

Prostate and Renal Cryoablation
CASE STUDY REVIEW

Briefing Series, Number 1

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**Curative Treatment Option
For Localized Recurrent Prostate Cancer
Following Radiation**

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International Society of Cryosurgery



Dear Reader,

The International Society of Cryosurgery is pleased to publish peer-reviewed case studies in urologic applications of cryosurgery.

Dr. John Foley presents a classic salvage prostate cryotherapy case. An element that distinguishes this case is the smooth recovery of the 74-year old patient, whose only complaint was waiting for clearance to resume driving his pick-up truck.

Dr. Foley received his medical degree at the Uniformed Services University of the Health Sciences (Bethesda, MD) and completed his Urology Residency at Walter Reed Army Medical Center. He became a staff urologist at a community level hospital in Fort Campbell, KY, with the 101st Airborne Division. He transferred to Brooke Army Medical Center (Fort Sam Houston, San Antonio, TX) in 1995 where he served as Chief, EndoUrology and Assistant Chief, Urology Service until his retirement from active service in 2005. He is now with Eastern Shore Urology Associates, a community practice in Easton, MD.

We are grateful to Dr. Foley for providing the clinical case, related images and discussion. We extend a special thank-you to Mr. Theodore Cephas for permitting publication of his story. We believe that adding the patient's perspective enriches these case reviews.

We acknowledge Endocare, Inc. (Irvine, CA, USA) for sponsorship of our series of cryoablation case studies.

Whether you are an experienced cryosurgeon, or a relative newcomer, I hope you find this case review to be of interest in the possibilities of salvage prostate cryoablation.

Sincerely,

Franco Lugnani, M.D.

President, International Society of Cryosurgery



ISC Overview

The International Society of Cryosurgery was founded in 1974 to promote continuing medical education in the field of cryosurgery from an experimental and clinical point of view. The overall aim of the ISC is to continue to develop and expand membership of the society.

The headquarters of the Society are based in Casa di Cura Salus, Trieste, Italy. The Society corresponds with around 700 members worldwide. Membership is open to anyone who has a professional interest in research and education in the fields of Cryosurgery, Cryobiology, Cryopreservation, and other disciplines related to the use of low temperature in medicine.

ISC Activities: To learn more please visit our website

<http://www.societyofcryosurgery.org/futuremeetings2.htm>

ISC Publication:

The Society produces a biannual publication 'Cryosurgery'

<http://www.societyofcryosurgery.org/Publications.htm>

which covers all aspects of Cryosurgery and Cryobiology.

ISC Officers and Board of Directors:

Please visit our website for a complete listing:

<http://www.societyofcryosurgery.org/Officers.htm>

The case study presented here reflects the outcomes for a single physician and patient. Outcomes for other physicians and patients may vary so choice of treatment is best determined between a physician and patient where the risks can be evaluated specific to the individual patient. Cryoablation of the prostate, like all prostate procedures, involves certain risks including risk of incontinence, impotence and rectal injury. Physicians and patients interested in cryoablation as a treatment for prostate cancer should familiarize themselves with the risks and long term outcomes as documented in recent published clinical data. For a bibliography of cryoablation published data please contact the International Society of Cryosurgery.

The Case Study Review is made possible by a grant from Endocare, Inc.



PATIENT EXPERIENCE

Mr. Theodore Cephas: My Cryotherapy

I'm 75 years old, and my wife is 74. We have two children and eight grandchildren. I used to work as a waterman, catching oysters and other shellfish. Now I'm a farmhand. I consider myself semi-retired, but I'm still actively working.

Before I was finally diagnosed with prostate cancer in 1998, I had three biopsies but none of them found cancer. At one time, my PSA was up to 14. Then the last biopsy, in 1998, was positive. I was kind of upset for a while, but after treatment I stopped worrying.

I had 39 radiation treatments. I don't recall any real side effects, but one or two times it seemed like my stomach was upset. Since I went every day about 8:00 a.m. for 15 minutes per treatment, I never lost time from work.

At first, my PSA went down to 4, where it stayed for a while, then went down even further. However, it finally started going back up. They put me on hor-

mones, and I had hot flashes. A few years later the doctor told me the cancer had come back, that we hadn't gotten it all. I didn't feel too good about that. I asked him how long before it might spread. He said, "It's moving slowly." He told me one or two things I could do, to try this or that. I just wondered how I was going to make it.

Then he told me about the freeze, and I said, "Well, how soon could I get it?" He sent me to Dr. Foley. When I asked him if he could do the cryo, he said, "I'm the man." The day of the procedure I came in around 10:00 a.m. By the time I knew anything afterward, I was in the recovery room and Dr. Foley had done it. I stayed overnight, and my wife took me home the next day.

I took some pills for pain—I don't recall what—but I didn't take them for long. I went out every night to feed my dogs. I wasn't allowed to drive for a couple of weeks, which was

worse than the operation. The first time I came in to have the catheter removed, he didn't do it, because things weren't working right. But when I came back, everything was good so they could remove it. The person who did it said I still couldn't drive. I asked, "Why not?" So they got Dr. Foley, and he cleared me. As soon as I got home, I got in my pick-up truck.

My last PSA was down to zero. I haven't had hormones since my cryo. As for radiation, I have talked with some others who had it, and it's not working for them like cryo worked for me. I have a friend in Baltimore who had beam radiation. His cancer came back and went to the bone. Now he's on chemotherapy.

Dr. Foley told me that the cryo cleaned everything up, and that I don't have aftereffects of radiation. My wife and I would recommend cryo to other patients.

The ideas and opinions expressed herein are strictly those of the interviewee.

INTRODUCTION

Salvage Cryotherapy

As many as 30-40% of men who undergo primary radiotherapy for prostate cancer may experience recurrence. Salvage cryotherapy is gaining momentum as a potentially curative treatment option for localized radiation-recurrent prostate cancer. With appropriate patient selection, salvage cryo offers excellent cancer control coupled with a lower morbidity profile than salvage radical prostatectomy. Salvage cryotherapy may also offer economic advantages within the healthcare system.

What published statistics don't reveal is the personal and professional experience of the individual urologist who makes day-to-day decisions with patients. Dr. John Foley's case study illustrates not only the apparent ease and success of Mr. Theodore Cephas' treatment; it also reflects his observations about key differences between cryotherapy and radiation in general. Dr. Foley says, "With cryo, I know I'm going to get the same effect—low, medium or high grade—assuming I can cover everything with lethal ice. I just like the consistency of cryo." In reviewing Mr. Cephas' history of fluctuating and rising PSA after his primary beam radiotherapy, Dr. Foley remarks, "When PSA values fluctuate over time they can produce anxiety and confusion on the natural history of the disease for the patient and the clinician."

The case study of Mr. Cephas' salvage cryotherapy integrates Dr. Foley's views, the description of Mr. Cephas' procedure, and a fine example of the growing recognition of salvage cryotherapy as an important modality post radiation failure.

Finally, the case study offers a unique perspective of salvage cryo, from Dr. Foley's beginning at Brooke Army Medical Center to his first exposure to cryo with Drs. Lee and Bahn, right through to his cryo training with Dr. Vestal, as well as his father's personal experience with salvage cryo in 2003.

American Cancer Society, "Recurrent Prostate Cancer: Cryosurgery Offers 'Curative' Treatment," (6/21/2002) [HYPERLINK "http://www.cancer.org" www.cancer.org](http://www.cancer.org)

Aaron Katz, M.D. 6-year study of 67 patients announced at the annual meeting of the American Urological Association (San Francisco:2004).

De la Taille & Katz. "Cryosurgery: Is It An Effective Option For Patients Failing Radiation?" Current Opinion in Urology (10:5) Sep. 2000.

CASE STUDY

Mr. Theodore Cephas

Mr. Cephas (DOB 1931) presented with radiation recurrent prostate cancer, diagnosed by a partner at Eastern Shore Urology Associates and referred to Dr. Foley for possible salvage cryotherapy.

Medical History

Mr. Cephas, age 74, is in good health. He works full time as a farm hand. He takes no medication; is on vitamin supplements. No history of cardiac issues, diabetes, etc.

Urologic History

10/1998 - Diagnosed with adenocarcinoma of the prostate, PSA 16, Gleason 3+3, Stage T1C. The original pathology report is unavailable, so tumor location is unknown.

12/1998 - Patient completes a course of external beam radiation. During the following 30 months, patient's PSA dropped, hovering near 3.7, and achieving nadir of 2.8.

4/2001 - PSA 3.7; rising PSA indicates biochemical failure

8/2001 - PSA 5.1

9/2001 - First hormone ablation administered; PSA responds, drops to nadir of 1.4

2002-05 - PSA rises from 1.4 to 4.78 over three years

12/05 - Bone scan negative

1/06 - CT scan (abdomen) negative

1/30/06 - Patient first seen by Dr. Foley. Denies lower urinary tract symptoms, has good force of stream and empties to completion (flow test), nocturia x1

PSA 3.2; PAP 0.2

Pre-cryo gland size: 20g, 36 mm (sagittal)

2/10/06 - Biopsy performed. Right base negative, mid 4+4, apex 4+3. Left side negative.

Treatment Considerations

Patient was offered hormonal therapy with the addition of anti-androgen medicine; and/or oncology consultation; pelvic lymph node dissection; salvage cryotherapy, with all of the standard risks and benefits discussed. He said no to all except the cryo, with the understanding that it might not cure him.

Treatment

Nov. 2005 - Patient received final Eligard injection (6 mos., 45 mg)

March 20, 2006 - Salvage cryotherapy performed by Dr. Foley

Intraoperative U/S reveals gland volume at 20g.

Double freeze/thaw with 6 probes, no pullback

Freeze Duration Times

Cycle 1: Probe 1 (DEN), 7:38

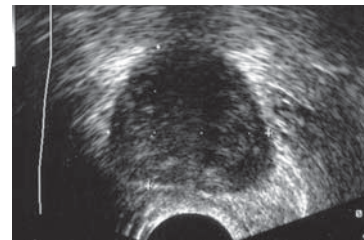
Probe 2 (RNVB), 7:37

Probe 3 (ANT), 6:14

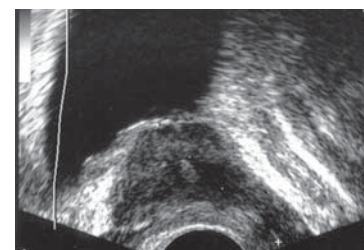
Probe 4 (LNVB), 5:51

Probe 5 (APEX), 3:33

Probe 6 (ES), 7:39



TRANSVERSE VIEW TAKEN AT THE SAME TIME.



SAGITTAL VIEW OF PROSTATE DURING PRE-TX BIOPSY ULTRASOUND

Temperatures: DNV -40, RNVB -33, LNVB -50, apex -68

Cycle 2: Probe 1, 7:35

Probe 2, 7:36

Probe 3, 6:43

Probe 4, 6:34

Probe 5, 3:59

Probe 6, 3:59

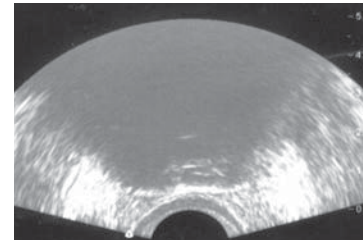
Temperatures: DNV -65, RNVB -41, LNVB -57, Apex -92

Results and Follow-up

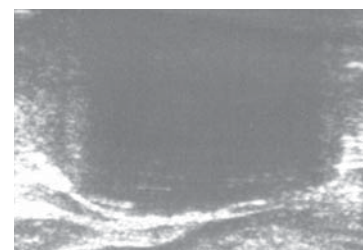
5/6/06 - At six weeks post-tx, patient had no voiding complaints. Daytime frequency every 2-3 hours, no incontinence, nocturia x1; no bowel problems, no pain, no numbness.

7/17/06 - PSA < 0.03, testosterone 168, (low value reflects aftereffects of Eligard, but recovering and not hypogonadal). Patient reports no side effects and is back at work.

3/1/07 - PSA < 0.03, AUA score 2/35, Bother index 1/6, No SUI. No sexual function (Patient declines treatment)



TRANSVERSE ULTRASOUND IMAGE NEAR COMPLETION OF SALVAGE CRYO FREEZE CYCLE



SAGITTAL ULTRASOUND IMAGE NEAR COMPLETION OF SALVAGE CRYO FREEZE CYCLE

PHYSICIAN DIALOGUE

Interview with John Foley, M.D., Eastern Shore Urology Associates

How did your early years in the military affect your medical practice?

When I came to Brooke Army Medical Center (Fort Sam Houston, San Antonio, TX) in 1995, I didn't have a strong bias for surgery or radiation. In the military, you're not paid for doing one thing over another, so you look at what's best for the patient. I try to keep an open mind, and always try to counsel patients on all of their options.

When did prostate cryotherapy get your attention?

I had been in San Antonio for three years when we got a new Hitachi ultrasound unit. I was interested in prostate ultrasound, and especially wanted more training in the color Doppler feature. Hitachi recommended going to Michigan to train with radiologists Duke Bahn, M.D. and Fred Lee, M.D. who were using the same machine.

Duke Bahn had six patients for ultrasound and biopsies. One was a brachytherapy patient who was in for a post-brachy biopsy. When Duke turned the color on, there was a fair amount of activity. The next patient was 12-months post-cryo. His chart showed a PSA of

0.1, and a symptom score of 3/35. With the color on, there was no flow. I started asking questions [about the efficacy of cryo].

How soon after did you begin performing cryo?

I took the cryo training course with Dr. Clif Vestal (UANT Dallas TX) less than two years later. But it took me a while to start doing cryo due to the Army's equipment acquisition. It took about 18 months. By the time I started performing cryo procedures, it was already 2002.

What influenced your positivism about cryo?

At Brooke Army Medical Center, we had a lot of prostate cancer patients because many retirees move to San Antonio. Over time I had patients with significant post-radiation complications, so I started getting a bad taste in my mouth for radiation. It wasn't just the side effect problem that was discouraging, but the management of these difficult-to-treat post-radiation complications was frustrating because I had not participated in the initial treatment.

What did you find as your experience grew?

As I developed my use of cryo, I

just liked the results better. I don't have to worry that if the patient is high-grade he may not respond as well to radiation, because I know I'm going to get the same effect—low, medium or high grade—assuming I can cover everything with lethal ice. I like the consistency of cryo. I just saw a patient at 2.5 months post-cryo. He was a 4 + 4, PSA of 5.9, and his PSA is now undetectable. With radiation, you may have to wait 24 months and you wonder, "When is it going to hit the nadir?"

You mentioned that your dad had salvage cryo. Who performed the procedure?

Dr. Clif Vestal did the procedure in 2003. It was about a week before I went to Kuwait. My dad had had a combination of seeds, beam and hormones. Despite the combination therapy, I think he was undertreated, but back then Radiology was not using doses as high as today. The good news is that the Salvage Cryo went well and my dad is doing fine.

The ideas and opinions expressed herein are strictly those of the interviewee.