

PROSTATE CANCER COMMUNICATION

CHOICES

Take
One!

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fibrillation and, later, a mild stroke. His physician failed to check his overall physical condition. Incomplete medical training associated with proper health investigation before treatment can be a problem.

Once a Gleason score is rendered, too often treatment is implemented before a thorough understanding of the possible effects on the patient's life are achieved. Surgery? Radiation? Cryoablation? HIFU? Hormone Therapy? et al. What a maze of possibilities exist. Get involved with your support group and benefit from their knowledge and experience.

We think one of the major oversights in treatment possibilities is no treatment at all or Active Surveillance (often called Watchful Waiting). Dr. Duke Bahn has quantified those tests that can be monitored by a patient over time in concert with his doctor without undergoing invasive treatment (see PAACT article in March, 2011 issue). An important element of this choice is the mental capacity to overcome a man's natural urge to do something to "cure" the disease. Be careful of that word. When someone uses it, make them define to you what they mean. It might be that they consider you "cured" if you don't experience signs over a much shorter time span than you expect.

If you are faced with making a treatment choice, be sure you develop an understanding of the possible side effects of the chosen treatment. Another unfortunate issue in dealing with prostate cancer is that it is difficult to predict how a patient will react to the treatment. Your physician may cite percentages of success, but there is yet no way to ensure what your experience will be. Be sure to check the experience of the doctor treating you. The most experienced doctor will achieve the best results. And, for sure, seek second opinions from unassociated doctors. This can be difficult because of insurance coverage limitations, but it will be in your best interest. Remember, you are your own case manager. Have confidence that unless you are diagnosed at a late stage the disease is generally slow moving. You have time to assess your treatment possibilities before committing.

Stay involved with your support group. You will find comfort in networking with others to help them as you are being helped. The natural tendency is to be involved through treatment and then disengage. There is value in continuing to stay involved to learn of advances in diagnosis and treatment. It keeps you aware of monitoring your own condition. Too many of the newcomers to our group are experiencing recurrence. Staying abreast of your condition and what is developing in the treatment of the disease will surely give you the opportunity to deal with it successfully. Remember, **YOU CAN LIVE WITH PROSTATE CANCER!**

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The Informed Prostate Cancer Support Group produced a DVD about Active Surveillance in cooperation with Dr. Duke Bahn. It is being distributed to interested prostate cancer support groups and other interested parties. Dr. Bahn commented "My reaction to the quality of this DVD is 'amazingly well done.'" An article by Dr. Bahn on the subject was included in the March, 2011 issue of "CHOICES." To get the DVD contact: Gene Van Vleet, e-mail: Gene@ipcsg.org, phone: 619-890-8447, address: PO Box 420142, San Diego, CA 92142. A donation of \$10 would be appreciated to help defray production costs. Make checks payable to IPCSG.

PSA vs CTC

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Over the years, there has been much controversy regarding the use of PSA as a screening tool. PSA testing has minimal effect on reducing mortality from prostate cancer. Initial results from two large screening trials in 2009 have suggested that routine PSA testing has little, if any, effect on reducing the risk of dying from prostate cancer. On the contrary, it has likely led to overdiagnosis and treatment of disease that is in fact nonlethal[6].

In addition, it is a known fact that as prostate cancer progresses, the utility of PSA as a prognostic factor declines. The tumor may continue to expand without an associated increase in PSA possibly because little PSA is being produced due to tumor cell dedifferentiation or because PSA production is being suppressed by systemic therapy. Prostate cancer tumors continue to become more heterogeneous as the disease continues to progress which leads to variability in tumor PSA expression which in turn leads to false positive or negative PSA results[1].

From a clinical point of view, it has been clearly documented that discordant symptoms, PSA, and bone scan results after treatment have frequently led to therapeutic dilemmas for both the clinician and the patient in which it is not clear whether to continue or abandon therapy when various indicators are not synchronous[5].

Over the last several years, clinicians and researchers have been attempting to discover a better marker, which may reveal more information on the nature of the disease itself or may be used as a surrogate endpoint to determine a tumor's response to therapy. There has been a clear need to discover a marker which may assist physicians in discontinuing treatment at an earlier time point which could effectively decrease morbidity from toxicity, reduce treatment costs, and allow patients to receive alternative management. By doing this, there can also be an increase in the pool of fit patients who would be available for clinical trials investigating novel agents.

More recently, circulating tumor cells (CTC's) have become a critical addition for surveillance of patients with cancer. Biological studies have suggested that early stage cancer has the potential to begin shedding cancer cells into the circulation early in development[2]. The ability to shed cells into circulation is an intrinsic property of tumors and this helps to provide unique information, which when applied, can significantly affect patient management and clinical trial design[3].

Veridex has devised the CellSearch System of detecting circulating tumor cells. The assay allows the detection of antigens in a heterogeneous mixture of cells and offers advantages over immunohistochemistry and Reverse Transcriptase Polymerase Chain Reaction (RT-PCR). It uses an epithelial cell adhesion prostate cancer antibody based, immunomagnetic capture and automated staining methodology[2]. It has also been documented that CellSearch can detect prostate cancer cells without PSA expression.

Circulating tumor cells are present at a wide range of frequencies in patients with various metastatic carcinomas. In multi-center prospective clinical trials, the number of CTCs determined using the CellSearch method was a significant independent predictor of progression-free survival and overall survival in patients with metastatic breast, colorectal, or prostate cancer. Several studies in patients with all three of these tumor types have shown that CTC enumeration before and after therapy is both prognostic and treatment predictive[4].

In the December 10, 2009 issue of *Journal of Clinical Oncology*, a special article was written entitled "Clinical Cancer Advances 2009: Major Research Advances in Cancer Treatment, Prevention, and Screening." Under "Notable Advances" within the article, was the 2008 FDA approval of CellSearch (Veridex, North Raritan, NH) for use in predicting survival and monitoring treatment in men with advanced prostate cancer[6].

The landmark trial by de Bono, et al. which led to the FDA approval of CTC use in advanced prostate cancer was a multicenter, prospective study demonstrating that CTC number at different time points after treatment was in fact, the strongest independent predictor of overall survival in castration resistant prostate cancer. In addition, robust evidence was given supporting that CTC counts predicted overall survival better than PSA algorithms at all time points based on comparative hazard ratios. Another study by Scher, et al. in the March 2009 *Lancet* further supported the superiority of CTCs compared to PSA by stating that there was no association between time to a single rise in PSA concentration and survival as well as a weak association between the time to second PSA increase and

survival time. In contrast, a single rise in CTC count was moderately associated with survival time demonstrating that CTCs were in fact more robust in measurement of progression when compared to PSA[7].

Overall, it seemed that baseline CTC and posttreatment CTC levels contained significant predictive and prognostic value. The CTC number was also more predictive than posttherapy changes in PSA, which led to the suggestion that CTC may also be an intermediate end point of efficacy, which can be used in clinical trials. This led to the prediction that CTC will become a vital component in the evaluation of antitumor activity of novel agents in phase II clinical trials as well as improve knowledge about the biology of prostate cancer[5]. Just this past June, ASCO reported on the final analysis of the phase III Abiraterone trial which was a double-blind, randomized, placebo-controlled trial comparing Abiraterone/prednisone to placebo/prednisone in the post-docetaxel setting. The concluding data clearly displayed that baseline and intermediate CTC levels after initiating therapy were in fact key predictors of overall survival.

In summary, once again there is an abundance of literature to support the lack of sensitivity and specificity that PSA has as a marker for prostate cancer whether using it for screening, baseline, or posttreatment predictive and prognostic utility. Once again, CTC has emerged as an incredibly accurate and independent predictor of overall survival in the treatment of prostate cancer. Patients and practitioners need to be aware that this is a vital piece of the puzzle which may assist physicians in making more accurate treatment recommendations in efforts to deliver the absolute optimal therapy possible.

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LAC-PAACT UPDATE¹

GREGORY H. TEUFEL, ESQ., CHAIRMAN²

As I regularly note in this update, LAC-PAACT is particularly helpful in addressing insurance and Medicare coverage issues related to advanced cancer treatments. I should also note that one of the ways we help people is by helping them find counsel in their local areas.

In recent months we have helped with finding or doing some due diligence to aid in selecting counsel in Michigan and Oregon for cancer survivors facing coverage issues. It can help a lot to have a lawyer help you find and choose a lawyer (just as it can be helpful to have a doctor help you search for and choose a doctor), and we are happy to do that. We have contacts all over the country, some of whom can be convinced to handle matters pro bono for a worthy cancer survivor.

We can also give useful suggestions to your local lawyer and provide support and resources that may help convince your local lawyer to take your case and ultimately help your chances of winning. So please, feel free to take advantage of these free services.

Please do not hesitate to contact us regarding any coverage or other legal issues related to advanced cancer treatments. We want to help and need your help in identifying the areas of greatest need.

We are also always seeking volunteers to help with LAC-PAACT activities. Even if you are not a lawyer, you can volunteer if you are inclined to help with law related issues.

1 LAC-PAACT is PAACT's legal advocacy committee. Despite the name of the committee, for various reasons, we generally cannot give you legal advice or act as your personal attorney. Please do not consider anything in this article as legal advice. If you want legal advice, we encourage you to consult a lawyer in your state, so that your specific situation and local laws can be considered.

2 Gregory H. Teufel, Esq. is a partner in the Litigation Department of Eckert Seamans Cherin & Mellott, LLC's Pittsburgh office. The views expressed are those of Mr. Teufel personally and not of the firm.

Also, if you know any lawyers that would be sympathetic to our cause, please make us aware of them and them aware of LAC-PAACT. Just contact Greg Teufel regarding volunteer opportunities with LAC-PAACT.

If you have been denied coverage for an advanced cancer treatment, be sure to let us know and we will see if there is anything we can do to help.

CONTACT LAC-PAACT

If you have any questions or comments, or any suggestions about how LAC-PAACT can best serve your needs, please do not hesitate to contact me. The preferred method to contact me is via email at gteufel@eckertseamans.com. You can also call me at work at (412) 566-5977, home (412) 421-7123, or on my cell phone (412) 596-6316, or send me a letter at Eckert Seamans Cherin & Mellott, LLC, U.S. Steel Tower, 600 Grant St., 44th Fl., Pittsburgh, PA 15219 or a fax at (412) 566-6099. Please remember that this article is not legal advice and we cannot generally give you legal advice or become your personal attorney.

WHAT THE HECK HAS BEEN GOING ON IN MY WORLD-PART 55!

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Note: A total of 55 times in a row (over 15 consecutive years...well at least it feels like a long time) I have written and volunteered for this newsletter, and I have yet to receive any financial compensation or personalized gifts for my efforts. I do believe that the folks that run PAACT will eventually put some money together and buy me a diet cola, give me a puppy that is already trained or simply pay me a million dollars in quarters so I will never have to worry about finding change for all the toll roads or casinos in the Midwest!

BREAKING NEWS STORY #1

207) MDV3100 is a pill that appears to have scored a major touchdown for those with hormone refractory prostate cancer (HRPC, also known as CRPC....). WE ARE REQUESTING THAT THE COMPANY MAKE THE DRUG AVAILABLE EARLIER, SOMETIME IN 2012, FOR THOSE THAT QUALIFY (Early Access), AND THIS COMPANY HAS BEEN WONDERFUL (actually fantastic) IN COMMUNICATING THAT THEY WILL ATTEMPT TO DO THIS!!! I BELIEVE THAT THIS COMPANY (known