NICE National Institute for Health and Care Excellence

NICE guidance

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

HealthTech guidance
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www.nice.org.uk/guidance/htg667

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.

Contents

This guidance replaces IPG756 and IPG424.

1 Recommendations

1.1 Evidence on the safety of focal therapy using high-intensity focused ultrasound for localised prostate cancer is adequate, but evidence on its efficacy is limited. Therefore, this procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Find out what special arrangements mean on the NICE guidance page.

1.2 Clinicians wanting to do high-intensity focused ultrasound for localised prostate cancer should:

- Inform the clinical governance leads in their healthcare organisation.
- Give people (and their families and carers, as appropriate) clear written information to support shared decision making, including NICE's information for the public. Use the recommendations in NICE's guideline on diagnosing and managing prostate cancer for information on treatment options and decision support.
- Ensure that people (and their families and carers, as appropriate) understand the procedure's safety and efficacy, and any uncertainties about these.
- Audit and review clinical outcomes of everyone having the procedure. The main efficacy and safety outcomes identified in this guidance can be entered into NICE's audit tool (for use at local discretion).
- Discuss the outcomes of the procedure during their annual appraisal to reflect, learn and improve.

1.3 Healthcare organisations should:

- Ensure systems are in place that support clinicians to collect and report data on outcomes and safety for everyone having this procedure.
- Regularly review data on outcomes and safety for this procedure.

1.4 Patient selection should be done by a multidisciplinary team.

1.5 Further research could include registry data or randomised trials. It should include details of patient selection, including size and classification of tumour, technique used and long-term outcomes such as quality of life.

2 The condition, current treatments and procedure

The condition

2.1 Prostate cancer can cause some lower urinary tract symptoms such as frequency, urgency, hesitancy, terminal dribbling and an overactive bladder. Localised prostate cancer is confined to the prostate and has not spread to nearby tissues or other parts of the body.

Current treatments

2.2 NICE's guideline on prostate cancer describes how to diagnose and manage prostate cancer. Decisions on treatment are based on imaging, tumour staging, risk assessment and prostate-specific antigen (PSA) levels. For some people, localised prostate cancer grows slowly or not at all, and treatment may not be necessary. In such cases, watchful waiting or active surveillance strategies may be appropriate. If treatment is needed, several options are available. These include radical treatments (such as radical prostatectomy, external beam radiotherapy and radical brachytherapy), focal treatments (such as focal high-intensity focused ultrasound [HIFU], focal cryoablation, irreversible electroporation, focal laser ablation and focal brachytherapy) and adjunctive treatments (such as chemotherapy and androgen deprivation therapy).

The procedure

2.3 Imaging and biopsy mapping are used to confirm that the tumour is suitable for focal therapy and to show its precise location. With the person under spinal or general anaesthesia, the bladder is catheterised using a urethral or supra-pubic catheter and the HIFU probe is inserted transrectally. Ultrasound imaging 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. This procedure differs from standard whole-gland HIFU in that only some of the prostate is treated. Transurethral resection of the prostate may be done at the same time as focal HIFU to reduce urinary symptoms.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 3 systematic reviews, 2 registry analyses, 1 propensity score weighted study, 1 retrospective case series and 1 retrospective cohort study. It is presented in the summary of key evidence section in the overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: recurrence-free survival, metastasis-free survival, improvement in quality of life, need for subsequent intervention and overall survival.

3.3 The professional experts and the committee considered the key safety outcomes to be: pain, bleeding, rectal damage, incontinence and loss of sexual function.

3.4 Three hundred and eight commentaries from people who have had this procedure were discussed by the committee. The committee also discussed 2 submissions from patient organisations.

Committee comments

3.5 There is more than 1 device available for this procedure and the technology is evolving.

3.6 The committee noted that there was limited comparative evidence in the literature, especially for studies comparing this procedure against active surveillance or radical treatments.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 756 has been migrated to HealthTech guidance 667. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.