NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Intraoperative electron beam radiotherapy for locally advanced and locally recurrent colorectal cancer

People with bowel (colorectal) cancer can have surgery to remove the tumour. If the tumour has spread to nearby tissues (locally advanced) or if a tumour that was treated has come back in the same place (locally recurrent), surgery sometimes cannot remove all of the cancer. In this procedure, electron beam radiation is delivered directly to the tumour during the surgery to remove it (intraoperative). Because the radiation delivered in this procedure is precisely targeted to the tumour, it can be a higher dose than normal radiotherapy. The aim is to remove any remaining cancer cells, stop the cancer from coming back and stop it from spreading further.

NICE is looking at intraoperative electron beam radiotherapy for locally advanced and locally recurrent colorectal cancer.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of professional experts with knowledge of the procedure.

This document contains the <u>draft guidance for consultation</u>. Your views are welcome, particularly:

- comments on the draft recommendations
- · information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

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 meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance

 prepare a second draft, which will go through a <u>resolution process</u> before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 4 January 2023

Target date for publication of guidance: April 2023

1 Draft recommendations

- 1.1 Evidence on the safety of intraoperative electron beam radiotherapy for locally advanced and locally recurrent colorectal cancer is adequate. Evidence on efficacy is inadequate in quality and quantity. Therefore, this procedure should only be used in the context of research. Find out what only in research means on the NICE interventional procedures quidance page.
- 1.2 Further research should preferably be in the form of suitably powered randomised controlled trials and should report details of patient selection (including tumour type and staging), the technique of radiotherapy and the extent of surgery undertaken, and key outcomes (as detailed in section 3.2 and 3.3).
- 1.3 Patient selection and the procedure should only be done in specialist centres by a multidisciplinary team experienced in managing colorectal cancer. The multidisciplinary team should include a colorectal surgeon, a clinical oncologist, a medical physicist, a radiographer, and an anaesthetist with specialist training in the procedure.

2 The condition, current treatments and procedure

The condition

2.1 Colorectal cancer is a common cancer. It typically occurs in people older than 50, with the risk increasing with age. About 5% to 20% of people with colorectal cancer have locally advanced disease, in which the cancer has invaded nearby tissues. After primary resection to remove the tumour, it returns in the same place in about 5% to 20% of people.

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Current treatments

2.2 There are various treatments for colorectal cancer, including resection, chemotherapy and radiotherapy. Treatment choice depends on the type of cancer, location and staging. The radicality of resection is the most important prognostic factor for survival. Resection is referred to as: R0, when there are clear margins around the tumour; R1, when there are microscopically involved margins; and R2, when there are macroscopically involved margins or gross residual disease.

The procedure

- 2.3 The procedure is done during surgery for locally advanced or locally recurrent colorectal cancer. Once the tumour is resected, the patient is positioned to receive a megavoltage electron dose from a linear accelerator. Either the operating theatre is equipped with a stationary linear accelerator, the patient is transferred to a dedicated room, or a mobile linear accelerator is brought into the theatre. Radiation-sensitive organs surrounding the tumour site can be displaced or shielded from the intraoperative electron beam radiotherapy (IOERT) field. A single large fraction of radiation (typically 10 to 20 Gy) is then delivered via an applicator directly to the tumour bed. The aim is to improve local control and increase survival rates.
- 2.4 There are several techniques for delivering intraoperative radiotherapy, including IOERT, high dose rate brachytherapy, and orthovoltage. This guidance relates to IOERT only, not high dose rate brachytherapy or orthovoltage techniques.

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3 Committee considerations

The evidence

- 3.1 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 7 sources, which was discussed by the committee. The evidence included 2 systematic reviews and meta-analyses, 4 case series and 1 cohort study. It is presented in the section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.
- 3.2 The professional experts and the committee considered the key efficacy outcomes to be: local recurrence, disease-free survival, overall survival, quality of life.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: damage to adjacent structures in the short and long-term, including ureteric strictures, wound complications, and bony necrosis.
- 3.4 Patient commentary was sought but none was received.

Committee comments

- 3.5 The committee was informed that this is a complex procedure that requires a multidisciplinary team as detailed in section 1.3, in addition to theatre staff trained to undertake this procedure.
- 3.6 The committee was informed that this procedure requires highly specialist equipment to deliver the radiotherapy, and specialist shielding in the operating theatre.
- 3.7 Most of the evidence came from people with rectal cancer.

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The committee was informed that this procedure can reduce the extent of surgery needed.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
November, 2022

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