

Template-guided biopsy of the prostate via the perineum

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

This leaflet is about when and how template-guided biopsy of the prostate via the perineum can be used in the NHS. 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.

This leaflet 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 conditions or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet 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 7.

What has NICE said?

There is evidence that some men with suspected prostate cancer who have had negative or inconclusive results from other biopsy methods will be more effectively diagnosed with prostate cancer using this procedure. There are no major safety concerns.

Therefore, this procedure can be offered routinely as an option for men under these particular circumstances provided that doctors are sure that:

- the patient understands what is involved and agrees to the procedure, and
- the results of the procedure are monitored.

Evidence was not found to support the use of this procedure to look for the exact location and extent of prostate cancer (mapping) to guide less invasive treatment or for regular checks (active surveillance) following less invasive treatment. If a doctor wants to use this procedure under these circumstances, they should make sure that extra steps are taken to explain the uncertainty about how well it works for active surveillance or mapping. This should happen before the patient agrees (or doesn't agree) to the procedure. The patient should be given this leaflet 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.

NICE has encouraged further research into this procedure.

This procedure may not be the only possible procedure for biopsy of the prostate.

Your healthcare team should talk to you about whether it is suitable for you and about any other options available.

Template-guided biopsy of the prostate via the perineum

The medical name for this procedure is 'transperineal template biopsy of the prostate'. 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. If prostate cancer is suspected, the patient may need a prostate biopsy. This involves removing very small samples of the prostate gland and checking them for cancer under a microscope. This is usually done using a needle passed through a probe in the rectum (back passage), a procedure called transrectal biopsy.

Transperineal template biopsy of the prostate involves using a grid (or template) to insert several fine needles through the skin in the area between the scrotum and the anus (the perineum) into the prostate gland in order to obtain several tissue samples for testing. The procedure is carried out with the patient under local or general anaesthesia.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS in men with suspected prostate cancer who have had negative or inconclusive results from other biopsy methods. If your doctor thinks transperineal template biopsy of the prostate is a suitable option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

If your doctor has offered you the procedure for mapping to guide less invasive treatment or for active surveillance, he or she should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure, discuss the possible benefits and risks with you, and explain the uncertainty about using the procedure in these circumstances. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- Are there alternative procedures?
- What are the risks of the procedure?
- What care will I need after the operation?
- 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 8 studies on this procedure.

How well does the procedure work?

A study reported that 53 out of 126 men who had a transperineal template biopsy and 58 out of 120 men who had a transrectal biopsy were diagnosed with cancer. The study also found little difference between the rates of cancer detection for the two tests when the results were checked against blood tests showing whether prostate problems are likely (prostate specific antigen or PSA tests). A study of 135 patients found that the results of transperineal template biopsy were more accurate than transrectal biopsy.

A study of 373 men who had transperineal template biopsy found that cancer was detected in 60 out of 79 men who had not had a previous biopsy, and 22 out of 64 men who had already had 3 or more previous negative biopsies. A study of 747 men who had transperineal biopsy reported cancer in 291 men.

No evidence was found to show that this procedure was effective at mapping to guide less invasive treatment of prostate cancer or active surveillance.

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 success factors include the rate of detection of prostate cancer and better identification of the exact location of tumours in the prostate.

Risks and possible problems

Blood in the semen was found in no patients out of 120 after transrectal biopsy and 2 patients out of 126 after transperineal template biopsy in the study of 246 men. In a different study, infection was reported in 1 out of 747 men who had transperineal template biopsy.

Difficulty urinating was reported in 114 out of 1631 men in 4 studies. One of these studies reported that 77 men needed to use a urinary catheter after leaving the hospital and another that 6 men needed a catheter overnight.

The study of 246 men found that 2 out of 120 men had a high temperature after transrectal biopsy compared with none out of 126 men after transperineal template biopsy.

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 include blood poisoning, bleeding, urinary tract infection and blood in the urine.

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. This 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 leaflet is about 'transperineal template biopsy of the prostate'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG237

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2331). 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

MidCity Place, 71 High Holborn, London, WC1V 6NA; www.nice.org.uk

ISBN 978-1-4731-8247-9

N2331 1P Oct 10

© National Institute for Health and Clinical Excellence, 2010. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of NICE.