Xofigo and Advanced Prostate Cancer

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Conference Sponsors and Registration

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Building on recent updates to our website—www.pcri.org—we are proud to announce the launch of the new Prostate Cancer Blue Community (PCBC). The PCBC is a simple yet powerful vehicle for patients and caregivers to interact with other prostate cancer patients. The PCBC is an online forum where you can ask questions and share your insights with other men from the comfort and convenience of your own home.

The New Blue Community

By Peter Scholz,
PCRI’s Web Content Manager

is structured around the Shades of Blue with six separate forums—one for each shade and another one for general questions and topics. Finding your shade is easy with our new online tool that utilizes information that you can obtain from your medical chart. The tool quickly tells you your shade by asking you a few brief questions. Once you know your shade you will be directed to the forum most suited to your personal case. This way, the PCBC helps men focus on the forum that is most relevant to each man’s specific situation. Each forum is moderated by a select group of experienced prostate cancer patients ensuring that the discussions stay on topic. These moderators will also be able to point you in the direction of the most important conversations helping you find the answers you need.

The Blue Community allows you to maintain as much privacy and anonymity as you wish to have. The anonymity of an online discussion may give confidence to discuss difficult topics that some might hesitate to mention at an in-person support group. Men also have the option of simply following the conversations of other patients. The PCBC also enables men to contribute to the dialog by sharing their personal story. Men can participate as much or as little as they are comfortable doing.

The PCBC enables men to be involved in multiple discussions simultaneously. Our new system helps you keep track of them all; when you post a response, or broach a new topic, you can “subscribe” to that topic. The website will then send you an email, updating you whenever a new reply is posted on that same topic. Even if you haven’t contributed to a certain topic, you can still subscribe to it and get updates every time a new post is added.

These enhancements, among others, make the Blue Community an engaging, simple, yet powerful way to learn more about your prostate cancer, and a great way to give back to the community. Sign up today at:

bluecommunity.prostate-cancer.org

And:

• Connect with other patients from the comfort of your own home and the convenience of your own schedule
• Access information about other patient’s experiences who are in similar circumstances
• Maintain your privacy while getting answers to difficult questions
• Be engaged in the multiple discussions while sidestepping topics that either don’t interest you or don’t apply to your case
• Learn more about prostate cancer; become empowered to understand your medical situation more clearly
The Prolaris Test for Prostate Cancer: An Introduction to a Novel Genomic Test and its Role in Improving Clinical Decisions: Part II, Radical Prostatectomy Genomic Testing.

John W. Davis, MD, FACS
Associate Professor, Urology
Director, Urosurgical Prostate Program
MD Anderson Cancer Center
Houston, Texas

In Part I of this two-part article, we introduced the concept of genomic testing in prostate cancer and established how such new information can augment what we can already estimate with basic clinical information. A common need in prostate cancer is to take patients diagnosed with early prostate cancer, and determine whether or not they have disease with significant lethal ability. Another clinical need is to look at patients who have undergone a radical prostatectomy (any technique) and found to have high-risk pathology features that may indicate they need post-operative radiation therapy or other treatments.

How often does this occur and what does it mean? There are nomograms that are available on the internet* that can predict these findings from the pre-treatment clinical information, as well as the next step of predicting the odds of biochemical recurrence (rising PSA) after a radical prostatectomy. In our own series, for example, we looked at men with commonly treated intermediate risk prostate cancer such as a normal DRE, PSA < 10, and Gleason 7, and found that their radical prostatectomy findings are quite diverse. Approximately 50% of men will have organ confined cancer that is Gleason 7, while the other half could have any single or combination of elevated risk such as positive nodes (10%), pT3a or pT3b (25%), or increase in Gleason to 8-10 (5%). Recently, the American Urological Association (AUA) and the American Society for Therapeutic Radiation Oncology (ASTRO) produced a joint guideline on post-operative radiation therapy in up to 35% of cases. However, most of our patients prefer to observe their PSA in the case of high-risk pathology and selectively use radiation for a detectible and rising PSA—often called the “salvage” radiation approach. Yet we do not have good clinical trial information as to whether this strategy is as good as the adjuvant—such a trial is nearing completion in the U.K [3].

In this area of clinical uncertainty, the Prolaris test can look at the same CCP** genes in radical prostatectomy tissue and give an estimate of 10-year biochemical recurrence [4-5]. The final prediction will incorporate what is known from the clinical information, and the same descriptors of less, more, or equal to average risk can be summarized.

- Gleason Grade—this time more accurate compared to a biopsy since the whole gland is sampled. It could be higher, lower or the same as the biopsy.
- Extra-prostatic extension—the finding of tumor cells invading the layer of fat around the prostate capsule. This is denoted as pathological stage pT3a.
- Seminal vesicle extension—the finding of tumor cells invading these adjacent structures off of the base of the prostate. This is denoted as pathological stage pT3b.
- Positive surgical margins—the finding of tumor cells touching the inked margin of the tissue the surgeon removed.
- Positive lymph nodes—if a lymph node dissection was performed.

* [www.nomograms.org, urology.ucsf.edu/research/cancer/prostate-cancer-risk-assessment-and-the-ucsf-capra-score]
** See part 1 for more info
Example A: Radical prostatectomy pathology shows Gleason 4+3, pT3a, a positive surgical margin, and normal lymph nodes. The PSA was 10 pre-treatment. Based upon clinical features alone, biochemical recurrence could be predicted at up to 57%, and AUA/ASTRO guidelines would strongly encourage immediate (meaning between 4-6 months post-operative) radiation. The CCP score however was a negative 1.1—much less aggressive than average risk, and the revised risk of biochemical recurrence was 31%. This patient selected observation.

Example B: A patient’s radical prostatectomy pathology showed Gleason 4+3, seminal vesical invasion, and positive surgical margin. His CCP score was positive 0.4, which is more aggressive than higher risk. His combined risk of biochemical recurrence is 87%, and was clearly recommended to consider adjuvant radiation.

Moving Forward:
Key Questions and Critiques for the Future of Genomic Medicine in Prostate Cancer

Let us continue with some simple terminology to help understand the role of Prolaris and other genomic tests. In addition to Prolaris, other commercially available genomic tests that use prostate cancer tissue as their source include Decipher from GenomeDX [6] and Oncotype Dx from Genomic Health [7] (other companies have additional products in testing). The Decipher test is only for post-operative testing and focuses on the highest risk patients who might develop early bone metastasis. The Oncotype Dx test is a biopsy test for only very favorable biopsies to determine if patients are at risk for upgrading/upstaging. Therefore the key questions to ask when reading about a novel genomic test are:

- What tissue can be tested? Biopsy versus radical prostatectomy or both.
- What questions are addressed? The most common are the surveillance question and the post-operative radiation question. With further study, perhaps more questions could be addressed.
- What information is returned to the patient and physician? In general, a genomic test will have its own unique scale and different cut-points for descriptive results such as the “more-aggressive than average risk.” These scales will have a learning curve for use by patients and physicians. Some tests are stand-alone predictors while others may incorporate the clinical data.
- What are the validation methods? Because prostate cancer is often slow growing, all of these diagnostic companies have tested their product on retrospective tissue banks. Therefore, the information they can give you depends upon what clinical information was known about the test subjects. For Prolaris, for example, the biopsy test was done on two observation cohorts in the U.K and the result is a mortality prediction. For the post-operative test, only the biochemical recurrence information was known.
- How many tests are informative? This will be worked out with more research. The concept to stress is that there is always a chance that a genomic test will return a result that is equal to clinical information and not really be that helpful, but other than it does rule out the most aggressive result.

Conclusions: Genomic testing is now a reality in prostate cancer. There are several choices available and each test has its intended question to address. The critiques of current genomic testing are that we need more information on the cost savings of testing select patient populations and subsequently making higher impact decisions. We need more evidence on “clinical utility,” meaning how many clinical decisions are clearly changed based upon the findings of a genomic test. In addition, none of the current tests are therapy linked, meaning we do not have hard evidence that altered therapy decisions based upon genomic tests lead to better outcomes. Such information may come with time as it has been established in other areas such as breast cancer [8].

References can be found online at http://pcrionline.org/
When: June 21st, 2014
Where: Shoreline Aquatic Park, Long Beach, CA

If you will be in the Los Angeles area the weekend of June 21st, don’t miss out on the fun! Whether you are a seasoned athlete or a casual walker, this event is a fantastic opportunity to raise awareness for prostate cancer. There will be food, prizes (including a chance to win an iPad mini) and fun for the whole family!

Visit http://losangeles.zeroprostatecancerrun.org/ for more information and to register today!

Interested in volunteering on race day? E-mail info@pcri.org to learn how you can help!

Dear Supporters,

The prostate cancer journey can be very exhausting. I know because my son and I traveled that path with my husband for 13 years before he lost his battle with prostate cancer in 2013. Along the way, PCRI helped re-infuse us with energy by showing us tools and resources we needed, helping to bring clarity and hope to our journey.

This goal of infusing men with resources and renewed energy is a priority at the PCRI. We call it “patient empowerment,” but since science and medicine are notorious for changing words and phrases, you may now hear it called “shared decision making.” The goal of empowering patients is challenging. Patients have unique cancer characteristics, and come from different perspectives and backgrounds.

The PCRI does its best to meet these individual needs by providing FREE access to experienced Helpline Facilitators. We also host a popular, patient-focused conference each September. And now we are launching the Blue Community, a FREE online discussion forum where patients and caregivers can interact, exchange information, and learn from each other’s experiences. The PCRI also provides a FREE quarterly newsletter that updates patients with the latest advances in prostate cancer care.

PCRI needs your financial support to keep these programs thriving. Donations to the PCRI are tax deductible. PCRI is audited annually and is continually certified as one of the Best Charities of America. As we move on into summer with Father’s Day approaching, keep the PCRI in mind as a place of support for you, and keep us in mind as a place that benefits from your continued support.

As always, a heart-felt thank you. And I hope to see you at our September Conference, on Blue Community, on Helpline, or wherever our paths cross.

Warm Regards,

Jan Manarite, PCRI Senior Educational Facilitator
The problem is that CT scans and conventional MRI scans miss the majority of lymph node metastases (about 70% of the time). This is because the most of the metastases are too small (<8 mm) for the CT scan to visualize them [1]. Choline PET scans are somewhat better but also are usually unable to detect metastatic nodes if they are smaller than 6 mm [16]. This is because there needs to be a minimum amount of tracer present in the lymph node before it reaches the threshold of detectability. Some studies show that surgical removal of pelvic lymph nodes only finds the nodes 59% of the time [2]. This is because the nodes are frequently located outside the surgical field. Finally, attempts to cover all the lymph nodes with a broad-based radiation field have limitations. Studies have shown that more than 50% of metastatic lymph nodes are outside the routinely prescribed radiation field [3] (Figure 1). Therefore, the effectiveness of standard lymph node radiotherapy leaves much room for improvement [4].

Studies evaluating intravenous Combidex® contrast in conjunction with MRI scanning indicate that normal lymph nodes can be distinguished from metastatic nodes even when the metastases are very small (>2 mm) [8-13]. Combidex-enhanced MRI scans have significant improvement of the detection of metastases compared to Choline PET scans. MRI with Combidex detected more metastatic nodes (738 vs 132) in more patients (23/29 vs 13/29) in smaller nodes (mean diameter 4.9 vs 8.4 mm) [14] (Figures 2 and 3).

Studies also indicate that a Combidex-enhanced MRI may obviate the need for surgical node dissection [2, 12] reducing both side effects and cost. A large prospective multicenter study demonstrated the cost-effectiveness [15, 16]. The accuracy of Combidex has also been favorably compared with predictive algorithms. [17-18]. Combidex opens up the possibility of doing selective radiation directed to these small, thus far undetected metastatic nodes [6]. The hope is that this early intervention will result in increased cure rates and less side effects [7, 19].
Combidex has Numerous Potential Applications
As of the time of writing this article 580 publications have addressed the use of Combidex. Many of these studies have evaluated Combidex for its possible applications outside its role in the detection of lymph nodes. Such applications include the diagnosis of “vulnerable” arteriosclerotic plaque, improving the diagnosis of bone metastases, multiple sclerosis, brain tumors, and kidney diseases. Nineteen studies have been published on using Combidex for the detection of small (2-3 mm) lymph node metastases in any cancer [1-19].

History
About fifteen years ago Combidex first became available for human use. The data from primary pharmacokinetic studies, a Phase I study, and the data in a Phase II study consistently showed that it is safe and well tolerated and that it has no effect on immune function. So far two attempts have been made to register Combidex by the FDA in the United States for clinical lymph node imaging and two attempts were made in Europe by EMEA. All of these four attempts were unsuccessful due to suboptimal trial design, suboptimal statistics, and suboptimal central reading.

Resurrection of Combidex in Nijmegen
I was the first researcher/radiologist to show the value of Combidex and publish studies validating its cost-effectiveness [8, 10, 16]. Unfortunately, during the recent economic crisis, development of Combidex ceased altogether. It became completely unavailable in April 2010. However, along with the help of businessman and advocate, Orn Adelsteinsson, PhD., our university in Nijmegen has been able to purchase all rights to Combidex along with all the documents and files from the original manufacturer. As of February 2014 based on the Combidex-files and approved GMP-quality control by a certified body Combidex-MRI is available again for all patients in Nijmegen.

Metastatic, hormone-resistant (castrate-resistant) prostate cancer metastasizes primarily to the bone. Extensive bone metastasis can be very painful and cause weakness that impairs quality of life. As such, treatment that improves both quality of life and and survival is needed. Prostate cancer mortality is directly related to metastatic bone disease or its complications.

Steven Eric Finkelstein, M.D.
National Director, 21st Century Oncology Translational Research Consortium (TRC)
Board Certified Radiation Oncologist
Scottsdale, Arizona

References can be found online at http://pcri.org/
May 15, 2013, the U. S. Food and Drug Administration approved radium 223 otherwise known as Xofigo for the treatment of patients with symptomatic bone metastases, without metastases to other visceral (soft tissue) sites. Xofigo is the sixth new agent the FDA has approved for advanced cancer in the last five years. It is a radio-therapeutic that mimics calcium, allowing it to form complexes with hydroxyapatite in areas of increased bone turnover; it homes in on and delivers a potent form of alpha-particle radiation right at the location of bone metastases.

The Study
The FDA approved Xofigo after a double-blind, randomized trial (ALSYMPCA) in patients with symptomatic bone metastases showed prolonged survival compared to men treated with a placebo. In the study, men were randomized either to Xofigo plus best standard of care, given every 4 weeks for a total of 6 cycles or to an indistinguishable placebo plus best standard of care. All patients were told to continue androgen deprivation therapy. The average age of the participants was 71. Fifty-eight percent of the men in the study had received prior chemotherapy with docetaxel (Taxotere). At the time the study began, about half of the men were taking a narcotic pain medication. Treatment administration consisted of slow (1 minute) intravenous injection once every 4 weeks. Treatment stopped after six cycles had been administered.

Findings
The objective of the study was to determine the overall survival benefits of Xofigo. In this study the men who participated started with very advanced disease. Therefore, survival in both groups was short. Despite the severity of the disease, Xofigo delayed mortality to a significant degree. The study determined that median survival for men on Xofigo was 14.0 months, and 11.2 months for men treated with placebo.

Side Effects
Overall, Xofigo was well tolerated. Nausea and diarrhea occurred in a few patients, 2% of patients experienced bone marrow failure with ongoing low blood counts.

Conclusions
We are still learning about the best method for using this novel agent. For example, ongoing clinical trials will determine the benefits of continuing treatment past the currently recommended dose of 6 cycles. Studies will also need to be done to see how treatment with Xofigo can combine with other existing types of treatment such as radiation therapy, Provenge, chemotherapy, and hormone therapy. Additionally, as therapeutic options in recurrent and advanced prostate cancer are rapidly expanding, there is great need to pursue imaging approaches that will permit the monitoring of tumor responses. All together, patients and doctors battling advanced prostate cancer are getting more and more viable and effective treatment options.

Patient Education Day
Where: St. Louis Convention Center, Missouri
When: June 8, 2014

Agenda
Prostate Cancer Breakout Session:
Jan Manarita, Moderator, PCRI
Patient Empowerment & Shared Decision Making
Fabio Almeida, M.D., Arizona Molecular Imaging
Finding Metastases with Better Imaging
Jeff Michalski, M.D. Siteman Cancer Center,
Targeting Bone Metastases with Radium 223

New Tool To Access Information on Clinical Trials
The PCRI website now has a new feature that will enable patients and treating physicians to connect and discuss clinical trials. Designed and maintained by The Clinical Trial Forum Network, this innovative service harnesses the very latest web technologies to educate and connect prospective patients with the respective research staff members who are conducting these trials at prominent local institutions.

• Search prostate cancer trials at leading institutions in Los Angeles area
• See what it’s really like to be in a clinical trial
• Monitor and participate in clinical trial discussion groups
• Ask questions of actual research professionals about clinical trials
• Get professional guidance on which clinical trials might fit your medical needs
• Get educated about emerging treatments in prostate cancer

Go to http://prostate-cancer.org/resources/clinical-trials/
Prioritize Diet, Not Supplements

There’s hardly anyone has not been bombarded with ads for various dietary supplements that promise to make you live forever as well as preventing, or stopping prostate cancer. They even come with a money-back guarantee. Billions of dollars are spent on marketing using terms such as “nutrigenic testing,” “personalized supplements,” “feed your genes right,” and “intelligent diet.” The problem is that the actual studies that would verify these claims don’t exist. These products are not regulated by the FDA so claims can be made without proof. To make things even more confusing, even when a study is published in a medical journal purporting to document a benefit, subsequent studies may end up being contradictory. In my opinion, supplements should supplement a good diet and exercise, not attempt to replace healthy lifestyle choices.

One Diet To Rule Them All
A healthy diet combined with appropriate therapy does decrease the growth rate of cancer cells. In addition, we all know that diet has beneficial overall health effects. Prostate cancer is not the only factor that affects survival and quality of life. Of the men who have been diagnosed with prostate cancer, more die from heart disease than from the prostate cancer. So, an optimal prostate cancer diet is the same as a “heart healthy diet.”

Exercise And Diet Are Complementary
The target for body fat content for men should be between 15% and 20%. This can be achieved by portion control (limiting total amount of food consumed) and by increasing energy expenditure with exercise. The body needs a minimum amount of caloric intake to manage daily functions. But excess calories that aren’t burned off through exercise end up being stored as fat. Here in America we tend toward a sedentary society. We sit most of the day in front of a computer, sit in our cars, sit down to a big dinner, then sit watching TV. Not much of a surprise that we have lots of obesity, heart disease, diabetes, and cancer. Don’t forget that these poor lifestyle choices can also cause poor sexual performance.

What Everyone Agrees on about Diet
The basic principles of a Heart Healthy diet are: low fat (specifically low omega-6 fats), low salt, low glucose-spiking starches and sugars and low red meat consumption. More fish, grains, fruit, vegetables and lots of water contribute to a heart healthy diet as well. Overall food consumption should be limited to what can be burned through exercise. Speaking of burning, foods should be cooked at lower temperatures to avoid charring. Exercise, stress management, and motivation round out a healthy lifestyle.

How do Supplements Play into a Healthy Lifestyle?
By now you’ve noticed that the topic of diet has a much larger scope than how it affects prostate cancer development or progression, but in terms of prostate cancer, how about all the supplements that are on the market that supposedly increase your survival or quality of life? The answer is, it’s still a mystery. Typically we don’t measure the amount of these supplemental substances in our blood. Even when we do measure them, blood levels aren’t a perfect indicator of the levels in the organs or tissues.

Of course we know that we need essential vitamins and nutrients, but a healthy diet includes these already. These nutrients are present in the fruits and vegetables we eat, and the body knows what to do with them.

The Example of Lycopene
Supplemental lycopene is illustrative of the problems we face when examining dietary supplements. It’s a beta carotenoid and a very potent antioxidant. It is the predominant carotenoid found in blood and various tissues (including the prostate). It can be found in watermelon, tomato (and tomato products), pink grapefruit, apricots, guavas, papayas, and persimmons. Some studies provide evidence that lycopene intake has no effect on prostate cancer while others show compelling evidence that dietary lycopene reduces the risk of developing the lethal variety of prostate cancer. Since we don’t measure lycopene levels in the blood or tissue, it’s hard to tell how much is the right amount, who needs more and who already has enough. Lycopene is not bad for you, but it is unclear about how beneficial extra lycopene is for your health.

But should we just take a pill because “it wouldn’t hurt?” Wouldn’t a better motivation be to choose a supplement because it’s actually proven to have a positive effect? Pills are no substitute for the benefits of exercise and a good diet.

What We Do Know
It is clear that a combination of a healthy diet and exercise—along with good treatment—are proven to maximize survival (from many health conditions), providing a good quality of life simultaneously. At most, supplements can only supplement a healthy lifestyle, and should definitely not be thought of as a replacement. Yes it is easier to take a pill for some peace of mind, but the benefits of pursuing a healthy lifestyle are far greater.

“Of the men who have been diagnosed with prostate cancer, more die from heart disease than from their prostate cancer. So an optimal prostate cancer diet is the same as a ‘Heart Healthy Diet.’”

By Stanley Brosman, M.D.
PCRI Medical Review Board
Pacific Urology Institute
Prostate Flash is:

- Simple to understand summaries of today’s breaking news about prostate cancer treatment, clinical trials, and quality of life research.
- Based on your diagnosis and current disease state. Nothing more, nothing less.
- Questions to ask your doctor, today.
- Latest treatment opportunities, some that your doctor may not yet know about!
- Curated and written by clinicians who are also prostate cancer patients or caregivers with dozens of years of experience.
- No “for-profit” bias. Prostate Flash is run entirely by Malecare Cancer Support.
- Three minutes to read. Prostate Flash sorts out the information that you need, saving you hours of work, grief, and stress.
- Completely anonymous. You don’t even have to make up a user name. Just provide an email address.
- Caregivers and partners of prostate cancer patients are encouraged to sign up for Prostate Flash, too!

Sign up at: http://prostateflash.org
Thanks to all of our conference sponsors:

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The official conference hotel is the Marriott LAX Airport Hotel located at 5855 W. Century Blvd, Los Angeles, CA. A limited number of discounted rooms are available for $99/night by calling 310-641-5700 and mentioning group code NCPNCPA, or by visiting www.PCRI.org for an online booking link. This group rate is available only until August 14, 2014. Discounted airline tickets to/from LAX are available by calling American Airlines at 800.433.1790 or visiting www.aa.com. Use group code 2194BV.

Discounted car rentals are available through AVIS by mentioning code D015467 when calling 800.331.1600. Self-parking at the venue is $12/day and valet parking is $25/day. Complimentary hotel shuttles are available at LAX (under the red sign).

Cancellations and refund requests will be honored only if made in writing no later than August 15, 2014.

**Prostate cancer will strike 1 in 6 men. Your generous donation helps us fight prostate cancer through research, education and increasing public awareness.**