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Cryotherapy as a primary treatment for 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/IPG145

- 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:

- N0939 (full guidance)
- N0940 (information for the public).

National Institute for Health and Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

www.nice.org.uk

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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 whether interventional procedures are safe enough and work well enough to be used routinely in the NHS in England, Wales and Scotland.

This information describes the guidance that NICE has issued on a procedure called cryotherapy when it's used as a first treatment for prostate cancer. It is not a complete description of what is involved in the procedure – the man'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 first treatment of 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 men 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 10).

About the procedure

Cryotherapy uses a cold temperature to freeze and destroy cancer tissue. It has already been used for men with prostate cancer, but mainly to help with cancer that has come back in the prostate after the man has had radiotherapy. The NICE guidance described in this leaflet covers the use of cryotherapy as a first treatment for cancer that hasn't spread far from the prostate.

Before having the cryotherapy, the man is given an anaesthetic – either general or one that numbs just the area of the prostate. A narrow warming tube called a warming catheter is then put into the urethra to stop the urethra being damaged by the cold temperature used in the cryotherapy. (The urethra is the tube that carries urine from the bladder to the tip of the penis.) Special probes called cryoprobes are put into the prostate, and argon gas is circulated through them. The argon gas makes the probes very cold and this freezes and destroys the surrounding tissue. The doctor carrying out the procedure uses images of the man's prostate to make sure the probes are in the correct place. Sometimes it's possible to move the probes so that the area of tissue frozen matches the area of the cancer exactly. Probes to check the temperature may also be put into the area through small openings made in the skin between the scrotum and anus.

After the procedure, the man has a catheter in place to empty urine for 1–2 weeks. This allows the area around the bladder and urethra to recover from the procedure.

How well the procedure works

What the studies said

PSA (prostate-specific antigen) is a protein usually found in very low levels in the blood. A rise in the blood level can be a sign of prostate cancer, and a drop in PSA is a sign that treatment has worked.

One study of 975 men showed that 5 years after having the cryotherapy, 52% of the men's PSA levels had stayed below 0.5 ng/ml, and 63% of the men's PSA levels had stayed below 1.0 ng/ml (52% is the same as saying 52 men out of every 100). This was taken to mean that these men had been free from cancer during the 5 years after their treatment.

Another study reported that 62% and 76% of men were free from prostate cancer for 7 years after having cryotherapy (using PSA levels of below 0.5 ng/ml and below 1.0 ng/ml to get the different percentages). In this study, the men had a biopsy 5 years after having the treatment. For this, a small amount of tissue was taken from the prostate and checked under a microscope for signs of cancer. In 87% of men in the study (514 out of 590), the biopsies were clear, with no sign of cancer.

In one study, some men had their prostate removed in an operation called a radical prostatectomy, while others had either standard or total cryotherapy. In standard cryotherapy just the prostate is frozen, and in total cryotherapy both the prostate and urethra are frozen. Six months later, 24 out of 49 men (49%) who had standard cryotherapy had a PSA level of 0–2.0 ng/ml. But the results were better with the men who had had the radical prostatectomy, as in this group 61 out of 83 men (73%) had a PSA level of 0–2.0 ng/ml. In the group that had total cryotherapy, 26 out of 27 men (96%) had a PSA level of 0–2.0 ng/ml 6 months afterwards.

Finally, another study said that nearly all the men who had cryotherapy (213 out of 223) were satisfied with their treatment when they were checked on 2 years afterwards.

What the experts said

The experts said that cryotherapy might not destroy all the cancer in the area. And the effects of having the procedure on the man's quality of life and long-term outlook are still not clear.

Risks and possible problems with the procedure

What the studies said

In the studies, the main problems men had after having cryotherapy were impotence (being unable to achieve or maintain an erection) and incontinence (leaking urine). Impotence affected 72% to 100% of men in studies. For incontinence, the results were that 1% to 18% of men were affected in the studies. The studies didn't say how many men had been impotent or incontinent before they had cryotherapy.

In five studies, a small number of men needed to have a procedure called a transurethral resection of the prostate (TURP for short) after they'd had cryotherapy. In this procedure, a surgical instrument is passed up the urethra and is used to cut away the middle of the prostate. The numbers of men who needed a TURP after cryotherapy went from 3 out of 76 men (4%) in one study to 4 out of 27 men (15%) in another one.

The formation of a fistula was another problem that affected a small number of men in the studies. A fistula is an abnormal connection that forms between two parts of the body, such as the urethra and the bowel. Other problems that were rare but affected men in the studies were: urinary infection; swelling of the scrotum; pain in the pelvic area; tingling and numbness in the penis; narrowing of the urethra; the formation of stones in the urethra where it passes through the prostate; damage to the bladder; paraphimosis, which is where the foreskin, once pulled back, can't be brought down to its original position; and abnormal sensation in the legs.

What the experts said

The experts said that the main potential problems were injury to the rectum (back passage) and formation of a fistula connecting the urethra and the rectum, impotence, incontinence and narrowing of the urethra.

What has NICE decided?

NICE has considered the evidence on cryotherapy. It has recommended that when doctors use this procedure as a first treatment for men with prostate cancer, they should be sure that:

- the man understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

NICE has also said that men considering this procedure should understand that there are uncertainties about the effects of cryotherapy on quality of life and long-term outlook. The risks and benefits of alternative treatment options should be clearly described to a man considering cryotherapy.

Studies carried out in the future should look into men's quality of life and the results of the cryotherapy (in the short and long term).

Other comments from NICE

Different types of cryotherapy probe are available and some may be more safe than others. The equipment is still being improved and refined.

The results from the studies were difficult to compare because the studies included different groups of men.

What the decision means for you

Your doctor may have offered you cryotherapy as a first treatment for 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 before you agree to it. In particular, you should understand that the effects of cryotherapy on a man's quality of life and long-term prospects are not yet clear. Your doctor should discuss this with you and describe the alternative treatment options.

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 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 issued interventional procedures guidance on the use of cryotherapy for recurrent prostate cancer (www.nice.org.uk/IPG119publicinfo), laparoscopic radical prostatectomy (www.nice.org.uk/IPG016publicinfo) and high-intensity ultrasound for prostate cancer (www.nice.org.uk/IPG118publicinfo). NICE has also issued guidance on urological cancer services (www.nice.org.uk/csguc), which includes prostate cancer.

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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