

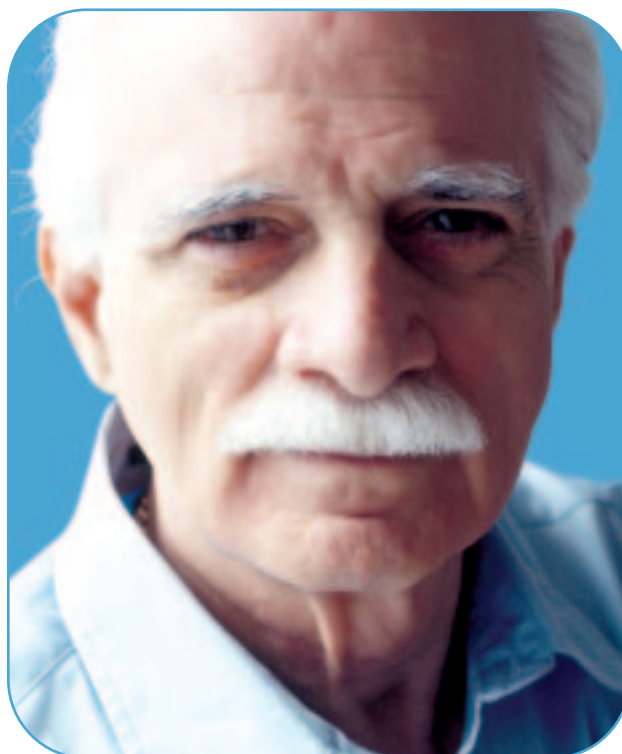
Prostate Cryotherapy Overview

Goals of Minimally Invasive Treatments

- Destroy the local disease
- Shorten hospital stay
- Reduce the number of postoperative morbidities and avoid unnecessary complications
- Shorten the recovery time
- Reduce the cost of the procedure

Cryotherapy Treatment

Cryotherapy (or cryosurgery) eradicates prostate cancer by freezing prostate cells. The doctor inserts needles into the prostate gland through the area between the scrotum and anus. The needles produce very cold temperatures. The latest generation of cryotherapy uses ultra-thin needles to produce iceballs of extreme sub-zero temperatures. The doctor uses ultrasound to guide the insertion of the needles and monitor the freezing process, which destroys the entire prostate including cancerous tissue.



Benefits

Because cryotherapy is minimally invasive, prostate cryotherapy has demonstrated fewer complications than other prostate cancer treatments.

The benefits of the procedure include:

- *Choice of general or regional anesthesia*
- *A fast recovery and lower risk of potential side effects and complications*
- *No radiation or radioactive substances are left in the body*
- *No major surgery, which means that you are back on your feet and back to your life quickly*
- *Cryotherapy is an excellent treatment option when previous treatments have failed*

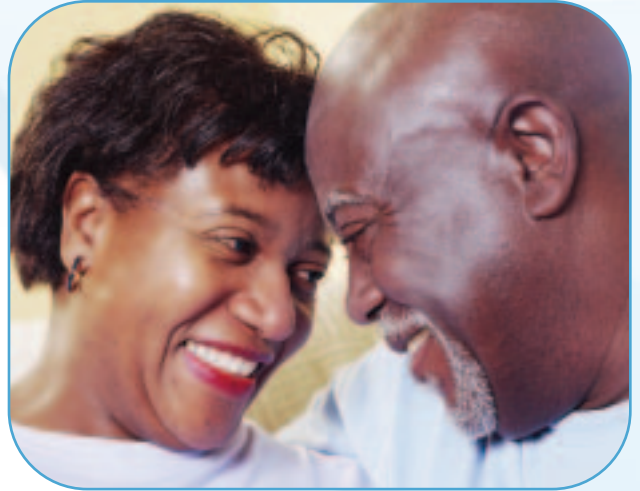
Recovery

Cryotherapy can be performed under regional anesthesia on an outpatient basis, but depending on your circumstances an overnight stay may be required. In most cases, the procedure takes less than two hours. Experience with the cryotherapy procedure shows minimal to no pain, and patients recover quickly. You can be back to your regular life soon after your cryotherapy procedure.

Results & Expectations

5-Year Data

A five-year multi-center study researched 975 patients who underwent cryosurgery as primary treatment from January 1993 to January 1998. The collected data indicated that cryotherapy can be performed with low morbidity and is comparable to the results gained with radiotherapy. Approximately 82% of patients had negative biopsies.



PSA Level	% of Patients
< 0.5	36 – 61%
< 1.0	45 – 76%

7-Year Data

During a study from March 1993 to September 2001, 590 patients were evaluated after receiving cryotherapy with curative intent for localized or locally advanced prostate cancer. Approximately 87% of patients had a negative biopsy.

Patient Risk Groups	Low Risk	Medium Risk	High Risk
PSA < 1.0	87%	79%	71%
Disease-free survival	92%	89%	89%

10-Year Data

In a study from October 1994 to March 2005, doctors reported on 193 patients that had biopsy-proven recurrent prostate cancer following radiation treatment. Of the 193 patients, 156 men showed PSA levels of less than 10 ng/mL. This 10 year experience supports the safety and efficacy of cryotherapy for salvage treatment. The chart that is shown to the right also summarizes outcomes of this study.

A 10-Year study at Allegheny General Hospital followed 963 patients. After 10 years, 70% of patients were disease free and 85% of patients had a negative biopsy.

Condition	Occurrence
Incontinence	6.2%
Increase urinary frequency	18.7%
Retention	1.4%
Scrotal/Penile swelling	2.1%
Rectal discomfort	10.4%
Fistula	0%
Blood transfusion	0%
Deep vein thrombosis	0%

Bahn *et al.*: Targeted Cryoablation of the Prostate: 7-Year Outcomes In The Primary Treatment Of Prostate Cancer. UROLOGY 60 (Suppl 2A): 3-11, 2002.

Cohen, Jeffrey K. Cryosurgery of the Prostate: Techniques and Indications. Reviews in Urology 6 Suppl 4: S20-S26, 2004.

Katz *et al.*: Cryosurgical Ablation of the Prostate (TCAP) for Patients Failing Radiation: 10-Year Experience, American Urologic Association Annual Meeting Presentation, May 2005

Long *et al.*: Five-Year Retrospective, Multi-Institutional Pooled Analysis of Cancer-Related Outcomes after Cryosurgical Ablation of the Prostate. UROLOGY 57: 518-523, 2001.

“How effective is cryotherapy for prostate cancer when compared to conventional surgery?”

Recovery – Comparison Chart (Comparison with Conventional Surgery)

Chance of Morbidity

Cryotherapy

Incontinence: 1 – 7%^{1,2}
 Impotence: 47 – 95%^{3,4,5}
 Rectal Injury: 0 – 0.5%^{1,2}
 (Fistula)

Surgery (Radical Prostatectomy)

Incontinence: 7 – 52%^{6,7}
 Impotence: 14 – 96%^{8,9}
 Rectal Injury: 1 – 19%^{6,10,11}
 (Urgency, Bleeding, Diarrhea)

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 7. Walsh, PC. Radical prostatectomy for localized prostate cancer provides durable cancer control with excellent quality of life: a structured debate. *J Urol* 2000 June; 163(6): 1802-1807.
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Testimonial from Patients

I believe that cryosurgery is very successful. It prolonged my life basically, I was told I would probably be gone in a couple of years and it's now 14 years later and things are fine. I live a normal, active life. There are no side effects from the treatment and we're very optimistic for the future. I've been told I'll die of old age first.

Larry Karl, Patient

As a prostate cancer survivor, I am happy to report the cryotherapy I have gone through, a treatment which has probably saved my life.

Yi Perry Huang, Patient

As an engineer, experienced in low temperature physics (cryo), I was convinced this process was the safest, most controllable and efficacious way of destroying cancerous tissue. I chose cryotherapy.

IW, Engineer and Cryotherapy Patient

My experience so far has greatly surpassed my hopes.

Primary Prostate Cancer Patient, treated with cryotherapy

“As an engineer, experienced in low temperature physics (cryo), I was convinced this process was the safest, most controllable and efficacious way of destroying cancerous tissue. I chose cryotherapy.”

Treatment Characteristics

Procedure Description

The cryotherapy procedure is performed in the operating room, and the patient receives anesthesia. There is no incision; up to 14 needles are inserted into the prostate to freeze the prostate and destroy it entirely. During the procedure, the prostate and needle placement are evaluated with ultrasound imaging. Argon and helium gases circulate through the needles providing the doctor with controllable freezing and thawing capabilities. The temperature within the prostate is lowered to -40°C for several minutes, which kills all prostate cells. The patient usually goes home on the same day of the procedure.



Are You a Candidate?

Choosing a treatment for prostate cancer is not easy. Today's traditional choices include surgery, cryotherapy, radiation and hormone therapy. Each of these may be used alone or in combination. Whether you have first-time or recurrent prostate cancer, there's a good chance you're eligible for cryotherapy — as long as your cancer has not spread beyond the prostate.

Compare the Advantages of Cryotherapy to Radical Prostatectomy and Radiation Therapy

	Treatment	Recovery
Cryotherapy	1-2 hour minimally invasive procedure in which the prostate is frozen but not removed	Single day out-patient procedure or 1 night in hospital, resume normal lifestyle in 2-3 days
Radical Prostatectomy	2-3 hour procedure to remove the prostate	Usually 3 days in hospital followed by a 3-5 week recovery
External Beam or 3-D Conformal Radiation Therapy	5 treatments per week for 6-8 weeks, up to two months of fatigue after full course of treatment	Side effects can occur, such as rectal discomfort and fatigue. Daily activities can be performed throughout the duration of treatment.
Interstitial Radiation (Brachytherapy)	Permanent implantation of 80-100 radioactive pellets into the prostate	Single day out-patient procedure. Normal lifestyle gained in 2-3 days; up to 3 months of residual pain and/or rectal discomfort

“What is it about the cryotherapy procedure that allows it to be considered minimally invasive?””

Cryotherapy places small needles into the prostate and freezes the entire gland. This procedure is minimally invasive in that it does not require an incision, and minimal bleeding occurs. The procedure is performed and monitored under ultrasound, and small temperature devices are placed in and around the prostate gland to monitor the temperature.

Doctor Testimonials

Cryotherapy offers patients a short recovery with proven results. My patients have been very pleased with their experiences.

Neal Shore, M.D., Grand Strand Urology, Myrtle Beach, SC

Cryotherapy, a minimally invasive treatment, allows us to treat prostate cancer without the added risks of surgery.

Richard Harris, M.D., Midwest Urology Associates, Melrose Park, IL

Cryotherapy should be considered a primary treatment and salvage therapy for prostate cancers. It is associated with the least amount of voiding symptomatology in the properly selected patients (i.e. patients with small prostates or patients without a history of a TURP).

James Bennett, M.D., Midtown Urology, Atlanta, GA

Presice™ technology has enabled us to better monitor the prostate cryoablation procedure, and we have been positively surprised with the minimal side effects. The pain and swelling that we used to see with the older technology is rarely seen today.

Arie Beldegrun, M.D., David Geffen School of Medicine at UCLA, Los Angeles, CA

There has been a clear expansion in the number of patients that have been treated with cryosurgery over the past few years - and the reason for that is simple. More publications are coming out. More patient groups are talking about cryosurgery. More patients are going out and telling other patients. Cryosurgery is the best kept secret in urology. My patients that are treated with cryosurgery are some of the happiest patients that I have ever treated. And, having done cryosurgery over the past ten years, I am convinced that cryosurgery clearly has a role in the management of prostate cancer patients.

Aaron E. Katz, M.D., Columbia-Presbyterian Medical Center, New York, NY

Cryotherapy has one of the highest patient satisfaction rates of any prostate cancer treatment.

Thomas Polascik, M.D., Duke University Medical Center, Durham, NC

17-gauge needle technology and cryosurgery allows patients and their physician options they didn't have before. It's one more tool to treat prostate cancer for those patients who need it, they now have something available to them that will allow destruction of the prostate and the tumor in a way that couldn't be accomplished before.

Jeffrey Cohen, M.D., Allegheny General Hospital, Pittsburgh, PA

Administering state of the art cryoablation has been extremely successful allowing definitive, outpatient treatment with the least toxicity to surrounding tissues. Using the SeedNet technique, Urologists easily acquire consistent, reproducible results with the highest patient satisfaction scores of all prostate cancer interventions.

Ned B. Stein, M.D. F.A.C.S., Memorial Hermann Southwest Hospital, Houston, TX

Using cryotherapy as an alternative treatment for prostate cancer allows our patients to return to their normal lifestyle in 7 to 10 days. Cryotherapy is a minimally invasive extremely effective outpatient alternative treatment for prostate cancer.

Robert Edelman, MD, Urological Surgeons of Long Island, Garden City, NY

The Recovery Experience

Post Procedural Lifestyle Issues

Some post procedural lifestyle issues that may be of concern are physical well-being, social well-being, emotional well-being and functional well-being. Cryotherapy patients report higher levels of satisfaction in each of these areas when compared to radical prostatectomy. Please see the Recovery Comparison Chart– Quality of Life score.

Support

A diagnosis of prostate cancer can trigger many emotions: fear, uncertainty, anger, anxiety and depression. However, hundreds of thousands of men have lived this same experience. To help ease the way for others, many have shared their experiences in coping with prostate cancer.

Here is a summary of what they have to say:

- Knowledge is power. Thoroughly educate yourself about the disease and treatment options.
- Be receptive to emotional support from family and friends.
- Your disease is also your partner's problem. Your partner should be part of your doctor visits and involved in your treatment decisions.
- Remember that prostate cancer is not the end of your masculinity.
- Seek out support groups.
- Be honest with yourself and your physician.
- Become an advocate for your personal health care.
- Don't be afraid to ask for professional emotional help.
- Don't stop learning about the disease. Prostate cancer diagnosis and treatment options are continually changing as new advances and discoveries are made. Continue to seek new information and keep abreast of recent findings and studies that may be beneficial.
- Ask your physician about 17-gauge needle cryotherapy for treatment of your prostate cancer.

“ I am eighty-four years old, and had a quadruple bypass three years ago, and I feel as if I was fifty.”



“Can cryotherapy help me eliminate some of the lifestyle problems that I’ve heard of occur with conventional surgery?”

Recovery – Comparison Chart (Comparison with Conventional Surgery)

Quality of Life Score – After Treatment (Max Score of 30)

Cryotherapy		Surgery (Radical Prostatectomy)	
Physical well-being:	26.1	Physical well-being:	25.4
Social/family well-being:	21.9	Social/family well-being:	21.6
Emotional well-being:	18.1	Emotional well-being:	16.6
Functional well-being:	24.6	Functional well-being:	20.9

Robinson *et al.*, *Urology* 2002, 60(2)Suppl 1:12-18.

Incrocci *et al.*, *Int. J. Radit Oncol. Biol. Phys.* 2002, 52(3):681-693.

Testimonials from Patients

I am eighty-four years old, and had a quadruple bypass three years ago, and I feel as if I was fifty.
Primary Prostate Cancer Patient, treated with cryotherapy

Two weeks after the SeedNet cryotherapy, I was on a vigorous hike in the Galapagos Islands, and, now at home, I am energetic, continent and enjoying life.

Geoff Edwards, Patient

Don't despair and don't think it's the end of the world because there are treatments available. Do your research. Do your homework. Become your own advocate. And I think an informed consumer is the best patient for prostate treatment. I don't think I take life for granted so much anymore.

Bill Perlmutter, Patient

There was just a little swelling and no pain. I was very comfortable. I just went on about my business. I did exactly what the doctor told me to do, just take it easy, but I was able to do anything I needed to do. I had no problem — I could go out if I wanted to.

George Barry, Patient

[My physician] discussed various types of treatment; he said that he thought cryosurgery was new but he thought that probably it was the best.

Father William Lydecker, Patient

I was disturbed that the cancer came back, but I was really fortunate to learn about the SeedNet procedure. The other alternative was invasive surgery and [cryotherapy] was a one-day procedure. I am now symptom-free and cancer-free.

Burt Klein, Patient with recurrent prostate cancer

The doctor explained the various options to me and it pretty much came down to, from my point of view, either prostatectomy, the full-scale surgical operation, or cryotherapy using the SeedNet machine. The advantage to me of the cryo was the amount of time that it would take out of my schedule for recovery.

G. Gordon Behn, Patient

Summary

Your Benefits

Because cryotherapy is minimally invasive, prostate cancer cryotherapy may have fewer complications than surgery.

The benefits of the procedure include:

- Choice of general or regional anesthesia
- A fast recovery and lower risk of potential side effects
- No radiation or radioactive substances that are left in the body
- No major surgery, which means that you are back on your feet and back to your life quickly
- Cryotherapy can also act as a salvage treatment for previous treatment failure

Your Experience

Since each person's experience is different, we encourage you to learn more about your treatment options. Thoroughly educate yourself about the disease and treatment options. Talk with your physician. Knowledge is power. It can help you understand the disease, how it affects you, how to decide on the best treatment, and what to expect as your treatment progresses. Initially, a diagnosis may leave you feeling powerless and at the mercy of the disease; however, the more you know about prostate cancer, the more you can take control of it and your future.

Share your experience with others. Seek out support groups. There are many prostate cancer support groups for both patients and partners. Check with health care providers and community organizations for groups in your area. The Internet can be used for finding information and emotional support. Prostate cancer does not make you an outcast; it qualifies you to join a unique group of people who draw strength from one another.

Your Expectations

Surviving prostate cancer means getting the right prostate cancer treatment at the right time. Prostate cancer treatment ranges from minimally invasive treatments, such as cryotherapy, to major surgery. The best prostate cancer treatment depends upon your age, general health, stage of your prostate cancer, cancer location and your personal decision. The more you know about prostate cancer treatment options, the better prepared you will be to choose the best prostate cancer treatment with the help of your doctor. Talk to your doctor today to find out if cryotherapy is a good option for you.

The more you know about prostate cancer treatment options, the better prepared you will be to choose the best prostate cancer treatment with the help of your doctor.