

# Cryotherapy for recurrent prostate cancer

Interventional procedures guidance  
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[www.nice.org.uk/guidance/ipg119](http://www.nice.org.uk/guidance/ipg119)

## 1 Guidance

- 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, refer to the Sources of evidence.

## 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, refer to the Sources of evidence.
- 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 Other NICE recommendations on cryotherapy for the treatment of prostate cancer

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 on prostate cancer diagnosis and management](#) is available. The IP guidance on cryotherapy for recurrent prostate cancer remains current, and should be read in conjunction with the clinical guideline.

### 4 Further information

4.1 [NICE has issued guidance on urological cancer services](#), which includes prostate cancer. The Institute has also issued [interventional procedures guidance on laparoscopic radical prostatectomy](#) and [high-intensity ultrasound for prostate cancer](#).

### Sources of evidence

The following document, which summarises the evidence, was considered by the Institute

when making its recommendations.

[Interventional procedure overview of cryotherapy for recurrent prostate cancer](#), June 2004.

## 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 2012:** minor maintenance.

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## Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).