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Information for the public

National Institute for Health and Clinical Excellence

Treating renal cancer using non-thermal high-energy pulses of electricity

NICE 'interventional procedures 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 renal cancer. 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 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 renal cancer 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 7.

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 renal tumour growing again, and patient survival after the procedure.

Other comments from NICE

NICE said that more evidence is needed about whether this procedure causes less damage to tissue near to the tumour (for example blood vessels) than other types of treatment using different types of energy to destroy the tumour.

Treating renal cancer using non-thermal high-energy pulses of electricity

Your healthcare team should talk to you about any other treatment options available.

The medical name for this procedure is 'irreversible electroporation for treating renal cancer'.

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

Renal cancer is cancer of a kidney. Pain and blood in the urine are symptoms. Treatment includes open or keyhole surgery to remove all or part of the affected kidney, drugs, or procedures that use very high frequency radio waves or freezing to destroy the tumour.

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 major blood vessels, 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. Your doctor 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 3 studies on this procedure.

How well does the procedure work?

In 1 study, 7 patients with renal cancer were treated with the procedure. They had a total of 10 tumours. When they were checked after 3 months by CT scan, 5 of the tumours had disappeared completely but 5 had got bigger. Two patients had a second procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that that the main things that need to be measured to decide if the procedure is successful are how thoroughly the tumour is destroyed, if, or how long it is before, the tumour comes back, and patient survival.

Risks and possible problems

Three studies, which also included people with non-renal cancers such as liver or lung cancer, reported problems with patients' heartbeat during the procedure. In the first study, this happened in 6 of 38 patients (only 2 of the 6 had cardiac synchronisation). One patient needed to be treated with an electric shock to restore the heart's rhythm but the others got better on their own. In the second study 21 patients had 28 procedures. Patients had irregular heartbeats during 7 of them and the patients' blood pressure also dropped in 4 of the 7. Cardiac synchronisation was used in the trial but with 'variable success'. In the third study 1 patient out of 6 had a problem with their heartbeat during the operation. It returned to normal after the procedure and was still normal when the patient was checked again 12 weeks later.

One patient in the study of 38, 7 of whom were being treated for renal cancer, had a partly blocked ureter (the tube that carries urine from the

kidney to the bladder) and levels of a waste product from the kidneys called creatinine also increased. The patient's ureter had been previously damaged by a different procedure. The blockage was treated using a stent (plastic tube).

The blood pressure of 2 patients with renal cancer increased considerably during the procedure in a study of 21 patients. One patient needed treatment. All patients in the study had temporary increases in blood pressure.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that in theory other problems could include damage to nearby organs, bleeding, bacterial infection and narrowing of the ureter.

More information about renal cancer

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

For details of all NICE guidance on renal 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. 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 document is about 'Irreversible electroporation for treating renal cancer'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/IPG443

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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