Issue date April 2012

Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

Treating localised prostate cancer using freezing (cryotherapy) needles in a targeted area of the prostate

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This document is about when and how targeted cryotherapy can be used in the NHS to treat people with localised prostate cancer. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This document is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe prostate cancer or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The document includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 9.

What has NICE said?

The evidence shows that there are no major safety concerns about this procedure. However, there is not a lot of evidence about how well the procedure works. There is also concern that prostate cancer is often multifocal, meaning that there is more than one cancerous area (or tumour) in the prostate gland. This procedure targets just one cancerous area at a time, therefore there is a risk that some cancerous areas may be missed. If a doctor wants to use targeted cryotherapy for localised prostate cancer, he or she should make sure that extra steps are taken to explain the uncertainty about how well it works, as well as the potential risks of the procedure, especially the effect it may have on the patient's sex life. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this document and other written information as part of the discussion. There should also be special arrangements for monitoring what happens to the patient after the procedure.

A specialist urological cancer healthcare team should decide which patients might benefit from the procedure and should carry it out.

NICE has encouraged doctors to consider asking patients to take part in a research study (called a clinical trial) looking at targeted cryotherapy for prostate cancer, especially whether cancer returns in the long term after treatment.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to national and international databases so that the safety of the procedure and/or how well it works can be checked over time.

Other comments from NICE

NICE noted that patients treated with targeted cryotherapy could avoid many of the risks of more extensive procedures that treat the whole prostate gland.

NICE also noted that during consultation patients who had undergone the procedure described its benefits but also problems with their sex life.

Treating prostate cancer using freezing (cryotherapy) needles on a targeted area of the prostate

This procedure may not be the only possible treatment for prostate cancer. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

The medical name for this procedure is 'focal therapy using cryoablation for localised prostate cancer'.

The procedure is not described in detail here – please talk to your specialist for a full description.

The prostate is a small gland near a man's bladder. Localised prostate cancer is cancer that is only in part of the prostate and has not spread. One symptom is difficulty passing urine but it is often diagnosed before symptoms develop.

Treatments include active surveillance (regular testing, with treatment only if and when necessary), surgery to remove the prostate, radiation treatment, and treating the whole gland by freezing (cryotherapy) or high-intensity focused ultrasound. All these treatments can affect patients' sex lives and can also give patients problems with their bowels and with passing urine (usually incontinence).

The aim of targeted cryotherapy is to destroy the area of the prostate that has cancer using freezing needles. It is intended for use only in patients who have cancer in one part of the prostate.

Tests such as blood tests, MRI (magnetic resonance imaging), ultrasound and biopsies are used to confirm the presence and location of the tumour and its suitability for treatment. The patient has either a general or a local anaesthetic and a catheter (a tube) is inserted into the bladder to drain urine.

Using ultrasound, fine needles are inserted through the perineum (the area between the genitals and the anus) into the prostate. The needles are cooled to freeze the targeted area and destroy the tissue. The surrounding tissue is protected from the effects of freezing and treatment is monitored using temperature probes and ultrasound.

After treatment patients usually have regular blood tests to measure the level of a protein called PSA (prostate-specific antigen). The levels of this protein in the blood are often higher in patients with prostate cancer. Imaging and biopsies (removing samples of cells) may also be used to find out if the cancer has returned, and the procedure can be repeated if necessary.

What does this mean for me?

If your doctor has offered you targeted cryotherapy for localised prostate cancer, he or she should tell you that NICE has decided that although the procedure is safe the benefits are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved and discuss the possible benefits and risks with you, including possible problems with your sex life. You should only be asked if you want to agree to this procedure after this discussion. You should be given written information, including this document, and be able to discuss it with your doctor before you decide.

NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information about this procedure. Your doctor will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the procedure?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 5 studies on this procedure.

How well does the procedure work?

In a study of 54 patients who had targeted cryotherapy, all of the 48 patients who were followed up were still alive after an average of 4.5 years.

Four studies looked at whether the disease might have come back after treatment by measuring levels of PSA. In one study 1160 patients had the procedure and when they were checked after 3 years 76% had low PSA levels. One hundred and sixty-four patients with high PSA levels went on to have biopsies: 43 of these had a positive biopsy (cancerous cells were found) when they were checked at 21 months.

In the study of 54 patients, 48 patients were checked again after 2 years and 94% had low PSA levels.

In a study of 60 patients, 51 were checked again after 15 months and 80% had low PSA levels. Thirty-five patients had a biopsy and 14 of these were positive (only one had cancerous cells in the part of the prostate that was treated with targeted cryotherapy, however; this patient had further treatment with cryotherapy applied to the whole prostate). Eleven of these patients were treated with the procedure again and 8 had low PSA levels when they were checked after an average of 15 months.

The fourth study in 25 patients also measured PSA levels but used a different definition of low PSA levels. In that study, 36% of patients had low PSA levels when they were checked again after 28 months. Seven patients had follow-up biopsies and 3 had positive results. All

were treated with the procedure again and had low PSA levels when they were checked again after an average of 28 months.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the main success factors were low PSA levels and no evidence of cancer in biopsies.

Risks and possible problems

Two studies looked at whether patients were still able to have sex after the procedure. In one, 40 out of 60 patients who could have sex before treatment were impotent immediately afterwards. A year later, at least 24 of the 40 patients had recovered their ability to have sex. In the other study (of 54 patients), 36 of the 40 who could have sex before treatment could still have sex after treatment.

Four studies measured urinary incontinence after the procedure. In the studies of 54 and 25 patients, no patients were incontinent after treatment. In the study of 60 patients, 2 of 55 who were checked after more than 6 months were incontinent but neither needed incontinence pads. In the study of 1160 patients, 8 of the 507 patients checked after a year were incontinent.

In the study of 1160 patients, 6 out of 518 patients who were checked after a year were unable to pass urine normally for more than 30 days directly after the procedure.

In all 5 studies there was only one instance of a fistula (an abnormal channel) forming between the back passage (rectum) and the urinary tube (urethra) after the procedure.

One patient in the study of 54 needed an operation to remove the prostate after the procedure because of dead tissue.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that possible problems included impotence and incontinence. In theory, they said that other problems could include urinary tract infection and pain.

More information about prostate cancer

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support.

For details of all NICE guidance on prostate cancer, visit our website at www.nice.org.uk

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. HealthTech guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This document is about 'focal therapy using cryoablation for localised prostate cancer'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG284

The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

National Institute for Health and Clinical Excellence

Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT; www.nice.org.uk

ISBN 978-1-4731-8599-9

Apr 12