NHS
National Institute for Health and Clinical Excellence

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High dose rate brachytherapy in combination with external-beam radiotherapy for localised prostate cancer

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

Information about NICE Interventional Procedure Guidance 174

Ordering information

You can download the following documents from www.nice.org.uk/IPG174

- 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:

- N1039 (full guidance)
- N1040 (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 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 high dose rate brachytherapy in combination with external-beam radiotherapy. 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 dose rate brachytherapy in combination with external-beam radiotherapy is safe enough and works well enough for it to be used routinely for the treatment of localised prostate cancer.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of high dose rate brachytherapy in combination with external-beam radiotherapy 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 10).

About the procedure

If cancer is discovered in the prostrate gland before it has spread to other parts of the body it is described as localised. The treatment that NICE has looked at is only for localised prostate cancer. Localised prostate cancer can be treated by an operation to remove the whole of the prostate gland (radical prostatectomy), by radiation (radiotherapy) to destroy the cancer, or by 'watchful waiting'. Watchful waiting means having regular check ups and blood tests but no treatment unless the cancer gets worse.

When radiation is aimed at a cancer from outside the body this is called external-beam radiotherapy, shortened to EBRT. Brachytherapy is radiotherapy aimed at the cancer from within the affected part of the body. For this, a substance that gives off radiation is put into the part of the body where the cancer is located. This radiation will treat the cancer internally.

To treat prostate cancer with brachytherapy, thin tubes containing radiation are put into the prostate through the skin behind the scrotum. A computer measures how much radiation is to be given out. The tubes are removed when enough radiation has been given in a particular area.

Using this method means that there is less radiation damage to surrounding healthy parts of the body, such as the lower bowel and the urethra.

Brachytherapy can be given quickly in a high dose, called high dose rate (or HDR) brachytherapy, or more slowly over a longer time (low dose rate brachytherapy). High dose rate brachytherapy, the new treatment that NICE has looked at, is sometimes combined with external-beam radiotherapy for complete radiotherapy treatment.

How well the procedure works

What the studies said

In one study that looked at what happened to men with localised prostate cancer treated with high dose rate brachytherapy and external-beam radiotherapy 86% of men (that is the same as 86 in every 100 men) lived for at least 5 years. In the same study 54% of men treated with only external-beam radiotherapy were alive after 5 years.

In studies that looked at what happened to men with localised prostate cancer treated with high dose rate brachytherapy in combination with external-beam radiotherapy 85% to 93% of the men were still alive after 5 years. In a study of 50 men, 42 (84%) treated with the combination were still alive after more than 7 years. In a large study of 611 men, 65% were still alive after 10 years.

The success of treatment for prostate cancer can be tested by measuring a chemical called prostate specific antigen (or PSA) that is present in tiny amounts in the blood. The lower the level of this chemical, the better the cancer is controlled.

In one study 5 years after men were treated with high dose rate brachytherapy in combination with external-beam radiotherapy about two-thirds of the men had PSA levels that showed that the cancer was well controlled. In men who were treated with external-beam radiotherapy alone less than half of the men had PSA levels that showed good control of the cancer. The 3-year checks on PSA for men treated with high dose rate brachytherapy were similar to those given low dose rate brachytherapy.

Other studies showed that after high dose rate brachytherapy and external-beam radiotherapy the PSA levels indicated that cancer was well controlled in most men after at least 4 or 5 years.

What the experts said

The experts noted the improvement in survival when men were given high dose rate brachytherapy together with external-beam radiotherapy for localised prostate cancer. They noted that PSA measurements also showed that this combination treatment was successful.

Risks and possible problems with the procedure

What the studies said

There is a risk of impotence (problems with getting and keeping an erection during sex) after cancer of the prostate is treated. After high dose rate brachytherapy, in men who did not have problems beforehand, different studies reported this to different degrees. One study found that 30 months after treatment 30% of the men were affected. A second study said that after 3 years 45% of men were affected. Another study said that after 5 years 14% were affected and yet another reported that 76% had problems after 7 years. (One reason why these percentages were so different may have been because what each study called 'impotence' varied among the studies.)

Narrowing of the urethra happened in between 1.5% and 7% of men who had been treated with high dose rate brachytherapy in three studies of 161 to 230 men.

Leakage of urine (incontinence) happened in 11% of men treated with high dose rate brachytherapy in one study, and this had become a permanent problem in 5% of the men after 3 years. Some leakage occurred in 3% of men (7 out of 230) in one study but less than 1% (1 out of 200) in another study.

A study that looked at 108 men 5 years after high dose rate brachytherapy showed 86% of those who survived did not have problems with urine leakage.

What the experts said

The experts said that the procedure has less side effects compared with other treatments. However, the experts noted that men given this treatment could have several unwanted effects in parts of the body near the prostate. As well as those already mentioned, there could be inflammation of the urethra, a sudden failure to be able to pass urine when the bladder is full, blood in the urine or in the fluid that is ejaculated, inflammation of the rectum causing constipation, damage to the bladder or the lower bowel, injury to the muscle that opens and closes the anus, or an abnormal trackway (a fistula) could develop between the bowel and the urethra.

What has NICE decided?

NICE has considered the evidence on high dose rate brachytherapy in combination with external-beam radiotherapy. It has recommended that when doctors use this procedure for people with localised prostate cancer, they should be sure that:

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

NICE has also said that arrangements should be in place so that the right doctors and healthcare professionals are involved in treatment and care of the patient.

Other comments from NICE

These recommendations do not apply to the use of high dose rate brachytherapy on its own. They only apply to the combination of the treatment with external-beam radiotherapy.

What the decision means for you

Your doctor may have offered you high dose rate brachytherapy (in combination with external-beam radiotherapy) for treatment of localised 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 high dose rate brachytherapy in combination with external-beam radiotherapy before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

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 high dose rate brachytherapy in combination with external-beam radiotherapy for treatment of localised 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 on low dose rate brachytherapy for localised prostate cancer (www.nice.org.uk/IPG132).

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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