Prostate Cancer Guide to Treatment Options

- Surgery
- Radiation Treatment
- Medical Treatment
- Clinical Trials
Table of Contents

Surgery.................................................................................................................. 3
  • Radical Prostatectomy ...................................................................................... 4
    – Radical Retropubic Prostatectomy (RRP) ......................................................... 4
    – Robot-Assisted Laparoscopic Prostatectomy (RALP) ........................................ 5
  • The Role of Surgery When Cancer Recurs ...................................................... 6
    – Salvage Radical Prostatectomy ....................................................................... 6
    – Prostate Cryoablation .................................................................................... 6
    – Salvage Cryotherapy ...................................................................................... 8
    – Surgery Side Effects ..................................................................................... 8

Radiation Treatment .............................................................................................. 12
  • External Beam Radiation .................................................................................. 12
    – Intensity Modulated Radiation Therapy (IMRT) .............................................. 12
    – Proton Therapy ............................................................................................. 13
    – External Beam Radiation with Hormonal Therapy .................................... 14
  • Prostate Implant ............................................................................................... 14
  • Post-operative Radiation .................................................................................. 15

Medical Treatment .................................................................................................. 16
  • Active Surveillance .......................................................................................... 16
  • Hormone Therapy ............................................................................................ 17
  • Chemotherapy .................................................................................................. 19
  • New Drugs ......................................................................................................... 19

Clinical Trials .......................................................................................................... 20
  • Patient Selection ............................................................................................... 20
  • Types of Clinical Trials .................................................................................... 20
  • MD Anderson Clinical Trials Involving Radiation Treatment ..................... 21
  • Other Clinical Trials ........................................................................................ 21

Resources ................................................................................................................. 22

Treatment Comparison Table ............................................................................... Appendix 1

Treatment Maps ........................................................................................................ Appendix 2
Surgery

Surgery is one option to treat prostate cancer. This section will help you learn more about the male reproductive system and different types of surgeries.

The urology prostate group surgeons are:

John W. Davis, MD          Curtis A. Pettaway, MD
Surena Matin, MD           Louis L. Pisters, MD
Brian Chapin, MD           John F. Ward, MD
Run Wang, MD, erectile dysfunction expert     Neema Navai, MD
O. Lenaine Westney, MD, incontinence expert  William Graber, MD, general urology

The Prostate and Surrounding Area

The terms below will help you understand the function of the prostate and the surrounding area. See Figure 1.

**Bladder** - The organ in the body that stores urine.

**Lymph node** - A rounded mass of tissue in various areas of the body. Lymph nodes filter lymph (lymphatic fluid), and they store lymphocytes (white blood cells). Cancer can spread to lymph nodes from its original site.

**Penis** - An external male reproductive organ. It contains a tube called the urethra, which carries semen and urine to the outside of the body.

**Prostate** - A gland in the male reproductive system. The prostate surrounds the part of the urethra (the tube that empties the bladder) just below the bladder, and produces a fluid that forms part of the semen.

**Rectum** - The last several inches of the large intestine (colon). The rectum acts as a holding area for body waste (stool) until a bowel movement occurs.

**Seminal vesicle** - A gland that helps produce semen.

**Testicle** - Egg-shaped glands found inside the scrotum that produce sperm and male hormones

**Urethra** - The tube through which urine flows out of the body. It empties urine from the bladder.
Radical Prostatectomy

A radical prostatectomy is the term used to describe the surgical removal of the prostate. The prostate can be removed either by open surgery or by laparoscopic surgery through small incisions. You have options when choosing a radical prostatectomy.

Radical Retropubic Prostatectomy (RRP)

Technique
In open surgery, a surgeon makes a 4-6-inch cut (incision) below the belly button. The surgeon removes the prostate and seminal vesicles (glands on top of the prostate) by cutting them away from their blood supply, the bladder and the urethra. Many times the cavernous nerves, which are needed for men to get erections, can be carefully saved during the surgery. The pelvic lymph nodes are also sometimes removed to find out if the cancer has spread outside the prostate. The surgery is complete when the surgeon re-connects the bladder to the urethra. A tube (called a Foley catheter) will then be placed into the bladder through the penis to allow the area to heal.

Most patients leave the hospital 24-48 hours following surgery with the Foley catheter in place. The Foley catheter is usually removed 7-14 days after surgery. Depending on the type of work, patients usually return to their job 2-6 weeks after surgery.

Outcomes
For patients with low to medium risk cancer that did not spread outside the prostate, there is a 90 percent (%) chance that the cancer will not return after 5 years. This number is less if the cancer has spread outside the prostate, involves the seminal vesicles or is found in the lymph nodes at the time of surgery. Additional treatment may be needed if the cancer is likely to have spread. For more information, see the “Radiation Treatment” and “Clinical Trials” sections.

Side Effects
Occasionally, men who had good control of their urine (no accidents) before surgery may experience stress-related leakage of urine. This can happen during coughing, heavy lifting and physical straining after surgery. If this happens, a urinary pad can help. Regaining urinary control is expected in over 90% of men one year after surgery.

Although erectile function, the ability to have an erection, may return in up to 80% of patients after surgery, this number is affected by several factors. These include:
• The patient’s age
• The quality of erectile function before surgery
• The experience of the surgeon
• Whether or not one or both cavernous nerves are saved during surgery

Recovery of erections can take up to 2 years after surgery and may require the use of aids. See “Erectile Dysfunction” on Page 10.
Robotic-Assisted Laparoscopic Prostatectomy (RALP)

Open RRP was the standard surgery to remove the prostate and treat prostate cancer for many years. With recent medical advances, a less invasive surgery is now routinely used. MD Anderson has treated patients with Robotic Assisted Radical Prostatectomy (RALP) since 2006. Many patients who choose RALP report having less pain and a shorter recovery time.

Patients in the following situations may not be good candidates for robotic surgery:
- Prior surgery in the abdomen may lengthen the procedure but it can usually be done.
- A high Gleason score. A Gleason score is given to prostate cancer based upon how it looks under a microscope. Your doctor will discuss your Gleason score with you.
- The cancer is near the bladder or may involve the seminal vesicles.

For more information, see “Clinical Trials” on Page 20.

Advantages of Robotic-Assisted Surgery:
- Smaller incisions
- Less blood loss and need for transfusion
- Decreased pain, discomfort and recovery time
- Shorter hospital stay
- Less scarring and improved cosmetic appearance

Technique
During the surgery, 6 one-fourth inch to three-fourth inch incisions are made in the abdomen. A thin tube with a camera on the end is placed into one of the incisions to help the surgeon see inside the body. Long thin instruments are placed in the other incisions to help the surgeon manipulate organs and perform the surgery. See Figure 2.

Outcomes
Many patients are discharged from the hospital the day after surgery. Like open surgery, a Foley catheter will be in place which is usually removed 7-10 days after surgery. Depending on their occupation, patients usually return to work about 2 weeks after surgery. Patients can resume their full activities such as exercise, travel and work 6 weeks after the procedure.

Although robotic prostatectomy is somewhat new, success rates are similar to an open surgery in these areas:
- Removes all of the cancerous cells so you are considered “prostate cancer free”
- Freedom from the cancer returning 5 years after surgery
Urinary control and sexual function (Some reports indicate that the ability to have erections may return several months earlier with RALP.)

Although these results are promising, more long-term follow up is needed to fully compare RALP outcomes to open surgery.

The Role of Surgery When Cancer Recurs

Salvage radical prostatectomy and salvage cryotherapy are procedures that can possibly cure patients when their prostate cancer returns (recurs) after receiving initial radiation therapy.

Salvage Radical Prostatectomy

Many patients are told by their local doctor that it is not possible to surgically remove the prostate if cancer recurs after having radiation therapy. This is because radiation causes scar tissue around the prostate. Many surgeons are uncomfortable operating in this case because of the change in tissue and the risk of serious side effects. However, our surgeons are experienced in removing the prostate if the cancer recurs after radiation therapy. This procedure is called a salvage radical prostatectomy.

Recovery

Most patients who have a specific type of salvage radical prostatectomy are in the hospital 2-3 days and recover from surgery (with the exception of incontinence, see page 9) within 4-6 weeks. For patients who undergo a different type of surgery that includes a reconstruction option, patients are typically in the hospital about 7-10 days with a 6 week recovery. Your doctor will give you more information about the type of salvage radical prostatectomy that is recommended for you.

Complications

A possible complication of a radical prostatectomy in patients with prior radiation is urinary incontinence (the accidental leakage of urine). This possibility in patients undergoing salvage radical prostatectomy following radiation therapy is much higher than the chance of incontinence in patients who have surgery as their initial treatment. For more information, see “Incontinence” on page 9.

Outcomes

For patients who have local recurrence of cancer (the cancer has not spread outside the prostate) following radiation therapy, salvage radical prostatectomy is the treatment with the best chance of cure. Approximately 60% of patients who have this surgery will be cancer free 5 years after the surgery. (This figure is based on regular PSA testing after surgery.)

An alternative treatment option is salvage cryotherapy which is much less invasive. See Page 8 for more information.

Prostate Cryoablation

Prostate cryoablation involves the controlled freezing of the prostate gland in order to destroy
cancerous cells. Freezing affects both the cancer cells and the normal cells of the prostate. This process may cause scar tissue to develop. Important factors influencing freezing injury are the rate of temperature reduction after the freezing begins, the time cells remain frozen and the heating rate during thawing. This treatment is often recommended for patients whose cancer has not spread outside the prostate or who have minimal spread beyond the prostate.

**Recovery**
Patients are usually discharged with a catheter in place for drainage the morning after surgery. Most men are able to urinate in about 10-15 days but some may require a longer recovery period. When the patient is able to urinate and empty the bladder, the catheter is removed. Antibiotics are usually taken by mouth for 10-14 days after surgery.

Surgery side effects may include:
- Fatigue (feeling tired) that usually lasts for 7-10 days
- Discharge from the urethra
- Swelling around the scrotum
- Numbness at the tip of the penis
- Passing flecks of tissue
- Pain or a burning sensation when urinating
- Increased urinary frequency and/or feeling an urgent need to urinate

A PSA test is usually done 3 months after the procedure. A prostate biopsy may be done 3-6 months after treatment to look for cancer cells depending on the PSA level. If the biopsy is negative, PSA levels are checked as needed for follow up.

**Complications**
Cryoablation complications have improved. However, some risks still exist. Patients commonly have problems with erections after the procedure.

Uncommon complications:
- Urinary leakage
- Inability to urinate - repaired with a minor surgical procedure to open the urethra (the tube that carries urine out of the body).
- Development of a passageway between the rectum and the urethra that can cause leakage of urine or stool.
- Irritation of the testicles.

Rare complications:
- Permanent, severe incontinence in about 1% of patients
- Infection in the prostate
- Permanent numbness in the penis

**Outcomes**
A recent research study reported that the 5-year rate for treatment success for patients with early and intermediate cancers ranged between 60-76%; for patients with larger or more aggressive
cancers, it was 41%. These results are encouraging and suggest that cryoablation may be a treatment option for certain patients.

**Salvage Cryotherapy**
Salvage cryotherapy can be used when a biopsy proves that there is cancer in the prostate after radiation. The cancer must be local, meaning it has not spread outside the prostate. The indications for salvage radical prostatectomy and salvage cryotherapy are almost the same.

**Technique**
Salvage cryotherapy is performed under a general anesthetic and is virtually identical to that described in the “Prostate Cryoablation” section on Pages 6-7.

**Recovery**
Salvage cryotherapy can be performed in either an outpatient setting or with an overnight hospital stay. After the procedure a Foley catheter is left in the bladder for approximately 2 weeks to drain urine from the bladder while the prostate swelling subsides.

**Short Term Side Effects**
- Approximately 10% of patients will have significant swelling of the scrotum and penis in the first few days or week following the procedure. This swelling usually resolves on its own after 2-3 weeks.
- There is a 10-15% risk of long term urinary leakage following salvage cryotherapy that can be managed by delayed placement of an artificial urinary sphincter approximately 1 year later if severe. For more information, see “Artificial Urinary Sphincter” on Page 10.
- In general, most patients that undergo salvage cryotherapy will experience erectile dysfunction which can be managed with a variety of erectile dysfunction therapies. These are discussed in “Erectile Dysfunction” on Page 10.

**Outcomes**
The chance of being cancer free 5 years after salvage cryotherapy based on PSA testing is between 55- 60%. Thus, salvage cryotherapy can be a curative treatment in some patients. However, based on the results of a recent study that compared the two salvage treatments, we believe that salvage radical prostatectomy has the best chance for cure.

**Surgery Side Effects**

**Incontinence**
Temporary urinary incontinence, or the loss of the ability to control urination, is common in men who have prostate cancer surgery. If you have surgery, you should prepare for this possibility and learn how incontinence can be treated.

There are different types of urinary incontinence and differing degrees of severity. Some men dribble urine, whereas others will have total leakage. Loss of urine with a cough, sneeze or laugh is called stress incontinence and is the most common type of urine leakage men have after prostate surgery. On the other hand, the need to frequently urinate with episodes of leakage is called urge incontinence.
How Prostate Cancer Treatment Causes Urinary Incontinence

When urine flows into the bladder from the kidneys, it is stored inside the bladder. Urine is held here by valves that stay closed until messages from the brain "tell" the valves to open and urinate. The prostate gland, which surrounds the urethra, also helps hold back urine until it is released.

Removing the prostate through surgery disrupts the way the bladder holds urine and can result in urine leakage. Sometimes, surgery can damage the muscle valves that hold the urine in.

If urinary leakage continues longer than 1 year, some men may require treatment for their incontinence. The degree of leakage can range from a few drops per day to total loss of urinary control. A thorough exam can determine the cause and extent of incontinence after trying conservative treatments, such as pelvic floor exercises. This exam includes:

- Questionnaire – A survey that asks when your leakage occurs and how this may affect you.
- A cystoscopy – A procedure that allows a doctor to view the bladder and urethra by inserting a tube with a tiny camera up the urethra and into the bladder.
- A urodynamic study – A test that can determine whether the bladder and urethra are functioning normally.
- A 24-hour pad test – A test to check the exact amount of leakage occurring within a 24-hour period.

These combined test results will help determine your best treatment option.

Treatment Options

Absorbent products (pads): Absorbent pads are the least invasive and least expensive treatment. A wound, ostomy and continence nurse (WOCN) in the urology department can give you suggestions and advice.

Penile Clamp: Penile clamps are external devices made of soft foam or other materials that wrap around the penis, putting pressure on the urethra and stopping the flow of urine, but not blood flow. They're removed to empty the bladder. Penile clamps are available from medical supply companies and require a prescription.

Catheters: Catheter drainage is a convenient way to manage severe urinary leakage and comes in two forms – internal and external. Either type of catheter can be attached to a leg drainage bag or nighttime drainage bag depending on the case. Internal catheters (also called indwelling catheters), are generally placed and changed by a medical professional on a monthly basis. The external catheters, called “Texas” or condom, can be changed by the patient or caregiver on a more frequent basis.

Medicines: There are no medicines available to treat incontinence related to physical activity, coughing or sneezing – called stress incontinence. Many medicines are available to treat overactive bladder or urge incontinence such as Ditropan®, Dettol®, Vesicare® and Enablex®. All of these medicines are proven to reduce urinary frequency, urgency and nocturia (getting up at
These medicines will not help if you have problems related to the urinary sphincter, a muscle that helps hold back urine. Patients who have stress and urge incontinence may need to use medicines combined with another therapy.

**Injection Therapy:** During urination, nerve signals cause the muscles in the walls of the bladder to contract, forcing urine out of the bladder and into the urethra. The urethra is the tube that carries urine from the bladder to the outside of the body. At the same time the bladder contracts, nerve signals cause the sphincter muscles surrounding the urethra to relax, allowing urine to pass through and out of the body. Prostate surgery can interfere with this process.

To help the urethra close in this area, an injection of different materials into the walls of the urethra may help the sphincter to close. The most commonly used material is composed of bovine collagen. Bovine collagen is made of sterile, purified collagen from cow skin. MD Anderson doctors are very experienced with injection therapy after a prostatectomy. Injection therapy is a treatment for men with mild stress incontinence who use 1 or less pads per day.

**Male Slings:** Male slings have been patterned after similar procedures for female incontinence. A sling is a device used to suspend the urethra. It is made from synthetic material or from the patient's own tissue and is used to create the urethral compression necessary to achieve bladder control. Generally, slings are used to treat men with mild to moderate stress incontinence who use 1-4 pads per day.

**Artificial Urinary Sphincter:** This patient-controlled device is made of silicone rubber and is composed of 3 parts: a pump, a balloon reservoir and a cuff that encircles the urethra and prevents urine from leaking. The use of the artificial sphincter has a high success rate and is the best treatment for men with moderate to very severe incontinence who use more than 4 pads per day.

**Erectile Dysfunction**

A man has erection problems if he cannot get or keep an erection that is firm enough for him to have intercourse. Erection problems are also called erectile dysfunction (ED) or impotence. All men, to some extent, will experience ED after prostate cancer treatment. The good news is that ED can be successfully managed through new advances in drug therapies and medical technology.

ED is mainly caused by nerve damage during prostate surgery. MD Anderson doctors have helped develop and use surgical techniques to save or restore erectile nerves during surgery. Also a group of new treatments called "penile rehabilitation" can help stimulate early recovery of erectile function and help to maintain penile size. MD Anderson is recognized worldwide as a leader in this approach. Treatments include:

- Medicines taken by mouth
- Medicines delivered into the penis that help produce erections
- Vacuum erectile devices

These therapies can also help men who have been treated with radiation and cryoablation.
ED can be managed; however no single treatment is effective for every patient. Our staff work with patients and their partners to provide individualized therapy after prostate cancer treatment.

**Penile Rehabilitation Options**

*Oral medicines:* Viagra®, Levitra® and Cialis® increase blood flow to the penis and are effective one-third to one-half of the time.

*Vacuum erection devices (VED):* The VED consists of a cylinder with an external pump that attaches directly to the end of the penis. The cylinder and pump are used to create a vacuum to help the penis become erect. While patient satisfaction with a VED varies, this is a safe, cost-effective and non-surgical treatment for ED.

*Penile injection therapy:* Medicine given through injections cause blood vessels to expand, increasing blood flow throughout the body. By increasing blood flow to the penis, the medicine helps cause an erection. Injections can induce erections strong enough for intercourse in more than two-thirds of men after prostate cancer treatment. Medicine is also available in suppository form. When given as a suppository, the medicine is placed into the urethra through the opening at the tip of the penis. This treatment is sometimes preferred by patients because no needle is used; however it is less effective than penile injection.

*Penile implant:* A penile implant is used when there is a clear medical cause for ED and when the problem is unlikely to improve naturally or with other medical treatments. In these cases, using implants can regain erectile function with a satisfaction rate of more than 90%. An inflatable penile implant (a penile prosthesis) provides a permanent cure with the highest success rate for curing ED.

For patients with complex medical conditions, the best treatment may involve combining 2 or more rehabilitation therapies.

Some couples may also benefit from speaking with a counselor regarding intimacy issues. Specialists are available in the behavioral science department.

For specific questions, please speak with your surgeon or a member of your health care team.
Radiation Treatment

This section explains radiation treatment and the different types of radiation. Radiation treatment is the use of high-energy beams to kill cancer cells and shrink tumors. Although radiation therapy is similar to an x-ray, the energy and dose of radiation in cancer treatment is much higher and is given over a longer period of time.

Several forms of radiation are available. Your radiation doctor, called a radiation oncologist, will recommend the best therapy based on the type, stage, location and amount of cancer you have. The radiation oncologists in the radiation oncology prostate group are:

Deborah Kuban, MD
Steven Frank, MD
Quynh-Nhu Nguyen, MD
Seungtaek Choi, MD

Usama Mahmood, MD
Shalin J. Shah, MD
Karen Hoffman, MD, MPH
Sean McGuire, MD, PhD

External Beam Radiation

External beam radiation is a common type of therapy for prostate cancer. Patients whose cancer is still in the local area around the prostate can usually be treated in this manner. Patients who have had radiation previously to the pelvic area or those who have inflammatory bowel type conditions may not be able to have this treatment. Therapy is usually given on an outpatient basis, using a machine called a linear accelerator. See Figure 3.

Usually, the total dose of radiation needed to be effective cannot be given all at once. Because of this, the dose of radiation is divided into smaller doses called fractions. A series of daily treatments, which take approximately 20 minutes each, are given 5 days a week (Monday through Friday) for 7 ½-8 ½ weeks, totaling 38-42 treatments.

Intensity Modulated Radiation Therapy (IMRT)

IMRT is a type of external beam radiation that uses x-ray beams to target the prostate cancer (tumor) from 5-8 different angles. See Page 13, Figure 4. During the treatment planning process a computerized tomography (CT) scan is taken of the area surrounding the prostate. The result of this scan will show the location of the bladder and rectum in relation to the prostate. This information will help focus the radiation on the prostate and avoid treating healthy tissue. See Page 13, Figure 5. Before each treatment, the position of the prostate is located by ultrasound or x-ray to ensure that the radiation beam is accurately directed to the tumor.
Proton Therapy
Proton therapy is another type of external beam radiation that uses streams of protons (small positively charged particles). The protons come from a large machine. Computerized treatment planning is done for this therapy also and the number of treatments is similar to IMRT. See Figure 6.

Some patients with locally advanced tumors (when the cancer has spread outside of the prostate) are not able to be treated with proton therapy because of the shape of the seminal vesicles and the position of the rectum.

Side Effects and Complications of External Beam Radiation
Side effects to the bladder, rectum and the urethra (the tube that carries urine out of the body) are usually mild to moderate. These may include:

- Frequency of urination, a stronger urge to urinate, waking up at night to urinate, burning when urinating and a weak urine stream.
- Soreness in the rectal area, more frequent bowel movements and occasional minor bleeding, similar to hemorrhoids.
Other side effects are:
- Fatigue – feeling tired during the course of treatment
- Impotence – not being able to have or sustain an erection – can occur 1 year or more after radiation is complete.

Some or none of these side effects may happen. When side effects happen, they are usually mild to moderate and are rarely severe. Most patients usually feel better a few months after treatment. Occasionally, the side effects may last longer. It is unusual for a patient to become incontinent (loss of urine control) after radiation.

**External Beam Radiation with Hormonal Therapy**
Patients with larger tumors or those who have an aggressive cancer often receive hormone therapy in addition to radiation. The length of hormone therapy can range from 6-24 months and is determined by the characteristics of the prostate tumor. For more information about hormone therapy, see the “Medical Treatment” section.

**Prostate Implant**

Internal radiation therapy (also called brachytherapy) uses a radiation source that is placed very close to or inside the tumor. A prostate implant involves placing 80-100 tiny radioactive seeds, each smaller than a grain of rice, directly into the prostate. See Figure 7. The seeds kill the cancer cells by gradually emitting radiation over a period of several months. The procedure is performed under anesthesia and takes about 2 hours.

Patients with early stage prostate cancer who have good urinary function and whose prostate is small to moderate in size are candidates for this treatment.
- An over-night hospital stay is usually not needed.
- It is a 1-time procedure.
- Patients usually return to most of their normal activities within a few days.

This treatment does not work well for men who have large prostates that extend behind the pubic bone.

**Side Effects and Complications of Implant**
The side effects of a prostate implant are similar to external beam radiation and include:
- Urinary frequency and irritation
- Rectal soreness and occasional bleeding
- Mild fatigue
- Rarely, the prostate swells more than usual immediately after the procedure, closing off the
urethra (urine tube). If swelling occurs, a catheter will be inserted and left in place for several days.

Side effects are mild in most patients and usually go away after treatment ends. Late complications are unusual.

**Post-operative Radiation**

If the prostate is removed (called a prostatectomy), but the doctor feels that some cancer cells remain, he or she may suggest radiation treatment after the patient recovers from surgery. Most patients receive 33-35 treatments using the IMRT technique. Side effects are similar to those listed above for external beam radiation.

**Outcomes for Radiation Options**

For early stage prostate cancer, both external beam radiation and implant provide excellent long-term results. Nearly 90% of patients will be free of prostate cancer 10 years or more after their treatment. Patients with more advanced prostate cancer which is not the most aggressive type will have a 75-80% chance to be free of cancer. Oftentimes, these patients also receive a short course of hormone therapy along with radiation. More advanced, aggressive cancers require longer hormone therapy or are treated with new drugs in addition to radiation on clinical trials.
Medical Treatment

This section describes the medical treatment options for prostate cancer. Medical treatments include hormone therapy, chemotherapy and new drugs which disrupt a particular function within the cancer cell. Medical treatments for prostate cancer can usually be stopped or changed, versus surgical treatment which is permanent. Active surveillance (watchful waiting) is included also.

Medical treatments are offered in the multidisciplinary clinic by the medical oncology prostate group:

Christopher Logothetis, MD, Department Chairman
Sumit Subudhi, MD, PhD
John Araujo, MD
Paul Corn, MD, PhD
Jeri Kim, MD
Eleni Efstathiou, MD, PhD
Ana Aparicio, MD
Shi-Ming Tu, MD
Amado Zurita-Saavedra, MD
Jennifer Wang, MD

Active Surveillance

Because prostate cancer often grows very slowly, some men – especially those who are older or have other serious health problems – may never need treatment for their prostate cancer. Instead, their doctors may recommend active surveillance, commonly known as "watchful waiting.” This approach involves closely monitoring the cancer without active treatment such as surgery or radiation therapy.

At MD Anderson, active surveillance is considered a treatment option for:

- Patients with early, low-grade prostate cancer or
- Patients with other serious illnesses for whom surgery, radiation or other treatments are not good options.

A patient with early stage prostate cancer must meet the following guidelines for his doctor to consider active surveillance therapy:

- A prostate biopsy shows a small amount of cancer.
- The cancer is low grade and not aggressive.
- A prostate-specific antigen (PSA) test result shows a normal value or a somewhat higher value caused by an enlarged prostate

A patient with other serious illnesses, such as an illness that requires continuing treatment by a health care provider, must:

- Have a life expectancy of less than 10 years or
- Have a life expectancy of less than 5 years and have a prostate cancer that is considered to be no risk during that time.

Active surveillance can also be used in patients who prefer to monitor their cancer rather than to
have surgery or other therapy immediately. It is important that these patients understand there is no test to reliably detect the growth or spread of prostate cancer very early. All patients who choose active surveillance must be willing to:

- Have a surgical biopsy when beginning watchful waiting and every year thereafter
- Have PSA tests every 6 months

Active surveillance is challenging for patients and their doctors because:

- There is no test that will help predict the growth of all cancers to avoid treatment delays.
- There is no test that will always identify the likelihood that cancer will spread to other parts of the body.

Men who choose active surveillance should discuss with their doctor what their treatment options will be as they grow older. Careful PSA testing and regular prostate biopsies are part of active surveillance for all men. In most cases, treatment options are likely to remain the same unless an unexpected event related to the cancer or general health occurs.

The risks of active surveillance will become lower as the ability to predict prostate cancer behavior improves. Men who choose the approach and participate in research studies help contribute information about prostate cancer and lower the risk for others.

**Other Treatments for Prostate Cancer**

**Hormone Therapy**

The goal of hormone therapy is to reduce levels of male hormones, called androgens, in the body. One of the main androgens is testosterone. Androgens, produced mainly in the testicles, stimulate prostate cancer cells to grow. See Figure 8. Lowering androgen levels often makes prostate cancers shrink or grow more slowly. However, hormone therapy does not cure prostate cancer.

Hormone therapy is either medical (pills or an injection), meaning the treatment can most often be reversed, or surgical (removal of the testicles), which is permanent.

**Medical Hormone Therapy**

Medical hormone therapy may use luteinizing hormone-releasing hormone (LHRH) agonists. LHRH agonists work by lowering the levels of luteinizing hormone (LH) from the pituitary
gland which in turn lowers the production of testosterone in the testes. Several different types of LHRH agonist drugs are available and are given by injections into the arm or buttocks ranging from once a month to once a year. These are all equally effective.

Anti-androgens are oral medicines that work by blocking the testosterone receptors in the prostate cells. Normally, testosterone would bind with these receptors and fuel the growth of prostate cancer cells. With the receptors blocked, testosterone cannot “feed” the prostate.

Flutamide, bicalutamide and nilutamide are 3 types of anti-androgens. They are usually given together with LHRH injections to prevent temporary hormone flares from affecting the cancer. This can happen early in LHRH agonist therapy. In some cases, doctors may prescribe only anti-androgen therapy. Anti-androgen therapy does not eliminate testosterone and therefore may have fewer or less severe side effects than other treatments.

Hormone therapy is commonly used for men with a rising PSA after surgery or radiation or for men whose cancer has spread. Hormone therapy given on an off-again, on-again schedule may provide the same benefit as continuous hormone therapy with reduced costs and improved quality of life, but more research is needed in this area.

**Total or combined androgen ablation:** Combinations of LHRH agonist and anti-androgens are called total or combined androgen ablation. Because this therapy results in more side effects and the long-term benefit of the combination is not proven, this therapy is seldom advised.

**Investigational hormonal therapeutics:** Researchers are working to develop stronger drugs to interfere with both androgen production and action. Hopefully with additional new drugs, prostate cancer can be treated more successfully.

**Surgical Hormone Therapy**
Orchiectomy, the surgical removal of the testicles, was once the standard hormone therapy for prostate cancer. Even though this is a type of surgery, its main effect is as a form of hormone therapy. In this operation, the surgeon removes the testicles, where 90% of the androgens (mostly testosterone) are made. With the testicles removed, most prostate cancers stop growing or shrink for a time. If your doctor recommends this treatment, you will meet with a surgeon.

For men who are unable to receive LHRH agonist therapy, orchiectomy is still a preferred treatment. It is an efficient, cost-effective and convenient method of reducing testosterone.

**Side Effects of Hormone Therapies**
Hormone therapies that lower the testosterone level can cause a range of side effects known as the androgen deprivation syndrome. The side effects include:

- Hot flashes
- Sleep problems
- Weight gain
- Muscle weakness
- Decreased sex drive
- Fatigue
- Mood and cognitive changes
- Decreased bone mass (osteoporosis)
- Impact on other medical conditions such as hyperlipidemia, hypertension, diabetes and coronary artery disease
- Changes in marital and social relationships

The frequency and severity of side effects are different for every man. Short-term hormone therapy is usually well tolerated. Some men remain on hormone therapy for many years without significant side effects, but most men on long-term therapy will have side effects. Several measures can be taken to prevent or reduce these side effects.

For men who will receive radiation treatment for intermediate or aggressive prostate cancer, 6 months to 2 years of hormone therapy may be an option. If this is your case, discuss possible side effects with your doctor.

**Chemotherapy**

The chemotherapy drug, docetaxel (Taxotere®) has shown recent improvements in both the survival and quality of life of men with advanced prostate cancer, specifically in men whose cancer has spread beyond the prostate and in whom hormone treatments are no longer effective.

Side-effects of chemotherapy include:
- Fatigue
- Drop in blood counts
- Risk of infection
- Partial hair loss

**New Drugs**

Clinical trials are people-based studies – not animal or lab studies – of new drugs or procedures. Doctors use clinical trials to learn whether a new drug is safe and effective in patients. Such studies are important when developing new treatments for diseases such as cancer. There are many types of these new drugs. Many of them are intended to disrupt a particular chemical pathway or function within the cancer cell. Clinical trials exploring the effectiveness of new prostate cancer drugs are usually available through major cancer centers such as MD Anderson.
Clinical Trials

Clinical Trials for Prostate Cancer Patients

This section explains what clinical trials are and describes several clinical trials that are available at MD Anderson Cancer Center to treat prostate cancer.

Clinical trials are research studies that involve people. The main purpose of a cancer clinical trial is to find a better way to treat cancer and/or reduce complications. All patients who participate in clinical trials are volunteers who can choose to stop participating in a clinical trial at any time.

Clinical trials are important to develop new treatments for cancer. Many of today’s standard cancer treatments – treatments that are accepted and widely used by medical experts – are based on the results of previous clinical trials. In some cases, patients may not personally benefit from participating in a clinical trial but by participating, new knowledge will be gained that may help future patients.

Patient Selection

Patients are selected for prostate cancer clinical trials based on factors related to the tumor. Some factors include:
- The stage of the cancer
- Their PSA level
- The way the cancer looks under a microscope

Your doctor may recommend a clinical trial to you based on your situation.

General types of clinical trials and those currently available at MD Anderson are listed below. Although this list is updated frequently, recently opened trials may not be listed. Your doctor will provide you with the most up-to-date and detailed information.

Types of Clinical Trials

Neoadjuvant Trial
In this type of trial, the patient will receive treatment before the prostate is surgically removed or treated with radiation. The “pre-treatment” may include a new prostate cancer fighting drug.

Adjuvant Trial
The patient will receive treatment after prostate surgery or radiation.
Salvage Therapy Trial
After the first treatment to cure the cancer, the patient receives treatment again because the cancer still remains or has returned. The type of treatment will depend on prior treatment and the specifics of the cancer.

MD Anderson Clinical Trials Involving Radiation Treatment

2012-1003 – A study for patients with localized, low to intermediate risk cancer. Patients will receive Hypofractionated proton therapy.

**Goal:** Learn if delivering proton beam therapy in less treatments but higher doses per treatment may help control prostate cancer just as well as the standard of care treatment. The safety of this treatment will also be studied.

**Treatment Time:** 15 treatments given 3 times per week for a total of 5 weeks.

2013-0982 – A study for patients with localized, intermediate to high risk cancer. The patient will receive the standard therapy (IMRT or proton therapy) and 6 months of androgen deprivation therapy plus 6 months of an oral hormone-type medicine.

**Goal:** Assess whether or not adding the oral hormone-type medicine to the standard treatment can help control prostate cancer better than the standard treatment alone. The safety of this treatment combination will also be studied.

PARTIQoL 2013-0555 – A study randomizing patients with localized, low to intermediate risk prostate cancer. The patient will receive either IMRT or proton beam therapy.

**Goal:** Compare the side effects of these different types of radiation therapy in treating prostate cancer.

2014-0359 – A study for patients with localized, low to intermediate risk prostate cancer to receive stereotactic body radiation therapy (SBRT).

**Goal:** Learn about the effects of SBRT on quality of life. Patients receive a small number of precise treatments with a high dose per day.

**Treatment Time:** 5 treatments over 2 weeks.

Other Clinical Trials

2007-0302 – This quality of life study will collect information on how surgery, radiation,
radiation with hormone therapy, cryotherapy and active surveillance and other treatments affect urinary, bowel and sexual function in patients.

2005-0619 – Active Surveillance - A study for patients with early, low-grade prostate cancer that monitors the rate at which the cancer grows when no treatment is given and which patients can be safely watched.

Resources

MD Anderson Cancer Center
Genitourinary Cancer Center Website
Click on “Prostate Cancer” for more information.

MD Anderson Radiation Treatment Center Website

myCancerConnection
This one-on-one support connects MD Anderson patients and their caregivers with others who have been there. Requests are matched by disease, type of treatment and experience. Support is open to patients, caregivers and cancer survivors who were treated anywhere.

National Cancer Institute (NCI)
The NCI is the federal government's principal agency for cancer research and training.
http://www.cancer.gov/types/prostate

UsTOO
UsTOO is an international volunteer nonprofit group. It provides peer-to-peer support and educational materials to help men and their caregivers make informed decisions about prostate cancer detection, treatment options and side effects.
http://www.ustoo.org/