NICE National Institute for Health and Care Excellence

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Information for the public

Selective internal radiation therapy using radioactive beads for primary liver cancer

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 selective internal radiation therapy (SIRT) can be used in the NHS to treat people with primary liver cancer (hepatocellular carcinoma). It explains guidance (advice) from NICE (the National Institute for Health and Care 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 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 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 9.

What has NICE said?

SIRT can be offered routinely as a treatment option for people with primary liver cancer provided that doctors are sure that:

- the patient understands what is involved and the uncertainties about SIRT's effectiveness compared with other treatments,
- the patient agrees to the treatment, and
- the results of the procedure are monitored.

A team of healthcare professionals experienced in managing liver cancer should decide who should have this procedure. It should only be done by healthcare professionals with specific training in the procedure and ways of reducing the risk of side effects.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a database at the UK SIRT register so that the safety of the procedure and/or how well it works can be monitored over time.

NICE has encouraged doctors to consider asking patients to take part in a research study (called a clinical trial) looking at how well SIRT for liver cancer works compared with other treatments.

Other comments from NICE

The Committee noted that it was difficult to assess how well the procedure worked because of other treatments patients received at the same time. It also noted that safety evidence from older studies may be out of date now that the way the procedure is carried out has changed.

Selective internal radiation therapy using radioactive beads for primary liver cancer

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

The medical name for this procedure is 'selective internal radiation therapy for primary hepatocellular carcinoma'.

Hepatocellular carcinoma is the medical name for a type of liver cancer, and primary means that the cancer started in the liver.

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

Treatments for liver cancer include: chemotherapy; transarterial chemo-embolisation (TACE), in which chemotherapy is administered directly into the tumour's blood supply through a catheter (a thin, hollow tube); surgery to remove the cancer; and radiofrequency ablation, which uses heat to kill cancer cells.

A cure is sometimes possible using surgery and sometimes the tumour is treated first to make it shrink so it can be removed. But more often treatment aims to slow the disease down and make patients more comfortable.

SIRT aims to kill cancer cells using tiny radioactive 'beads', causing as little damage to the surrounding tissues as possible. Occasionally, in some patients the beads may pass through the liver and lodge in other organs, potentially damaging them. A scan may be done before the procedure to assess the risk of this happening, and the technique altered slightly. Using a local anaesthetic, the beads are injected into the artery that supplies blood to the liver (the hepatic artery). This is done by inserting a catheter into a blood vessel in the groin and on into the hepatic artery. The beads become trapped in the tiny blood vessels

that supply and surround the cancer and release radiation directly into the cancer cells to kill them.

SIRT may be repeated, depending on the response.

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 using SIRT for liver cancer 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.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. 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

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 21 studies on this procedure.

How well does the procedure work?

Two studies (involving 86 and 325 patients) looked at survival after treatment. In the study of 86 patients (half had SIRT and half had TACE) patients who had SIRT survived for 42 months compared with 19 months for patients who had TACE. In the study of 325 patients treated with SIRT, survival was between 10 and 24 months, depending on how advanced the cancer was.

The study of 86 patients, and 3 other studies (involving 245, 291 and 35 patients), reported how the cancer responded to treatment. In the study of 86 patients, within 6 months the cancer had shrunk in 58% of patients treated with SIRT, compared with 31% of patients treated with TACE. By around 34 months the cancer had shrunk by more than half in 61% of patients who had SIRT and by 52 months it had shrunk in 37% of patients who had TACE. In the study of 245 patients the cancer had shrunk in 49% of patients treated with SIRT (about half the study patients) by around 23 months and 36% of patients treated with TACE by around 33 months. The disease got worse after around 13 months for patients treated with SIRT compared with 8 months for patients treated with TACE.

In the study of 291 patients, 34 had treatment that aimed to shrink the cancer so that they could then have treatment that might cure their liver cancer. Of these patients, 32 went on to have a liver transplant and 2 had surgery to remove the cancer, by around 31 months. In the study of 35 patients, the cancer shrunk enough in 8 patients treated with SIRT

so that they were able to have liver transplants, 12 days to 210 months later.

Quality of life, assessed by a questionnaire, was similar in 9 patients who had SIRT and 5 patients who had chemotherapy with cisplatin, 6 months after treatment.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that success factors are response to treatment, survival, quality of life, slowing or halting the spread of the cancer, and whether the cancer shrinks enough to be able to attempt a cure, such as surgery or a liver transplant.

Risks and possible problems

In the study of 71 patients, 2 of 27 who had received SIRT, and 4 of 44 who had TACE, died within 30 days of treatment.

In a study of 80 patients, radiation from the beads caused inflammation of the lungs in 4 patients between 1 and 6 months after treatment with SIRT; 3 of these patients died from respiratory failure (when the lungs do not work effectively) and 1 patient died because their cancer worsened.

The study of 71 patients reported that 3 of 27 patients had inflammation of the stomach (gastritis) and stomach ulcers caused by radiation after having SIRT, compared with 9 of 44 patients who had TACE. Two patients in the SIRT group needed to have part of their stomach removed because of this.

Inflammation of the gallbladder that was possibly a result of SIRT treatment occurred in 2 patients in the study of 80 patients. Both patients had their gallbladder removed, 21 and 243 days after treatment.

One patient treated with SIRT had narrowing of the bile duct (the narrow tube that carries bile from the liver to the bowel). This caused bilirubin (the coloured substance in bile produced by the breakdown of red blood cells) to accumulate, causing yellowing of the skin (jaundice) and other toxic effects, and tiredness.

In a separate study, 1 month after having SIRT a patient had temporary thrombocytopenia, which means that the number of platelets (a type of blood cell) had decreased, which can increase the risk of bleeding.

In the study of 86 patients, post-embolisation syndrome (fatigue and flu-like symptoms, commonly seen after SIRT or TACE) lasting between 7 and 10 days, was reported in 60% of patients in the SIRT and TACE groups.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that possible problems include scarring of the liver and skin ulcers. They also said that in theory, other problems could include liver failure, high blood pressure in the veins that carry blood from the abdominal organs to the liver and liver disease caused by radiation.

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 provides national guidance and advice to improve health and social care. Interventional procedures 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 'Selective internal radiation therapy for primary hepatocellular carcinoma'. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/HTG314

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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