

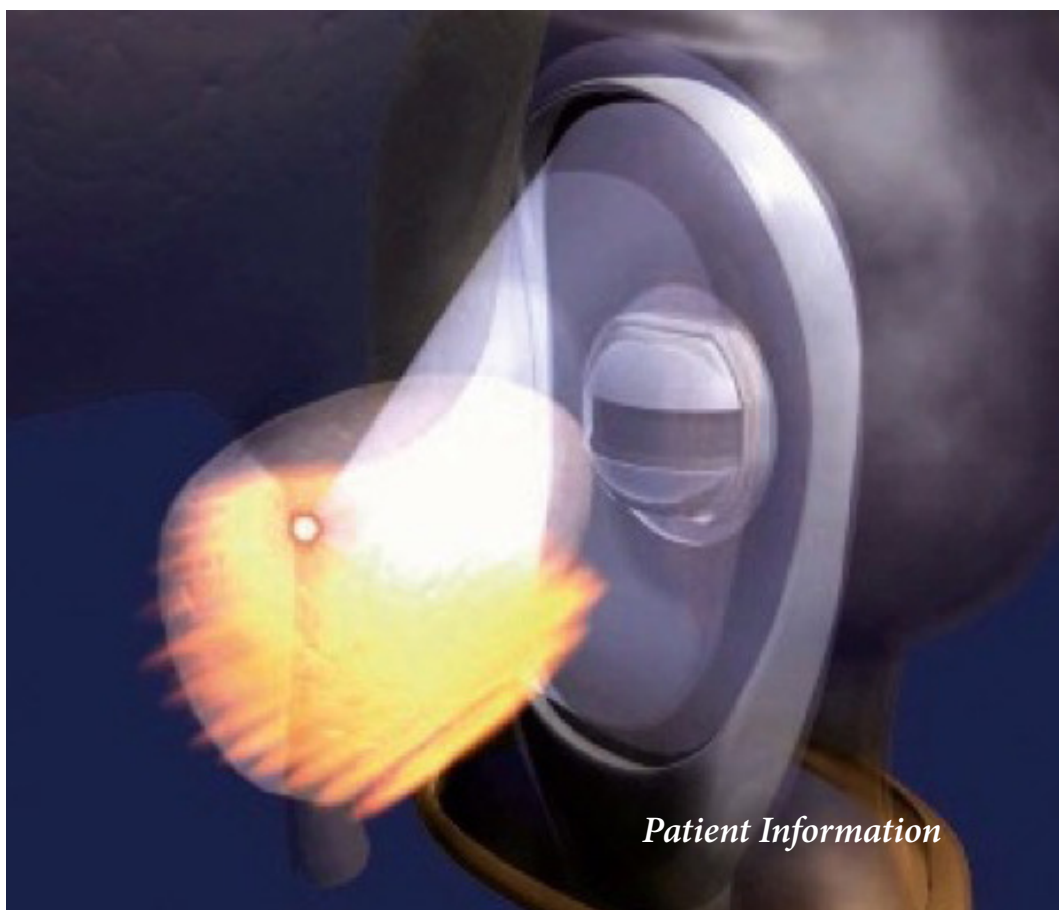


Weill Cornell Medicine



NewYork-Presbyterian

High-Intensity Focused Ultrasound (HIFU) for Prostate Cancer



Patient Information

The Prostate

The prostate is a part of the male reproductive system. The prostate is not involved in sexual intercourse directly. Its function is to add nutrients and fluid to sperm. Normally the size of a walnut, the prostate tends to grow with age. It is located in front of the rectum and just below the bladder. It surrounds the urethra, the tube that carries urine and semen through the penis.

What is Cancer?

All body organs are composed of cells that are specialized to the type of job that they do. Human cells are dying and being replaced constantly and this process occurs by cell division. Cancer is caused by a defect during the division of normal cells which turns them into malignant (cancerous) cells. Malignant cells grow much faster than healthy ones and can spread into surrounding tissue. Typically malignant cells will grow and multiply forming a mass of tissue known as a tumor. First located in one organ, a tumor may grow into surrounding tissue and also spread throughout the body. When tumor cells are transported through the blood and lymph systems to reach remote organs, we use the term metastases (from the Greek word meaning displacement).

Prostate cancer

Prostate cancer is the most common cancer in men; responsible for one in three of all male cancers. There are more cases of prostate cancer every year than lung and colon cancer.

The aggressiveness of prostate cancer can vary; some cancers develop very slowly and have no symptoms, whereas others spread quickly, invading surrounding tissue and forming metastases. The risk of prostate cancer increases with age. Prostate cancer is diagnosed in about 1 of every 7 men during their lifetime but only 1 in 38 will die of this disease. There are generally no signs or symptoms during the early stages of the disease, and these appear depending on where the cancer is located in the prostate and whether it has spread.

Assessment & Diagnosis

If diagnosed early the chance of recovery from prostate cancer is very high. Prostate cancer can be detected in routine screening. A doctor will perform a digital rectal examination of the prostate to feel for any abnormalities such as hardness or increased size. A doctor may also carry out a blood test to record levels of prostate specific antigen (PSA). PSA is a protein produced by both normal and cancerous prostate cells and high levels of PSA can be a sign of cancer. The PSA test helps identify tumors that cannot be detected by digital rectal examination (about 30% of cases of all prostate cancers). Some cancers are detected during treatment of benign prostate hypertrophy.

The Benefits of HIFU

The ablation of prostate tissue with High Intensity Focused Ultrasound is an option with many advantages:

- Non-invasive procedure
- Destruction of the cancerous tissue with minimal effect to the surrounding organs
- Does not use radiation
- Can be performed under spinal anesthesia
- Can be performed in one session
- Other therapeutic alternatives can be considered if results are unsatisfactory

What happens after treatment?

Most patients are discharged from the hospital a few hours after the procedure and go back to eating normal food the evening after treatment. The urinary catheter is generally removed 5 days later. Antibiotics are prescribed after HIFU to prevent any infection of the urinary tract. In the period after treatment you may experience some discomfort including mild bleeding at the start of urination, frequent and sometimes urgent urination, urine leakage during physical exertion or coughing. Infections with fever are rare but possible and may require additional antibiotics. These side effects disappear in the weeks following the treatment.

What long-term follow up is required?

Usually PSA levels are checked every three months and a biopsy is undertaken six months after treatment.

Tests to assess the prostate and to check for cancer include:

1. Biopsy: A sample of prostate tissue is removed with a fine needle for examination.
2. MRI or CT scan: Imaging of body organs to detect for possible cancer in the lymph nodes, liver or other organs.
3. Bone scan: Imaging of all bones to check for any cancer in the bones.

Classification

Cancers are diagnosed at different stages of development and progression and are classified into:

- Localized prostate cancer: The tumor is confined to the prostate itself.
 - Stage T1: Only a few cells have turned cancerous and so cancer can only be detected via a biopsy. The cancer is not palpable on a rectal examination.
 - Stage T2: The cancer is a little bigger and makes the prostate gland harder. The prostate can now be detected on a rectal examination.
- Locally advanced prostate cancer (stages T3 and T4): The tumor spreads into surrounding organs.
 - Stage T3: The prostate cancer has spread to the shell of the prostate gland.
 - Stage T4: The cancer has grown outside of the prostate.

Treatments for prostate cancer

Treatments for prostate cancer include:

- Surgery (radical prostatectomy). The whole prostate is removed with the seminal vesicles (which produce semen), the connected canals (which carry the sperm), part of the neck of the bladder and the surrounding lymph nodes. Surgery requires general anesthesia and lasts about three to four hours.
- External radiotherapy. This treatment involves the use of radiation (very high energy rays) directed at the prostate gland to kill cancerous cells. Most healthy cells have a special repair mechanism if affected by this type of radiation but cancer cells do not, and so are killed. Radiotherapy does not require anesthesia and treatment is generally given during regular visits over several weeks.
- Brachytherapy. This treatment is performed under general anesthesia most of the time and involves the implantation of tiny radioactive seeds directly into the prostate gland to irradiate and destroy the cancer cells.
- Cryotherapy. Guided by ultrasound, the prostate gland is frozen solid killing the cancerous cells. The procedure is done under general or spinal anesthesia.

- High-intensity Focused Ultrasound (HIFU). Ultrasound waves are used to generate heat within the prostate gland to destroy the cancer and / or the entire prostate gland if needed.

High Intensity Focused Ultrasound

High Intensity Focused Ultrasound is a minimally-invasive ablation which can be used for cases of localized (contained) prostate cancer. Ultrasound waves are focused with extreme precision instantly and effectively destroying the targeted cells within the prostate. The ultrasound waves are delivered via a probe which is inserted into the rectum. The procedure lasts one to three hours and can be performed under general or spinal anesthesia.

The procedure requires no hospital stay and has a low complication rate. The prostate tissue will be destroyed by the thermal effect of HIFU (temperature rising to 85°C), therefore there is no radiation involved.

Who should undergo HIFU?

Candidates for HIFU might be a patient who requires treatment for localized prostate cancer and who is interested in minimally invasive treatment modality.

Are there reasons or circumstances in which HIFU procedure is not a possible option?

This type of procedure is not the most appropriate for men with very large prostates but if this is the case a TURP (Transurethral Resection of the Prostate) can be performed several weeks before the HIFU treatment to reduce the size of the gland so that the HIFU procedure is made possible. In some cases HIFU is not recommended for men who have experienced hardening of the rectal wall due to previous cancer treatments.

Is HIFU FDA approved?

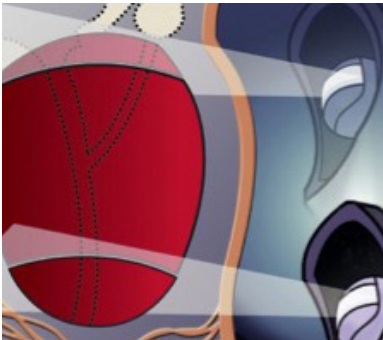
Yes, HIFU is FDA-approved. The first treatment was performed in 1993 in Europe.

How does HIFU work?

The Urologist uses the HIFU device to ablate prostate tissue. A probe is being inserted into the rectum. This probe includes an imaging component which allows the doctor to view the treatment area on a computer screen. The probe also includes a transducer which emits the focused ultrasound waves. The doctor inputs a treatment plan into the computer, which then controls and aims the ultrasound waves robotically. These are focused with extreme precision onto the targeted cancerous cells in the prostate, causing a very brief rise in temperature (around 85° C). The targeted tissue is then instantly and effectively destroyed, while the surrounding tissue is preserved.

The HIFU machine has numerous safety checks which are constantly monitored throughout the procedure to ensure patient safety. This means that the treatment is always delivered to the same high standard and quality.

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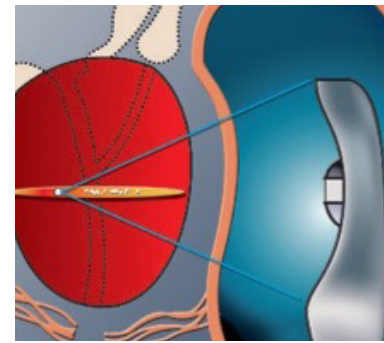
1. The targeted prostatic volume is localized with a transrectal ultrasound imaging probe.

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2. At the focal point of the ultrasound beam, a sharp temperature rise destroys the cancer cells.

The procedure can then start - 400 to 600 shots of High Intensity Focused Ultrasound waves are generally given. The procedure can last between one and three hours.

Why is catheterization needed after the procedure?



Procedure

The patient will be asked to come into hospital/surgery center the day of the procedure. He will need to use a digestive preparation (enema) to prepare the rectum the morning of the procedure. The procedure is generally performed under general anesthesia to ensure the patient remains completely still. The patient will lie on the right-hand side and the doctor will place a gel-coated probe into the rectum. The doctor locates the prostate and the area to be treated. The HIFU

The prostate swells after treatment and presses on the urethra (canal which transport the urine from the bladder) so catheterization to remove urine is necessary until the swelling subsides. The catheter is then being removed in the office 5-7 days after the procedure.

Is the HIFU procedure painful?

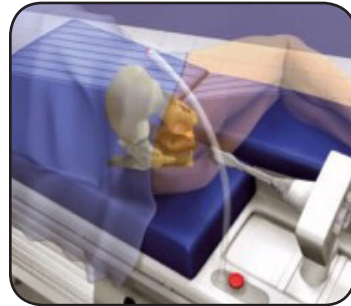
The procedure itself is not painful as it is carried out under anesthetic. Pain at the end of the treatment is rare, although most patients feel a slight discomfort which disappears after a few days. The procedure is minimally invasive so there are no wounds and patients do not experience the burning sensation often associated with radiotherapy.

HIFU Treatment step-by-step

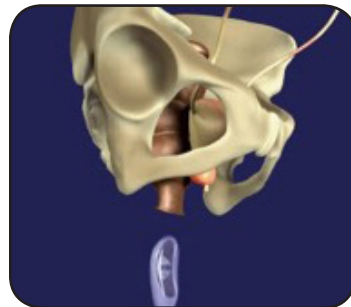
1. The patient lies down on his right hand side and stays in this position throughout the treatment.



2. This picture illustrates the position of the probe in relation to the rectum and the prostate (here in orange color).



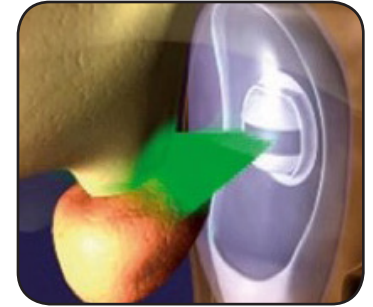
3. Due to the closeness of the prostate to the rectal wall, the treatment is performed optimally using the transrectal approach.



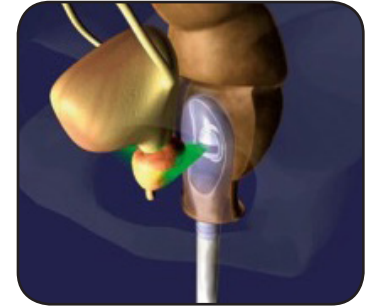
4. The probe is lubricated and then inserted into the rectum via the anus. The prostate is then accessible for ultrasound ablation.



5. The imaging transducer in the middle of the probe allows a very precise three-dimensional reconstruction of the area to be treated and to be seen on a monitor.



6. The whole prostate is scanned and visible on the computer screen.



7. On the screen, the surgeon plans each step of the treatment with a microscope precision.



8. Finally, the machine produces High Intensity Focused Ultrasound waves which destroy the cancer cells.

