

High-intensity focused ultrasound for prostate cancer

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

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Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0840.

A version in Welsh and English is also available, reference number N0841. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0841. The NICE interventional procedures guidance on which this information is based is available from the NICE website (www.nice.org.uk/IPG118guidance). Copies can also be obtained from the NHS Response Line, reference number N0839.

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About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called high-intensity focused ultrasound for prostate 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 high-intensity focused ultrasound is safe enough and works well enough for it to be used routinely for prostate cancer.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of high-intensity focused ultrasound 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 pages 9 and 10).

About high-intensity focused ultrasound for prostate cancer

The aim of high-intensity focused ultrasound (or HIFU for short) is to heat and destroy the area of the prostate with cancer. The heat is generated using ultrasound energy. The patient has an anaesthetic (either a general or a spinal anaesthetic), and then a probe that contains the equipment for the procedure is inserted into the area through the rectum (back passage). The probe gives out a beam of ultrasound, which is focused so that it heats and destroys the prostate tissue with the cancer. The probe has a cooling balloon around it to protect nearby areas from the high temperature. After the procedure, a catheter is left in place for passing urine while the prostate heals.

Sometimes, part of the prostate is surgically removed before the man has HIFU treatment. HIFU treatment can be repeated if necessary.

How well it works

What the studies said

In some studies, small samples (or biopsies) of prostate tissue were taken from men who'd had HIFU treatment. The biopsies were checked for signs of cancer. In one study, there were no signs of cancer in the biopsies from 37 out of 62 men (60% of the men). In another study that took

the biopsies around 3 years after the HIFU treatment, there were no signs of cancer in the biopsies from 75 out of 94 men (80%).

In three other studies that checked on men after around 2 years, the proportion of men who'd had HIFU and who appeared to be free from prostate cancer went from 56% (28 out of 50 men) to 66% (67 out of 102 men).

Finally, there were negative biopsy results (that is, no signs of cancer in the biopsies) in 87% to 93% of men in studies that checked on men between 1 year and 2 years after the HIFU treatment.

What the experts said

The experts said that men who have HIFU need to be checked on over longer periods of time to see whether having the treatment makes them more likely to live longer than men who have other treatments for prostate cancer. This information isn't available from the studies that have been carried out so far.

Risks and possible problems

What the studies said

In the studies, the most common problems after HIFU treatment were urinary infections and stress urinary incontinence (leakage of urine when

coughing, sneezing or making a sudden movement). In one study, 4% (6 out of 137 men) had urine infections, while in another study, 48% (46 out of 96 men) had these infections. Stress incontinence affected 8% (9 out of 111 men) in one study and 22% (23 out of 102 men) in another study. In a small number of men, an abnormal connection called a fistula was made between the rectum and the urethra (which carries the urine down to the penis) – this happened in less than 1% (1 man out of 137) in one study, and 3% (3 out of 111 men) in another study.

Impotence (the failure to get or maintain an erection) was another problem after the procedure. The studies reported different results for this. In one, just under a quarter of the men who had HIFU treatment had impotence afterwards. In another study, all the men were impotent after the treatment. The studies weren't clear about how many men were impotent before the treatment, though, so these results have to be treated with caution.

Other problems were difficulties passing urine, inflammation of the urethra and the tissue that lies around the testicle, abscess in the prostate, inflammation, burns in the rectum and pain in the pelvic area. In some men, parts of the urine system became narrower as a result of the treatment.

What the experts said

The experts said that the possible problems that could happen with HIFU were urinary incontinence, the formation of a fistula, damage to the bowel and erection problems. But they said that HIFU treatment seemed to be safer than other treatments that involve destroying or removing part of the prostate. Two experts said that some doctors were concerned that it might be difficult to control the ultrasound energy and the heat during the procedure, so that other areas could be damaged by mistake.

What has NICE decided?

NICE has considered the evidence on high-intensity focused ultrasound for prostate cancer. It has recommended that when doctors use it for men with 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

NICE said that in the evidence it looked at, most of the men who had HIFU had prostate cancer that had not spread.

What the decision means for you

Your doctor may have offered you high-intensity focused ultrasound (HIFU) treatment. 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 HIFU treatment 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.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on high-intensity focused ultrasound for prostate cancer is on the NICE website (www.nice.org.uk/IPG118guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0839. 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 the NICE website page www.nice.org.uk/page.aspx?o=36469. There is also interventional procedure guidance on laparoscopic radical prostatectomy (removal of the prostate using keyhole surgery; www.nice.org.uk/IPG016guidance).

If you want more information on prostate cancer, a good starting point is NHS Direct (telephone 0845 4647) or NHS Direct Online (www.nhsdirect.nhs.uk).

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