

High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer

Interventional procedures guidance

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[nice.org.uk/guidance/ipg174](https://www.nice.org.uk/guidance/ipg174)

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. However, 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.

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.

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 (HDR) brachytherapy in combination with external-beam radiotherapy for localised prostate cancer 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 A multidisciplinary team should be involved in the planning and use of this procedure.

2 The procedure

2.1 *Indications*

- 2.1.1 Treatment options for prostate cancer depend on whether the disease is localised to the prostate gland. Current management options for localised prostate cancer include radiotherapy, radical prostatectomy, cryotherapy, high-intensity focused ultrasound and 'watchful waiting'.
- 2.1.2 Radiation therapy can take the form of either external-beam radiotherapy (EBRT) or brachytherapy. Brachytherapy can be given at either low or high dose rates.

2.2 *Outline of the procedure*

- 2.2.1 HDR brachytherapy is a form of radiotherapy in which radiation delivery is targeted directly at the prostate gland via a radiation source that is temporarily implanted within the prostate, as opposed to an external source.
- 2.2.2 This procedure is usually done under general anaesthesia but may be performed under local anaesthesia with sedation. Thin plastic tubes are inserted through the perineal skin behind the scrotum into the prostate gland. A radioactive source is then inserted into each tube. A computer controls how long the radioactive source remains in each of the tubes, so that the amount of radiation can be targeted effectively. This allows a higher dose to be given to the tumour tissue than to the urethra and rectum. The tubes are then removed, leaving no radioactive material in the prostate gland.

2.3 *Efficacy*

- 2.3.1 In a matched case series, actuarial 5-year survival with HDR brachytherapy in combination with EBRT was found to be greater than with EBRT alone (86%

versus 54%, respectively; $p < 0.001$). Across a number of case series, 5-year survival rates after HDR brachytherapy and EBRT were estimated to be 85%, 89% and 93%. In one series, 84% (42/50) of men survived to 7.2 years' follow-up. In another case series of 611 men, survival was calculated to be 65% at 10 years.

2.3.2 Five-year biochemical control (assessed by measurement of prostate-specific antigen [PSA]) has been shown to be more common with HDR brachytherapy in combination with EBRT than with EBRT alone (67% versus 44%; $p < 0.001$); 3-year biochemical control with HDR brachytherapy is similar to that with LDR brachytherapy (98% versus 97%, respectively). In two case series, overall 5-year biochemical control was found to be 77% and 82%, and in a third case series, 4-year biochemical control was found to be 75%. One series found that only 5% (2/42) of survivors at 7.2 years had a PSA level greater than 1 ng/ml. In another series, mean PSA fell from 10 ng/ml to 1.1 ng/ml, and in 85% (170/200) of men, the PSA nadir was below 1 ng/ml over 30 months' follow-up.

2.3.3 In a case series that reported outcomes of prostate biopsy findings following HDR brachytherapy in combination with EBRT, there was no evidence of viable cancer in 86% (36/42) of men; however, the percentage of men with residual cancer may have been higher, given the limited sensitivity of the biopsy technique employed. For more details, refer to the 'Sources of evidence' section.

2.3.4 The Specialist Advisors noted that the benefits of the procedure include improved biochemical and overall survival.

2.4 Safety

2.4.1 The definitions used to measure potency outcomes following HDR brachytherapy varied across the studies included. In men who were potent at baseline, impotence occurred in 30% at 30 months, 45% at 3 years, 14% at 5 years and 76% (31/41) at 7 years.

2.4.2 Urethral stricture (where it was reported separately from other urological complications) occurred in 1.5% (3/200), 4% (6/161) and 7% (17/230) of men.

2.4.3 Early urinary incontinence was reported in 11% of men in the HDR arm of a comparative study, and incontinence had persisted in 5% of men at 3 years'

follow-up. A case series recorded grade 2–3 incontinence in 3% (7/230) of men, but in another series this occurred in less than 1% (1/200) of men.

2.4.4 Survival free of urinary incontinence was estimated to have been achieved in 86% of men at 5 years in a case series of 108 men. For more details, refer to the 'Sources of evidence' section.

2.4.5 The Specialist Advisors noted that the procedure had reduced side effects compared with other treatments. They also noted that theoretical adverse events include urethritis; urethral stricture; proctitis; incontinence; acute retention; impotence; haematuria; haematospermia; bladder, rectal and sphincter injuries and rectourethral fistula.

2.5 *Other comments*

2.5.1 These recommendations do not apply to HDR brachytherapy for localised prostate cancer when used as monotherapy (in other words, as the single primary treatment modality). The Committee was informed that use of the procedure as monotherapy is currently the subject of research studies.

2.5.2 It was noted that a variety of radiation dosage schedules has been reported in the literature.

2.5.3 The data were difficult to interpret because of the heterogeneous groups of men in the studies.

2.5.4 It was noted that men with prostate cancer often die from unrelated causes.

3 Further information

3.1 The Institute has issued cancer service guidance '[Improving outcomes in urological cancers](#)'.

3.2 The Institute has issued interventional procedures guidance on [low dose rate brachytherapy for localised prostate cancer](#), [cryotherapy for recurrent prostate cancer](#), [cryotherapy as a primary treatment for prostate cancer](#), [laparoscopic radical prostatectomy](#) and [high-intensity focused ultrasound for prostate cancer](#).

Andrew Dillon
Chief Executive
May 2006

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 brachytherapy for prostate cancer',
November 2005.

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Other NICE recommendations on brachytherapy

Further recommendations have been made as part of the clinical guideline on prostate cancer published in February 2008, as follows:

Brachytherapy is not recommended for men with high-risk localised prostate cancer.

Clinical and cost-effectiveness evidence was reviewed in the development of this guideline which has led to this more specific recommendation. More information is [available](#). The IP guidance on high dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer remains current, and should be read in conjunction with the clinical guideline.

5 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.

It has been incorporated into the [NICE pathway on prostate cancer](#), along with other related guidance and products.

We have produced a [summary of this guidance for patients and carers](#). Tools to help you put the guidance into practice and information about the evidence it is based on are also [available](#).

Changes since publication

29 November 2011: minor maintenance

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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 [Healthcare Improvement Scotland](#).