NICE guidance

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

Interventional procedures guidance
Published: 6 June 2023

www.nice.org.uk/guidance/ipg763

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.

1 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 guidance 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 sections 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.

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. This can happen in the operating theatre if it's equipped with a stationary linear accelerator. Otherwise, the person 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 Gy to 20 Gy) is then delivered by 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.

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 summary of key evidence 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 and 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 The committee received and discussed 2 commentaries from a representative of patients who had experience of this procedure.

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.

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

ISBN: 978-1-4731-5222-9

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation