NICE National Institute for Health and Care Excellence

NICE guidance

Cryotherapy as a primary treatment for prostate cancer

HealthTech guidance

Published: 23 November 2005

www.nice.org.uk/guidance/htg91

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 IPG145.

1 Recommendations

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

1.2 The effects of cryotherapy as a primary treatment for 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. They should provide them with clear written information and, in addition, use of the 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 has been used for prostate cancer mainly as a salvage procedure for local recurrence following radiotherapy. More recently, it has been used as a primary treatment for patients with localised or locally advanced prostate cancer.

2.1.2 Treatment options depend on the extent of the cancer. Current treatments for localised prostate cancer include watchful management, radiotherapy and radical prostatectomy.

2.2 Outline of the procedure

2.2.1 Cryotherapy may be performed under general or regional anaesthesia. A warming catheter is initially inserted into the urethra to prevent it being damaged by cold. Cryoprobes 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 the cryoprobes, generating very low temperatures which freeze and destroy 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 to 2 weeks, depending on the postvoid residual urine volume.

2.3 Efficacy

2.3.1 The main outcomes reported by the studies were biopsy results and survival rates. In addition, different PSA values were used to define biochemical disease-free survival. In most of the studies, the procedure was used concomitantly with hormone therapy which may have an effect on PSA levels.

2.3.2 One study of 975 patients reported a 5-year actuarial biochemical disease-free survival of 52% or 63%, depending on the PSA cut-off value (less than 0.5 ng/ml and less than 1.0 ng/ml, respectively). Another study of 590 patients reported a 7-year actuarial biochemical disease-free survival of between 62% and 76%, depending on the criteria used (PSA less than 0.5 ng/ml and less than 1.0 ng/ml, respectively). The proportion of patients with a negative biopsy was 87% (514 of 590) after a mean follow-up of 5 years.

2.3.3 One non-randomised study reported that 6 months after standard cryosurgery or total cryosurgery (where the urethra was also frozen), 49% (24 of 49) and 96% (26 of 27) of patients respectively had a PSA level of between 0.0 ng/ml and 2.0 ng/ml, compared with 73% of patients (61 of 83) after radical prostatectomy. Another study reported that 96% of patients (213 of 223) were satisfied with their cryotherapy treatment after a mean follow-up of 2 years. For more details, refer to the overview.

2.3.4 The specialist advisors stated that total ablation may not be achieved with this procedure and its effects on quality of life and survival are uncertain.

2.4 Safety

2.4.1 The main complications were impotence, affecting between 72% (39 of 54) and 100% (76 of 76) of patients, and incontinence, affecting 1% (1 of 76) to 19% (10 of 54) of patients. However, not all studies reported the proportion of patients who had been impotent or incontinent before the cryotherapy treatment. Five studies, including a total of 1,891 patients, reported that between 4% (3 of 76) and 15% (4 of 27) of patients required a transurethral resection after the cryotherapy procedure. Four studies reported fistula as a complication, affecting between less than 1% (2 of 590) and 2% (1 of 54) of patients. Other complications included urinary tract infection, scrotal swelling, pelvic pain, penile tingling and numbness, stricture, stone formation in the prostatic urethra, bladder perforation, paraphimosis and paraesthesia in the legs. For more details, refer to the overview.

2.4.2 The specialist advisors stated that the main potential adverse events included rectal injury and fistula, impotence, incontinence and urethral stricture.

2.5 Other comments

2.5.1 In recommending that further research and audit should address long-term survival, it was 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. The technology for this procedure is continuing to evolve.

2.5.3 The data were difficult to interpret due to the heterogeneous groups of patients in the studies.

3 Further information

Sources of evidence

The evidence considered by the committee is 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.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 145 has been migrated to HealthTech guidance 91. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-9094-8

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.