NICE guidance

Focal therapy using cryoablation for localised prostate cancer

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg423

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 patients (Understanding NICE guidance) 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.

> 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 Efficacy

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 1160 patients treated by focal cryoablation (total 5853 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% (45/48) and 80% (41/51) of patients at mean 2-year and 15-month follow-up respectively. In a case series of 25 patients 36% (9/25) 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 1160 patients, 164 patients underwent biopsy because of increased post-treatment serum PSA levels. Of these, 26% (43/164) had a positive biopsy at median 21-month follow-up. The case series of 60 patients reported positive findings in 40% (14/35) 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% (8/11) were biochemically disease-free at mean 15-month follow-up. In the case series of 25 patients, 28% (7/25) 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 (40/60) of patients who were sexually potent before treatment became impotent immediately after treatment in the case series of 60 patients. Seventy-one per cent (24/34) of patients for whom data were available at 12-month follow-up had regained potency. In the case series of 54 patients 90% (36/40) 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% (2/55) of the patients followed up for more than 6 months (neither patient required incontinence pads). The register report of 1160 patients reported urinary incontinence in 2% (8/507) of patients at 12-month follow-up.

2.4.3 Rectourethral fistula was reported in less than 1% (1/1160) of patients in the register report of 1160 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% (6/518) of patients at 12-month follow-up in the register report of 1160 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

3.1 For related NICE guidance see the NICE website.

Information for patients

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

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 procedures guidance process.

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.

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 Healthcare Improvement Scotland.

Accreditation