NHS
National Institute for Health and Clinical Excellence

Understanding NICE guidance

Information for people who use NHS services

Using selective internal radiation therapy to treat bowel cancer that has spread to the liver

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how selective internal radiation therapy (often called SIRT) can be used in the NHS to treat people with cancer that has spread from the bowel to the liver. 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.

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 bowel cancer 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.

Information about NICE interventional procedure guidance 401
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What has NICE said?

The available evidence indicates that the procedure appears safe to use.

For patients who have not had chemotherapy before

NICE has said that more evidence is needed about how well SIRT works in patients who have not previously been treated with chemotherapy. Doctors are recommended to ask these patients to take part in a research study (called a clinical trial), such as the FOXFIRE trial. If it is not possible for a patient to take part in a clinical trial or if they choose not to, NICE has said that SIRT may still be offered provided that the doctor explains the uncertainty about how well it works. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

For patients who have had chemotherapy before

For patients who have previously been treated with chemotherapy, there is evidence that SIRT can prolong the time it takes for the cancer to get worse, but more evidence is needed about survival and quality of life. NICE has said that if a doctor wants to offer this procedure, they should explain the uncertainty about how well it works. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

A specialist hepatobiliary cancer healthcare team should decide which patients might benefit from the procedure. The procedure should be carried out by trained healthcare professionals.

NICE has said that SIRT is a potentially beneficial treatment, but that more research needs to be done to show that it works. NICE may review the procedure if more evidence becomes available.

Other comments from NICE

The Committee considered quality of life after any kind of treatment to be of great importance to patients. The Committee considered that SIRT may be a potential option for some people in whom chemotherapy has failed. The Committee also considered a number of patient commentary questionnaires from patients who described benefits from SIRT.

Treating bowel cancer that has spread to the liver using selective internal radiation therapy

The medical name for this procedure is 'selective internal radiation therapy for non-resectable colorectal metastases in the liver', or SIRT. The procedure is not described in detail here – please talk to your specialist for a full description.

'Colorectal metastases in the liver' is the medical term for secondary cancer of the liver, when cancer from the bowel (colorectal cancer) spreads to the liver. For some patients the cancer in the liver is not suitable for surgical removal.

SIRT uses radiation delivered to the tumour in the liver to kill the cancer cells. It may be used alone or in combination with normal chemotherapy. Using a local anaesthetic, microscopic radioactive 'beads' are injected into the artery that supplies blood to the liver (the hepatic artery). This is done by inserting a very fine tube called a catheter into a blood vessel in the groin, and passing it into the hepatic artery. The beads become trapped in the tiny blood vessels that surround the tumour and release radiation directly into the diseased liver. Occasionally in some patients they may pass through the liver and lodge in the lungs, potentially causing radiation damage. A special type of scan may be done before the procedure to assess the risk of this happening, and the technique altered slightly.

SIRT may be repeated, depending on the response achieved.

This procedure may not be the only possible treatment for bowel cancer that has spread to the liver. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

What does this mean for me?

NICE has decided that more information is needed about this procedure. Your doctor may talk to you about having this procedure as part of a research study (also called a clinical trial) so that details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

Your doctor should tell you that NICE has decided that although the procedure is safe, there are uncertainties about how well it works. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

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 11 studies on this procedure.

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

How well does the procedure work?

In 3 studies involving a total of 135 patients, the patients who had SIRT plus chemotherapy survived for between 2.7 and 16.6 months longer than the patients who just had chemotherapy.

A study of 70 patients showed that after 3.5 years, tumours had responded better to SIRT plus chemotherapy than chemotherapy alone. A study of 44 patients showed that it took 3.4 months longer for the cancer to grow or spread in the patients who had SIRT and chemotherapy.

Out of a study of 50 patients who were all treated by SIRT, the tumours of 2 patients shrank enough to be treated with surgery. In the same study, after 6 weeks 14 patients said that their anxiety levels had significantly reduced (compared with how they felt before the procedure).

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 success factors are how well the tumours respond to treatment, survival and whether the tumours could then be treated with surgery or chemotherapy.

Risks and possible problems

In a study of 100 patients who had SIRT, 1 died after 9 weeks from damage to the liver caused by the radiation and 1 died because of damage to the pancreas (acute pancreatitis) and intestines.

The study of 44 patients showed that 1 out of the 21 patients treated by SIRT plus chemotherapy and 6 out of the 22 patients treated by chemotherapy alone had severe side effects (toxicity). The study of 70 patients showed no significant difference between the groups.

In the study of 21 patients, 1 patient of the 11 treated by SIRT plus chemotherapy had a liver abscess that needed draining following treatment. In a study of 140 patients who had SIRT, 3 had problems with their liver damage following treatment.

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 pain, vomiting, anorexia, fatigue, high blood pressure in the veins that carry blood from the abdominal organs to the liver, and problems delivering the radioactive beads. Other possible problems include inflammation of the lungs, intestinal haemorrhage or ulceration, inflammation of the gall bladder and pancreas, as well as skin and liver problems linked to radiation.

More information about cancer

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. For details of all NICE guidance on 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 leaflet is about 'Selective internal radiation therapy for non-resectable colorectal metastases in the liver'. This leaflet and the full guidance aimed at healthcare professionals are available at **www.nice.org.uk/guidance/IPG401**

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2580). 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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