NICE guidance

Focal therapy using cryoablation for localised prostate cancer

Interventional procedures guidance
Published: 26 April 2012

www.nice.org.uk/guidance/ipg423

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 focal therapy using cryoablation for localised prostate cancer raises no major safety concerns. However, evidence on efficacy is limited in quantity and there is a concern that prostate cancer is commonly multifocal. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake focal therapy using cryoablation for localised prostate cancer should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers understand the uncertainty about the procedure's efficacy and the risks (specifically the risk of sexual dysfunction), and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Patient selection and treatment should be carried out by a multidisciplinary urological cancer team.

1.4 NICE encourages further research into focal cryoablation for localised prostate cancer. This should take the form of controlled studies comparing the procedure against other forms of management. Studies should clearly define patient selection criteria and should report outcomes including local recurrence in the long term.

1.5 Clinicians should collect data on all patients undergoing focal cryoablation (including details of case selection, methods of follow-up and outcomes) for local audit. Clinicians should enter details about all patients undergoing focal therapy

using cryoablation for localised prostate cancer onto the European Registry for Cryosurgical Ablation of the Prostate (EuCAP) register, and review clinical outcomes locally.

2 The procedure

2.1 Indications and current treatments

2.1.1 Symptoms of localised prostate cancer include difficulty in passing urine, although the condition is often diagnosed at an asymptomatic stage.

2.1.2 Treatment options for patients with localised prostate cancer include active surveillance, radical prostatectomy, external beam radiotherapy, brachytherapy, and ablation of the whole gland using cryotherapy or high-intensity focused ultrasound (HIFU). All radical treatment options are associated with substantial risks of sexual, urinary or bowel dysfunction. Focal therapy using cryoablation is intended to be used in patients with localised prostate cancer – specifically patients with tumours that are confined to 1 prostatic lobe.

2.2 Outline of the procedure

2.2.1 Imaging and biopsy mapping studies are used to confirm that the tumour is suitable for focal therapy and to show its precise location. Using local or general anaesthesia, the bladder is catheterised. Using transrectal ultrasound and a template placed on the perineum, fine needles are inserted transperineally into the prostate. Pressurised argon is passed through the needles to freeze the targeted area of the prostate, destroying the tissue. Implantable temperature probes and transrectal ultrasound guidance are used to monitor the treatment, and steps are taken to protect surrounding tissue from the effects of freezing.

2.2.2 After treatment patients are usually followed up regularly with prostate-specific antigen (PSA) measurements, imaging, and repeated biopsies to detect recurrence.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 A case series of 54 patients reported overall and disease-specific survival of 100% of 48 patients at mean 4.5-year follow-up. In a register report of 1,160 patients treated by focal cryoablation (total 5,853 patients), the biochemical recurrence-free rate (as defined by the American Society for Therapeutic Radiation and Oncology [ASTRO]) was 76% (absolute numbers not given) at 3-year follow-up. Two case series of 54 and 60 patients reported biochemical recurrence-free survival of 94% (45 out of 48) and 80% (41 out of 51) of patients at mean 2-year and 15-month follow-up respectively. In a case series of 25 patients 36% (9 out of 25) were considered to be biochemically disease-free (defined as a PSA nadir of 1.0 ng/ml or less) at median 28-month follow-up.

2.3.2 In the register report of 1,160 patients, 164 patients underwent biopsy because of increased post-treatment serum PSA levels. Of these, 26% (43 out of 164) had a positive biopsy at median 21-month follow-up. The case series of 60 patients reported positive findings in 40% (14 out of 35) of patients who had a follow-up biopsy (tumours were in the untreated lobe except for 1 patient who had a positive biopsy result from the lobe that was treated by the procedure; this patient was treated with whole gland cryoablation). Eleven of these patients were treated with a second focal cryoablation procedure, after which 73% (8 out of 11) were biochemically disease-free at mean 15-month follow-up. In the case series of 25 patients, 28% (7 out of 25) had repeat biopsies and residual or recurrent cancer was found in 3 of these patients. All of these patients underwent repeat focal cryoablation and were biochemically disease-free at median 28-month follow-up.

2.3.3 The Specialist Advisers listed key efficacy outcomes for this procedure as biochemical disease-free survival and biopsy-proven absence of cancer.

2.4 Safety

2.4.1 Sixty-seven per cent (40 out of 60) of patients who were sexually potent before treatment became impotent immediately after treatment in the case series of 60 patients. Seventy-one per cent (24 out of 34) of patients for whom data were available at 12-month follow-up had regained potency. In the case series of 54 patients 90% (36 out of 40) of the patients who were potent before treatment remained potent after treatment.

2.4.2 With regard to urinary continence, the case series of 54 and 25 patients reported that all patients were continent after treatment. The case series of 60 patients reported incontinence in 4% (2 out of 55) of the patients followed up for more than 6 months (neither patient required incontinence pads). The register report of 1,160 patients reported urinary incontinence in 2% (8 out of 507) of patients at 12-month follow-up.

2.4.3 Rectourethral fistula was reported in less than 1% (1 out of 1,160) of patients in the register report of 1,160 patients at 12-month follow-up. In all 4 case series, there were no reports of fistulae developing after the procedure.

2.4.4 Prolonged urinary retention (>30 days) was reported in 1.2% (6 out of 518) of patients at 12-month follow-up in the register report of 1,160 patients.

2.4.5 The case series of 54 patients reported that 1 patient required a transurethral prostatectomy for the removal of sloughed tissue.

2.4.6 The Specialist Advisers listed adverse events reported in the literature as erectile dysfunction and incontinence. They considered theoretical adverse events as urinary tract infection and pain.

2.5 Other comments

2.5.1 The Committee was mindful of the variable natural history of prostate cancer: this underpinned the recommendation for controlled studies and the need for details of long-term outcomes.

2.5.2 The Committee noted the potential for this procedure to avoid many of the complications of more radical treatments for localised prostate cancer in properly selected patients, if further evidence supports its efficacy.

2.5.3 The Committee noted a number of patient commentaries that described benefits from the procedure, but which reported instances of sexual dysfunction.

2.5.4 The Committee noted variation in the methods used to deliver focal therapy using cryoablation for localised prostate cancer and that techniques are continuing to evolve.

3 Further information

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.

ISBN: 978-1-4731-6393-5

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.