

Cryotherapy as a primary treatment for prostate cancer

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg145

1 Guidance

- 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 Institute'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 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 1–2 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 (< 0.5 ng/ml and < 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 < 0.5 ng/ml and < 1.0 ng/ml, respectively). The proportion of patients with a negative biopsy was 87% (514/590) 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% (24/49) and 96% (26/27) of patients respectively had a PSA level of between 0.0 and 2.0 ng/ml, compared with 73% (61/83) of patients after radical prostatectomy. Another study reported that 96% (213/223) of patients were satisfied with their cryotherapy treatment after a mean follow-up of 2 years. For more details, refer to the Sources of evidence.
- 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% (39/54) and 100% (76/76) of patients, and incontinence, affecting 1% (1/76) to 19% (10/54) 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 1891 patients, reported that between 4% (3/76) and 15% (4/27) of patients required a transurethral resection after the cryotherapy procedure. Four studies reported fistula as a complication, affecting between less than 1% (2/590) and 2% (1/54) 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 Sources of evidence.
- 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

- 3.1 The Institute has issued guidance on [urological cancer services](#), which includes prostate cancer. The Institute has also issued interventional procedures guidance on the use of [cryotherapy for recurrent prostate cancer](#), [laparoscopic radical prostatectomy](#) and [high-intensity focused ultrasound for prostate cancer](#).
- 3.2 Further recommendations have been made as part of the clinical guideline on [prostate cancer](#) published in February 2008.

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

['Interventional procedure overview of cryotherapy as a primary treatment for prostate cancer'](#), October 2004.

Information for patients

NICE has produced [information on this procedure for 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.

4 Other NICE recommendations on cryotherapy for the treatment of prostate cancer

The National Institute for Health and Clinical Excellence (NICE) has issued full guidance to the NHS in England, Wales, Scotland and Northern Ireland on cryotherapy as a primary treatment for prostate cancer in November 2005.

Further recommendations have been made as part of the clinical guideline on prostate cancer published in February 2008, as follows:

High intensity focused ultrasound (HIFU) and cryotherapy are not recommended for men with localised prostate cancer other than in the context of controlled clinical trials comparing their use with established interventions.

Clinical and cost-effectiveness evidence was reviewed in the development of this guideline which has led to this more specific recommendation. More information is [available](#). The IP guidance on cryotherapy as a primary treatment for prostate cancer remains current, and should be read in conjunction with the clinical guideline.

5 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 procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Changes since publication

22 January 2012: minor maintenance.

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.