

High dose rate brachytherapy for carcinoma of the cervix

Interventional procedures guidance

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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 Guidance

- 1.1 Current evidence on the safety and efficacy of high dose rate brachytherapy for carcinoma of the cervix appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 Clinicians should ensure that patients have appropriate counselling and pain management. In addition, use of NICE's information for the public is recommended.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 There are two main types of cancer of the cervix. The most common, squamous cell carcinoma, usually develops from the cells which cover the outer surface of the cervix (the ectocervix). The other, adenocarcinoma, usually develops from the glandular cells that line the cervical canal (the endocervix). The stage of the cancer is defined by its size and by the extent of spread beyond the cervix.
- 2.1.2 The most common symptoms of cervical cancer are abnormal vaginal bleeding or discharge and discomfort during intercourse.
- 2.1.3 Cancer of the cervix can be treated with surgery, radiotherapy, chemotherapy or a combination of these treatments. Surgery is often the main treatment for cancer of the cervix in its early stages (where cancer is found only in the cervix).

Chemotherapy is occasionally used before surgery, shrinking the cancer to make the operation simpler. However, it is mainly given in combination with radiotherapy, either as a primary therapy or after surgery.

- 2.1.4 Brachytherapy can be given in low, medium or high dose rates. Low dose rate brachytherapy delivers radiation slowly. In order to administer a radiation dose that will eliminate the cancer, applicators need to be in place in the vagina for 2 to 3 days.

2.2 Outline of the procedure

- 2.2.1 High dose rate (HDR) brachytherapy was developed to reduce the radiation hazard to staff, and to reduce the length of inpatient treatment, with a requirement for isolation of the patient. HDR brachytherapy may be used for palliation of advanced disease, but this guidance refers only to HDR brachytherapy used with curative intent.
- 2.2.2 Applicators are put in place in the cervix and connected to an afterloading machine which delivers radiation at a high dose rate, typically for a few minutes. The treatment is often repeated several times, a few days apart, on an outpatient basis. This procedure gives a high dose of radiation to the cervix and the adjacent area, but a low dose to tissues and organs more than a few centimetres away. Practically all HDR brachytherapy is given in conjunction with external-beam radiation therapy.

2.3 Efficacy

- 2.3.1 In two randomised controlled trials (RCTs) that compared patients treated with HDR and those treated with low dose rate (LDR) brachytherapy, the overall survival (across all stages of disease) with HDR was 68% and 54% at 3- and 5-year follow-up, respectively, compared with 71% and 55% after LDR brachytherapy. These differences were not significant.
- 2.3.2 In an RCT, the overall 5-year survival (across all stages) in 31 patients who had

received HDR brachytherapy was 61%, compared with 63% in 29 patients who had received medium dose rate (MDR) treatment. In the same study, local disease-free survival was achieved in 67% of patients who had received HDR brachytherapy compared with 78% in the MDR-treated patients.

- 2.3.3 Distant metastases occurred in 6% (15 out of 236), 19% (372 out of 1,992) and 22% (43 out of 200 and 25 out of 112) of HDR-treated patients in RCTs and a case series. Where the outcome was reported, local recurrence occurred in 6% (7 out of 112), 21% (415 out of 1,992) and 22% (51 out of 236) of HDR-treated patients, with follow-up ranging from 3 to 10 years. For more details, refer to the [overview](#).
- 2.3.4 Some of the Specialist Advisors stated that HDR brachytherapy had equivalent efficacy to LDR brachytherapy.

2.4 Safety

- 2.4.1 In a large case series of 1,992 patients, with a median 8-year follow-up, the overall bowel and bladder complication rate was 35%. Radiation Therapy Oncology Group grade 3 or 4 complications occurred in 7% of patients. In an RCT that compared HDR and MDR brachytherapy, the grade 2 complication rate among HDR-treated patients was 13% (4 out of 31). In the MDR arm, there were grade 2 complications in 3% (1 out of 29) of patients.
- 2.4.2 Where reported separately, rectal complications (all grades) affected 4% to 20% (22 out of 112) of patients, and bladder complications affected 4% (8 out of 200) of patients. Serious complications such as bowel obstruction, severe rectal bleeding and stenosis, which required subsequent surgery, occurred in 2% and 6% (11 out of 200) of patients in two case series. For more details, refer to the [overview](#).
- 2.4.3 The Specialist Advisors reported that complications include diarrhoea, bleeding, colitis and cystitis, and also fistulae requiring surgery. They noted the possibility of long-term problems affecting the bowel, bladder and rectum.

2.5 Other comments

2.5.1 Consultees highlighted that this procedure can be very painful.

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the [overview](#).

Information for the public

NICE has produced [information for the public on this procedure](#). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).