NICE National Institute for Health and Care Excellence

NICE guidance

Low-energy contact X-ray brachytherapy for rectal cancer

HealthTech guidance

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www.nice.org.uk/guidance/htg763

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG809, IPG659 and IPG532.

1 Recommendations

Early-stage and locally advanced rectal cancer

1.1 Low-energy contact X-ray brachytherapy can be used as an option to treat early-stage and locally advanced rectal cancer:

- when the tumour is 3 cm or less and has not spread beyond stage T3b N1 M0 (with limited nodal involvement), and:
  - the person chooses not to have surgery, or
  - the risks of surgery are unacceptably high.

  People with larger tumours (with limited nodal involvement) may become eligible for this procedure if neoadjuvant treatment (external beam radiotherapy with or without chemotherapy) reduces the tumour to 3 cm or less and it has not spread beyond stage T3b N1 M0.

Metastatic rectal cancer

1.2 More research is needed on low-energy contact X-ray brachytherapy to treat metastatic rectal cancer before it can be used in the NHS.

1.3 This procedure should only be done as part of formal research and a research ethics committee needs to have approved its use.

What research is needed

More research, in the form of randomised controlled trials and prospective registries for metastatic rectal cancer, is needed on:

- patient selection including tumour type and suitability of surgery
- role of neoadjuvant treatment
- treatment intent
- patient-reported outcomes (such as quality of life and functional outcomes)
- survival
- long-term outcomes.

What this means in practice

Early-stage and locally advanced rectal cancer

There is enough evidence on the safety and efficacy of this procedure for healthcare professionals to consider low-energy contact X-ray brachytherapy as an option for early-stage and locally advanced rectal cancer.

Healthcare professionals should always discuss the available options with the person with rectal cancer before a joint decision is made (see NICE's page on shared decision making).

Hospital trusts will have their own policies on funding procedures and monitoring results. NHS England may also have policies on funding of procedures.

Metastatic rectal cancer

There is not enough evidence on the safety and efficacy of this procedure for metastatic rectal cancer. Low-energy contact X-ray brachytherapy for metastatic rectal cancer should only be done as part of formal research.

For everyone having the procedure

Auditing of outcomes

Healthcare professionals doing this procedure should collect data on safety and outcomes of the procedure. Enter details about everyone having this procedure into the ColoRectal database (CR-DB). Regularly review the data on outcomes and safety.

Who should be involved in the procedure

Patient selection should be done by a colorectal cancer multidisciplinary team that includes a clinical oncologist and a colorectal surgeon with specific training in this procedure and expertise in local excision techniques. The procedure should only be done in centres specialising in managing rectal cancer.

Why the committee made these recommendations

Clinical evidence for this procedure includes randomised controlled trials and observational studies. This shows that, in people with early-stage or locally advanced rectal cancer, low-energy contact X-ray brachytherapy can achieve long-term control of the condition while preserving the rectum and surrounding structures. Because radical surgery is avoided, patients may not need a permanent stoma. This substantially improves their quality of life. So, the procedure can be used as an option for early-stage and locally advanced rectal cancer.

For people with metastatic rectal cancer, there is not enough evidence on the efficacy and safety of this procedure. So, it should only be done in research in this population.

2 Information about the procedure

2.1 Low-energy contact X-ray brachytherapy (CXB) aims to improve local control or cure rectal cancer. The procedure (also known as the Papillon technique) involves inserting an X-ray tube through the anus and placing it in close contact with the tumour to kill cancer cells and reduce the size of the tumour. The tube emits low-energy X-rays that only penetrate a few millimetres, which minimises damage to deeper tissues.

2.2 Low-energy CXB for rectal cancer is usually delivered in an outpatient setting. The person having the procedure is given an enema before treatment to clear the bowel. During the procedure they are in a knee-to-chest, prone jackknife (lying on their front, with hips flexed at a 90-degree angle so that their head and legs are lower than their hips) or supine (lying flat on their back) position. Local anaesthetic (with or without sedation) and glyceryl trinitrate are applied to the anal sphincter to numb the area and relax the sphincter muscles. A sigmoidoscope (a rigid or flexible tube with a video camera and light that is used to look at the lower part of the large intestine, including the rectum) is inserted to check the size and position of the tumour. A rigid endorectal treatment applicator is then inserted and placed in contact with the tumour. A contact X-ray tube is placed into the applicator and treatment begins. If the tumour does not respond to low-energy CXB or recurs after treatment, surgery may be done.

2.3 Several different devices are available to do this procedure in the UK. All deliver a beam of 50-kV X-rays.

3 Committee discussion

The condition

3.1 Rectal cancer forms in the tissues of the rectum. The most common symptoms are rectal bleeding, pain and feeling like there is a lump in or around the anus. Less common symptoms include itching and changes to bowel habits. The likelihood of developing rectal cancer rises sharply with age, or if there is a familial genetic predisposition. For many people with the condition, the cancer is asymptomatic and detected through the national bowel cancer screening programme.

Current practice

3.2 Management of rectal cancer depends on the cancer stage and individual patient factors. Surgery has traditionally been the gold standard for early-stage rectal cancer, but radiotherapy or chemoradiotherapy with a 'watch and wait' approach is increasingly used. Advanced tumours are usually treated with surgery, such as transanal excision, endoscopic submucosal dissection or total mesorectal excision. If surgery is not suitable or the person chooses not to have it, chemoradiotherapy may be used to shrink the tumour. NICE's guideline on colorectal cancer recommends preoperative radiotherapy or chemoradiotherapy for rectal cancer of stages cT1 to T2, cN1 to N2, M0 or cT3 to T4, any cN, and M0. Radiotherapeutic options include external beam radiation therapy (EBRT) or brachytherapy, in which radioactive material is placed inside or near the tumour.

Unmet need

3.3 Organ-preserving techniques and procedures have been increasingly adopted because they offer improvements in quality of life and reduce the risks and complications associated with surgery. So, they have become preferred by people with rectal cancer who do not wish to have surgery. One alternative to

surgery, EBRT, is associated with a range of side effects, including skin discomfort, because it is an external application of radiation. When used with EBRT, low-energy contact X-ray brachytherapy (CXB) may provide a more targeted, organ-preserving option for local control by focusing radiation directly to the tumour without substantially increasing toxicity. Low-energy CXB may be particularly beneficial for some people, such as older people with comorbidities for whom surgery may not be an option because the risk is unacceptably high.

The evidence

3.4 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 13 sources, which was discussed by the committee. The evidence included 1 systematic review and meta-analysis, 2 randomised controlled trials and 10 observational studies, and is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview. Several different devices were used in the studies informing this guidance. All delivered a beam of 50-kV X-rays.

3.5 The professional experts and the committee considered the key efficacy outcomes to be:

- quality of life
- organ preservation
- avoiding a permanent stoma
- clinical response
- survival
- recurrence.

3.6 The professional experts and the committee considered the key safety outcomes to be:

- proctitis

- rectal bleeding
- mortality
- dermatitis.

3.7 Fifty-one commentaries from people who have had low-energy CXB, or their carers, were available. The committee highlighted the lived experience of people who have had this procedure, with every respondent stating that they would recommend it to other people with rectal cancer.

Committee comments

3.8 The committee noted that small polyps should be removed endoscopically as a first-line treatment, and that people with only small polyps would not be eligible for this procedure.

3.9 One of the clinical experts explained the opposing risk profiles of low-energy CXB and surgery. Low-energy CXB is less invasive but has a higher risk of local recurrence, while surgery offers more definitive control but has higher upfront risks such as surgical complications and long-term side effects.

3.10 The committee noted that providing a less-invasive treatment option for rectal cancer may encourage people to use screening services.

3.11 The committee noted that people who have larger tumours (larger than 3 cm) that have reduced in size after neoadjuvant treatment and have limited nodal involvement may become eligible for this procedure.

3.12 The committee emphasised the importance of organ preservation (the rectum and surrounding structures) provided by low-energy CXB and its impact on quality-of-life outcomes.

3.13 The committee noted that regular ongoing surveillance is needed for people who have this procedure, with repeat imaging and endoscopies recommended for 5 years after the procedure.

3.14 The committee was informed that the device applicator is only suitable for tumours of 3 cm or less.

Equality considerations

3.15 The prevalence of rectal cancer is strongly related to age, with 75% of cases occurring in people aged 50 or over. Incidence rates for colorectal cancer are lower in Asian and Black ethnic groups, and in people of mixed or multiple ethnicities, compared with the White ethnic group, in England.

3.16 People from ethnic minority backgrounds are less likely to use screening services. This may lead to a delay in diagnosis and treatment.

3.17 People from ethnic minority backgrounds may have higher prevalence of stoma rejection.

3.18 The committee noted that there are only a few centres in the UK that specialise in managing rectal cancer and performing low-energy CXB. So, people living further from these centres may not have access to this procedure.

4 Committee members and NICE project team

This topic was considered by NICE's interventional procedures advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Tom Clutton-Brock
Chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Jakob Falloon
Technical lead

Amy Crossley
Technical adviser

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Update information

Minor changes since publication

December 2025: Interventional procedures guidance 809 has been migrated to HealthTech guidance 763. The recommendations and accompanying content remain unchanged

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.