

Understanding NICE guidance

Information for people who use NHS services

Treating secondary cancer of the liver by freezing (cryotherapy)

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 freezing (cryotherapy) can be used in the NHS to treat people with secondary cancer of 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 secondary cancer of 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 the back page.

What has NICE said?

Evidence suggests that this procedure is safe for patients with secondary cancer of the liver. However, there are uncertainties about how well it works. If a doctor wants to use cryotherapy for secondary cancer of the liver, they should make sure that extra steps are taken to explain that other treatments that aim to destroy cancer cells (called 'ablative' treatments) are available, as well as the uncertainty about how well the procedure works and the potential risks. 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 with expertise in the use of ablative techniques should decide which patients might benefit from the procedure and should carry it out.

Other comments from NICE

There is limited evidence on the safety of this procedure when performed using keyhole techniques rather than as part of open surgery.

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

Cryotherapy

The medical name for this procedure is 'Cryotherapy for the treatment of liver metastases'. The procedure is not described in detail here – please talk to your specialist for a full description.

Liver metastases is the medical term for secondary cancer of the liver, when cancer in one part of the body (for example, primary bowel cancer) spreads to the liver.

Liver resection, in which parts of the liver containing cancerous cells are cut away surgically, is the most effective treatment but it is not suitable for many patients. Other treatments include chemotherapy, radiotherapy and ablative techniques that use energy sources to destroy the cancer cells. A combination of treatments may be used.

Cryotherapy may be a treatment option for patients with small cancers (usually up to 4 cm in diameter). It can be done as part of open surgery with the patient under general anaesthesia, or using keyhole techniques with the patient under local or general anaesthesia. One or more cryotherapy probes are inserted into the cancer using keyhole techniques; this is done through a small cut made in the skin. The tip of the probe is then cooled to below freezing, which creates an ice ball within the surrounding tissue that aims to destroy the cancer cells.

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 6 studies on this procedure.

What does this mean for me?

If your doctor has offered you this procedure, he or she should tell you that NICE has decided that although it 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 operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

How well does the procedure work?

In a study of 123 patients, 9 out of 63 patients treated by cryotherapy and chemotherapy were alive without cancer at 10 years, as were 3 out of 60 patients treated by liver resection and chemotherapy. A study of 415 patients comparing resection plus cryotherapy with resection alone reported average survival of 29 months and 34 months, respectively.

In a study of 326 patients, average survival was 29 months. Cancer grew back in 136 patients at an average of 32 months after the procedure. In the same study, among 280 patients who had computed tomography (CT) scan results available, the cancer had stabilised (that is, was no larger) in 68 patients and had worsened in 56. A partial response was seen in 115 patients. Total destruction of the cancer was reported in 41 patients.

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 aims of the procedure are tumour destruction and patient survival.

Risks and possible problems

Death, during or shortly after, the procedure occurred in 1 out of 55 patients who had cryotherapy and in 8 out of 168 patients who had liver resection in a study of 223 patients. Complications that occurred

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

during, or shortly after, the procedure were reported in 6 patients in the cryotherapy group and 44 in the resection group. Seven deaths were reported in the study of 326 patients, including 1 from liver failure and 1 from 'cryoshock syndrome' (a rare complication that can cause multiple organ failure and severe blood clotting). A report of 1 patient treated with a second course of cryotherapy (during open surgery) stated that the patient died of liver failure related to a severe MRSA infection and a blood clot near the liver 2 months after the procedure.

Infections caused by cryotherapy were reported after 12 procedures in a study of 150 patients (158 procedures), mostly within 3 weeks of treatment. A fever was reported in 108 patients in the study of 326 patients.

In the study of 223 patients, bleeding complications were reported in 2 of 55 patients who had cryotherapy and in 2 of 168 patients who had liver resection.

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 other known complications of the procedure include damage to structures inside (such as bile ducts) and outside the liver.

More information about liver 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 liver 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 'cryotherapy for the treatment of liver metastases'. This leaflet and the full guidance aimed at healthcare professionals are available at

www.nice.org.uk/guidance/IPG369

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2383). 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.