

Focal therapy using high-intensity focused ultrasound for localised prostate cancer

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NHS Evidence has accredited the process used by the NICE Interventional Procedures Programme to produce interventional procedures guidance. Accreditation is valid for three years from January 2010 and applies to guidance produced since January 2009 using the processes described in the 'Interventional Procedures Programme: Process guide, January 2009' and the 'Interventional Procedures Programme: Methods guide, June 2007'

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1 Guidance

- 1.1 Current evidence on focal therapy using high-intensity focused ultrasound (HIFU) 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 HIFU 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 therapy using HIFU 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 HIFU (including details of case selection, methods of follow-up and outcomes) for local audit and for submission to national and/or international registers when these become available. The [European Registry for Cryosurgical Ablation of the Prostate \(EuCAP\) register](#) is being developed to receive data on focal therapy using HIFU for localised prostate cancer. When this facility is available clinicians should submit data on all patients undergoing focal therapy using HIFU for localised prostate cancer to that register.

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 HIFU. All radical treatment options are associated with substantial risks of sexual, urinary or bowel dysfunction. Focal therapy using HIFU 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. With the patient under local or general anaesthesia, the bladder is catheterised and the HIFU probe is inserted transrectally. Real-time ultrasound imaging guidance and/or magnetic resonance guidance is used to position the probe and to monitor the procedure. Pulses of HIFU are directed at the targeted part of the prostate, inducing tumour necrosis by a thermal effect and causing cavitation (which can be visualised by ultrasound to assess the adequacy of treatment) until satisfactory ablation of the target area is judged to have occurred.
- 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 12 patients reported overall and cancer-specific survival of 83% (10/12) and 100% respectively at median 10.6-year follow-up. Recurrence-free survival was 90% at 5 years and 38% at 10 years (absolute numbers not reported).
- 2.3.2 In the case series of 12 patients, treatment failure (defined as any positive biopsy and/or need for salvage therapy prompted by rising PSA levels) was observed in 42% (5/12) of all patients. In 1 patient prostate cancer was managed by further focal HIFU treatment and in 4 patients by androgen deprivation. All 5 patients were alive at 9.5–11-year follow-up.
- 2.3.3 In a case series of 20 patients, 10% (2/20) of patients had magnetic resonance imaging (MRI) findings suggestive of low volume recurrence of disease. One patient opted for active surveillance and the other was re-treated with focal HIFU. In case series of 12, 29 and 20 patients, there was no histological evidence of cancer in 92% (11/12), 77% (13/17) and 90% (17/19) of patients respectively at 12-month follow-up.
- 2.3.4 In the case series of 29 patients, median PSA levels decreased from 5.36 ng/ml before treatment to 3.42 ng/ml and 1.52 ng/ml after 2 and 3 years respectively. In the case series of 20 patients, mean PSA level decreased by 80% after treatment.
- 2.3.5 The Specialist Advisers listed key efficacy outcomes for this procedure as biochemical disease-free survival, absence of viable cancer on repeat biopsy, and MRI evidence of cancer ablation.

2.4 Safety

- 2.4.1 The case series of 20 patients reported a decrease in erectile dysfunction score (using the International Index of Erectile Dysfunction scoring system on a scale of 0–30; lower value indicates worse function) from a mean of 20.9 points at baseline to 14.3 points at 1 month ($p = 0.004$). However, scores at 3, 6, 9 and 12 months were not significantly different from baseline (mean scores of 17.9 [$p = 0.278$], 21.7 [$p = 0.705$], 23.3 [$p = 0.198$] and 21.8 [$p = 0.619$] respectively). Ninety-five per cent (19/20) of patients had erectile function sufficient for penetrative sex at 12-month follow-up.

2.4.2 In the case series of 12 patients, 1 patient developed epididymo-orchitis and another had an asymptomatic urinary tract infection.

2.4.3 The Specialist Advisers listed adverse events reported in the literature as bladder neck stenosis, acute retention and erectile dysfunction in those who are preoperatively potent.

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.

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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