

## Understanding NICE guidance

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Information for people who use NHS services

# Treatment of rectal cancer with preoperative high dose rate brachytherapy

*NICE 'interventional procedures guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.*

This leaflet is about when and how preoperative high dose rate (shortened here to HDR) brachytherapy can be used to treat people with rectal cancer in the NHS in England, Wales, Scotland and Northern Ireland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

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 rectal 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.

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. The guidance does not cover whether 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.



## What has NICE said?

There is evidence to show this procedure is safe and works in the short term. However, there are still uncertainties over its safety and how well it works in the long term.

If a doctor wants to use preoperative HDR brachytherapy for rectal cancer, he or she should make sure that extra steps are taken to explain the uncertainty and the likely benefits and 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 leaflet and other written information as part of the discussion.

There should also be special arrangements for monitoring what happens after the procedure. NICE has encouraged doctors to consider asking patients to take part in a research study (called a clinical trial) to record how well this procedure works and how safe it is.

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

## High dose rate brachytherapy

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

Rectal cancers are usually removed by surgery. HDR brachytherapy can be carried out before surgery to shrink the cancer and make it easier to remove without also removing the anus.

One end of a tube is gently inserted into the rectum. The other end is then attached to a radiotherapy machine and radiation is administered, through the tube, directly into the cancer tissue in the rectum. This causes the cancer to shrink. Surgery to remove the cancer is done a few weeks later.

## 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.

## How well does the procedure work?

Surgeons were able to remove the cancer and preserve the anus in 69 out of 96 patients who had received HDR brachytherapy prior to their operation. Out of 115 patients who did not have HDR brachytherapy before their operation, it was not possible to remove the cancer and preserve the anus in 48 patients.

HDR brachytherapy also reduced the chance of the cancer growing back. Over 4 years, the cancer grew back in 8 out of 96 patients treated with HDR brachytherapy, compared with 24 out of 115 patients who had surgery without HDR brachytherapy.

It was not clear whether HDR brachytherapy increased the chances of patients surviving without the cancer recurring. The number of patients alive with no signs of cancer after 4 years was similar whether or not they had had HDR brachytherapy before surgery. The probability of surviving 5 years was also similar (62–65%).

The expert advisers said the long-term effects of HDR brachytherapy are not yet clear.

## Risks and possible problems

In one study, all 49 patients treated with HDR brachytherapy developed inflammation of the rectum and 2 developed anal skin problems. Between 38% and 74% of patients in another study developed problems, depending on the brachytherapy dose.

Several other problems were reported in the studies, some of which may have been due to the surgery. These included: opening of surgical wounds (5–24%), narrowing of the rectum (3–4%), infection in the wound (3–6%) or the pelvis (2–11%), blockage (7–11%) or damage (11%) to the small bowel (occasionally needing further surgery) and formation of a fistula (an abnormal opening) between the rectum and bladder or vagina (5–16%).

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

### What does this mean for me?

If your doctor has offered you HDR brachytherapy 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 leaflet, 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. So it has recommended that some details should be collected about every patient who has this procedure in England and Wales. These details will be held confidentially in an electronic database, and will not include patients' names. If you do not agree to your 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 procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

### More information about rectal cancer

NHS Direct online ([www.nhsdirect.nhs.uk](http://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. 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](http://www.nice.org.uk/aboutguidance)*

*This leaflet and the full guidance aimed at healthcare professionals are available at [www.nice.org.uk/IPG201](http://www.nice.org.uk/IPG201)*

*You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1171).*