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Cryotherapy for recurrent prostate cancer

Understanding NICE guidance –
information for people considering the
procedure, and for the public



Ordering information

You can download the following documents from www.nice.org.uk/IPG119

- this booklet
- the full guidance on this procedure

For printed copies of the full guidance or information for the public, phone the NHS Response Line on 0870 1555 455 and quote:

- N0836 (full guidance)
- N0837 (information for the public)

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About this information

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. One of NICE's roles is to produce guidance (recommendations) on the use of medicines, medical equipment, diagnostic tests and clinical and surgical procedures within the NHS in England and Wales.

This information describes the guidance that NICE has issued on a procedure called cryotherapy for prostate cancer that returns after initial treatment (this is known as recurrent cancer). It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether cryotherapy is safe enough and works well enough for it to be used routinely for the treatment of recurrent prostate cancer.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of cryotherapy and how well it works
- asked experts for their opinions
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 9).

About cryotherapy for recurrent prostate cancer

Recurrent cancer is cancer that has returned after initial treatment. If other treatments haven't worked, surgery may be an option for men with recurrent prostate cancer that's not spread to other places in the body. The surgical procedure NICE has looked at, called cryotherapy, aims to freeze and destroy the part of the prostate affected by the cancer.

In cryotherapy, special needles or probes are put into the prostate. Argon gas is then circulated through these. This makes the needles or probes very cold, and the surrounding prostate freezes and is destroyed. At the start of the procedure, a narrow 'warming' tube is put into the urethra (the tube that carries urine from the bladder to the tip of the penis) to stop it from being damaged by the cold. Probes that monitor the temperature may also be inserted into the area through a small opening made in the skin in the area in front of the anus.

The doctor uses images of the prostate to check that the probes or needles are being put into the correct position. In some versions of this procedure, the needles are positioned or repositioned so that the area matches the exact shape of the tissue to be destroyed. A catheter for urine is left in place for 1–2 weeks after the procedure.

How well the procedure works

What the studies said

Different studies used different ways of seeing whether the cryotherapy worked. This made it difficult to compare the results. Some studies looked at PSA levels. PSA stands for prostate-specific antigen, which is a substance that's not normally found in the blood, or is found in very low levels. An increase in PSA levels can be a sign of prostate cancer, and a decrease in PSA levels can be a sign that cancer treatment has worked.

After a successful operation to remove the prostate, a man's PSA level should be under a certain amount (this is 0.1 nanograms per millilitre, or 0.1 ng/ml). In one study that NICE looked at, the PSA level dropped

to under 0.5 ng/ml in nearly all the men who had cryotherapy (this happened in 114 out of 118 men). In another study, 26 out of 43 men had PSA levels under 0.1 ng/ml after the procedure.

Some different studies looked at whether the cancer came back. They measured this by looking at the men's PSA levels, but the studies used different PSA levels to define being 'recurrence-free'. In one study, over three-quarters of men were said to be 'recurrence-free' after 6 months and two-thirds were recurrence-free after 12 months following the procedure. In another study, nearly three-quarters of men were recurrence-free after 2 years.

In another study, small samples of prostate tissue (biopsies) were taken from 38 men who'd had cryotherapy some years beforehand to check for signs of cancer. None of the biopsies showed signs of cancer. Another study did biopsies 6 months after the cryotherapy. This study found that biopsies were negative (that is, no signs of cancer) in 87 out of 110 men.

Risks and possible problems with the procedure

What the studies said

The numbers of problems reported in the different studies varied greatly. There is some evidence that the equipment and techniques for doing cryotherapy have been improving since they were first used, and that this has led to fewer problems for patients.

Problems reported in the studies included:

- impotence (problems getting or maintaining an erection), which affected 108 out of 150 men in one study, and 12 out of 14 men in another
- incontinence (leakage of urine), which affected 3 out of 38 men in one study
- pain around or in the rectum, which affected 27 out of 150 men in one study, and 15 out of 38 men in another study.

Another problem was the formation of an abnormal connection called a fistula between two parts of the body that wouldn't normally be connected. In one study this happened in 2 out of 150 men, while in another study it happened in 4 out of 118 men.

What the experts said

The experts said that the main problems were urinary incontinence, impotence, damage to the rectum and the formation of fistulas. But they also pointed out that serious problems were rare and that the likelihood of these problems should be compared with the likelihood of problems with the other treatment options.

What has NICE decided?

NICE has considered the evidence on cryotherapy. It has recommended that when doctors use it for men with recurrent prostate cancer, they should be sure that:

- the man understands what is involved, and that it's not clear how the procedure affects men's day-to-day lives or how long the effects last
- the man understands what alternative treatments are available to him
- the man agrees (consents) to the treatment, and
- the results of the procedure are monitored.

NICE has also said that information is needed to help fill the current gaps in knowledge about the effects of the procedure on men's lives.

Other comments from NICE

Different types of device are used to generate the low temperatures, and some may be safer than others. Also, NICE has pointed out that the equipment used for cryotherapy is still being refined.

What the decision means for you

Your doctor may have offered you cryotherapy for recurrent prostate cancer. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of cryotherapy for recurrent prostate cancer before you agree to it. Your doctor should discuss the benefits and risks with you. You should also know that there are some uncertainties about the effects of the procedure, and your doctor should explain the alternative treatments that are available for you.

Further information

You have the right to be fully informed and to share in decision-making about the treatment you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

The NICE website (www.nice.org.uk) has further information about NICE, the Interventional Procedures Programme and the full guidance on cryotherapy for recurrent prostate cancer that has been issued to the NHS. The evidence that NICE considered in developing this guidance is also available from the NICE website.

NICE has also issued guidance to the NHS on the way that health services should be organised for people with urological cancers (prostate cancer is one of these). You can find out more about this from www.nice.org.uk/csguc. There is also interventional procedure guidance on:

- laparoscopic radical prostatectomy (removal of the prostate using keyhole surgery) – go to www.nice.org.uk/IPG016guidance
- high-intensity ultrasound for prostate cancer – go to www.nice.org.uk/IPG118guidance

If you have access to the internet, you can find more information on prostate cancer on the NHS Direct website (www.nhsdirect.nhs.uk).

You can also phone NHS Direct on 0845 46 47.

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