Prostate Cancer Support Association of New Mexico

LIFELINE

Supporting those with prostate cancer and their families since 1991

Quarterly Newsletter
January 2024
Volume 31, Issue 1

Issue Highlights

Visit our website:
www.pcsanm.org

Email us:
pchelp@pcsanm.org

Support Group Meetings

Meetings are held at Bear Canyon Senior Center, 4645 Pitt St. NE in Albuquerque, from 12:30 p.m. to 2:45 p.m. on the first and third Saturday of most months. Many meetings may also be accessed virtually.

Meeting topics and login information may be found at:

https://www.pcsanm.org/meetings/

Please call 505-254-7784 or email pchelp@pcsanm.org with questions.

Never Thought This Would Happen to Me

By Jonathan Brown, PCSANM Member

After I was diagnosed with prostate cancer, I was at a loss as to how to deal with this crisis. I began by telling several friends and family of my diagnosis only to hear the familiar reply, "Oh, it's nothing to get excited about because nobody ever dies from '*That Cancer.'* Just don't worry about it; it's not like it can kill you." This, as you might expect, did nothing to help me cope with my "new future friend." I have come to realize that people really don't understand what I am experiencing. Probably because they have not been through it.

Shortly after discussing options with my urologist, I started to research prostate cancer treatment options on the internet. I found copious articles related to this disease and plenty of statistics. Instead of finding comfort in all these numbers and facts, they magnified my fears and anxiety. Kind of scary stuff. Along the way, fortunately, I discovered the Prostate Cancer Support Association of New Mexico, in Albuquerque. I called and spoke with them regarding my current situation and was relieved to find that I was not alone in my fight. They invited me to attend a support group meeting. These sessions continue to be provided to our community on the first and third Saturdays every month.

Inside the facility where the sharing session takes place, I was warmly greeted by three different board members and was asked what they could offer to me to help me better understand this disease. As I learned, there are many men with prostate cancer. I also learned that I was not alone in this fight after all. I had the good fortune to land in a good place with caring people who have plenty of experience and willingness to help me begin my journey forward. My "new future friends," as I call them. I was surprised at the openness of the participants and have come to appreciate their candid humor. At one encounter, I was afforded unlimited time on the telephone with several board members who answered all of my questions thoroughly. This has allowed me to relax a little and try to take it "one day at a time," allowing me to look hopefully towards my future.

My experiences with this group have helped to prepare me for my upcoming cancer treatments in ways that I could not have received from anyone else. I am thankful to all that have helped me to realize that I am truly not alone with my prostate cancer, as I had once believed.

PLEASE SUPPORT PCSANM!
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In Memory

With deep sympathy and regret, we list these names:

Thomas Fitch

Christian Hartwigsen

Jan Marfyak

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Prostate Cancer Foundation: November 17, 2023

FDA Approves Enzalutamide for Recurrent Prostate Cancer at High Risk of Metastasis

Patients who have been treated for localized prostate cancer and are now seeing their PSA rise rapidly are at high risk of metastasis and of death from prostate cancer. Now, patients and their doctors have a new treatment option that decreases these risks.

The FDA has approved enzalutamide alone OR in combination with hormone therapy (such as leuprolide) for patients with *high-risk biochemical recurrence*. This approval is based on the results of a large randomized clinical trial called EMBARK.

Who is eligible for this treatment?

Eligible patients have been treated for localized prostate cancer (usually with surgery or radiation therapy) and are now experiencing high-risk biochemical recurrence. In general, this means patients with a rapidly rising PSA and no metastases seen on imaging scans. Additionally, patients are not being treated with hormone therapy. Patients with a PSA doubling time of 9 months or less are at high risk of metastasis and death from prostate cancer.

What is the treatment?

Enzalutamide is a newer form of treatment for prostate cancer called an androgen receptor pathway inhibitor. It is an oral pill taken daily. It was already approved and in use to treat advanced prostate cancer. Under this approval, patients can take enzalutamide alone OR with standard hormone therapy such as leuprolide.

What benefit was shown in the clinical trial?

The EMBARK trial made two separate comparisons:

- Enzalutamide + leuprolide vs leuprolide alone
- Enzalutamide alone vs leuprolide alone

Both enzalutamide treatment regimens were superior to leuprolide alone.

The trial evaluated "metastasis-free survival," meaning the number of patients in each treatment group who remained alive and free from metastases. After 5 years of follow-up, 87% of patients treated with enzalutamide + leuprolide had no metastases, compared with 80% of patients treated with enzalutamide alone and 71% of patients treated with leuprolide alone.

Renal & Urology News: December 13, 2023

Same-Day Prostate Cancer Surgery Associated with Satisfaction, Lower Cost

Natasha Persaud

Same-day robotic-assisted radical prostatectomy (RARP) lowers costs without compromising patient satisfaction or increasing complications, investigators report.

Among 392 men undergoing RARP at 2 academic centers, 206 patients were discharged on the same day and 186 were admitted.

In a propensity-score analysis, the likelihood of complications was similar for the same-day discharge vs inpatient group. Body mass index was the only significant predictor of complications. Patient ratings of pain in the hospital and at home as well as side effects from pain medication did not differ. Satisfaction ratings on the validated Patient Satisfaction Outcome Questionnaire administered at 30 days after RARP also did not differ between groups, Jim Hu, MD, MPH, of New York Presbyterian Hospital-Weill Cornell Medicine in New York, New York, and colleagues reported in *The Journal of Urology.*

On average, RARP cost $7777 for the same-day discharge group and $8915 for inpatients. Overnight admission alone cost $963. Same-day discharge RARP saved $2106 or 19% in total direct health care costs compared with inpatient RARP, the investigators reported.

"These findings confirm studies highlighting comparable safety and outcomes of SDD RARP, but our study is the first to also compare patient satisfaction using a validated instrument as well as health care costs, using the most accurate methodology," Dr Hu's team wrote.

In an accompanying editorial, Dejan K. Filipas, MD, and colleagues from Brigham and Women's Hospital in Boston, Massachusetts, acknowledged the current "misalignment" of economic incentives. "While hospitals stand to make significant cost savings, these benefits do not trickle down to the medical teams," they wrote.

In a separate commentary, Daniel Oberlin, MD, of Golden Gate Urology in Berkeley, California, wrote, "By allowing patients to recover in the comfort of their homes, health care systems can achieve substantial cost savings without compromising patient outcomes. In an era where health care costs are skyrocketing, such findings are invaluable. Finally, patients who went home the same day reported equal satisfaction levels compared to those who stayed overnight."

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Urology Times: December 13, 2023

First Physicians to Implant BioProtect Balloon in US Describe Benefits of the Spacer

Hannah Clarke

In this interview, **Shawn Zimberg, MD**, and **Dean Laganosky, MD**, discuss the BioProtect Balloon Transplant System, a rectal spacer that received FDA clearance in August 2023 for use during prostate cancer radiation.[1] Zimberg–a radiation oncologist and medical director at Advanced Radiation Centers (ARC) of New York, a division of Integrated Medical Professionals (IMP) –performed the first procedures in the US in October 2023. Laganosky–a urologist with MidLantic Urology (MLU)– performed his first procedures in November 2023, becoming the first to do so in Pennsylvania. Both IMP and MLU are affiliates of Solaris Health.

Could you explain how the BioProtect Balloon Implant System fits into the prostate cancer radiation paradigm?

Laganosky: The BioProtect rectal spacing device is a new next-generation rectal spacing option for patients undergoing prostate cancer radiation therapy. It's geared at helping to provide and improve quality of life and protection when you get radiation therapy, to keep that radiation focus to just the prostate gland and not spread unintentionally to the other structures such as the rectum. This device is a balloon that is applied underneath the prostate gland to lift up the prostate and shield the rectum posteriorly. It [uses] far less material than current gel options that are on the market and can provide an enhanced amount of space to provide that additional protection as well.

Zimberg: Historically, certainly in the last number of years, there's been only one, and then more recently, a second gel, that is used to produce that space. Those gels do provide a space, but they do tend to be asymmetric, and they can only provide a certain amount of space because they don't have the tensile strength to separate those two in the same way as this balloon. The BioProtect balloon solves those problems. Because it's a balloon, it's perfectly symmetrical always, and the amount of space that can be created is much more than with the gel. In some cases, it’s double the amount of space, so that allows us to get a much better decrease in rectal radiation exposure.

You both were among the first to perform procedures with the BioProtect Balloon in the US. Could you highlight your clinical experience with the spacer so far?

Laganosky: From a clinical standpoint, our group and myself were the first urologists in the country to place the BioProtect Balloon in early November. It's been nothing but a positive experience and a relatively straightforward outpatient procedural option, similar to the gels that we've placed for many of these patients for years now. This takes about 10 to 15 minutes; it's a small incision on the surface of the skin underneath the scrotum, typically done under local anesthesia. Patients are driving themselves there and typically driving themselves home, and are very comfortable returning to activity right after the procedure.

Zimberg: I have been using spacers for quite some time. I was one of the principal investigators of the SpaceOAR trial, which is the original gel product. I was also one of the principal investigators of the BioProtect Balloon [trial]. I was lucky enough to be the first in the country to place this balloon in one of our prostate cancer patients. Over the past three or four weeks, we've done almost 50 cases, more than I think anyone in the country, both for external beam radiation protection of the rectum, as well as for brachytherapy seed implants. Patients have done tremendously well.

Before a patient gets radiation, they go through a planning process that we call a simulation. It's almost like an architect making a blueprint, because everyone's body is a little bit different. When we have that symmetrical balloon vs an asymmetrical gel, for example, the symmetry and being able to plan the radiation so that it appropriately gets to the prostate and avoids the rectum and other tissues is much better. The physicians, dosimetrists, physicists, and radiation therapists who are giving the patient treatment every day all find this to be a much better product.

Could you expand on how urologists decreased radiation exposure prior to BioProtect?

Laganosky: [Before] this, SpaceOAR was the premier initial gel option for rectal spacing. It was a new and novel therapy that provided protection that no other product gave to [patients undergoing] radiation. When you look at the side-by-side clinical data for individuals who get a rectal spacing option vs those that don't, the ones that do have much better quality of life, reduced rectal and GI toxicity, and also less urinary symptoms and sexual adverse effects from the radiation therapy. SpaceOAR came around in 2018 and has a CT compatible gel version as well, that we use for many of our patients. It is our standard of care to provide a gel with every patient. Other options exist on the market, such as Barrigel, but these are hydrogels that are placed into a space behind the rectum. Where BioProtect comes in is it's an enhanced, newer form of this that [it], is less material; it is dissolved reliably at about three to six months. It's broken down into water and urinated out by the body, similar to the gels. Where this comes into play though is it can provide an additional amount of space and an enhanced amount of protecting or shielding in the

Urology Times: December 13, 2023

First Physicians to Implant BioProtect Balloon in US Describe Benefits of the Spacer

Hannah Clarke

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appropriately selected patient. Although we still do still offer gels and do a tailored evaluation of each patient for rectal spacing for our radiation therapy program, those who can get BioProtect Balloon would likely benefit from the enhanced amount of space and protection.

Could you go more in-depth with the data on this spacer?

Laganosky: This has been studied in multiple institutional trials. Dr. Zimberg has also been a part of many of these trials as well and he was the first provider in the country to place the rectal spacing balloon. What we find is the average amount of space is about 1.7 cm of space, whereas most gel options can give you 1.3 cm of space, but maybe in a less reliable fashion. This is a reproducible, easily applied device that can give you consistent results throughout most patients who will be candidates for this.

Zimberg: The BioProtect Balloon trial (NCT03400150) was a randomized FDA pivotal trial that mirrored the older SpaceOAR trial (NCT01538628) conducted years ago. It was a 2:1 randomization that looked at the amount of space that could be created, looked at the safety profile of placing the balloon, and looked at some of the dosimetric constraints. In other words, how much could we spare the rectum? When we look at the metrics that we [use] when we create a radiation plan, could we reduce the dose to the rectum? In fact, the results of the trial showed that in every single one of the metrics that we look at, the balloon was far superior in reducing the amount of radiation that the rectum is exposed to, both in its own trial, and we recently published a study looking at the dosimetry compared with the gel in the SpaceOAR trial.[2] That makes sense, because it is better space; you're creating more distance between the rectum and the prostate. It would make sense that you're going to get less radiation exposure.

Some of the other things that were found is that the balloon keeps its shape. At three months, when you look at the shape of the balloon, it hasn't lost any space, less than 4%. When you compare that same three-month volume decrease, or space decrease, in the two gels, it's a far [better] decrease. So, the gels are resorbing, or they're changing shape, or something like that. The balloon holds its shape. Then when you go to six months, the balloon has fully disappeared, which is what you want. When you're done with the radiation, you don't want that foreign body in there anymore. The gels have some significant amount still visible, even at nine months or twelve months in some cases.

To wrap up, could you speak to the importance of this technology in improving patient care?

Laganosky: The goal of everything that we do is to try to improve patient outcomes, and in particular patient quality of life and their cancer control. As we move toward new treatments for cancer patients in terms of therapies for the cancer process, we should also be very focused on how we can also protect from some of the adverse effects and mitigate some of the risks of those therapies. This is a premium example of ways that we can potentially advance some of the protective measures that we take for our patients, keeping them safe throughout the therapies that are necessary for their cancer. As we're all focused on trying to improve patient care outcomes, this type of therapy provides enhanced quality of life and really positive and easy experiences on the patient's body when they're going through these experiences.

Zimberg: This is a game changer. The amount of space that we can create to move the rectum away from the radiation field is so significant, and the symmetry is what we're looking for. Because the balloon has a very thin wall and most of that space is saline, there's much less foreign body material in the patient than with the gels, which have almost ten times the amount of material. Patients that have prostate cancer are going to get a far better treatment with radiation, a safer treatment, and a more symmetric treatment. For the rectal spacers, it's all about the dosimetry. We're putting this in for the radiation benefit. So, when we can move the dose away from the rectum, that is going to allow us to get a better outcome for the patients. We've seen that not only do spacers improve rectal complications, but they may also provide a benefit in urinary and sexual function. We're hopeful that when the data come out more long-term, since this is a newer product, we'll also see improvements along the lines for those functions too for men.

Is there anything else you'd like to add?

Zimberg: So far, the experience has been quite good. The patients are very happy with the procedure. It's fairly identical to what the prior gels were. Being able to improve outcomes in terms of decreasing exposure to radiation is what we do in radiation oncology, working with the urologist closely who diagnosed the prostate cancer and very often puts these in. I think the data are clear how much better this product is in terms of being able to spare the rectum from doses of radiation.

Loma Linda Health: September 18, 2023

3 Life-Extending Care Advancements for Patients with Advanced Prostate Cancer

Lisa Aubry

Diagnoses of advanced-stage prostate cancer in men have risen in the past decade, according to the American Cancer Society. At the same time, advances in prostate cancer care are securing more possibilities for those patients to live longer and to maintain a better quality of life than ever before, says Joel Brothers, MD, a medical oncologist at Loma Linda University Cancer Center.

“The treatment landscape is just exploding with many new or improved options, not just in prostate cancer, but in many types of cancer,” he says. “Even though metastatic prostate cancer is incurable, treatments are constantly improving. Patients can live for many years, if not decades, with their cancer under control from the help of newer treatments.”

For September’s Prostate Cancer Awareness Month, Brothers outlines three top advancements in care that are changing outcomes for patients with advanced prostate cancer.

Brothers advises patients to keep informed of potential treatment options and discuss specifics with an expert to create a personalized treatment plan.

Triple combination therapy

Triple combination therapy has become an increasingly accepted medical approach for treating patients with prostate cancer that has metastasized or spread to parts of the body beyond the prostate. The therapy combines three treatments — androgen deprivation therapy, chemotherapy, and novel hormone therapy — each targeting the cancer cells differently. Clinical trials in the past year have indicated that triple combination therapy increases the chances of successfully treating metastasized cancer. The trials also show that triple combination therapy can improve patients’ overall outcomes and extend life when compared to chemotherapy and androgen deprivation alone.

“Triple therapy adds to a growing body of literature over the past decade demonstrating that patients who start additional treatments earlier in the course of their treatment live longer,” Brothers says. “However, triple therapy may not be right for every patient, and a personalized approach is needed.”

Testing for biomarkers and targeted therapy

Molecular markers, also known as biomarkers, are measurable characteristics in the molecular structure of a tumor that provide essential information about that tumor's origin, behavior, features, and response to treatment.

Experts identify these markers by performing blood tests or biopsies of the tumors and analyzing the samples through various laboratory tests, including molecular profiling and genetic sequencing. Roughly one in five patients with prostate cancer have mutations in genes that manage DNA repair, says Brothers. A type of targeted therapy called PARP inhibitors are medicines that interfere with the cancer cells' repair process by making it hard for cancer cells to fix themselves. This hindrance slows down the cancer cells’ growth and can make other treatments more effective against the cancer.

Brothers says such targeted therapies can extend patients’ lives for months and tend to be better tolerated than traditional medicines. Clinical trials are looking into using PARP inhibitors in earlier lines of treatment or in combination with other treatments like hormone therapy.

PSMA-directed radioligand therapy

Most patients with metastatic prostate cancer have prostate -specific membrane antigen (PSMA), a protein found at high levels on the surface of prostate cancer cells. PSMA-directed radioligand therapy targets PSMA and delivers radiation directly to the cancer cells of patients with metastatic prostate cancer. The therapy pairs with PSMA PET scanning, an imaging technique designed to locate prostate cancer cells using high-precision technology.

Read: PSMA imaging, therapy open new doors for prostate cancer patients at Cancer Center

Brothers says PSMA therapy is well-tolerated with few side effects and has been shown to improve survival in patients who have been heavily pretreated for prostate cancer. PSMA therapy is currently FDA-approved as an option only for patients who tried other treatments that did not slow their cancer's spread. But Brothers expects to be able to offer PSMA therapy to more patients in the future. For instance, clinical trials are underway to test PSMA therapy in patients who haven’t previously received chemotherapy.

“I’m very hopeful and optimistic that with continued research, outcomes will continue to significantly improve for prostate cancer patients and all patients with cancer,” Brothers says.

UCLA Health: August 28, 2023

PSA Levels After Treatment May Not Be a Reliable Predictor of Survival for Patients with Prostate Cancer

Denise Heady

FINDINGS

A UCLA-led study found treatments that reduce the risk of being diagnosed with a cancer recurrence based on rising prostate-specific antigen (PSA) levels after radiotherapy, commonly referred to as biochemical recurrence, do not necessarily improve a patient's long-term overall survival.

The team of investigators found that while biochemical recurrence was associated with a higher risk of death, it still did not meet the criteria to be a reliable surrogate endpoint for overall survival. As defined by the FDA, a clinical outcome directly measures whether people in a trial feel or function better, or live longer. A surrogate endpoint is a specific, relatively early outcome that reliably predicts for a clinical outcome that occurs in the longer-term.

Biochemical recurrences occur much earlier in the disease course than metastases or survival, and could potentially be the ideal surrogate endpoint for prostate cancer. Therefore, the team evaluated whether biochemical recurrence could be a useful surrogate endpoint for death. This has implications for not only designing clinical trials, but also for evaluating the benefit of various forms of treatment intensification and for counseling patients.

"One reason for our finding could be that many patients in the study died from causes unrelated to prostate cancer," said Dr. Amar Kishan, an associate professor of radiation oncology at the David Geffen School of Medicine at UCLA and a researcher at the UCLA Health Jonsson Comprehensive Cancer Center, and senior author of the study. "The strength of the correlation between biochemical recurrence and overall survival varied depending on how deaths from non-cancer-related causes were accounted for. However, it is important to note that we looked specifically at death, and not at quality of life. Certainly, biochemical recurrence could impact quality of life. Unfortunately, high-level data tracking this are lacking, and it is something our group, and others, are hoping to explore further."

BACKGROUND

Biochemical recurrence develops in almost one-third of men with prostate cancer after treatment with prostatectomy or radiation therapy for localized prostate cancer. It often occurs early on in the course of prostate cancer and indicates the cancer might be coming back. Because of this, it has been theorized to be a potential marker to predict a patient's overall survival outcome. However, previous analyses have yielded conflicting conclusions about whether or not biochemical recurrence could be a reliable predictor of overall patient survival.

METHOD

The researchers collected and analyzed data from 11 different studies evaluating radiation therapy dose escalation, the use of androgen deprivation therapy and androgen deprivation therapy prolongation to evaluate the potential of biochemical recurrence as a predictor of survival. Overall, 10,741 patients were included in the analysis.

IMPACT

Despite the potential of using biochemical recurrence as a potential marker to predict overall survival in patients with prostate cancer, the results of the study indicates that it should not be the main focus or primary measure in future clinical trials for localized prostate cancer. Instead, metastasis-free survival, which refers to the period without cancer spreading to other parts of the body, is a more suitable endpoint for future trials involving radiation therapy in localized prostate cancer cases.

Continued from page 3

In other words, patients treated with the combination had a 58% lower risk of developing metastases or death vs. patients treated with leuprolide alone. Patients treated with enzalutamide alone had a 37% lower risk vs. patients treated with leuprolide alone.

What are the side effects?

Enzalutamide has known side effects, including hot flashes and fatigue. The side effect profile was as expected, in that no new safety issues were seen in the trial. Certain side effects were more common in the combination group, including fractures and cognitive/ memory impairment. More patients in the combination group (21%) discontinued treatment due to adverse events compared with 10% in the leuprolide-alone group and 18% in the enzalutamide-alone group.

What does this mean for patients?

If your PSA is rising after treatment for localized prostate cancer, talk to your doctor about any additional testing you should have and about your treatment options, including potential benefits, risks, and side effects.

Prostate Cancer Support Association of New Mexico

PCSANM *Lifeline* Newsletter
Celebrating 33 years of supporting men and their families

Prostate Cancer Support Association of New Mexico, Inc.
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A Message from the Chairperson

January 2024

In 2023, as we all continued to adapt to life with COVID and became increasingly comfortable gathering in groups once again, PCSANM was hard at work. The association expanded its support efforts by attending a variety of health fairs around the state. In addition, under the leadership and direction of Terry Riddle, a local woman whose husband died from prostate cancer in 2021, PCSANM hosted its first golf tournament to raise prostate cancer awareness within the community and funding for the association. PCSANM also held its 12th annual prostate cancer conference, which attracted 99 attendees and eight exhibitors, in addition to four amazing presenters.

After years of declining support group meeting attendance due to COVID, attendance began to rise once again: nearly 150 more individuals signed in to meetings in 2023 than in 2022 and in 2021. PCSANM has yet to return fully to its pre-COVID meeting sign-in numbers, but we are pleased with this trend. It shows that more of those who stand to benefit from our services are again seeking support. Discussion at meetings seems to be vigorous, frank (both in a productive way) and according to feedback, very helpful. Our goal is to keep these gatherings an illustration of our mission statement in action, in particular by providing emotional support following diagnosis, during treatment and beyond.

If you have never attended a support group meeting, we invite you to join us in 2024. If you're a regular, we hope you'll continue to be a part of our prostate cancer community, benefiting from the camaraderie and contributing your valuable experience and perspective to those who may need it. As the months go by, stay tuned for information on this year's golf tournament, the annual conference, and perhaps some opportunity we haven't yet identified. Looking forward to sharing 2024 with you!

Rod Geer
Chairperson of the Board, PCSANM