

Low dose rate brachytherapy for localised prostate cancer

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 short- to medium-term efficacy of low dose rate brachytherapy 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 Most of the evidence on the efficacy of low dose rate brachytherapy for localised prostate cancer relates to the reduction of prostate-specific antigen (PSA) levels and to biopsy findings. The effects on quality of life and long-term survival remain uncertain. Clinicians should ensure that patients understand these uncertainties and the alternative treatment options. Use of NICE's information for the public is recommended.
- 1.3 A multidisciplinary team should be involved in the planning and use of this procedure. NICE has issued a cancer service guideline on improving outcomes in urological cancers.
- 1.4 Further research and audit should address quality of life, clinical outcomes and long-term survival.

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 and 'watchful waiting'.

- 2.1.2 Radiation therapy can take the form of external-beam radiotherapy or brachytherapy. Brachytherapy may be given at either low or high dose rates. Low dose rate brachytherapy may be used alone (monotherapy) or in combination with external-beam radiotherapy.

2.2 Outline of the procedure

- 2.2.1 Low dose brachytherapy is a form of radiotherapy in which radiation is delivered directly to the prostate gland by small radioactive pellets (called seeds).
- 2.2.2 Under general or spinal anaesthesia and ultrasound guidance, the seeds are inserted via needles passed through the skin of the perineum. In low dose rate brachytherapy, the seeds are left in place permanently and emit low-dose radiation over several weeks or months.

2.3 Efficacy

- 2.3.1 The literature search found no randomised controlled trials that compared low dose rate brachytherapy with other kinds of treatment. Evaluation of the effectiveness of brachytherapy was made difficult by the diversity of the techniques used, the patient selection criteria applied and the different follow-up intervals reported.
- 2.3.2 A recent large cohort study that compared almost 3,000 patients undergoing low dose rate brachytherapy (either as monotherapy or combined with external-beam radiotherapy) with external-beam radiotherapy (>72 Gy) or radical prostatectomy, found no difference in biochemical-recurrence-free survival between the three treatments at 5- or 7-year follow-up. In a comparative study in which 869 patients were treated with low dose rate brachytherapy, a 0.5 ng/ml prostate-specific antigen (PSA) nadir level was reached in 86% (748 out of 869) of patients after therapy. No comparison of long-term effects could be made because the

outcomes for patients treated with radical prostatectomy were not recorded beyond 2 years.

- 2.3.3 In a comparative study involving 1,819 patients, overall survival at median follow-up of 58 months in patients with T1 or T2 cancer was found to be similar among those undergoing low dose rate brachytherapy (93%; 679 out of 733 patients), radical prostatectomy (97%; 721 out of 746 patients) and external-beam radiotherapy (96%; 325 out of 340 patients).
- 2.3.4 In another study, physical function scores in 92 patients treated with low dose rate brachytherapy and 327 patients treated with radical prostatectomy showed no significant changes from baseline in either group at 24 months. For more details, refer to the [overview](#).
- 2.3.5 The Specialist Advisors considered low dose rate brachytherapy to be an established procedure and stated that the results are comparable with those achieved with surgery or external-beam radiotherapy in well-selected patients.

2.4 Safety

- 2.4.1 Complications were generally not well reported, but included irritative or obstructive urinary symptoms, rectal symptoms and sexual dysfunction. In one study involving 869 patients undergoing low dose rate brachytherapy, the impotence rate was 10% to 15%, compared with 45% in 208 patients undergoing radical prostatectomy. The incontinence rate was less than 1% in both groups.
- 2.4.2 Two case series included in a Health Technology Assessment Review reported disease-specific quality of life to be lower in patients receiving brachytherapy than in both those receiving external-beam radiotherapy alone and those in a healthy population. However, this review did not differentiate between low dose rate and high dose rate brachytherapy. For more details, refer to the [overview](#).
- 2.4.3 The Specialist Advisors noted potential complications such as incontinence, infection and erectile dysfunction.

2.5 Other comments

- 2.5.1 The data are difficult to interpret because of the other treatment modalities often used alongside this procedure.
- 2.5.2 In recommending that further research and audit should address long-term survival, it was noted that men with prostate cancer often die from unrelated causes.
- 2.5.3 It was also noted that the appropriate length of long-term follow-up would depend on the stage and grade of the tumour.

3 Further information

- 3.1 NICE has issued [interventional procedures guidance on laparoscopic radical prostatectomy](#), [high-intensity focused ultrasound for prostate cancer](#), [cryotherapy for recurrent prostate cancer](#) and [high dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer](#).
- 3.2 This guidance should be read in conjunction with [NICE's guideline on prostate cancer: diagnosis and management](#).

Sources of evidence

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

Information for patients

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

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Endorsing organisation

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