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Cryotherapy for Prostate Cancer *By Robert S. Hollabaugh, Jr. MD*

Introduction

The prostate gland is a focus of medical concern for all men after age 40. Both benign and malignant conditions can affect the gland. Benign enlargement of the prostate (BPH) can cause urinary difficulties, and will affect almost all men as they get older. Of even greater concern, 1 in 6 men will develop prostate cancer, making prostate cancer the second most common cancer and the second leading cause of cancer death in American men.

The American Cancer Society estimates 234,000 new cases of prostate cancer were diagnosed in 2005 and more than 29,000 men died from the disease. The good news is that most cases are diagnosed while the cancer is still within the prostate (localized or organ confined), and these cases usually have a high cure rate. Several curative options exist for localized prostate cancer: surgical removal, radiation therapy, and cryotherapy. Certain factors may favor one therapy over another in any given case, but in general, all three options are performed with the intent of curative therapy.

Cryotherapy is the use of subzero temperature to destroy abnormal tissue. The dead tissue is then sloughed or reabsorbed by the body. Cryotherapy has a long history dating back to the mid-1800's when physicians used ice and salt mixtures to treat breast and cervical cancer. The first widespread use of cryotherapy was with dermatology, using freezing treatment to manage skin cancers. Cryotherapy used for solid organ treatment required the development of probes which could be inserted into an organ to freeze a targeted area. Over the past 20 years, the sophistication of medical technology has greatly improved the quality of the probe-delivery system as well

as the imaging techniques used to monitor the freezing process. It is these advances in delivery and imaging that have revolutionized prostate cryotherapy. The latest generation of cryotherapy equipment allows for very precise mapping of the prostate gland anatomy (including the nerve bundles responsible for erection) and accurate monitoring of the ice temperatures both in and adjacent to the prostate gland. The accuracy and precision available today give excellent rates of cancer control, with a greatly improved side-effect profile. In 1999, cryotherapy of the prostate gained Medicare approval for the treatment of prostate cancer. Advances continue to improve outcomes with cryotherapy, and ongoing clinical studies around the country continue to affirm the positive results of the treatment. While cryotherapy was originally utilized only in cases of failed radiation therapy, it is now considered as a primary option for newly diagnosed prostate cancer.

Treatment Options for Prostate Cancer

RADICAL PROSTATECTOMY

Radical Prostatectomy is perhaps the most well-known treatment for prostate cancer, and involves the surgical removal of the entire prostate gland. For decades this surgery required an incision in the lower part of the abdomen to allow access for the surgeon to remove the prostate. In recent years, advances in technology and instrumentation have led to a new treatment approach combining the benefits of open surgery with the benefits of less-invasive laparoscopic techniques. Doctors at the Conrad Pearson Clinic are now performing robotic-assisted laparoscopic radical prostatectomy. Rather than a large incision, the robotic operation uses very small incisions which allow for faster healing and less pain. It is

quickly becoming a standard in prostate cancer surgery. Radical prostatectomy is performed in the hospital, under general anesthesia and usually requires a 2 day hospital stay. Learning how to perform robotic prostatectomy requires taking advanced study courses and dedicating many hours to training, and competence is achieved only after performing the operation many times.

RADIATION THERAPY

Not all cases of prostate cancer are best treated with radical surgery, and in fact, many cases need consideration for other therapies. Radiation therapy can also offer excellent rates of cure for localized prostate cancer. It is available in two broad categories: External Beam therapy, and Brachytherapy (radioactive seed implantation). Efficacy is nearly the same with each method, but the application is different. For brachytherapy, the urologist places radioactive seeds in the prostate tissue using a computer generated model that allows for delivery of radiation dosing for a prescribed amount of time once implanted. The radioactive seeds are put in place using needle guides while the patient is under anesthesia. Each seed is about the size of a grain of rice, and does not have to be removed later. Usually about 70 seeds are placed, but that is determined by the actual size of the prostate. The procedure is performed in a hospital with patients usually going home the morning after surgery. External beam radiation therapy focuses radiation from a source outside the body and aims it at the prostate tissue. Currently the most advanced form is called Intensity Modulated Radiation Therapy (IMRT). IMRT uses computer models and CT scan technology to focus radiation dosing on the precise area of the prostate, avoiding radiation exposure to other nearby organs. Less exposure to neighboring

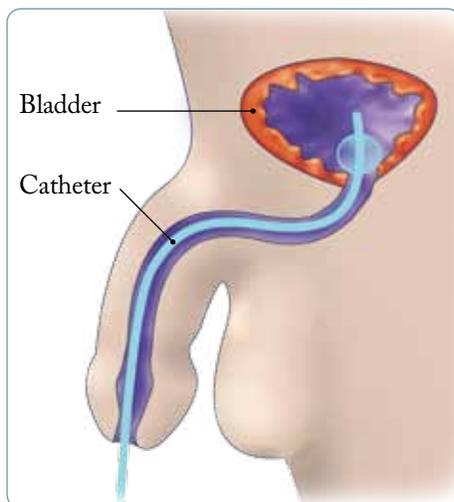
organs means much less complications related to collateral radiation damage. The course of treatment is usually a 20 minute, daily regimen over a period of about 6 weeks. It requires no anesthesia, and patients are usually at near normal activity levels throughout the course of therapy. Success rates for either form of radiation therapy are excellent.

CRYOTHERAPY

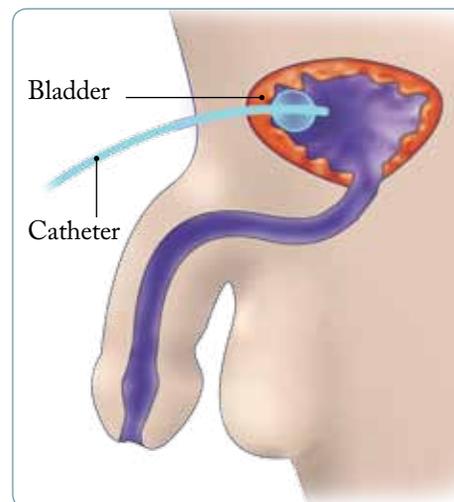
The newest of the curative treatment options available for prostate cancer is Cryotherapy, or freezing therapy of the prostate. This procedure, also called Cryoablation of the prostate, is usually performed in an outpatient setting, with patients going home the day after surgery. Under anesthesia, several needle-like probes are placed into the prostate gland thru the skin under the scrotum which allow for freezing of the prostate tissue. This freezing process destroys the cancer cells. At the end of the procedure, the probes are removed. Patients spend the night in the hospital for observation, and go home with a suprapubic catheter for 3-7 days to make sure that there are no problems with urination. While cryotherapy of the prostate does not have as long of a proven track record as radiation or surgery, current data from around the country using the latest generation equipment shows excellent cancer control rates. Because it is a simple outpatient procedure and has a favorable side effect profile, cryotherapy is rapidly growing in popularity among both urologists and prostate cancer patients alike.

Decision Making

Lots of different factors are used in deciding what course of treatment is best for a particular case of prostate cancer. The doctor's assessment of the extent of disease is perhaps the most important initial consideration. Using the patient's test results and statistics, your urologist will try to determine if the cancer is confined to the prostate or not. If it is likely organ-confined, then all treatments can be considered legitimate options. If it is not organ confined, assessment must focus on whether the cancer is widespread or just locally advanced. Cases with widespread metastatic prostate cancer usually rely on hormone deprivation therapy or new chemotherapy regimens to treat the cancer. Metastatic prostate cancer is not curable with surgery, radiation therapy, or cryotherapy. In some cases the cancer may not be metastatic, but doctors think that the cancer is locally advanced; in other words, the cancer is growing thru the capsule of the prostate gland. In these circumstances, surgery will not likely be able to remove all of the cancer. Also, it is difficult to safely deliver radiation at the needed level to the areas outside the prostate gland. Cryotherapy can treat some areas outside the prostate capsule with some limitations. In any



A Foley catheter carries urine out of your bladder through your urethra.



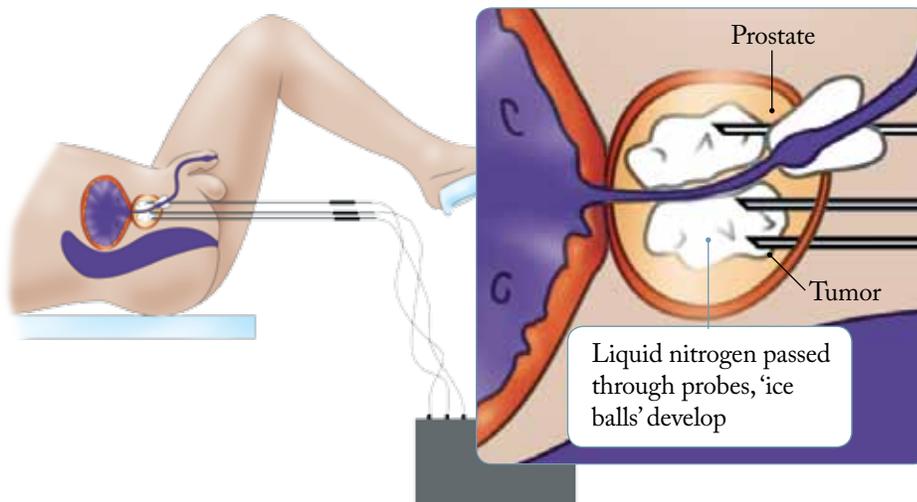
A suprapubic catheter carries urine out of your bladder through a small incision in your abdomen.

case, statistics can shed light on the successes of treatment in these circumstances.

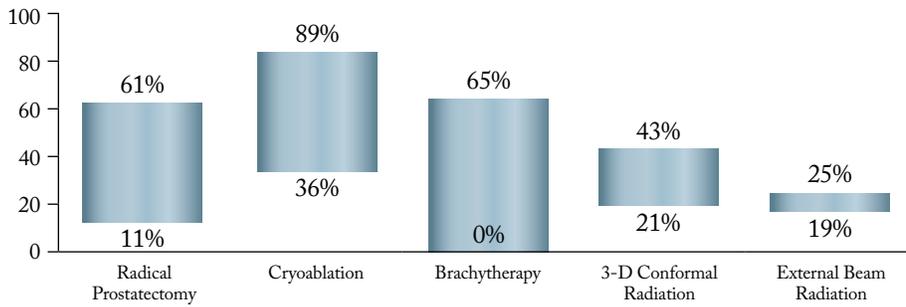
The chances of treatment failure or success can be assessed by categorizing prostate cancer with regard to Stage, PSA level, and Gleason Score. Patients with Early Stage (T1 or T2a), PSA less than 10 ng/dl, and Gleason 2-6 are considered "Low Risk" for treatment failure. If any one of the criteria is not met, then the patient is "Moderate Risk." If any two of the criteria are not met, then the patient is "High Risk" for failure. While there are many other methods for risk stratification, this one is fairly simple and lots of statistical data regarding treatment

failure has been reported using this methodology. The following tables show the cure rates of the different therapies based on the risk categories, as published in professional urology journals over the past 10 years. While this is not an absolute answer as to what therapy is best for a certain situation, it gives some assessment of relative cure rates for different circumstances and treatment options. The high and low percentages seen in each category represent the best and worst study results for the given type of treatment. Obviously, most results were somewhere in between the high and low reports. As you can see, for low risk patients, all of the treatment choices have excellent cure rates.

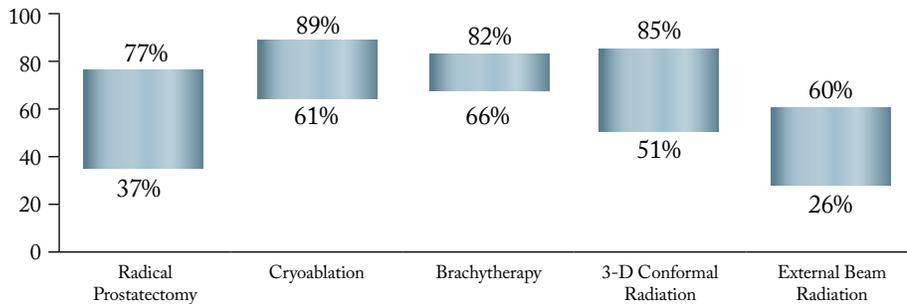
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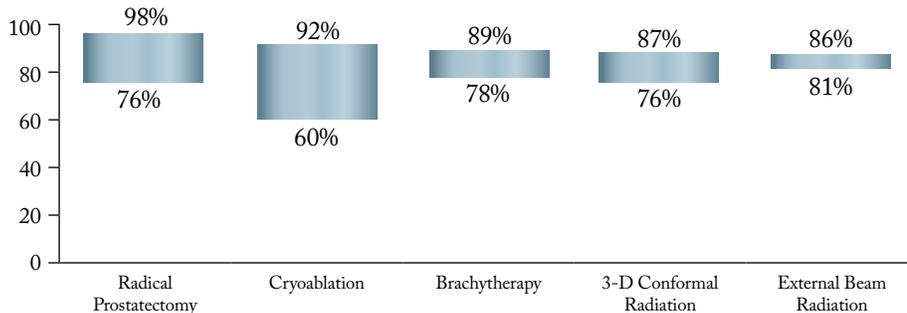
RANGE BIOCHEMICAL DISEASE FREE RATES REPORTED IN THE LAST 10 YEARS FOR HIGH-RISK DISEASE



RANGE BIOCHEMICAL DISEASE FREE RATES REPORTED IN THE LAST 10 YEARS FOR MODERATE-RISK DISEASE



RANGE BIOCHEMICAL DISEASE FREE RATES REPORTED IN THE LAST 10 YEARS FOR LOW-RISK DISEASE



Complications

BLEEDING

With any type of surgery, there can be bleeding or infection. Traditionally, radical surgery had the highest risk of bleeding, with blood transfusions being commonly required during surgery. Today's refined surgical techniques and robotic applications have made the major concern of blood loss less worrisome. Radiation therapy, either external beam or seed therapy, can cause radiation injury to the bladder or rectum which sometimes causes bleeding. Cryotherapy, while not surgically removing the prostate gland, will

cause destruction of the gland which can also cause temporary bleeding.

INFECTION

Any manipulation of the urinary tract can cause infection. Usually, antibiotics are prescribed following prostate treatment, and the risk of major infection is low with any of these options.

RECTAL INJURY

Because the prostate gland is situated very near the rectum, injury to the rectum is possible. Whether it be surgery, radiation, or cryotherapy, if the rectum is injured, an abnormal connection to the urinary tract (called a fistula) can develop.

If this develops, further surgery to correct the fistula will be required. Less than 3% of people undergoing prostate cancer treatment will develop a fistula.

ERECTILE DYSFUNCTION AND INCONTINENCE

Erectile Dysfunction and Incontinence are usually the major concern for patients faced with treating prostate cancer. All treatment options can effect sexual function and urinary control. For patients already having problems in these areas prior to treatment, the problem almost certainly will worsen. Return to preoperative status and function is the hope. The best recovery results are achieved in younger patients with early stage cancer in general good health.

DEATH

All cases involving general anesthesia have certain risks associated with being put to sleep for surgery. Most patients with significant pre-existing medical conditions will need to get evaluated by the internist or general medical doctor prior to surgery to identify situations where the risk may outweigh the benefit of surgery. Even in ideal cases, however, problems can arise and there is always the chance that heart conditions or lung conditions may complicate the course of surgery and recovery. The stress of surgery can bring on a heart attack, a stroke, a seizure, or another problem. Most of these situations, while complicated, are managed to recovery, but death remains a possibility.

Post Operative Recovery

INCISIONS

After cryosurgery, there will be a gauze dressing over the punctures beneath the scrotum. This can be removed 24 hours after surgery. At that time the wound can stay open to the air. For a few days, the wound may weep fluid or spot blood. Use gauze as needed and put Neosporin ointment on the small incisions twice a day for the first week to help prevent infection. Clean the wound by letting shower water and soap rinse over it. Do not scrub the incision as this will irritate it. A quick (2 minute) rinse in the bathtub is allowed, but do not soak in bath water for at least 7 days, as soaking will slow the wound healing process.

SUPRAPUBIC AND FOLEY CATHETERS

The suprapubic catheter (SP) was inserted in the operating room during your procedure. (Occasionally it is not used) It goes thru the skin of the abdomen into the bladder. It is a safety measure to make sure that your bladder can empty in the event that you cannot urinate in the days following cryotherapy. If you are urinating easily 3-7 days after surgery, the SP

tube can be removed in the office. If there is any question as to the ease of urination, it is safe to leave the SP tube in for up to several months. The catheter connects to a drainage bag that needs to be emptied from time to time. On the catheter is a valve. In order for the catheter to drain properly the valve must be open (valve arms parallel to the tubing). To close the valve, turn the arms perpendicular to the tubing. If you are urinating with no problems, keep the valve closed, an open it only if you cannot urinate. If you are testing your ability to urinate, close the valve for several hours and allow your bladder to fill up on its own. If you get a strong urge to urinate with a full bladder but cannot urinate any, open the valve to let the bladder drain out. This testing cycle can be done several times per day until you get to the point where you can urinate easily.

If the doctor did leave a foley catheter in the penis, it will usually be removed 5-7 days later. It is not dangerous to have it for longer than that if needed. It is normal for urine to come around the catheter from time to time. Also there will usually be some blood or yellowish discharge that comes around the catheter. This is normal for as long as the catheter is in place.

URINARY CONTROL

After any treatment on the prostate gland, urinary control can be temporarily affected. In many cases, a simple Kegel exercises routine can effectively control the problem. Nearly all women have heard of Kegel exercises, usually related to childbirth. The Kegel routine however can be effective to both men and women to regain urinary control **IF DONE PROPERLY**. Kegels are **NOT** simply "tightening up the belly muscles" or "clenching the buttocks." The best way to correctly perform Kegels is as follows. For the first week, learn to isolate the proper muscle for urinary sphincter control. Whenever you feel the urge to urinate, go to the restroom and let the urine flow begin; then stop the stream. Pay attention to the muscle you are contracting to stop the stream, as this is the sphincter muscle. Then in the weeks to come, you can exercise this muscle at times other than when you are urinating. To do a repetition of Kegels, one must tighten up the muscle and hold it for a count of 5, then relax it. A repetition of Kegels means you "Tighten-count to 5-Relax" five times in a row.

This should be done multiple times each day as a daily exercise. Try to do it every time you come to a stoplight in your car or every time you see a commercial on the television. The Kegel Routine must become activity of daily living-**FOREVER**. These exercises develop tone for the sphincter and greatly help in regaining or maintaining urinary control.

BLOOD IN CATHETER

For as long as there is a catheter in the bladder, there will likely be some blood both in the catheter and around the catheter. This is normal as the catheter rubs the lining of the bladder and will make it bleed from time to time. It will likely come and go, and come again. Almost always, the bleeding is an insignificant amount of blood. Remember, a single drop of blood turns the whole toilet bowl red; similarly, only a few drops will make the drainage bag of urine look like pure blood. Sometimes, heavy bleeding will clog up the tube. If no urine has come out of the tube for 4 hours, and you feel a strong urge to urinate, contact the clinic or go to the emergency room to get the catheter irrigated.

BLADDER SPASMS

Bladder spasms can develop whenever anything irritates the bladder. The spasms feel like an intense urge to urinate, and sometimes can be downright painful. They usually last for 5-30 seconds, however, sometimes they may last longer and come rather frequently. Most of the time they are related to the catheter irritating the bladder lining. Once the catheter is removed, spasms will subside. If the spasms are terrible, there are some medications that can help.

DIET

When you go home after surgery, you may resume eating whatever you like. In general, however, you may want to avoid spicy foods and caffeine beverages early in the recovery, as these things irritate the bladder. Try to drink plenty of water (6 eight ounce glasses each day) to maintain good urine production.

ACTIVITY

In the weeks following surgery it is important to get up out of the bed and leisurely stroll around the house two or three times each day. This protects the lungs and circulation. Laying in bed

constantly may feel good, but is a major risk for pneumonia and blood clots following surgery. Try not to lift anything heavier than a phone book for the first week following surgery, as the strain will only aggravate healing and make things sore. Recreational exercising and sports should be avoided for 6 weeks.

DRIVING

You should avoid driving until 2 weeks after surgery. You may feel well enough to drive, but your reflexes are much slower. Because you won't react as quickly, the risk of an auto accident is higher. Car wrecks only complicate surgery and healing. Let someone else do the driving for two weeks, unless it is an absolute emergency.

CONSTIPATION

Narcotics and anesthesia constipate people. It is not unusual to have no bowel movement for 3-5 days following surgery. **DO NOT USE AN ENEMA** or put anything inside the rectum. Gentle measures like natural food laxatives (prunes) or Metamucil usually work. If not, take 30 cc of mineral oil daily. It is fine to try milk of magnesia or other over the counter oral laxatives as well. Be cautious; too much laxative will likely result in several days of diarrhea. Remember, the narcotic pain medication that you are taking is making the constipation worse.

EMERGENCIES

A very worrisome concern following major urologic surgery is the development of blood clots. These may form in the leg and, if they break loose, can pass to the lungs. This is called a **PULMONARY EMBOLUS (PE)** and is a life-threatening condition. Signs of clots in the leg include one-sided leg pain or swelling (although not everyone has this). Signs of pulmonary embolus include sudden shortness of breath, pain on deep breathing, sudden weakness or fainting, and coughing up blood.

IF YOU THINK THAT YOU HAVE ANY OF THESE SYMPTOMS, GO THE EMERGENCY ROOM OR CONTACT YOUR DOCTOR IMMEDIATELY.

The best way to prevent clots or a PE is to remain active by walking, wearing compressive stockings (the white tight hose from the hospital), and avoid sitting or laying for long periods.

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