NICE National Institute for Health and Care Excellence

NICE guidance

Cryotherapy for recurrent prostate cancer

HealthTech guidance
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www.nice.org.uk/guidance/htg71

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 IPG119.

1 Recommendations

1.1 Current evidence on the safety and efficacy of cryotherapy, as measured by a reduction of prostate-specific antigen (PSA) levels and biopsy findings, appears adequate to support the use of this procedure in patients with recurrent prostate cancer provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 The effects of cryotherapy for recurrent prostate cancer on quality of life and long-term survival remain uncertain. Clinicians should therefore ensure that patients understand the uncertainties and the alternative treatment options. Use of NICE's information for the public is recommended.

1.3 Further research and audit should address quality of life, clinical outcomes and long-term survival.

2 The procedure

2.1 Indications

2.1.1 Cryotherapy may be used to treat locally recurrent carcinoma of the prostate that has been refractory to other treatments, such as radiotherapy or hormone therapy.

2.1.2 Treatment options for locally recurrent prostate cancer after radiotherapy are limited and include salvage radical prostatectomy, salvage cryotherapy and salvage brachytherapy.

2.2 Outline of the procedure

2.2.1 Cryotherapy may be performed under general or spinal anaesthesia. A warming catheter is initially inserted into the urethra to prevent it being damaged by the cold. Cryoneedles or probes are inserted into the prostate, using imaging for guidance. Temperature monitor probes may also be placed percutaneously through the perineum. Argon gas is then circulated through these needles or probes, generating very low temperatures and causing the formation of ice around the prostate gland which destroys the affected tissue. Newer cryotherapy techniques allow these needles to be removed or repositioned so that the frozen zone conforms to the exact size and shape of the target tissue. After the procedure, a suprapubic catheter is inserted and left in place for 1–2 weeks, depending on the post-void residual urine volume.

2.3 Efficacy

2.3.1 Various efficacy outcome measures were used in the studies identified, making comparisons of efficacy across studies difficult. A frequently used marker was PSA, a protein produced by both normal and cancerous cells in the prostate gland. Reduction in the PSA level is used as a marker for ablation of malignant

tissue in studies of prostate cancer treatment, together with negative prostatic biopsies.

2.3.2 In one study, lowest level PSA < 0.5 ng/ml was reported in 97% (114/118) of patients who had undergone cryotherapy; in another study, a level of < 0.1 ng/ml was reported in 60% (26/43) of patients. These studies included patients with recurrent prostate cancer or rising PSA levels, and those who were undergoing salvage therapy. After medial retropubic prostatectomy, PSA levels are expected to be < 0.1 ng/ml.

2.3.3 In a study of 43 patients, biochemical-recurrence-free survival (recurrence defined as an increase in PSA level of > 0.2 ng/ml above nadir) was reported as 79% at 6 months and 66% at 12 months; and in a study of 38 patients (recurrence defined as an increase in PSA level of > 0.3 ng/ml above nadir), as 86% at 12 months and 74% at 24 months. One case series reported negative biopsy in 100% (38/38) of patients followed up for a median 82 months. Another case series reported negative biopsies in 79% (87/110) of patients at 6-month follow-up. For more details, see the overview.

2.4 Safety

2.4.1 Complication rates varied substantially among the studies and there is some evidence to suggest that complications have decreased with improvements in technique and instrumentation. Among the studies identified, the following complications were reported: impotence in 72% (108/150) and 86% (12/14) of patients; incontinence in 8% (3/38) of patients; and perineal and/or rectal pain in 18% (27/150) to 39% (15/38) of patients. Other reported complications from the case series included fistula formation in 1% (2/150) to 3% (4/118 and 2/59) of patients. For more details, see the overview.

2.4.2 The Specialist Advisors listed the main complications as urinary incontinence, impotence, rectal injury and fistula formation. However, severe complications are rare and comparison needs to be made with the complication rates in alternative options.

2.5 Other comments

2.5.1 In recommending that further research and audit should address long-term survival, it is noted that prostate cancer patients frequently die from unrelated causes.

2.5.2 There are different types of cryotherapy device, and these may have different safety profiles.

2.5.3 The technology for this procedure is continuing to evolve.

3 Further information

Sources of evidence

The evidence considered by the committee is in the overview.

Information for patients

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

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 119 has been migrated to HealthTech guidance 71. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.