

PROSTATE CANCER COMMUNICATION

Take
One!

CHOICES

VOLUME 27, NUMBER 1 • March, 2011
FOUNDER: LLOYD J. NEY, SR. - FOUNDED 1984



ACTIVE SURVEILLANCE FOR LOW-RISK PROSTATE CANCER

Also In
this issue:

LAC-PAACT Update

Molecular Pathology

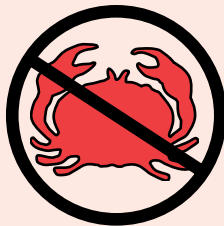
What the Heck Has
Been Going On In
My World

and More!

**National Cancer
Survivors Day**
Sunday, June 5th

Life Without Prostate Cancer:
Imagine The Possibilities!

PAACT, INC.



PROSTATE CANCER COMMUNICATION
CHOICES

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In an effort to conserve space and be able to insert as much material as possible in the newsletter, references from various articles are intentionally omitted. If you would like to obtain those references, please contact PAACT, we keep all of the original articles and the references used on file.

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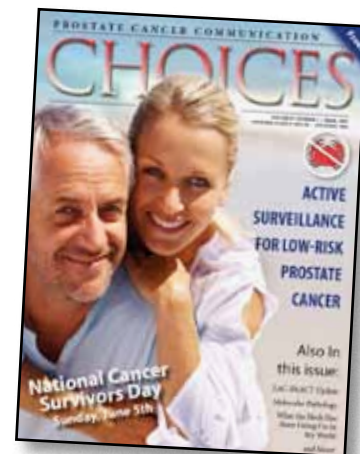
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From the Presidents Desk

With this issue, we are pleased to unveil our new look and a new name for our newsletter... CHOICES. At Paact, we have a passionate belief in patient empowerment through knowledge. We believe that prostate cancer patients have the right to know all the options for Detection, Diagnosis, Evaluation and Treatments. That's why the name CHOICES seemed so appropriate. Rest assured, each issue will continue to have the same informative thought provoking content. We will also continue to provide you with the latest information on new treatments, medicines, and procedures. Additionally, you'll be seeing a new look on our website in the near future, and we're also a member on Facebook, so be sure to visit us there...become our friend, and start to enjoy the PAACT online community. We hope you enjoy the changes we have in store for you in 2011 and look forward to another wonder year.



Sincerely,
Richard H. Profit Jr.

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ACTIVE SURVEILLANCE FOR LOW-RISK PROSTATE CANCER: SELECTION CRITERIA AND FOLLOW-UP PLAN

BY DUKE K BAHN, MD

INTRODUCTION:

The incidence of prostate cancer detection has more than doubled since the wide acceptance of the serum Prostate-Specific Antigen (PSA) test as a screening tool. There is a possibility that many of the PSA screen detected cases are over-detections with subsequent over-treatments. The rate of over-detections is estimated to be as high as 56% (Etzioni: J. NCI. 94, 2002). Still many men are undergoing standard treatments, such as surgery, robotic surgery, external beam radiation, brachytherapy, and androgen ablation therapy. These are invariably associated with jeopardizing quality of life, mainly urinary and sexual functions. Lately, active surveillance (AS) has become a more accepted management strategy for certain men with low-risk disease. Several studies revealed that AS in the management of low-risk patients resulted in fairly acceptable outcomes, with only a limited number of patients requiring additional treatment. Barocas et. al. reported a review of 1,886 men with prostate cancer of which 16.3% were classified as low-risk cases using Epstein surveillance criteria (PSA <10, Stage <T2a, PSA density <0.15, number of positive tissue cores <33%, absence of Gleason pattern 4 and 5). Only 9% of men with known low-risk disease chose AS. A recent publication (Gorin & Soloway, Urology, Jan 2011) demonstrated that patients are heavily influenced by physicians in their decision to elect AS. Notably, the majority of the patients were not offered AS at diagnosis.

PROS AND CONS OF AS:


The main advantage of AS is an avoidance of the collateral damage and loss of function that are associated with a decrease in the quality of life. Another advantage would be an overall lower cost to society by not having an expensive medical procedure and not losing productivity. The main disadvantage of AS is the possibility of losing a “window of opportunity” to cure the disease. Therefore, it is extremely important to carefully identify patients with low-risk disease, adhere to close monitoring and proper intervention if there is any evidence of cancer progression. Unfortunately, there is no agreed upon or validated patient stratification method yet. Another disadvantage would be the perceived psychological

burden with AS. However, a few studies, mainly by European researchers, revealed that there was no difference in the psychological well being between the AS group and the group with treatment.

SELECTION CRITERIA FOR AS (BAHN CRITERIA OF PERFECT 10):

Low Risk Disease (Perfect 10)
Bahn's Criteria for Active Surveillance

1. Gleason 6 or less, may be up to 7=3+4
2. PSA less than 10 ng/mL (PSA Density < 0.15)
3. Stage: T1c -T2a, T2b with co -morbidity
4. Positive Biopsy Cores: less than 1/3 of cores
5. Percentage of tumor invasion: less than 50%
6. PSA doubling time: > 2 yrs, prefer >3 yrs.
7. Tumor neovascularity on color -Doppler: 1+ or less
8. Tumor volume on CD -TRUS: less than 1cc
9. Urine PCA -3 gene test: less than 35 (Tumor < 0.5cc)
10. Ploidy: Diploid



Differentiating between low-risk disease that may be indolent for the rest of a patient's life and immediate- or high-risk disease that may be life threatening prostate cancer is quite a difficult task. I have developed more extensive and stringent criteria than most physicians use as a low-risk stratification (ex: D'Amico Criteria: PSA <10, Gleason <7, Stage <T2a, Epstein Criteria: see the Introduction)

1. Gleason Grade 6 or less. In some cases, Gleason 7= 3 + 4 may be acceptable if accompanied by significant medical co-morbidity or short life expectancy (less than 10 years). Gleason grade is proven to be one of the most important independent predictors for cancer aggressiveness and final outcome.
2. Serum PSA level < 10ng/ml. I prefer to use PSA density <0.15 instead: (PSA density= Serum PSA/Prostate Volume), because PSA is produced by normal prostate glandular tissue as well as cancerous tissue. A large prostate gland is often associated with a higher PSA

as normal. Other main influences to PSA would be underlying prostatitis. That may be the reason for a high PSA and also a fluctuating PSA.

3. Stage: T1c (cancer not felt by DRE nor seen on ultrasound, but needle biopsy is positive) to T2a (cancer is in ½ or less of one side, either in the right or left lobe and is either felt by DRE or seen on ultrasound). T2b (cancer is in more than ½ of one side) or even T2c (cancer is in both lobes) with comorbidity or a short life expectancy. This stage used is based on a systemic biopsy, not by a color-Doppler US guided target biopsy. A target biopsy usually takes a fewer number of biopsy cores, but diagnoses 2-3 times more cancer than a systemic biopsy. It also comes with a higher Gleason grade and a higher stage of disease. It is not uncommon to see a systemic biopsy actually underestimate and under-stage a cancer.
4. Positive biopsy core number: less than 1/3 of total cores taken. It is a general observation that a higher number of positive tissue cores among biopsy specimens is associated with a larger volume cancer with advanced stage.
5. Percentage of tumor invasion seen in biopsy tissue core: less than 50% in any one core. The same logic is applied here as with number of biopsy cores.
6. PSA doubling time: more than 2 years, prefer more than 3 years. PSA doubling time may indicate the time needed for the tumor to double in size. Dr. Klotz's landmark paper on an AS study showed only two deaths out of almost 300 men with AS. These two patients had a PSA doubling time of less than 2 years.
7. Tumor neovascularity (abnormally increased blood supply) on color-Doppler US: 1+ or less. It is known that the higher the abnormal blood supply to the tumor mass, the higher the Gleason grade tumor with aggressive biological behavior.
8. Tumor volume measured by color-Doppler US: less than 1 cc. The larger the tumor volume, especially in the peripheral zone of the prostate, the greater the chance to have an extracapsular penetration of the tumor escape towards the nearby neurovascular bundles or to the seminal vesicles (becoming T3 stage). The tumor in the transition zone is often detected when it is large and still contained in the prostate. The transition tumor seems to have less aggressive biological behavior than the peripheral zone tumor. A small volume tumor in the transition zone with Gleason 6 would be a good cancer to watch.
9. Urine PCA-3 gene test: less than 35. Recently developed Prostate Cancer Antigen 3 (PCA-3) is considered to be

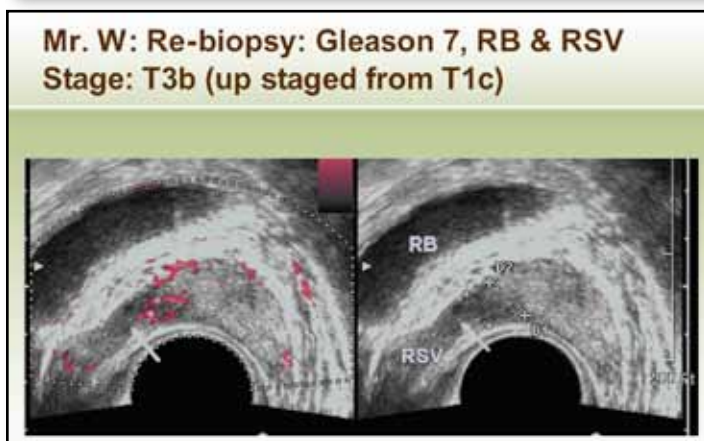
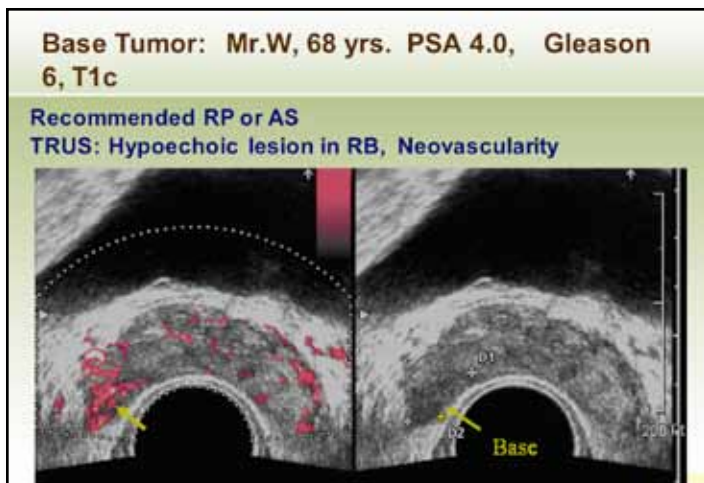
prostate cancer specific and highly over expressed in cancer. Multiple papers were published to identify the sensitivity for positive biopsy. Even though there are controversies, a high PCA-3 result (especially >100) was related to a positive biopsy. In addition, PCA-3 scores were significantly lower in low-volume and clinically insignificant prostate cancers. Ploussard (Eur Urol. Dec. 2010) reported a strong correlation between the PCA-3 score and tumor volume. The risk of having a significant cancer that is larger than 0.5 cm(3) was increased threefold in men with a PCA-3 score of >25 compared to men with a PCA-3 score of <25. It is also suggested by some researchers that it can be used as a tumor marker (same as PSA) in cancer management.

10. Ploidy: Diploid. Measurement of the nuclear DNA content allows classification of human cancers as either diploid or aneuploid. This test is performed with biopsy tissue specimens. Even though its popularity has faded lately, it may be added information that a cancer would indeed be low-risk disease. There are many reports supporting evidence for favorable survival in prostate patients with DNA diploid tumors.

If a patient's cancer features meet all 10 criteria (they receive a perfect 10 score), it would indeed be low-risk, probably clinically not a significant cancer and requires no aggressive treatment. In this case, AS is justified and encouraged. The first 6 criteria in this list are more important than the rest. If a patient's cancer does not meet more than 6 criteria, it could be considered as an intermediate or even a high-risk disease. A recent study by Cooperberg, et al (J Clin Oncol, Jan. 2011) reviewed AS outcome data in a low-risk versus an intermediate-risk group. The conclusion was "Selected men with intermediate-risk features would be appropriate for AS, and are not necessarily more likely to progress. AS for these men may provide an opportunity to further reduce overtreatment of disease that is unlikely to progress to advanced cancer."

ROLE OF COLOR-DOPPLER TRANSRECTAL ULTRASOUND (CD-TRUS) :

It is extremely important to have an accurate Gleason grade, cancer stage, cancer location, cancer volume, and cancer vascularity to access the risk stratification by using the perfect 10 criteria. In the event we use under-staged or under-estimated data from a random systemic biopsy, the criteria may end up choosing an inappropriate cancer management option with subsequent failure. Further investigation with CD-TRUS with targeted and staging biopsy would limit this mistake. The tumor volume by CD-TRUS measurement is usually larger than conventional black and white (Grey scale) ultrasound and the tumor neovascularity can be measured only when CD-TRUS technology is applied. Here is a good example:



Mr. W: His cancer was diagnosed as Gleason grade 6, as seen in one of 12 systemic biopsy tissue cores. It was staged as T1c. With a PSA of 4 ng/mL, it was classified as a low-risk disease and he was offered AS along with other aggressive therapy including radical prostatectomy. He made up his mind for AS and wanted to have a CD-TRUS to establish a new baseline for future reference. The CD-TRUS revealed a greater than 1cc sized, highly vascular tumor at the right base portion of the prostate with possible right seminal vesicle (RSV) invasion. A targeted and staging biopsy was performed and confirmed that it was a Gleason 7=4+3 tumor with right seminal vesicle invasion. The percentage of the tumor in the specimen was also larger than the original biopsy. His cancer was re-staged as a T3b upstaged from T1c. A cancer with a T3b stage is considered as a locally advanced disease and belongs to the high-risk category. Definitely, he was not a candidate for AS and he may not be a good candidate for radical surgery as well, due to the seminal vesicle invasion. He had to reconsider all the definite cancer treatment options carefully.

PUBLISHED OUTCOMES WITH AS:

Klotz and Choo were the first to report on prospective AS results. With a median follow-up of 72 months, 34% came off AS (101/331 patients). The reasons were a rapid PSA rise (15%), clinical progression (3%), histological progression (4%), and patient preference (12%). The overall survival rate

was 85% and the disease-specific survival rate was 99%. The triggers for leaving AS included: DRE becoming positive, PSA rising with a doubling time of less than 3 years, and a follow-up biopsy showing cancer with a Gleason 7=4+3 or higher. It is my opinion that if all of the patients underwent CD-TRUS with a proper staging biopsy at the time of the initial diagnosis, some of these men would have not been a candidate for AS. Several other publications including Klotz's updated data are similar to this report. Interestingly, data from the Swedish researchers and Memorial Sloan-Kettering did not find differences in outcomes between immediate radical prostatectomy (RP) and delayed RP (after leaving AS) in the low-risk disease group.

FOLLOW-UP SCHEDULE:

There is no agreed upon strategy for managing patients. However, these are the general guidelines used in most practices.

- A PSA every 3 months for 2 years, then every 6 months assuming the PSA is stable.
- A follow-up biopsy (preferably a target biopsy) at one year and then every 3-5 years until age 80, assuming that the follow-up PSAs remain stable.
- A CD-TRUS on alternate visits along with a DRE.

Recently, the urine PCA-3 test was proposed as a tumor marker (as in PSA) in the management of AS. It is still too early to recommend this as a routine practice. More studies are needed.

In addition to a CD-TRUS to objectively monitor the known cancer, other imaging modalities, especially contrast enhanced & diffusion weighed MRI could be used to monitor the cancer.

MOVING FROM ACTIVE SURVEILLANCE TO GROWTH ARREST:

Dr. Charles Meyers developed an interesting concept that would be beneficial to men with AS. He recommends a good diet, supplements and proper exercise that could likely improve a man's general health. Most men with low-risk prostate cancer die from reasons other than prostate cancer, such as heart attacks, strokes, diabetes and colon cancer. He recommends:

- Avodart or Proscar
- A Mediterranean heart healthy diet
- Exercise
- Reverse vitamin D deficiency
- Pomegranate juice or extract capsules
- Lycopene
- Fish or fish oil

THE CRITICAL TRIAL

- Antioxidants
- And to aggressively treat hypertension, high cholesterol and high blood pressure, reverse obesity, and timely colonoscopies.

One paper was recently published with the goal of determining the effect of Proscar or Avodart on pathologic progression in men on AS (Finelli et al. Eur Urol Dec. 2010). 93 out of 288 men (32%) experienced pathologic progression and abandoned AS during a median follow-up of 38.5 months. Men taking Avodart or Proscar experienced a lower rate of pathologic progression (18.6% vs 36.7%) and were less likely to abandon AS.

FOCAL THERAPY FOR PROSTATE CANCER:

Focal therapy for localized prostate cancer has gained in popularity recently. Cryoablation is a commonly used technology. Multiple single institution reports show good cancer control with minimal side effects. Bahn reported 0% urinary incontinence and 10% sexual dysfunction (J Endourology 2006). Current standard care options are either AS or radical treatment. Focal therapy would be a good compromise, a middle ground approach. It may avoid both under- or over-treatment. It is important to have a unifocal or unilateral disease to consider this option. In case of a significant psychological burden with AS or the identification of minimal disease progression during AS management, focal therapy could be a reasonable choice. Precise identification of the cancer location, size and extent by CD-TRUS is extremely important to perform a target freezing procedure that is done under TRUS guidance.

CONCLUSION:

We have experienced a great prostate cancer stage migration during the last two decades. The debate on over-detection and over-treatment of prostate cancer is still ongoing. AS became an increasingly popular option for selected men. It appears to be proven safe in the intermediate time frame. Selection criteria, a follow-up plan and triggers for intervention were discussed. The role of CD-TRUS in the identification of an AS candidate and in the follow-up management was also addressed. There is an interesting concept of "Moving AS to Growth Arrest" by using Avodart or Proscar as a main ingredient. If a patient is uncomfortable with AS and also uncomfortable with radical therapy, or disease progression is confirmed during the course of AS management, focal therapy could be an option as a minimally invasive treatment. Unfortunately, most patients with low-risk disease are not offered AS as an option. It is important to have an organization like PAACT for public education and patient empowerment.

*By Duke K Bahn, MD
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Ventura, CA
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Clinical Professor of Urology, Keck School of Medicine,
University of Southern California*

STUDY BACKGROUND

Dendritic Cells are known to be important mediators of antigen recognition and mobilization of immune responses, and several Dendritic Cell based cancer vaccines are currently under investigation. Recent work has suggested that Dendritic Cell efficacy may be significantly enhanced following cryoablation of local tumor.

The CRITICAL Study is a phase I/IIa investigation of an autologous Dendritic Cell product administered locally immediately following cryoablation of the prostate. **Participation in this trial may be an alternative for a select group of patients with few other options.**

STUDY PROCESS

1. White blood cells are collected from patients through a therapeutic aphaeresis procedure and processed at a cell manufacturing facility.
2. Cryoablation procedure immediately followed by local administration of Dendritic Cell Product.
3. Regimen of low dose chemotherapy to deplete T-reg cells and enhance Dendritic Cell activity further.
4. Series of Follow up visits to assess safety and efficacy.

INCLUSION CRITERIA

- Men \geq 18 years of age and any race.
- Histologically documented primary adenocarcinoma of the prostate
- Prior history of:
 - Androgen Deprivation Therapy; or
 - Organ-preserving therapy for primary prostate cancer.
- In case of recurrence, subject must have evidence of prostate cancer by a positive biopsy revealing adenocarcinoma within the past 6 months of screening.
- TxNxM1a and/or TxNxM1b disease limited to three total metastatic sites as evidenced by lymph node metastases and /or bone metastases at time of screening.
- Androgen-independent prostate cancer.
- Life expectancy of greater than or equal to 12 months.

LAC-PAACT¹ UPDATE

BY GREGORY H. TEUFEL, ESQ., CHAIRMAN²

- Adequate hematological function.
- Adequate renal function.
- Adequate liver function.
- Superficial veins as adequate for the performance of leukapheresis.

EXCLUSION CRITERIA

- The presence of lung, liver or brain metastases malignant pleural effusions or malignant ascites.
- Moderate or severe symptomatic metastatic disease.
- ECOG performance status ≥ 2 accessed at study screening visit.
- Chemotherapy treatment at any time prior to study screening.
- Radiation therapy for metastatic disease, including intravenous radioactive strontium therapy.
- Initiation or discontinuation of bisphosphonate therapy within 28 days prior to study screening.
- Treatment with any of the following medications or interventions or with any other investigational product within 28 days of study screening.
- Treatment with any investigational vaccine within 2 years of enrollment.
- Pathologic long-bone fractures, imminent pathologic long-bone fracture or spinal cord compression.
- Impending untreated spinal cord compression or urinary outlet obstruction.
- Paget's Disease of bone.
- History of stage III or greater cancer, excluding prostate cancer.
- Prior or currently active autoimmune disease requiring management with systemic immuno suppression.
- Any infection requiring parenteral antibiotic therapy or causing fever (body temperature 100.5°F (or 38.1°C) within 1 week prior to study screening.
- Known allergy, intolerance, or medical contraindication to receiving the contrast dye required for CT imaging.
- History of asthma, anaphylaxis, or other known serious adverse reactions to vaccines.

*For More information please contact:
Duke Bahn, M.D., Prostate Institute of America
888.234.0004*

It has been my privilege to share many stories of success in fights for coverage for prostate cancer treatments as well as to hear about many successful battles with the disease itself. It is much harder to hear (and I never before have passed on) any of the less fortunate tales, but I was moved by one recent situation that I will briefly share with you.

Bob was diagnosed with prostate cancer in 2002 and had a failed radical prostatectomy that year. He was only in his 40s at that time. He was given only 6 months to live by one oncologist, but fought valiantly against the disease for 8 years. He passed away September 28, 2010.

Bob and his wife had to deal with many coverage issues as they exhausted one treatment option after another, having some success with some treatments and no success with others. Though we were able to provide some helpful advice and I think all of his coverage battles ended in his favor (or were addressed through forgiveness of requests for refunds of coverage), they left him understandably rattled about the prospect of continuing to seek more and more treatment options and risk saddling his wife with large medical bills that may or may not be covered by insurance.

Bob's wife would have been supportive of further treatments despite that risk, but it came to the point where he decided to fall back on the more limited range of care options available for free at the VA, rather than risk leaving his wife with serious financial problems. Fortunately, he had the VA available to him due to his military service. For the same reason of concern, for the financial well being of his wife (now widow), Bob valiantly continued to work at his job as a park ranger as long as possible. It really shook me to see someone prematurely transition to palliative care (against medical advice) because insurance would not reliably cover the only chances he had left to meaningfully prolong his life.

The whole situation was the harshest lesson, in more than fifteen years of helping with coverage battles for prostate cancer victims,

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.

of how--win or lose--these battles take their toll, both on the cancer victims and on their loved ones; the stress, the humiliation of people who had always paid their bills on time suddenly overwhelmed, the time--so much time--on the phone, writing letters and emails, researching and figuring out so many confusing issues, when they may have so little time left to waste, and the loss of confidence, as to coverage, that people will treat you fairly and reasonably and that everything will work out well in the end.



We are particularly helpful in addressing insurance and Medicare coverage issues related to advanced cancer treatments. Please do not hesitate to contact us regarding any coverage or other legal issues related to advanced cancer treatments. We want to help, and we need your help in identifying the areas of greatest need.

We are always seeking volunteers to help with LAC-PAACT activities. Even if you are not

I don't know how much better it could have been for Bob and his wife if he had continued treatments rather than switch to palliative care when he did. Who knows, they could have been one step away from some new miracle treatment that would have given him ten more good years or at least a few more good months or even years.

It is a tragic tale of the great harm that improper coverage denials can cause from start to finish. Coverage issues actually delayed his diagnosis, when he encountered road blocks trying to get a second opinion, when the first signs of prostate trouble appeared as early as 1996. Treatment was halted, against medical advice, at one point, due to an improper coverage denial. In the end, treatment was halted permanently due to insurance concerns.

But at the same time, it is a tale of great courage, stamina, and perseverance, on the part of both Bob and his wife. The struggles they faced together during his long battle with the disease, the love they showed for each other, their strength and resiliency, was inspirational. We know there are a lot of people out there struggling like these two did. Be assured of our commitment to help you any way we can.

a lawyer, you can volunteer if you are inclined to help with law related issues. 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.

Please remember, 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.

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MOLECULAR PATHOLOGY: A PARADIGM SHIFT IN HOW WE LOOK AT PROSTATE CANCER

BY DOUGLAS O CHINN, MD

“Prostate cancer is a highly heterogeneous disease, and the treatments offered and administered should better reflect that heterogeneity. We need to do a better job at risk stratifying disease and offering a set of truly personalized therapeutic options”

– Oliver Sartor MD, AUA News Dec 2010.

This statement highlights the current conundrum every prostate cancer patient faces: “what is best for me?” Can we do a better job of predicting who needs total gland treatment and who may do well with focal therapy or active surveillance, or even more importantly, can we predict which treatment is NOT for the individual patient? Currently, 15-40% of patients have recurrence of cancer after definitive therapy, even though the tumor biology appears to match those cured. The problem is, grade for grade, and stage for stage, not all prostate cancer is the same. Patients with the same Gleason score can have different outcomes, even if matched by risk groups. What are we missing?

TRADITIONAL RISK STRATIFICATION

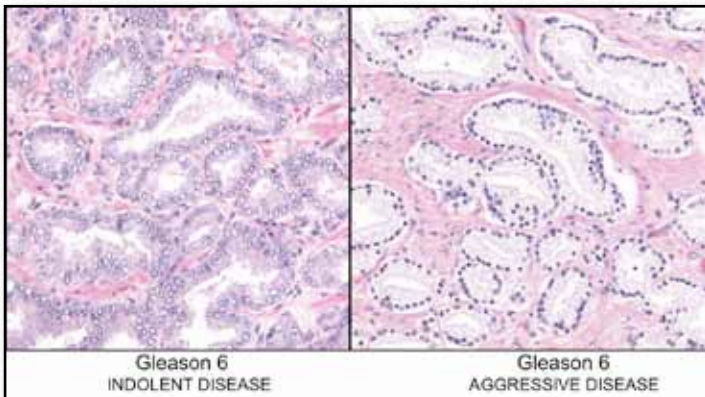
Over the past few decades, a number of risk assessment tools utilizing risk grouping and nomograms (i.e. D’Amico, Partin’s tables and Kattan nomogram), have been developed to provide clinicians with a standardized, reproducible, and evidence-based approach to prostate cancer treatment. These risk tools rely on similar features: pretreatment serum PSA, biopsy Gleason grade and score, the number of positive cores in a biopsy, and clinical tumor stage.

Although such prognostic tools have shown accuracy, it is well understood that they have limitations and rely on similar clinical and pathological variables in an attempt to determine cancer biologic behavior, which is a subjective approach. These tools do not incorporate measurable features of the actual tumor sample or its molecular profile. A perfect example is the role of the Gleason score, which is a widely used prognostic indicator of patient outcome. Unfortunately, Gleason score has deficiencies. Gleason grading, first introduced in 1966 by Dr. Gleason, assesses prostate glandular architecture (looking at stained samples of tissue under a light microscope) rather than cytological morphology and cannot discriminate between indolent versus life-threatening disease. This type of evaluation is very subjective and based upon the individual interpretation of the pathologist. Interestingly, it has been said that even Dr. Gleason could not always read the same slide consistently. More importantly, Gleason score does not repeatedly predict outcomes of therapy, as different patients with the same Gleason score do not always have the same outcome results or disease free survival rates. Two tumors with the same Gleason score can progress very differently. Therefore, the predictive outcome of Gleason score is limited. Since all risk assessment tools utilize Gleason score as part of the equation, their effectiveness is compromised, and we are still faced with the fact that personalized outcomes are not possible and patients are lumped into broad risk groups.

The ability to risk stratify is essential to providing optimal care for the patient. Today’s climate places significant value on early detection of prostate cancer, resulting in the diagnosis of indolent prostate disease; the cancer may or may not adversely affect the patient’s life span without treatment. For those who choose treatment, 60-85% of treated prostate cancer patients do not have their prostate cancer return. Consequently, are we over treating patients whose risk of cancer progression is very unlikely, given the fact that no treatment is without side effects? Furthermore, can we better identify patients who will fail traditional surgery and may benefit from procedures with fewer side effects? Clearly, more parameters are required to improve and personalize patient specific risk stratification.

FIGURE 1

Examples of visual identification through a microscope. The challenge is identifying which patient will progress into aggressive disease. Light-based microscopic examination of tissue cannot discriminate between indolent (slowly developing) and life threatening disease.



Current pathology analysis, based upon the Gleason scoring system, merely looks for changes in the architecture of the prostate tissue from the normal benign tissue. It is important to note that the cancer cells are usually scattered throughout the prostate tissue (multifocal) and not clumped or grouped together in just one area. The cancer cells are graded based on the architecture of the prostate tissue seen under a light microscope. The more advanced the cancer, the higher the Gleason score. However, prostate biopsies are still fraught with sampling errors, meaning cancer can be missed, and Gleason grades may vary within the prostate cancer itself. Unfortunately, higher Gleason grade and larger tumor volume are often discovered AFTER treatment; therefore, the information is discovered too late. In systems pathology, special stains and artificial intelligence are used that are better able to observe these changes, eliminating the subjective human variable.

SYSTEMS PATHOLOGY

Systems pathology embodies a paradigm shift on how we look at the pathology of prostate cancer. In 2008, Aureon Biosciences introduced a prognostic test, Prostate PxA, using systems pathology. By using systems pathology, it is possible to provide the patient with a personalized risk assessment of their cancer at the time of diagnosis. This revolutionary approach integrates information from tissue architecture, clinical data, and the cellular localization and quantification of molecular information. The results are assessed by mathematical formulas or algorithms that generate a personalized risk prediction score between 1 and 100. The score correlates directly with the likelihood of prostate cancer disease progression within 8 years of a radical prostatectomy. Disease progression is defined as PSA rise after castration, evidence of soft tissue or

bone metastasis, and/or death by disease. In addition to disease progression, Prostate PxA is able to predict the likelihood of a favorable surgical outcome post-prostatectomy. Favorable pathology is defined as organ confined disease post prostatectomy, a Gleason score less than or equal to 6 with no pattern 4 or 5 disease, and a PSA nadir. Patients with unfavorable pathology are more likely to have disease progression within 8 years post-diagnosis.

What exactly is systems pathology measuring? The systems pathology platform combines histological (the microscopic structure of tissue), molecular (looking at proteins called biomarkers), and clinical information by integrating three advanced technologies: image analysis, biomarker detection, and clinical data.

Image Analysis

Most cancer image analysis systems do not utilize the architecture of the tissue, which provides important information about the cancer. In prostate cancer, the architecture of the tissue specimen is a critical feature used by pathologists to determine the aggressiveness of the cancer. Systems pathology digitally captures the architecture of the individual cells and these digital images are used to generate a variety of statistical measurements.

The image process begins with a digital image (Figure 2) and proceeds to an image segmentation (the automated system breaks the image into component pieces), followed by object classification in which each of the segmented areas are labeled as part of the tissue (lumen, nuclei, stroma, and cytoplasm). This process results in objective feature statistics.

FIGURE 2

Image Processing

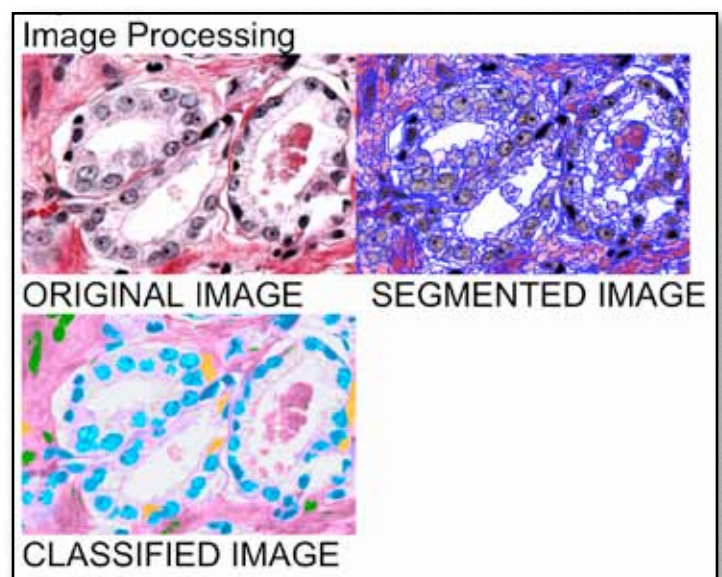
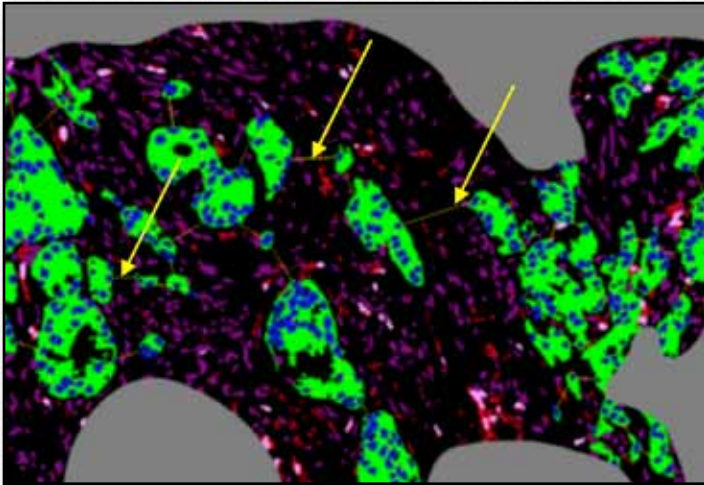


FIGURE 3

Image Analysis Based Upon Image Processing



In this gland structure image analysis, the cancer tissue is labeled green. Image analysis measures the distances between cancerous tissue nuclei (see arrows). The longer the lines, the further the cancer nuclei are from each other, which means there is more cancer cell dispersion (vs. more clumped together) and this is associated with more invasive and aggressive disease.

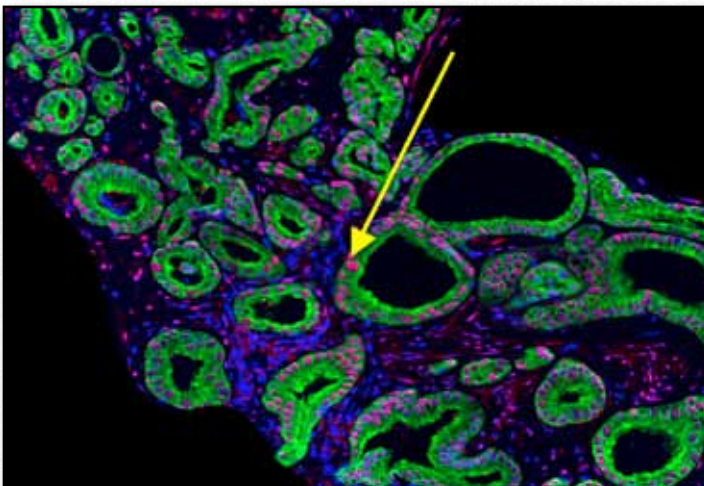
Green is cancer cells, and image processing is measuring the distance between the nuclei (blue) of the cancer cells (yellow arrows).

Biomarker Detection

Specific biomarkers (proteins found throughout the cell), such as Androgen Receptor (AR) and Ki67, are thought to be important in the prediction of prostate cancer progression. The automated system allows for multiple antibodies - to specific cell proteins - to be tagged with immunofluorescence, allowing computerized spectral imaging to identify specific cancer tumor markers from the surrounding tissue, enabling a more sensitive and quantitative measurement of biomarkers.

FIGURE 4

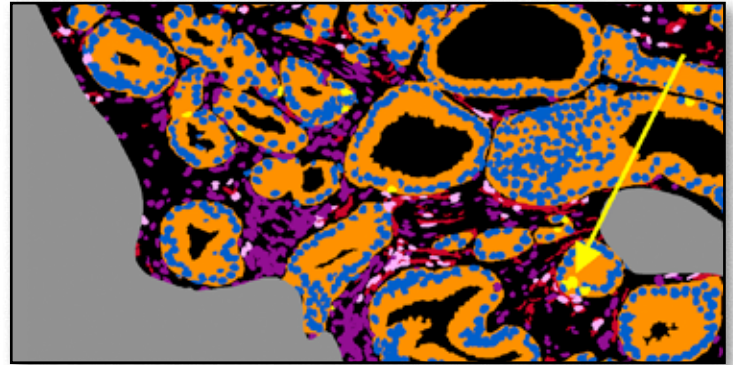
Images of Immunofluorescent (IF) derived biomarkers-AR



Using image processing, benign glands are digitally masked, and only the cancer glands are seen. This allows artificial intelligence to distinguish and accurately access the amount of biomarkers only in cancer cells. The AR positive epithelial nuclei appear in pink.

FIGURE 5

Images of Immunofluorescent (IF) derived biomarkers-Ki67



Again, digitally masked images allow artificial intelligence to discern cancer from benign glands and focus on tumor markers positive only in cancer cells: The Ki67 positive epithelial nuclei appear yellow.

Clinical Data

Clinical information, such as Gleason score, pathological stage, and PSA values are integrated.

Features extracted from the data are analyzed using advanced mathematics, via computational machine learning (i.e. artificial intelligence or AI). Artificial Intelligence focuses on algorithms that enable computers to learn, recognize patterns, make decisions, and improve performance. The AI methodology “learns” from the cumulative prostate cancer data and improves upon the existing ability to provide an accurate prediction for patients.

Features that were integrated into the predictive models were clinical features (PSA, biopsy Gleason score and dominant Gleason grade, histomorphometric features (reflect cellular and architecture of tissue), and a biomarker expression profile which included Androgen Receptor (AR) and Ki67.

CONCLUSION

Significant patient challenges exist to understand and predict risk assessment. Stratifying and assessing risk severity is important as multiple treatment options exist. Complex decisions must be made by the patient and clinician. Choosing the most optimal treatment is the ultimate goal.

Understanding the “true” nature of each individual cancer can help the patient decide upon the choice and timing of treatment. Systems pathology strives to replace subjective analysis with quantitative information that removes the inherent subjectivity of preoperative risk assessment tools.

Systems pathology provides the physician with additional, objective information, allowing them to better guide and counsel patients in making the most-informed treatment decision. This 21st century technology is the most comprehensive and accurate way to predict the progression of prostate cancer at the time of diagnosis.

By Douglas O Chinn, MD

Arcadia, CA

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WHAT THE HECK HAS BEEN GOING ON IN MY WORLD-PART 30!

BY MARK A. MOYAD, MD, MPH

Note: A total of 30 times in a row I have written and volunteered for this newsletter, and I have yet to receive any financial compensation or personalized gifts for my efforts like a case of exotic juices such as Acai, Goji, Noni or even Prune Juice! Wait, prune juice may not be an exotic juice, but it still has magical powers because it could help me relax, take a seat, and allow me to catch up on my reading (get what I'm saying)!

Note: In the last issue I wrote 27 new and different stories, and if you add that to the past 159 stories I have written in the past we will start today with number 186 (does that make sense — it does to me). Oh, and Michigan finally beat Michigan State in basketball! Just had to throw that ridiculous non-related piece in there to ameliorate the pain I have felt for years and years of losing to those fellow Michiganders!

BREAKING NEWS STORY!

186) Is XL184 (also known as “Cabozantinib”) for real, because this drug sounds incredible?!

(Reference: Media throughout the U.S. on February 17, 2011 and www.exelixis.com, and ASCO GU Symposium, February 17-19, 2011 in Orlando, Florida)

BOTTOM LINE:

XL184 is helping patients reduce or eliminate their bone lesions in a phase 2 trial and shrinking tumors in some organs of the body (liver, lungs etc...), but whether the drug works long-term is not yet known. Regardless, this preliminary data looks really amazing/outstanding!

WHAT ELSE?

There is a drug out there in the prostate world that is getting more attention than a politician from South Carolina coming back from Argentina. Individuals are writing to me and telling me that this drug apparently “melts away cancer in the bones.” I have heard more about this drug from behind the scenes (in the rumor mill) compared to any other in a long, long time! So, is all this stuff true? Hype?

The company Exelixis, Inc. (San Francisco, CA) and researchers (for example, Dr. David Smith from the University of Michigan Medical Center and other researchers from around the country) just reported updated data from their phase 2 clinical trial in patients with metastatic castration-resistant prostate cancer. The drug actually reduced or stabilized metastatic bone lesions in NEARLY ALL patients that were evaluated by a bone scan. This actually occurred in 85% of the evaluated patients! Are you kidding me! How often do you see this happen?! Also, the drug reduces bone pain and the use for narcotic pain medication, and it even increased hemoglobin in patients with anemia. The drug may also help patients that have and have not been treated with taxotere chemotherapy! What is the catch? The median time patients were followed so far is only 3.8 months (some followed less than 1 month and others for as long as 15 months), so researchers are

“In other words, it is really a compound that disrupts the ability of a tumor to feed itself and probably works in multiple other ways to stop the signals that allow a tumor to grow.”

XL 184 is a small molecule that was designed to block signals that allow a tumor to grow.

not sure if patients will do better long-term, **but oh my gosh this is encouraging** (should have used a swear word to emphasize my point - that is what my basketball coach taught me in high school)!

Fatigue, reduced appetite and other gastrointestinal issues, and an increase in blood pressure were some of the side effects that were found with this drug. However, the percentage of patients that experienced real serious problems with these side effects or other serious side effects was remarkably low! For example, extreme fatigue that required more clinical attention, and a reduction in appetite occurred, in 15% and 2% of patients, respectively.

Tell me more! Okay! XL 184 is a small molecule that was designed to block signals that allow a tumor to grow. In other words, it is really a compound that disrupts the ability of a tumor to feed itself and probably works in multiple other ways to stop the signals that allow a tumor to grow. This drug is also being studied in patients with certain types of thyroid cancer, brain tumors, lung cancer and other cancers that have advanced including pancreatic, liver, gastric, melanoma, breast and ovarian cancer. In fact, the drug is in the final phase 3 trial for patients with medullary thyroid cancer.

The drug can be taken as a daily flavored liquid or a gelatin capsule. This is also what I believe is really amazing, because taking the drug on a regular basis would be so simple!

Will this drug really be a breakthrough drug for cancer patients? Stay tuned, but you have to admit that it is getting really exciting out there in research and this drug is just one prime example of why patients and their families may have options soon that we never ever, even dreamed of just

a few years ago! Cool stuff (I like to use hip 1970s vernacular whenever I get really excited...better than using a swear word I guess)!

ANOTHER BREAKING NEWS STORY!

187) Abiraterone Acetate is an oral drug that works for some men with prostate cancer that are running out of options, and the drug has an Expanded/Early Access Program (EAP)!

Reference: Need to call Centocor Ortho Biotech at 800-457-6399 for HRPC patients that are trying to get this as an option or go to the following websites for locations of where to get it

(<http://www.clinicaltrials.gov/ct2/show/NCT01217697?term=abiraterone&recr=Open&rank=6>

or <http://www.prostatecancerearlyaccess.com/index.html>)

BOTTOM LINE:

The company Johnson & Johnson (J&J) provides a pill known as "Abiraterone," which was recently found in a phase 3 trial to improve survival in men with prostate cancer that are no longer responding to Taxotere® chemotherapy or two past chemotherapy regimens (at least one of which had to be Taxotere)! Wow! And, for men that are running out of options there is an opportunity to get this drug NOW by talking to your doctor (before it is FDA approved)! However, hopefully this drug will be FDA approved by the time you read this article or in early 2011.

WHAT ELSE?

Nothing is more important right now than knowing that this is an option for patients running out of options. Talk to your doctor, please!

188) Belly fat increases must be discussed before the first hormone/LHRH injection.

(Reference: Hamilton EJ, et al. Clin Endocrinol, published early on-line, 2010)

BOTTOM LINE:

Androgen deprivation appears to increase subcutaneous AND visceral fat.

WHAT ELSE?

Androgen deprivation therapy (ADT) improves survival in the right patients, but it is also well-known that it comes with a catch or a list of side effects. One well-documented side effect is weight gain, but researchers were not sure what type of weight gain. This was a 12-month prospective observational study of 26 men with a mean age of 70.6 years diagnosed with non-metastatic prostate cancer and followed during their first year on ADT. Mean BMI, weight, and waist circumference (WC) was 27.6,

will barely budge, but if you lose some inches of visceral fat from exercise, diet or even gastric bypass surgery your cholesterol will drop faster than the popularity of a golfer caught in a sex scandal. So, what now? Buy bigger pants before the first injection? No! I have always believed that these numbers could be significantly reduced with regular aerobic and resistance exercise that needs to begin right before the first injection. This has already been demonstrated in a number of preliminary studies. So, the non-exercise excuse is OVER! Every individual about to get hormone therapy needs to get some exercise daily or every other day to prevent one of the most common side effects of the drug.

189) Creatine powder supplements may prevent some of the side effects of statins (cholesterol lowering drugs).

(Reference: Shewmon DA, Craig JM, Ann Intern Med 2010;153:690-692)



176 pounds, and 38.7 inches, respectively. Visceral (deep belly fat) and subcutaneous (right below the skin) abdominal fat area increased significantly. Lean tissue mass decreased significantly by 3.6%, and fat mass increased by 14%. Insulin resistance also increased significantly by 12%, but there were no changes in blood glucose or blood pressure. Visceral fat area was correlated with insulin resistance and testosterone deficiency. Mean weight and WC increases after 12 months on ADT were 1.8 pounds, and 0.7 inches, respectively.

Visceral fat (aka deep belly fat) can be associated with worse overall health outcomes compared to subcutaneous fat accumulation. This is why you can have a 20-pound liposuction of your subcutaneous fat and your cholesterol and blood pressure

BOTTOM LINE:

Creatine monohydrate powder taken in small amounts daily may prevent and reduce the side effects of cholesterol lowering drugs.

WHAT ELSE?

Statins (cholesterol lowering medications) are one of the best selling prescription medications in the world, but have one strong limitation, which is muscle and joint discomfort. A variety of methods have been used as a way to prevent and reduce this side effect, but with no good option except for reducing the dosage or eliminating the medication itself. Other options need to be investigated, especially with the increasing role of statins for the

potential prevention and potential adjuvant treatment for several diseases (including prostate cancer I believe). Creatine is a traditional muscle-enhancing supplement that could impact muscle pain, weakness, or cramping so it needed to be tested in a preliminary study with these statin drugs. This was a case series of creatine supplementation in 12 patients intolerant to at least 3 statins. A muscle discomfort score was calculated based on muscle pain, weakness, and cramping. Creatine was in the form of monohydrate powder, and each 5-gram (1 teaspoon) dose was taken with approximately 8 ounces of water. Patients were monitored and scored at 5 different time points: beginning, after consuming a 10 gram daily loading dose for 5 days, after taking 5 grams daily (maintenance dose) with their statin drug for 6 weeks, after taking the statin alone and reporting muscle symptoms, and after taking 10 grams of creatine again (loading dose) for 5 days. The entire testing period lasted from 2-3 months depending on the response.

Muscle discomfort was prevented with creatine in 8 out of the 10 participants that completed the preliminary study. Moyad (hey, that's me) is a big fan of statins, but what do we tell individuals that are worried about statin side effects? First (option 1), no one should take a supplement to prevent statin side effects when the majority of individuals do not have side effects on statins. This would be a waste of money and time. Second (option 2), if someone is having such side effects they should talk to their doctor about changing the dose, the drug, or the frequency of the drug and they can get similar numbers in some cases, but without side effects. Third, if after trying these other options there exists at least the possibility of trying this creatine trick, because muscular intracellular creatine depletion could theoretically be occurring in some individuals when they take statins. For example, the authors point out that taking some steroid medications can cause these muscle changes and without changes in blood chemistry, but there is obviously discomfort experienced by the person taking the drug, and this may occur from creatine depletion. I like option 1 and 2 above because adding more pills and powders long-term to treat a side effect is a pain, costly, and will not make life easy.

A Belgian Malinois shepherd dog was trained for over 2 years to scent, and locate urine of men with prostate cancer.

190) Trained dogs may be able to detect prostate cancer.

(Reference: Cornu J-N, et al. Eur Urol 2010; published online early)

BOTTOM LINE:

A dog smelling human urine to detect cancer is one small paw step for man, and one giant leap for mankind, and it may explain why dogs always want to put their noses in the pelvic area of so many individuals!

WHAT ELSE?

Volatile organic compounds in the urine have been suggested as potential commercial markers of cancer detection. Recently, a small study found that bladder cancer could be detected by trained dogs, so then why not try a similar experiment with prostate cancer patients?



A Belgian Malinois shepherd dog was trained for over 2 years to scent, and locate urine of men with prostate cancer. After this time a double-blind procedure was utilized and urine was utilized from 66 patients referred to a urologist for an elevated PSA or abnormal DRE. All patients had a biopsy and 33 had cancer and 33 were negative biopsy controls. During each “run” there were 5 samples without cancer and 1 sample with cancer (6 total) and the dog had 1 chance to signal which of the samples were from a patient with cancer. The dog detected the correct cancer sample in 30 of the 33 cases presented to it. Of 3 cases that the dog missed, one patient was re-biopsied and cancer was found. Perhaps dogs can be trained to detect prostate cancer, but this study also suggests that specific compounds can be located in the urine and used as novel cancer detection agents.


I always thought that the only reason my dog buried himself in my crotch when I came home from work was because he was looking for a doggy treat in the wrong location or he smelled another dog, not because he was looking for prostate cancer! Still, it is intriguing that dogs have been trained to detect explosives, drugs, squirrels, poop...so why not other compounds that can detect cancer or other diseases? There have been some preliminary studies already completed in individuals with bladder, breast and lung cancer that has demonstrated the ability of some dogs to detect these tumors with a greater chance than just luck. What about urine that has been slightly altered from its normal look and smell? You think an advanced form of Lassie, Benji or Old Yeller could still detect the positive sample?! I would love to see what a dog can do after someone eats a pound of asparagus (ouch! That would confuse them - right? Boy, oh, boy, would that be a fun experiment!).

191) What the heck is this new “carisome” test for detecting prostate cancer by locating “microvesicles?”

(Reference: www.carislifesciences.com/prostate-cancer-screening, or call 1-877-702-2747 for areas that offer it or 1-800-979-8292)

BOTTOM LINE:

The Carisome Prostate cMV 1.0 test is a blood test commercially available right now, that could help determine if a man has prostate cancer, or may truly need a biopsy (or another biopsy). Hopefully it may also help selected patients with prostate cancer to determine if their cancer has returned, but more research is needed to determine how precisely accurate the test is right now. This is the catch; preliminary data is good on hundreds of patients, but there isn't any long-term data available on thousands of patients just yet. If your doctor is having



When your blood sample is sent to a lab it looks for what is known as “circulating microvesicles” (also known as “cMVs”) that could come from prostate cancer.

trouble deciding if you need a biopsy, you could ask for this test to determine if it may help in the final decision to have a biopsy or not.

WHAT ELSE?

When your blood sample is sent to a lab it looks for what is known as “circulating microvesicles” (also known as “cMVs”) that could come from prostate cancer. These microvesicles may actually come from the membrane-bound structures from a cancer cell that is secreted into the blood stream. In other words, some cancer cells give off some trash or debris that leaves the cell and this test may be able to detect this, which means it could signal that you do have prostate cancer. This does not mean you have metastatic or advanced disease, but is just intended to determine if you have cancer. It takes about 3-5 business days to receive the results of this test after it is sent from your doctor's office.

There are 1 of 4 potential results that can occur with this test:

-POSITIVE means that the patient might have prostate cancer.

-NEGATIVE means that the test suggests there is no cancer.

-BORDERLINE-means they are not sure if there is cancer or not.

-NON-EVALUABLE means there is not enough of what is needed in the sample to make a decision.

The test is currently not intended to replace any other tests that your doctor uses, and it is really only a test of RISK. So, it does NOT provide information right now on how far the cancer has spread, size of cancer, aggressiveness of the cancer... The good news is that many insurance programs cover the test but there still may be a cost to you so do some investigative work here my friends. You do not want to end up like me - a poor doctor working for PAACT for free for over 10 years!

192) Vitamin D continues to be overrated and calcium requirements have NOT changed!

(Reference: Medical Reference: www.iom.edu/Reports/2010/Dietary-Reference-Intakes-for-Calcium-and-Vitamin-D.aspx)

BOTTOM LINE:

The official word is in! Despite all the hype on vitamin D, the Institute of Medicine (IOM), which is one of the leading medical and independent authorities that change dietary requirements, believes that Americans are getting plenty of vitamin D right now!

WHAT ELSE?

I don't want to say it, however, I'm going to anyway! Vitamin D was getting too much hype outside of bone health. Why do we need more than 800-1000 IU per day? It is because "experts" stated that it could cure or treat all sorts of situations and cancers! What! Most of the prostate studies have shown no benefit and some harm with getting too much vitamin D, yet no one wanted to believe it! So, finally after more than a decade the IOM got back together on this subject, and they basically said that vitamin D is overrated after looking at a 1000 studies on 25 health outcomes (except for bone health). Be careful with these supplements! Some patients may need a blood test but many others do not need it. For example, individuals on hormone therapy may need it because there is an increase in bone loss with androgen deprivation therapy (ADT) for prostate cancer. In addition, the calcium recommendation of a daily intake of about 1200 mg a day TOTAL was not changed at all. Remember, if you are getting 1000-1200 mg of calcium daily from food there is NO NEED TO TAKE A CALCIUM SUPPLEMENT. So, what happens if you get too much calcium and/or vitamin D? Well, for starters it can increase the risk of kidney stones, and your arteries might take in too much calcium that could potentially contribute to heart disease! Fun stuff! The "D" in vitamin D stands for "Dumb" if you believe that mega-doses

are the solution to all of life's problems! Wow, that was harsh but I had to make the point! Bring on the semi-hate mail and threatening letters from all those vitamin D lovers!

193) Resveratrol, the miracle anti-aging supplement, drug, etc...was as over-rated as the Minneapolis Metrodome Roof's ability to hold snow!!

(Reference: <http://online.wsj.com/article/BT-CO-20101201-712683.html>)

BOTTOM LINE:

Better to get low amounts of resveratrol from red wine, red grapes or peanuts compared to the supplement or drug!

I don't want to say it, however, I'm going to anyway! Resveratrol was getting too much hype! I wrote about it and lectured about it and told people that these supplements or drugs coming from the skin of grapes were too over hyped! So many people jumped on the resveratrol bandwagon that there was no more room and the wagon broke down! So, what happened that you probably did not hear about my friends! A large pharmaceutical company (GlaxoSmithKline or GSK) purchased this compound along with some other products from a small company (Sirtris Pharmaceuticals) for over 700 MILLION DOLLARS in 2008!!! Anyhow, the clinical trial that tested this drug (SRT501) was stopped because of a lack of activity and it may also have indirectly or directly increased the risk of kidney problems and kidney failure! Basically, continuing to get red wine or eating peanuts in moderation can be healthy and makes a lot more sense compared to taking a chance of these high concentrations of resveratrol dietary supplements. We have no reason to believe that resveratrol in grapes and wine is unhealthy unless you just drink too much wine and the alcohol will be damaging enough! Until someone provides some exciting research I would put my resveratrol supplements next to my shark cartilage supplements in the largest toilet you can find and hit the flush button/lever several times just to make sure you are free of this temptation! Did you notice there were a lot of toilet jokes in my column this time! I wonder why? Perhaps my therapist can explain this?! I am sure it has something to do with my parents!

THAT IS ALL FOLKS!

See you in the Summer when we can talk about how the Michigan Football team will surprise everyone, including me, and win the Big Ten title this year, and why it is never smart to double up on your oatmeal and All-Bran consumption right before you go to your "no talking/noise allowed" meditation class!

*By Mark A Moyad, MD, MPH
University of Michigan
Ann Arbor, Michigan*

FREE MEDICAL CONSULTATION

PAACT MEMBERS and non-members may contact PAACT headquarters directly (616-453-1477) to speak with our counselor (Richard H Profit, Jr.) for a free unlimited medical consultation regarding DIAGNOSIS, EVALUATION, DETECTION AND TREATMENT options for prostate cancer. Mr. Profit has worked with doctors in all aspects of treatment. A few of the doctors that he has visited/observed during treatments/procedures/surgeries/etc. are listed to the right.

Duke Bahn, MD (Color Doppler/TRUS, Cryosurgery, actively involved in clinical trials using Provenge® and cryotherapy)

Michael Dattoli, MD (Brachytherapy)

Fred Lee, MD (Color Doppler Transrectal Ultrasound/ color enhanced TRUS)

Robert Leibowitz, MD (Triple Hormone Blockade® [THB®], Testosterone Replacement Therapy [TRT])

Gary Onik, MD (Cryosurgery)

Ash Tewari, MD (Robotic Prostatectomy)

ABIRATERONE ACETATE UPDATE

To all,

Many of you who have advanced disease may have been watching a drug in development called Abiraterone Acetate. It is not yet FDA approved, but trials look very good, and side effects appear to be very few. Most common side effects are fluid retention (30.5%), and low potassium (17.1%).

While we wait for FDA approval, which is likely – Abiraterone is now available in a **couple of clinical trials** that have **no placebo**. **One is currently recruiting in Detroit as of January 28, 2011.**

Keep an eye on this link for Ft. Wayne, IN.

The link is being updated almost weekly.

***Study of Abiraterone Acetate in Patients with Advanced Prostate Cancer**

<http://www.clinicaltrials.gov/ct2/show/NCT01217697?term=abiraterone&recr=Open&rank=6>

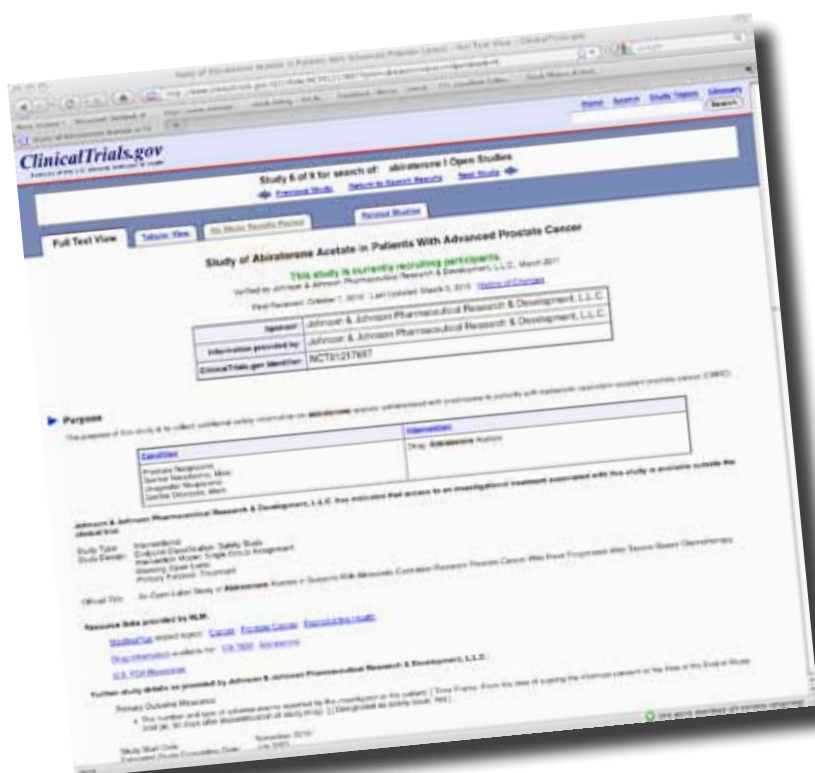
Here are some basic trial details.

Basic Criteria:

1. testosterone less than 50
2. metastatic
3. **failed chemo**
4. no more than 2 different types of previous chemo

To find **address for Detroit site**, call Centocor Ortho Biotech at (800) 457-6399

Also, print out and show to your physicians for discussion.



LETTER TO THE EDITOR

Since I haven't heard or seen anything at all about it on the news, I just wanted to make sure that you are aware of the incredible new service that is now available to persons dealing with cancer, thanks to research done here in Grand Rapids at the Van Andel Institute:

New just since sometime in May this year, a Van Andel Institute subsidiary called Intervention Insights, Inc. (web site: www.interventioninsights.com) is able to transform the issue of "What should we try next?" in the treatment of advanced cancer patients from a guessing-game into an exact science. The way it works is that a cancer patient's own local doctor(s) take a biopsy sample of the patient's cancer and send it to the lab Intervention Insights uses; they analyze it down to a molecular level to identify its critical operational and growth pathways so that those can then be compared with all available medicines to determine which of those medicines are the best at defeating those particular pathways. That information is then sent to the patient's doctor, so they no longer have to rely on "what seems to work best for the average patient in this condition," but instead will know with some degree of certainty exactly which specific medicines are most likely to successfully defeat this particular patient's cancer.

In my humble opinion, this is the most significant breakthrough in cancer treatment in decades. For example, one of the participants of the on-line advanced prostate cancer support groups I frequent mentioned one time that he'd participated in a clinical trial in which 24 out of 25 men tested received no benefit whatsoever from the medicine being tested. But he was the 25th guy, and it held his cancer in place for six years! ---No doctor would ever think of using it on one of their prostate cancer patients, because it doesn't do any good 96% of the time. But what if it is a perfect six-year match for your specific cancer? How would you ever know? Now, for the first time ever, there is a way to find out. It isn't cheap. The fee is about \$4,000, plus the cost of the biopsy, but if it makes the difference between a person's doctors having to guess what to try next, or having a scientific basis for that decision based on a molecular analysis of that patient's own cancer cells, it may be a small price to pay. Too many cancer patients are being told to "go home and get their affairs in order because there is nothing more we can do," when, in fact, there are lots more things that could be done, but until now there hasn't been a way to tell which one or ones might work, so rather than torture the patient with a bunch of failed guesses, doctors give up.

Please consider doing an article/announcement about this new option in the next "Prostate Cancer Communication" newsletter and/or putting something up on your web site about it. It could save some lives! — J.A.

The 24th National Cancer Survivors Day is Sunday, June 5th.

Be sure to get involved!

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FINANCIAL SUMMARY REPORT (JANUARY 1, 2010 THROUGH DECEMBER 31, 2010)

	<u>GENERAL FUND</u>
BALANCE ON HAND DECEMBER 31, 2009	<u>1,454,545.30</u>
REVENUES RECEIVED -	
Membership Contributions	58,324.06
Memorial Income	5,177.00
Trusts & Bequests	336,611.33
Investment Income	51,367.03
Miscellaneous Income	73.69
TOTAL REVENUES	<u>451,553.11</u>
TOTAL BALANCE ON HAND AND REVENUES	<u>1,906,098.41</u>
EXPENDITURES-	
Investment Withholding	219.02
Employee Wages	96,420.05
Payroll Taxes	7,754.13
Insurance (Health, House, Workman's Compensation)	32,094.84
Outside Services, Labor	5,478.38
Rent	15,000.00
Meals, Motel, and Transportation	4,700.91
Auto Expense	1,198.97
Printing	22,386.14
Postage and Delivery	23,680.08
Telephone	3,499.20
Service Plans/Licenses & Permits	4,080.22
Program Expense-Conference Exhibit Fees	833.00
Office and Computer Supplies	5,773.31
Utilities - Refuse	76.00
Repairs (Building, Equipment)	450.00
Miscellaneous	2,173.48
TOTAL EXPENDITURES	<u>225,817.73</u>
BALANCE ON HAND DECEMBER 31, 2010	<u>1,680,280.68</u>
ASSETS:	
Checking Account	48,106.21
Petty Cash	50.00
Savings Account	29.63
Certificates of Deposit, Stocks, and Bonds	1,508,279.15
Money Market Funds	264,516.96
Equipment	13,289.89
NET ASSETS:	<u><u>1,834,271.84</u></u>
FOUNDATION FUND BALANCE:	<u><u>286,651.40</u></u>

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