High dose rate brachytherapy for carcinoma of the cervix

Interventional procedures guidance Published: 22 March 2006

www.nice.org.uk/guidance/ipg160

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 the Institute's <u>information for the public</u> 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 years 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% (15/236), 19% (372/1992) and 22% (43/200 and 25/112) of HDR-treated patients in RCTs and a case series. Where the outcome was reported, local recurrence occurred in 6% (7/112), 21% (415/1992) and 22% (51/236) of HDR-treated patients, with follow-up ranging from 3 to 10 years. For more details, refer to the Sources of evidence section.
- 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 1992 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% (4/31). In the MDR arm, there were grade 2 complications in 3% (1/29) of patients.
- 2.4.2 Where reported separately, rectal complications (all grades) affected 4% to 20% (22/112) of patients, and bladder complications affected 4% (8/

200) of patients. Serious complications such as bowel obstruction, severe rectal bleeding and stenosis, which required subsequent surgery, occurred in 2% and 6% (11/200) of patients in two case series. For more details, refer to the Sources of evidence section.

The Specialist Advisors reported that complications include diarrhoea, 2.4.3 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.

Andrew Dillon Chief Executive March 2006

3 **Further information**

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of high dose rate (HDR) brachytherapy for carcinoma of the cervix', August 2005.

Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind.

of 6

4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a <u>summary of this guidance for patients and carers</u>. Information about the evidence it is based on is also <u>available</u>.

Changes since publication

20 January 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.