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NHS
National Institute for Health and Clinical Excellence

Low dose rate brachytherapy for localised prostate cancer

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 the Institute's *Information for the public* is recommended.

1.3 A multidisciplinary team should be involved in the planning and use of this procedure. The Institute has issued a cancer service guideline on *Improving Outcomes in Urological Cancers* (www.nice.org.uk/csguc).

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 3000 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 years follow-up. In a comparative study in which 869 patients were treated with low dose rate brachytherapy, a 0.5 ng/ml PSA nadir level was reached in 86% (748/869) of patients after therapy.

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This guidance is written in the following context

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

Interventional procedures guidance is for health professionals and people using the NHS in England, Wales and Scotland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

NHS Quality Improvement Scotland

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 1819 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%; 679/733 patients), radical prostatectomy (97%; 721/746 patients) and external-beam radiotherapy (96%; 325/340 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 Sources of evidence (see right).

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/obstructive urinary symptoms, rectal symptoms and sexual dysfunction. In one study involving 869 patients undergoing low dose rate brachytherapy, the impotence rate was 10–15%, 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 Sources of evidence.

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 The Institute has issued interventional procedure guidance on laparoscopic radical prostatectomy (www.nice.org.uk/IPG016), high-intensity ultrasound for prostate cancer (www.nice.org.uk/IPG118) and cryotherapy for recurrent prostate cancer (www.nice.org.uk/IPG119). It is also preparing guidance on high dose rate brachytherapy (www.nice.org.uk/ip_305).

3.2 The Institute is also developing a clinical guideline: *Prostate cancer: diagnosis and treatment* (www.nice.org.uk/page.aspx?o=98574).

Andrew Dillon
Chief Executive
July 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. This information is available from www.nice.org.uk/IPG132publicinfo

Sources of evidence

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

Interventional procedure overview of low dose rate brachytherapy for localised prostate cancer, January, 2005

Available from www.nice.org.uk/ip251overview

Ordering information
Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0887. *Information for the public* can be obtained by quoting reference number N0888.

The distribution list for this guidance is available at www.nice.org.uk/IPG132distributionlist

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