PERCUTANEOUS CRYOABLATION

IS A MINIMALLY INVASIVE,
IMAGE-GUIDED TREATMENT THAT
DESTROYS (ABLATES) TUMORS AND
OTHER TARGETED TISSUE WITH
EXTREME COLD WHILE SPARING SURROUNDING HEALTHY TISSUE.

What are some common uses of the procedure?

How does percutaneous cryoablation work?

After anesthesia or conscious sedation is administered, one or more cryoprobes (slender needles) are inserted into or near the tumor. I use CT or Ultrasound imaging scans to guide placement and verify that the cryoprobe tip is precisely positioned. Once each cryoprobe is in place, a cryogen (freezing agent-Argon gas) is circulated inside the probe to create a very cold iceball at the tip. The iceball encompasses (engulfs) the entire tumor plus a safety margin beyond the tumor edges, which is verified by a CT or Ultrasound scan. Once this is accomplished, I will then warm and remove the cryoprobe(s). Cryotherapy can be applied percutaneously, or surgically. When the lesion is situated below the skin surface, a needle-like therapy probe or applicator needs to be placed through the skin. Occasionally, a surgical incision is required.
Cryotherapy is used to treat:

- Bladder, bone, breast, cervical, liver, lung, pancreas, prostate, kidney cancers and soft tissue abdominal or pelvis especially if surgical resection is not possible.

Cryotherapy is also being used to treat tumors in other parts of the body, such as the kidneys, bones (including the spine), lungs, and breasts (including benign breast lumps called fibroadenomas). Although further research is needed to determine its long term effectiveness, cryotherapy has been shown to be effective in selected patients. Cryoablation of breast cancer is still considered investigational. The FDA and AMA (American Medical Association) still consider surgery, radiation and chemotherapy the standard of care for the treatment of breast cancer.

How does ice destroy cells and what is left?
How does the procedure work?

Lethal ice destroys tumors with a combination of effects. Basically, freezing dries out cells and damages them beyond repair. It leaves behind harmless tissue that is absorbed by the body over time; however scar tissue inside the body will remain.

Cryotherapy uses argon gas to create extremely cold temperatures to destroy diseased tissue. Tumors located below the skin surface and deep in the body, I use image-guidance to insert one or more cryoprobes, through the skin to the site of the diseased tissue or tumor and then deliver the argon gas.

Living tissue, healthy or diseased, cannot withstand extremely cold conditions and will die from:

- Ice formation in the fluid outside cells, which results in cellular dehydration.
- Ice formation within the cell. At approximately -40°C (-40°F) or less, intracellular lethal-ice crystals begin to form and will destroy almost any cell.
- Bursting from both swelling caused by ice expansion inside the cell or shrinking caused by water exiting the cell.
- Loss of blood supply. Cells die when their blood supply is choked off by ice forming within small tumor blood vessels, causing clotting. Since the average blood-clotting time is approximately 10 minutes, the extreme cold is maintained for at least 10-15 minutes, if not longer, to assure that lethal-ice temperatures have been reached. Direct observation of the ablation temperature is possible with some apparatuses.

Because cryotherapy consists of a series of steps that lead to cell death, tumors are repeatedly frozen and thawed; typically, two or more freeze-thaw cycles are used depending on the location of the tumor and size of the tumor.

Once the cells are destroyed, the white blood cells of the immune system work to clear out the dead tissue. The tumor will not completely disappear but becomes a dead tumor and/or scar.

Who is a candidate for percutaneous cryoablation?

Almost any adult with an unresectable (non-operable) tumor that requires treatment may be a candidate for percutaneous cryoablation. Because many patients can be treated under conscious sedation, patients who cannot receive general anesthesia may also be excellent candidates for cryoablation. Patients with extensive metastatic disease may or may not be candidates for cryoablation. I will inform you if cryo is appropriate for you.

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How long does the procedure take?

Your physician can best answer that question, but a typical percutaneous cryoablation procedure takes about 1 1/2–2 hours.

How should I prepare?

Nothing to eat or drink after midnight the day before your procedure. Only take medication by mouth which is necessary such as blood pressure or diabetes medication.

No blood thinners 72 hours prior to a procedure.
Patients who are taking certain medications, such as blood thinners, may be required to stop several days prior to the procedure. Diet restrictions prior to the procedure and what to bring with you will vary for each person.

What will happen after the procedure?

A dose of antibiotics is given before cryotherapy as a way to guard against infection. For deeper treatments involving tumors, patients should avoid blood thinning medications for the recommended period of time before the treatment.

You should report to your doctor all medications that you are taking, including herbal supplements, and if you have any allergies, especially to local anesthetic medications, general

anesthesia or to contrast materials containing iodine (sometimes referred to as "dye" or "x-ray dye"). Your physician may advise you to stop taking aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs) or blood thinners for a specified period of time before your procedure.

Image-guided ablation of benign and metastatic tumors involving bone and metastatic soft tissue tumors may be performed with the use of general anesthesia or moderate sedation. The method of anesthesia or type of sedation must be recorded. All patients require hemodynamic monitoring in compliance with national hospital accreditation standards and local institutional standards. When an ablation is performed in the region of an adrenal gland, it is necessary to monitor blood pressure continuously through the use of a radial arterial catheter to recognize and treat a rapid increase in blood pressure resulting from ablation of adrenal tissue. Use of these additional forms of hemodynamic monitoring should be reported.

Women should always inform their physician and x-ray technologist if there is any possibility that they are pregnant. Many imaging tests are not performed during pregnancy so as not to expose the fetus to radiation. If an x-ray is necessary, precautions will be taken to minimize radiation exposure to the baby.

If the procedure is complicated due to the size and location of the tumor a short, overnight hospital stay after cryotherapy of deep tumors may be required. Percutaneous cryotherapy can be performed as an outpatient service, but may require a short, overnight hospital stay. I will determine this after the procedure.

You should plan to have a relative or friend drive you home after your procedure.

You may be asked to wear a gown during the procedure.

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What does the equipment look like?

In this procedure, ultrasound or computed tomography (CT) imaging, a cryoprobe may be used.

Ultrasound scanners consist of a console containing a computer and electronics, a video display screen and a transducer that is used to do the scanning. The transducer is a small hand-held device that resembles a microphone, attached to the scanner by a cord. Some exams may use different transducers (with different capabilities) during a single exam. The transducer sends out high-frequency sound waves (that the human ear cannot hear) into the body and then listens for the returning echoes from the tissues in the body. The principles are similar to sonar used by boats and submarines.

The ultrasound image is immediately visible on a video display screen that looks like a computer or television monitor. The image is created based on the amplitude (loudness), frequency (pitch) and time it takes for the ultrasound signal to return from the area within the patient that is being examined to the transducer (the device placed on the patient's skin to send and receive the returning sound waves), as well as the type of body structure and composition of body tissue through which the sound travels. A small amount of gel is put on the skin to allow the sound waves to travel from the transducer to the examined area within the body and then back again. Ultrasound is an excellent modality for some areas of the body while other areas, especially air-filled lungs, are poorly suited for ultrasound.

The CT scanner is typically a large, box-like machine with a hole, or short tunnel, in the center. You will lie on a narrow examination table that slides into and out of this tunnel. Rotating around you, the x-ray tube and electronic x-ray detectors are located opposite each other in a ring, called a gantry. The computer workstation that processes the imaging information is located in a

separate control room, where the technologist operates the scanner and monitors your examination in direct visual contact and usually with the ability to hear and talk to you with the use of a speaker and microphone.

The traditional MRI unit is a large cylinder-shaped tube surrounded by a circular magnet. You will lie on a moveable examination table that slides into the center of the magnet.

The computer workstation that processes the imaging information is located in a separate room from the scanner.

Cryotherapy to treat tissue located inside the body requires image guidance and a cryotherapy applicator or cryoprobe, a thin wand-like device with a handle or trigger or a series of small needles. The cryoprobe is connected via tubing to a source of nitrogen or argon. Most cryotherapy units use argon gas and are approved by the U.S. Food and Drug Administration (FDA).

The cryotherapy system is generally housed in the procedure room. It has a computer that can be used to control the flow of the cooling agent, which is typically stored in nearby gas tanks.

Other equipment that may be used during the procedure includes an intravenous line (IV), ultrasound machine and devices that monitor your heart beat and blood pressure.

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How is the procedure performed?

Percutaneous image-guided procedures such as cryotherapy are most often performed by a specially trained interventional radiologist in an interventional radiology suite, surgery suite or occasionally in the operating room.

This procedure is often done on an outpatient basis. However, some patients may require admission following the procedure. I will consult with you as to whether or not you will be admitted.

You will be positioned on the examining table.

For tumors deep inside the body that can be approached through the skin, I will perform a percutaneous procedure and insert thin, needle-size applicators or cryoprobes.

You will be connected to monitors that track your heart rate, blood pressure and pulse during the procedure.

A nurse or technologist will insert an intravenous (IV) line into a vein in your hand or arm so that sedative medication can be given intravenously. Moderate sedation may be used. As an alternative, you may receive general or regional anesthesia.

The area where the applicators or cryoprobe are to be inserted will be shaved, sterilized and covered with a sterile drape.

A very small skin incision is made at the site.

Using imaging guidance, I will insert one or more applicators or cryoprobes through the skin to the site of the diseased tissue. Once the applicators or cryoprobe(s) are in place, the argon gas is delivered. Aside from the cryoprobe(s), nothing else enters the body. An "ice ball" is created by a rapid decrease in the temperature at the tip of the probe. This causes all water in the area

around the tip of the probe to freeze. Imaging is used to guide the placement of the applicators, and monitor the freezing process. The "ice ball" can be visualized using ultrasound, CT or MRI.

Some tumors require multiple applicators to freeze completely. For prostate cancer, six to eight applicators are inserted through the perineum (the tissue between the rectum and the scrotum and penis) using ultrasound guidance.

At the end of the procedure, the applicator(s) are removed and pressure will be applied to stop any bleeding. The opening in the skin is covered with a bandage. Typically, no sutures are needed.

Your intravenous line will be removed.

The entire procedure is usually completed within one to three hours.

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What will I experience during and after the procedure?

Devices to monitor your heart rate and blood pressure will be attached to your body.

You will feel a slight pin prick when the needle is inserted into your vein for the intravenous line (IV) and when the local anesthetic is injected. Most of the sensation is at the skin incision site, which is numbed using local anesthetic. You may feel pressure when the catheter is inserted into the vein or artery.

If you receive a general anesthetic, you will be unconscious for the entire procedure, and you will be monitored by an anesthesiologist or nurse anesthetist.

If the procedure is done with sedation, the intravenous (IV) sedative will make you feel relaxed, sleepy and comfortable for the procedure. You may or may not remain awake, depending on how deeply you are sedated.

You may experience discomfort from having to be still during the procedure.

How long is the recovery period?

After your treatment you'll move to the recovery area—either as an outpatient (with discharge the same day) or followed by a (short) hospital stay, depending on your procedure. Your care team will review anticipated recovery and discharge time, restrictions when you go home, possible complications and necessary medications.

While each person is different, most patients recover quickly. Typically, patients may go home the same day. However; if the case is quite complicated or patient has issues with pain control or hydration, they may stay overnight for observation up to 23 hours. Most patients make a full recovery within a week or so. However, as with any medical procedure there are risks, and you should always closely follow your doctor's advice.

Following percutaneous cryotherapy, you should be able to resume your usual activities within one to three days.

You should avoid lifting heavy objects for at least 72 hours. You can resume your usual activities in 3-5 days depending on the location of the tumor.

You may experience a fever up to 102 degrees, nausea, vomiting, pain, elevated white blood cell count, blood in urine or stools, leaking of fluid outside the incision or the fluid may mobilize

to other parts of the body, but will be resorbed by the body over the next two weeks. If you had cryoablation of the lung you could develop a pleural effusion or pneumothorax (collapse of lung), bleeding, infection or abscess. The tumor and beyond the tumor has been frozen therefore the mass will feel larger and hard. It will decrease in size over time but will never disappear as it is now scar tissue.

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Who interprets the results and how do I get them?

I will determine the results of the procedure and will send a report to your referring physician, who will share the results with you.

Frequency of Imaging:

There are no established standards for posttreatment imaging of tumors. Therefore, the decision to image after treatment should be determined on a case-by-case basis.

The necessary frequency of imaging after image-guided ablation is related to the natural history of the underlying primary neoplasm and metastases, which can vary widely as to rates of progression. For patients treated with the goal of local control and disease remission, the patient should undergo either an ultrasound, a contrast-enhanced CT or MR imaging examination approximately 4 weeks after the treatment to document the presence or absence of viable tumor. Depending on the patient's symptoms, it may be appropriate to perform an ultrasound, CT or MR imaging at 3– 6- month intervals after an early scan has been obtained. Positron emission tomography/CT imaging may also be employed if appropriate based on tumor histology and clinical indication. PET CT scan should not be ordered or obtained at least six months after the cryoablation as you may receive a false positive report. The frequency of follow-up imaging remains to be defined from a cost-effectiveness standpoint.

I recommend a follow-up visit after your procedure or treatment is complete in one month. Follow up imaging is to be performed one and three months after the procedure with either ultrasound, CT with contrast and/or MRI with contrast. **No PET CT for at least six months.**

The visit may include a physical check-up, imaging procedure(s) and blood or other lab tests. During your follow-up visit, or telemedicine visit you may discuss any changes or side effects you have experienced since your procedure or treatment.

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What are the benefits vs. risks?

Benefits

- For percutaneous cryotherapy, the patient may stay overnight or be released several hours after the procedure. Overnight stays for pain control are usually not needed.
- Percutaneous cryotherapy is less traumatic than open surgery since only a small incision ¼ cm in size is needed to pass the probe through the skin, which limits damage to healthy tissue. Consequently, percutaneous cryotherapy is less costly and results in fewer side effects than open surgery. A patient usually can resume activities of daily living 24-72 hours after the procedure depending on the location of the tumor, if not sooner. However, caution about heavy lifting may extend for several days after abdominal treatment.

- For treatment of fibroadenomas, cryotherapy causes minimal scar tissue and no apparent post-treatment calcifications.

Risks

- Like any percutaneous procedure, bleeding may result—both from the puncture and the freezing of tissues such as the liver, kidney or lung.
- Damage to normal structures may occur. During liver cryotherapy, the bile ducts may be injured. During kidney cryotherapy, the ureter or collecting system may be damaged. The rectum may be damaged during prostate cryotherapy. Any treatment of the abdomen may result in damage to the bowel and cause a hole in the bowel, which may release bowel contents into the abdomen that can lead to potential life-threatening infection. I take many precautions in preventing this from happening.
- If freezing occurs near the diaphragm, fluid can accumulate in the space around the lungs.
- If the procedure is in or near the lung, the lung may collapse.
- Nerve damage may result. Completely frozen nerves can cause motor weakness or numbness in the area supplied by the nerves.
- Complications related to medications, including anesthesia, administered during the procedure may occur.
- Women should always inform their physician or x-ray technologist if there is any possibility that they are pregnant. *See the Safety page for more information about pregnancy and x-rays.*
- This procedure may involve exposure to x-rays. However, radiation risk is not a major concern when compared to the benefits of the procedure.

Specific possible complications related to the cryotherapy of prostate cancer:

- Permanent impotence since nerves controlling sexual potency are commonly involved in the freezing process. However, nerves can regenerate, resolving the problem in some patients.
- While the patient is under anesthesia, a bladder tube is positioned to drain urine until the swelling of the bladder neck—as a result of the procedure—resolves.
- May cause urethral sloughing; that is, blocking of the urine stream with dead tissue. Sloughing is reduced by keeping the urethra warm with sterile water circulating continuously through a catheter placed in the urethra during the procedure.

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What are the limitations of Cryotherapy?

Cryotherapy is an alternative cancer treatment when surgical removal of a tumor may be difficult or, for some patients, impossible. But its long-term effectiveness is still being examined. Currently, little published data deal with the long-term results of percutaneous cryotherapy but long-term follow-up for prostate cancer suggests cancer-control rates are similar to surgery or radiation therapy.

Cryotherapy is considered a localized therapy. It can only treat disease at a single site. It cannot treat cancer that has spread to other parts of the body. Because physicians treat the tumors they see on radiologic images, microscopic cancer may be missed. Follow up imaging, circulating tumor cells and cancer markers should be performed in 30-90 days to evaluate the

success of the procedure. Sometimes retreatment is necessary due to the aggressiveness of the tumor, if there is lymph node involvement, metastases or hidden cancer stem cells which may no longer be quiescent.

Although its use in the bone, kidney, liver and lung is promising, percutaneous cryotherapy research is ongoing to determine longer term clinical outcomes. The standard of care for the treatment of cancer is surgery, radiation and chemotherapy. Therefore; most insurance companies consider cryoablation investigational or “experimental”. I believe in cryotherapy with immunotherapy. I foresee this form of tumor ablation to be the future of cancer treatment. If you have an aggressive tumor or multiple tumors you may have to return for multiple procedures. I only cryoablate tumors. I cannot see cancer cells therefore I cannot cryoablate cancer cells. I cannot predict how your tumor will respond after any form of cryoablation of your tumor. It is a process. Individuals who are the most successful in interventional oncology treatments are those individuals who come in with an early diagnosis, have a single tumor, less aggressive tumor, willing to work hard and hit the tumor from many different perspectives and finally have a Great attitude and willing to fight this disease.