Selective internal radiation therapy using radioactive beads for bile duct cancer

This document is about when and how selective internal radiation therapy (SIRT) can be used in the NHS to treat people with bile duct cancer (primary intrahepatic cholangiocarcinoma). It explains guidance (advice) from NICE (the National Institute for Health and Care 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 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 bile duct 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 8.
What has NICE said?
There is not much good evidence about how well this procedure works or how safe it is. If a doctor wants to use SIRT for bile duct cancer, they should make sure that extra steps are taken to explain the uncertainty about how well it works and the potential risks of the procedure. This should happen before the patient agrees (or doesn’t agree) to the procedure. The patient should be given this document 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 team of healthcare professionals experienced in managing liver cancer should decide which patients should have this procedure or enter a clinical trial of it. The procedure should only be done by healthcare professionals with specific training in its use, including ways of reducing 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 checked over time.

NICE has encouraged doctors to consider asking patients to take part in a research study (called a clinical trial) looking at using SIRT for bile duct cancer. The research should record patients’ details, the tumour’s response to treatment, survival, quality of life and any other treatments used before, after or at the same time as SIRT. NICE may review the procedure if more evidence becomes available.

Comments from NICE
NICE said that bile duct cancer is rare and does not follow the same course in every patient. Therefore, collecting good evidence was difficult, which is why NICE encourages more research.
Selective internal radiation therapy using radioactive beads for bile duct cancer

The medical name for this procedure is ‘selective internal radiation therapy for primary intrahepatic cholangiocarcinoma’.

Cholangiocarcinoma is the medical name for bile duct cancer and primary means that the cancer started in the bile duct.

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

The bile ducts are narrow tubes that carry bile, a fluid made in the liver, to the bowel where it helps digest fats.

Bile duct cancer is rare. The choice of treatment depends on things like exactly where the cancer is and how advanced it is, and how well the patient’s liver is working.

Treatments include surgery to remove the cancer, chemotherapy and photodynamic therapy, which uses a light-activated drug with a laser to destroy abnormal cells. If the cancer is advanced, treatment options include surgery to bypass the blockage in the bile duct or to help to keep the bile duct open.

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 they 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

This procedure may not be the only possible treatment for bile duct cancer. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.
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 thin tube called 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?
If your doctor has offered to use SIRT for bile duct cancer, he or she should tell you that NICE has decided that the benefits and risks are uncertain. 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 document, and have the opportunity to discuss it with your doctor before making your decision.

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

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 7 studies on this procedure.

**How well does the procedure work?**

Two studies, of 24 and 19 patients who had SIRT, looked at survival after the procedure. In the first study 17 patients who had SIRT alone survived for 32 months, compared with 4 months in 7 patients who had chemotherapy before the procedure. In the second study, 19 patients who had SIRT survived for 12 months.

The study of 24 patients found that 18 months after the procedure the cancer stayed the same in 15 of 22 patients, responded to SIRT in 6 of 22 patients or got worse in 1 of 22 patients. One patient went on to have a liver transplant 18 months after treatment with SIRT.

In 2 studies involving a total of 49 patients treated by SIRT, the cancer shrank enough in 2 patients to allow it to be removed by surgery, at 8 and 18 months after treatment.

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

**Risks and possible problems**

In the study of 24 patients who had SIRT, 2 patients died within 30 days. One patient died from a pulmonary embolus, which is a blockage by a blood clot in the artery to the lungs. The other patient’s cancer had grown and spread.
In the same study, 2 patients had a build-up of fluid in the space surrounding the lungs (pleural effusion) within 18 months and 1 patient had a stomach ulcer, which needed surgery.

In the study of 25 patients, in the months following SIRT tiredness was reported in 64% of patients, nausea in 16% and vomiting in 8%.

One patient in the study of 19 patients developed severe thrombocytopenia within 30 days, which means that the number of platelets (a type of blood cell) had decreased, which can increase the risk of bleeding.

As well as looking at these studies, NICE also asked expert advisers for their views. They said that possible problems include liver scarring 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 bile duct cancer
NHS Choices (www.nhs.uk) may be a good place to find out more.

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. 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 ‘selective internal radiation therapy for primary intrahepatic cholangiocarcinoma’. This document and the full guidance aimed at healthcare professionals are available at guidance.nice.org.uk/IPG459

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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