assessed. Liver tumours bigger than 5 cm did not respond to treatment and all the patients had other tumours, which continued to grow.

A study of 44 patients with liver tumours that had spread found that 95% of the patients who had the procedure had survived without any local recurrence of the tumour at 6 months and 60% of patients had survived at 12 months. Another study of 28 patients with liver tumours that had spread found local recurrence in 6% (3/54) of tumours. There was also 1 patient whose tumour was still there 6 months after treatment.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that the main things that need to be measured to decide if the procedure is successful are patient survival, tumours being stopped from growing, if, or how long it is before, the tumour(s) come back, and avoiding damage to nearby blood vessels and organs.

Risks and possible problems

Four studies reported problems with patients' heartbeats during the procedure. In the first study, of 38 patients, 6 had irregular heartbeats during the procedure, despite 2 of these having cardiac synchronisation

to prevent this happening. One of the patients needed to be treated with an electric shock to the heart, but the others got better on their own. In the second study, 28 procedures were carried out in 21 patients. During 7 of the procedures, patients had irregular heartbeats and in 4 of these patients' blood pressure also dropped. In the third study, of 18 procedures, 1 patient had an irregular heartbeat and a drop in blood pressure during the procedure. The fourth study looked at 9 patients and 1 patient had an irregular heartbeat during the procedure. The patient was treated and their heartbeat went back to normal before discharge.

In 3 of the studies, patients' lungs collapsed because of air in the chest cavity. The first study was of 45 patients with various types of tumour, including liver tumours. The lung collapsed during 7 out of 50 procedures but it's not clear whether this was in patients with liver tumours because the study did not say. The 2 other studies had a total of 59 patients, who between them had 29 liver tumours. The lung collapsed during 1 procedure in each of these studies.

Patients' blood pressure increased temporarily either during or after the procedure in all patients in a study of 21 patients and in 1 patient in a study of 45.

In 1 of the studies (which included 38 patients), levels of a liver enzyme and a pigment called bilirubin were measured in the blood of patients both before and after the procedure. High levels of either of these can indicate that a person's liver is damaged. The levels of the liver enzyme were found to have increased 24 hours after 40 of the procedures (out of a total of 42). After 9 procedures, levels of bilirubin had also increased. However, levels had returned to normal within a month for almost all patients – only 1 patient's liver enzyme levels had not returned to normal at this time.

In a study of 28 patients, 1 patient had a blood clot in the main vein from the liver after the procedure.

In a study of 44 patients, 1 patient lost bladder control after the procedure. This got better without treatment.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that a problem that could develop after the procedure was a condition called 'post-ablation syndrome', which causes flu-like symptoms and tiredness lasting for 2–3 days. They also said that in theory problems could include damage to nearby organs, bacterial infection, malignant cells from the tumour becoming dislodged and growing in the site where the needles were inserted, and bleeding.

More information about liver cancer

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

For details of all NICE guidance on liver cancer, 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 ‘irreversible electroporation for the treatment of liver metastases’. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG304

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 document in their own information about this procedure.

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