

Understanding NICE guidance

Information for people who use NHS services

Treating superficial bladder cancer with microwave heat and chemotherapy

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

This leaflet is about when and how microwave heat and chemotherapy can be used in the NHS to treat people with superficial bladder cancer. 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. The word 'procedure' means any surgery, test or treatment that involves entering the body through skin, muscle, a vein or artery, or body cavity. 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 bladder 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. Some sources of further information and support are on the back page.



What has NICE said?

The evidence that NICE looked at only involved small numbers of patients. There did not appear to be any major safety worries linked to the procedure but there was only a very small amount of evidence about how well it works. For these reasons, NICE has said that this procedure should only be carried out as part of a research study (also called a clinical trial).

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

Using microwave heat and chemotherapy to treat superficial bladder cancer

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

Transitional cells are a special type of cell that form the inner lining of the bladder. Cancer of the transitional cells is the most common type of bladder cancer. If the cancer has not grown from the bladder lining into the muscle of the bladder wall it is called superficial. Superficial cancer usually develops on the bladder wall. It can be treated by removing the cancer using a telescope inserted into the bladder. The name for this procedure is transurethral resection or TUR. Chemotherapy medicine or BCG vaccine may also be used inside the bladder as a treatment on its own or as well as surgery. This new technique uses microwaves to heat the bladder. Microwave heat and chemotherapy can be used before TUR to try to shrink the cancer or it can be done after TUR to try to prevent the cancer returning.

Using microwave heat and chemotherapy to treat superficial bladder cancer can be done on an outpatient basis. It is done using a local anaesthetic gel. Treatment sessions usually last for 40–60 minutes and are usually repeated weekly for 4–8 weeks or sometimes longer. A hollow tube called a catheter is inserted into the bladder through the urethra (the tube that carries urine out of the body from the bladder). The doctor sometimes uses ultrasound to check the position of the instruments. On the end of the catheter is a small balloon, an antenna and several temperature-sensing instruments.

The balloon is gently inflated. The antenna uses microwave energy to heat the cells on the wall of the bladder, while the temperature-sensing instruments make sure the temperature does not get too hot. A chemotherapy medicine is flushed through the catheter into the space between the balloon and the bladder wall, then it is pumped out and cooled and the process is repeated.

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 six studies on this procedure.

What does this mean for me?

Your doctor can only offer you this procedure as part of a clinical trial. NICE has recommended that some details should be collected about every patient who has this procedure in the UK. These details will be held confidentially in an electronic database and will not include patients' names. If you do not agree to the details being entered into the database, you can still have the procedure.

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?

NICE looked at studies that used microwave heat and chemotherapy before TUR. Two studies showed that using the combination of microwave heat and chemotherapy worked better than using chemotherapy on its own. Using microwave heat with chemotherapy worked in 19 out of 29 patients in two studies of 29 patients, compared with 5 out of 23 and 10 out of 36 patients who had been treated with chemotherapy alone. Two other studies showed that the combination worked in 31 out of 44 and 21 out of 28 patients.

Studies also showed that microwave heat together with chemotherapy meant that the cancer came back slightly less frequently. A study that followed patients' progress for 3 years showed that the cancer came back in 8 out of 29 patients who had the combination, compared with 9 out of 23 patients who had chemotherapy alone. NICE also looked at studies that used microwave heat together with chemotherapy after TUR. One study that followed patients' progress for 2 years showed that the cancer came back less frequently in patients who had the combination. In the study the cancer came back in 6 out of 42 patients who had the combination, but it came back in 23 out of 41 patients who had chemotherapy alone. A study of 90 patients reported that there was a 14% risk of the cancer coming back after 1 year and a 25% risk of it coming back after 2 years.

The expert advisers said that there is uncertainty about how well the procedure works. One adviser said that there has not been much investigation into the long-term effects of the procedure or which patients it is most suitable for.

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

Risks and possible problems

Most patients reported symptoms of cystitis (frequent and/or urgent passing of urine) for a couple of days after each treatment session. One study reported that in the patients who had the combined treatment, the average severity of the cystitis symptoms scored 18 out of a maximum score of 24, compared to a score of 13 from the patients who had chemotherapy alone. In one study 17 out of 42 patients reported pain during the combined treatment, compared to none during the chemotherapy-alone treatment. Another study of 28 patients reported that 6 patients had pain during the treatment, 16 had pain on passing urine, 4 had bladder spasms and 2 developed a urinary tract infection.

A small number of patients had internal damage to the tube that carries urine from the bladder to outside the body (urethra). In the studies this happened in 3 out of 42, 1 out of 44, 1 out of 28 and 4 out of 90 patients. Skin rashes were also reported. In the studies this happened in 1 out of 44, 2 out of 28, 2 out of 24 and 5 out of 42 patients.

The expert advisers said that in theory, heat damage to the bladder, skin problems, bladder problems, leakage of the chemotherapy medicine and infection of the abdominal cavity are also possible.

More information about bladder cancer

NHS Direct online (www.nhsdirect.nhs.uk) may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

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 'Intravesical microwave hyperthermia with intravesical chemotherapy for superficial bladder cancer'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/PG235

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1351).

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