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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Radiofrequency ablation for the treatment of colorectal metastases in the liver

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 radiofrequency ablation (RFA) can be used in the NHS to treat people with colorectal metastases in the liver. 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 colorectal metastases in the liver 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 7.

What has NICE said?

This procedure can be offered routinely as a treatment option for people with colorectal metastases in the liver who have already had or who cannot have more invasive surgery (liver resection) 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 specialists in hepatobiliary (liver) cancer should be involved in ensuring the right patients are offered the procedure.

Other comments from NICE

NICE noted that the evidence was not consistently reported and therefore difficult to interpret.

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

Radiofrequency ablation for the treatment of colorectal metastases in the liver

The medical name for this procedure is 'radiofrequency ablation for the treatment of colorectal liver metastases'.

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

Colorectal cancer is the second most common cancer in women and the third most common cancer in men in the UK. In some patients, cancer cells can spread from the bowel to other parts of the body to form one or more secondary tumours, also known as metastases. For bowel cancer, metastases most commonly occur in the liver.

Liver resection, in which parts of the liver containing secondary deposits are cut away surgically, is the most effective treatment, but this is not suitable for many patients. Other treatment options include chemotherapy, radiotherapy and other types of energy sources used to destroy the tissues.

Radiofrequency ablation uses a source of heat produced from a high frequency electrical current called radiofrequency to destroy (ablation) cancer cells. It can be done through the skin or during surgery. This may be done under local or general anaesthesia. One or more needle electrodes are placed into the tumour(s) using imaging guidance. A high frequency current is applied to the electrodes, which heats them, destroying the tissue around the electrodes.

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 it 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 operation?
- 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 an analysis of 11 studies and an additional 7 studies on this procedure.

How well does the procedure work?

In the analysis of 11 studies, 1 study of 46 patients reported that patients treated by RFA survived on average 44 months from diagnosis compared with 54 months in patients treated by surgical resection. Six other studies reported survival rates from 1 out of 6 patients at 11 months post procedure to 7 out of 8 patients at 2 to 6 months post procedure.

In a study of 243 patients unable to have surgical resection because of poor response to chemotherapy or an existing health condition making surgery dangerous, survival was 20% at 3 years and 18% at 5 years after RFA.

A study of 418 patients reported that patients treated by surgical resection had overall survival rates of 73%, 65% and 58% at 3-, 4- and 5-year follow-up, respectively. These survival rates were significantly higher than those from patients treated by RFA alone, or by RFA plus resection. In the same study, there was little difference in survival between patients treated by RFA alone and RFA plus surgical resection.

A study of 258 patients reported higher 3-year disease-free survival (patients were alive without cancer) in patients treated by surgical resection only (40%) compared with resection plus heat energy (34%). Both studies showed that RFA was less effective than surgical resection (when possible) at preventing the tumour from growing back or spreading to other parts of the liver.

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 success of the procedure should be measured by overall survival rates and by the rate at which the metastases grow back.

Risks and possible problems

In a study of 309 patients involving 617 treatments, 7 cases of bleeding requiring a blood transfusion were reported. There were also 4 cases of heat damage to the body's internal organs.

In the analysis of 11 studies, 3 of the studies reported complications in up to a third of patients. These complications included bowel perforation, wound infection, postoperative bleeding, narrowing of the bile duct and spreading ('seeding') of cancer cells into the abdomen.

In a study of 122 patients, 2 patients had complications that required intervention (drainage of bile from the abdomen in 1 patient and repair of an abnormal connection between the biliary and bronchial systems in another). Minor complications included bleeding in the abdomen (3 patients), an abnormally enlarged bile duct (4 patients) and persistent pain (3 patients).

A case study reported a patient who developed an abnormal opening leading from the lower stomach to the site of electrode insertion, which resolved within 6 months. Another patient developed pain and a high fever 5 days after the procedure due to an abscess in the liver. The patient recovered without further complications following drainage of the abscess.

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. They were aware of reports of damage to the gall bladder

and bile ducts and of slow heartbeat following the procedure. Other possible complications could include injury to the bowel or lungs, or the membranes that protect them.

More information about colorectal metastases in the liver

Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on colorectal metastases in the liver, 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. 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 'radiofrequency ablation for the treatment of colorectal liver metastases'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/HTG208

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2063). 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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