

PROSTATE CANCER COMMUNICATION

PROSTATE CANCER COMMUNICATION NEWSLETTER • VOLUME 19, NUMBER 3 • SEPTEMBER 2003

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3-D Saturation Biopsy Mapping of the Prostate: A new biopsy technique that promises to resolve many issues in the diagnosis and management of patients with prostate cancer.

By Winston E. Barzell, M.D.
Urology Treatment Center
Sarasota, FL
Phone: 941/917-8488

There are several dilemmas facing both patients and their physicians in the diagnosis and management of prostate cancer. These fall in the area of diagnosis, management and treatment.

Diagnostic Dilemmas: A significant number of men may be harboring prostate cancer that by conventional means goes undetected on repeated biopsy performed by the standard transrectal ultrasound technique. While there are numerous reasons for this, the most notable is that portions of the prostate (known as the transition zone and apex) are not readily accessible using the transrectal route for biopsy.

Patients who are at high risk of going undiagnosed are those with cancer predictive factors such as: a persistently rising PSA, a falling free PSA, a strong family history of prostate cancer, and atypia or PIN on previous transrectal biopsies.

When patients who had at least three previous negative transrectal biopsies done by the standard technique are subjected to this newer 3-D saturation mapping, approximately 40% turn out to have a biopsy that is positive for prostate cancer. In half of this 40% with a positive biopsy, the amount of cancer discovered appears to be insignificant and can be watched, but in the other half (or 20% of the entire group undergoing 3-D mapping) the cancer is significant and warrants treatment. Indeed we have had instances where patients with 3 prior negative transrectal biopsies performed at renowned institutions, were found to have extensive high Gleason score cancer on 3-D mapping biopsies.

Let's Conquer Cancer in OUR Lifetime

Therapeutic Dilemmas:

1. Watchful waiting group: What to do when minimal cancer is found on transrectal biopsy and a patient is considering a watchful waiting approach.

Dr. Jonathan Epstein, a pathologist at Johns Hopkins, and his colleagues have identified a sub-group of patients who are likely to have insignificant cancer when subjected to a radical prostatectomy. If pre-operative transrectal biopsy reports meet certain criteria, Dr. Epstein found that 50% of the patients have insignificant cancer. These patients with insignificant cancer can be safely managed with watchful waiting. The problem, however, is trying to identify the other 50% of the group that has significant cancer that should be treated (presumably cancer that has been under-diagnosed because of under-sampling). In other words, is the minimal cancer on transrectal biopsy a result of a “lucky” hit (i.e. the needle just happens to hit the one small area of cancer) or does it reflect “the tip of the iceberg” (i.e. there is extensive cancer but it was missed by most of the needles)?

By putting patients who had minimal cancer on previous transrectal biopsy through a 3-D saturation

mapping and obtaining anywhere from 30-80 biopsies of the prostate depending on the prostate size, one can readily sort out the 50% of patients who need active therapy versus the 50% who can be safely watched. In ten patients, to date, who fulfilled the above criteria, I was able to safely recommend expectant management in 4 patients.

2. Failed primary therapy: Patients who have failed primary therapy such as previous external radiation therapy, brachytherapy (seeds) or cryoablation (freezing) can be considered for salvage treatment such as additional so-called “remedial” brachytherapy or possibly one-sided cryosurgery. When such patients undergo 3-D saturation mapping, one can accurately assess the location and extent of cancer recurrence and in this way logically plan therapy. For example, if it turns out that the cancer is only on one side, then, one could recommend one-sided cryosurgery (freezing). If it turns out that the patient has failed brachytherapy and has cancer in an area where there were an inadequate number of seeds placed, one can add “remedial” seeds in the location of the cancer recurrence. In my limited experience to date, the 3-D mapping has been invaluable in recommending ra-

CANCER COMMUNICATION

Published Quarterly by: PAACT, Inc.

Patient Advocates for Advanced Cancer Treatments
1143 Parmelee NW
Grand Rapids, MI 49504

Director... Richard Profit
Editor ... Richard Profit & Staff
Webmaster... Art Schlefstein

Postmaster: Send address changes to:
Prostate Cancer Communication
P.O. Box 141695
Grand Rapids, MI 49514

Phone: 616/453-1477
Fax: 616/453-1846

E-Mail: paact@paactusa.org
PAACT Web Page: <http://www.paactusa.org>
Newsletter: <http://www.paactusa.org>

Editor:

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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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tional treatment to these patients who have failed primary therapy.

3. Focal therapy group: There has been a recent move by some to recommend focal or one-sided therapy when the cancer is very small and only affects one side of the prostate. This is akin to a subtotal mastectomy in women who have small breast cancers. (It should be noted however that the effectiveness of one sided treatment of prostate cancer has not yet been established)

In an attempt to find which patients might be suited for one-sided therapy, 3-D saturation mapping is crucial. In this sub-group of patients who have minimal one-sided cancer, 3-D saturation mapping is done on the opposite, unaffected side to assure that no cancer is present on what will ultimately be the untreated side. In other words, before treatment on one side only is undertaken, let's make sure that the other side does not have cancer. In about 15 patients who were considered for focal one-sided cryosurgery, I have found that 3-D mapping was invaluable in selecting those patients who might safely have one-sided treatment.

In summary, therefore, patients who have a rising PSA, and/or a low and falling free PSA (especially when associated with a strong family history), and multiple prior negative transrectal biopsies should consider 3-D saturation transperineal mapping to settle the issue in a final and definitive fashion. Additionally, those patients with seemingly minimal low grade cancer who are uncertain on whether to have treatment or be managed with watchful waiting should have a 3-D mapping so that they can rationally choose the appropriate course. Furthermore, patients who have failed primary treatment and are considering salvage procedures can sometimes benefit from 3-D saturation mapping especially if additional brachytherapy or salvage cryoablation is being considered. Finally, patients with limited one-sided cancer who are being considered for one-sided treatment should only do so if 3-D mapping of the unaffected side is negative for the presence of cancer.

What is 3-D mapping?

Systematic "saturation" biopsies of the prostate by the transperineal route was first described and advocated by Dr. Igel and his associates at the Mayo Clinic. I have adapted and modified this procedure so

that now we routinely obtain between 30-80 biopsies (depending on prostate size). These biopsies are obtained by the transperineal route (between the scrotum and rectum), the same approach utilized in brachytherapy and cryoablation. Information from these biopsies can be used to create a virtual 3-D map of the prostate identifying the location and extent of the cancer and, while this procedure was initially intended to help with the diagnosis of prostate cancer, I have recently extended the indications to include patients in the "therapeutic dilemma" category discussed above. For a more detailed description of the procedure please refer to an article written by Barzell and Whitmore in "Urology Times", May 2003, www.urologytimes.com.

Transperineal 3-D mapping is an extremely well tolerated procedure and to date, my colleagues and I have performed over 80 cases without any significant complications. While most of the patients were done as outpatients under general anesthesia, five patients underwent the procedure under local anesthesia in our office, where it was exceedingly well tolerated and in terms of patient discomfort not much different from office transrectal biopsies. It is our belief that with further experience this will ultimately become an office procedure in appropriately selected patients.

I firmly believe that 3-D saturation biopsy mapping of the prostate will become a part of the armamentarium of most urologists treating patients with prostate cancer.

WHAT THE HECK HAS BEEN GOING ON IN MY WORLD - PART I?

By Mark A. Moyad, M.P.H.

So, it is time to bring you up to date on some of the latest news. Some of it is good, some bad, and some indifferent (just like life). Keep in mind that some studies looked at preventing prostate cancer and some studies looked at changing the course of this disease after men were diagnosed with prostate cancer. Regardless, whatever looks good for prevention may be effective for men after a diagnosis and vice versa so you should keep this in mind. Let's get started because there is a lot to talk about in the world of complementary and preventive medicine.

1) ZINC SUPPLEMENTS IN EXCESS MAY BE BAD FOR ME?

In a disturbing way, this latest study gives me a sense of vindication. In 2000, when I wrote the book *The ABCs of Nutrition and Supplements* I mentioned that I do not recommend zinc supplements in high dosages. Well, I received some hate mail because many men did not understand why I would not recommend a supplement that so many alternative medicine books seem to advocate for prostate problems. The reason I could not recommend these supplements in high dosages was because there was no strong data to support the use of these supplements. In fact, several dietary supplement and dietary studies of men who took zinc found that it may increase the risk of prostate enlargement and could cause immune suppression. Regardless, the bottom line is that we did not have any large studies on zinc supplements and prostate cancer until now.

A recent investigation from the Health Professionals Follow-Up Study of 46,974 U.S. men followed for 14 years found something very interesting (Leitzmann MF, et al. *Journal of the National Cancer Institute* 95:1004-1007, 2003). A total of 2,901 cases of prostate cancer were diagnosed during this study. Compared with men that did not use zinc supplements, men who consumed more than 100 mg/day of zinc supplements had over 2 times the risk of being diagnosed with advanced prostate cancer. In addition, men who took individual zinc supplements for 10 or more years also had a risk of advanced cancer that was over 2 times more than those who did not. What does this mean to you??? Well, until we get more data men should NOT take individual zinc supplements, especially those that contain 100 or more milligrams per day of zinc itself. I am not worried about the amount of zinc in a multivitamin (like One-A-Day or Centrum), but I am worried about high-dose zinc supplements. Zinc is absorbed in the prostate and may even help with the uptake of testosterone. Regardless, this first large study is very concerning. So, it is better to be safe than sorry right now. The bottom line is that most of you should stay away from large dosages of zinc supplements until we get more data!!!

Currently, some eye doctors are recommending zinc supplements for macular degeneration (a specific eye disease that could lead to blindness). In some cases the benefit of zinc for this situation may outweigh the risk of prostate cancer and vice versa. The amount of zinc that was used in the macular degeneration re-

search was 80 mg a day for those with intermediate to advanced stages of this disease. So, talk to your eye doctor about this latest research to decide if zinc is right for you. Otherwise, for most other individuals, high-dose zinc supplements should be avoided until we get more data.

2) WHY IS IT IMPORTANT THAT I MAINTAIN A NORMAL WEIGHT AFTER BEING DIAGNOSED WITH PROSTATE CANCER???

If I live to be 100 years old (a big if), I am not sure that we will see a larger study than the one that was published recently (Calle EE, et al. *The New England Journal of Medicine* 348:1625-1638, 2003). A study of over 900,000 U.S. adults (404,576 men and 495,477 women) who were free of cancer in 1982 were followed for a total of 16 years. Men who were obese had a 20% increase in the risk of dying of prostate cancer and men that were severely obese had a 34% increase of dying from prostate cancer. This study was very concerning because not only is obesity a risk factor for many diseases, it seems that preliminary research suggests that obesity somehow places a man at a higher risk of dying from prostate cancer. Lets face the facts, weight and weight gain is not a fun subject to talk about, but the fact is that maintaining a healthy weight may be one of the best things you can personally do to reduce your risk of dying early from a number of diseases.

3) CAN AN ASPIRIN A DAY KEEP THE PROSTATE CANCER AWAY???

I have talked for years about the potential benefits of taking aspirin. It seems that many men and women that could qualify for aspirin therapy are not taking it, and many individuals that do not qualify for aspirin are taking it. Regardless, in the Health Professionals Follow-up Study of 47,882 U.S. men (mentioned earlier in this article), researchers found a potential reduction in the risk of metastatic prostate cancer in those men that took aspirin almost daily (Leitzmann MF, et al. *Cancer Epidemiology, Biomarkers & Prevention* 11:1108-1111, 2002). It seems that baby aspirin or regular aspirin may be beneficial but first talk to your doctor to see if you qualify for aspirin or ask your doctor to go the website www.med-decisions.com to see if you may qualify for aspirin therapy. Aspirin can increase the risk of internal bleeding and ulcers so you want to be 100% sure that you qualify for aspirin therapy. Regardless, it is pos-

sible to reduce the risk of a first or second heart attack by taking aspirin, and aspirin may reduce the risk of colon cancer so it is not surprising that aspirin may have an effect on prostate cancer. Again, do not start taking aspirin until your doctor gives you the green light!

4) CAN LOWERING MY CHOLESTEROL HAVE AN IMPACT ON PROSTATE CANCER???

A recent study from the Netherlands of approximately 300,000 individuals found that those individuals taking cholesterol-lowering drugs may reduce their risk of prostate cancer (Beiderbeck AB, et al. American Society of Clinical Oncology 22:846 abstract #3400, 2003). Again, as with aspirin therapy I have mentioned for years that keeping your cholesterol low may not only reduce the risk of a heart attack, but may also have an impact on prostate cancer. Of course, this is only a preliminary study, but what the heck! We have to look at the big picture here. Check with your doctor ASAP to see what your cholesterol level is at this time. You may qualify for a cholesterol-lowering drug or you may be asked to change your diet to reduce your cholesterol level. Anyhow, keep in mind that what is heart healthy is also generally considered to be prostate healthy!!! Apart and in addition to diet, there are so many ways to reduce a high cholesterol level that you and your doctor should discuss them.

5) ARE GARLIC AND OTHER SIMILAR COMPOUNDS GOOD FOR MY PROSTATE???

Again, keep in mind that what is heart healthy is generally found to be prostate healthy. Therefore, it should not be a surprise that a recent study from China found that those men that consumed Allium vegetables (garlic, scallions, onions, leeks, and chives) were found to have a lower risk of prostate cancer compared to men that did not consume these types of vegetables (Hsing AW, et al. Journal of the National Cancer Institute 94:1648-1651, 2002). Regardless, garlic and other similar vegetables seem to be heart healthy so I would encourage men to eat these things. Now, I am not talking about garlic supplements but dietary garlic. Of course be careful with garlic because when consuming this vegetable it could create a lot of problems in the romance category so make sure you stick to moderation.

6) DOES FINASTERIDE (Proscar®) REDUCE

THE RISK OF PROSTATE CANCER?

You may have read recently about the potential good news and bad news scenario of taking 5 mg of finasteride (Thompson IM, et al. New England Journal of Medicine 349:213-222, 2003). Basically, over 18,000 men 55 years of age or older with a normal DRE and a PSA level of 3 or lower were either given 5 mg of finasteride daily or placebo for 7 years. Men taking finasteride reduced their risk of prostate cancer by approximately 25%!!! Wow!!! However, there was a higher risk of being diagnosed with more aggressive prostate cancer (Gleason 7-10) in the finasteride group versus the placebo (“sugar pill”) group. A better way of looking at the confusing results of this study is that if 1,000 63 year old men are followed yearly for 7 years there will be about 60 prostate cancers diagnosed and about 18 of these 60 cancers will be aggressive. However, if these same men were to take finasteride for 7 years there would only be about 45 cancers diagnosed, but 22 of these cancers would be more aggressive. Why did this happen??? It is possible that 1) finasteride does not actually increase the risk of aggressive prostate cancer but it gives the appearance of more aggressive disease. In other words, it is possible that this was just a pathology error. In other words, finasteride may give the appearance of a more aggressive prostate cancer because it shrinks the prostate, 2) it is possible that by reducing the levels of more potent testosterone (DHT) that cells in the prostate become more aggressive because they develop more androgen independence, 3) it is possible that finasteride reduces the prostate gland enough so that it is easier to detect a more aggressive cancer on biopsy. Blah, blah, blah... what does this all mean to you???

Talk to your doctor about the latest results of this study. The researchers in this study are performing more tests to see whether or not finasteride actually increases the risk of aggressive prostate cancer. Currently, we do not have an answer to this question. Ultimately, as the men in this study are followed we will have a better answer. In the meantime, it is important to keep in mind that a total of 5 men in the finasteride group and 5 men in the placebo group died in this study from prostate cancer. Approximately 99% of the men in this study died from other causes including cardiovascular disease. Therefore, and in my opinion, knowing your cholesterol level as well as your PSA is obviously very important. Personally, I think that this study was brilliant and the

researchers and patients in this study should be given a lot of credit. I am excited that finasteride may have an effect not only on prevention but could favorably impact prostate cancer, but I am waiting for more results. In the meantime, another drug called “dutasteride” is being tested (ask your doctor to keep you up to date on the latest results of finasteride and dutasteride to see what role these drugs have on prostate cancer).

There is so much more to discuss when it comes to the latest research on prostate cancer and we will cover this in the next issue of PAACT. I apologize, but I need to get some rest and get the next article ready for the next issue. In the meantime, I do sleep with a clear conscience because the book that we put out several years ago seems to be supported more than ever by the latest research. If you want to order the book call 1-800-462-6420 (National Book Network) and ask for the ABCs of Nutrition and Supplements for Prostate Cancer by Mark Moyad. This is a shameless promotion but I am proud to say that most of the predictions in this book seem to be supported by the latest research! Now, if you do not want to spend the money you could always photocopy portions from the library or your doctor’s office or you could print out some of the articles from the internet. Regardless, I wish all of you the best of health and a wonderful summer and fall and look for more recent research in the next issue of PAACT.

Update on Triple Androgen Blockade and Finasteride (Proscar®) Maintenance

Steven Tucker, M.D.

Robert Leibowitz, M.D.

Compassionate Oncology Medical Group

2080 Century Park East, Suite 1005

Los Angeles, CA 90067

(310) 229-3555

Steven.Tucker@cshs.org

Men diagnosed with prostate cancer (PC) face a variety of challenges. They must first overcome the sheer terror of the word ‘cancer.’ Then they must grapple with conflicting opinions regarding prostate cancer evaluation: ‘Do I need a bone scan, endorectal MRI, CT scan, 2nd opinion expert pathology report?’ Then men ask, ‘What are my treatment choices? Should I choose radical prostatectomy, radiotherapy

(IMRT), brachytherapy (seeds), androgen deprivation therapy (ADT), or watchful waiting?’ Understandably, the next question is, ‘What are the long term complications? Will I be impotent or incontinent? Will I suffer from bowel problems, such as soiling or bleeding?’

Historically, younger, healthier patients, as well as those men with low risk disease, have been encouraged to undergo radical prostatectomy or radiation therapy in an effort to be “cured” of PC. Few doctors advocated watchful waiting and even fewer advocated ADT as the first or ‘primary’ treatment (PADT) for newly diagnosed PC. Despite differences between urologists and radiation oncologists about the definition of “cure” (urologist prefer PSA less than 0.2 while radiation doctors use 3 successive rising PSA’s backdated to the midpoint), PC recurrence after surgery or radiation has become easier to identify and a large percentage of men will face a rising PSA, in spite of surgery or radiation therapy. Given the lack of a survival benefit for men treated with prostatectomy¹ or radiation therapy, a strategy to manage or control PC seems more logical and appealing than radical efforts to achieve a “cure.” We have always maintained that primary hormone therapy, without local therapy, is the best way to manage newly diagnosed PC.

Other physicians (including urologists and radiation oncologists) are increasingly recommending primary hormone therapy. A report in the *Journal of the National Cancer Institute* found a marked increase in the use of PADT between 1989 and 2001². Specifically, for men with low risk PC the rate of ADT as initial therapy increased from 4.6% to 14.2%; for intermediate risk PC the rate increased from 8.9% to 19.7%; and for high risk PC the rate increased from 32.8% to 48.2%. These numbers do not reflect all the men getting neoadjuvant or adjuvant ADT, only those men treated with PADT. Additionally, two series of men with clinically localized PC treated successfully with PADT have been reported this year^{3,4}.

Akaza and colleagues studied 151 Japanese men with clinically localized PC treated with approximately 2 years of continuous PADT alone. At a median follow-up of 78 months the overall survival rates were identical to those from a normal Japanese population of the same age group. Only fifteen percent of the

patients developed metastatic disease on ADT and PC specific survival (an analysis of deaths from PC only; excludes all other causes of death) was 93% at more than 5 years follow-up. In the second report, De la Taille and colleagues reported on the use of rapid cycling intermittent PADT for both newly diagnosed and metastatic PC. Their study included 60 men with previously untreated “localized” PC, 12 men with newly diagnosed metastatic PC, and 74 men with recurrent PC after failed prostatectomy or radiation therapy. For the 72 men with no prior therapy, only 2 developed metastatic disease at 5 years of follow-up. It is not clear from the authors if these two men were from the 12 men who actually started with metastatic disease. Only 6 of 146 patients in the entire cohort of men developed metastatic disease.

Future trials need to further define the role of ADT in newly diagnosed PC and incorporate PADT into established national treatment guidelines. Patients of all risk groups and stages must be informed that PADT is an acceptable treatment option for men with “clinically localized” PC. Resources such as the National Cancer Institute web site document the frequent usage of primary ADT⁵ (see <http://www.cancer.gov/newscenter/pcos>). We strongly agree with these conclusions and recommend that future prospective randomized clinical trials of primary triple androgen blockade (TAB) followed by finasteride (Proscar®) maintenance be compared to radical local therapy or watchful waiting in future trials.

As readers of PAACT know, we have pioneered the use of TAB followed by finasteride maintenance and published our preliminary results in the spring of 2001⁶. We would now like to update those results.

As of May 2003, we have treated 171 men with clinically localized, non-metastatic PC with TAB followed by finasteride maintenance. All men refused surgery or radiation therapy in favor of TAB. All men had biopsy proven disease, and the vast majority of men have had their pathology slides reviewed by an expert (either Dr. Jonathan Epstein at Johns Hopkins Hospital or Dr. David Bostwick at Bostwick Laboratories). The average age is 65.8 with a range from 46 to 86. The pretreatment data for these men are summarized in the Tables 1-3.

PSA Risk Group	Mean PSA	Count
< 4	2.8	20
4 - < 10	6.5	88
10 - < 20	13.8	36
> 20	31.6	27
Mean PSA	11.6	171

Gleason Score	Count
4	3
5	10
6	69
7	69
8	12
9	6
10	2

Clinical Stage	Percent
T1c	43%
T2a	39%
T2b	10%
T3	8%

Of particular note, 74 of 171 (43%) men meet the standard definition of high risk disease (PSA > 20, **or** clinical T3 lesion, **or** Gleason score > 7). The mean baseline PSA for this high risk subset of men is 17.4 ng/ml. Only 40 of 171 (23%) men have low risk disease (PSA < 10, **and** clinical T1 or T2a, **and** Gleason score < 7). Clinical staging showed the majority of men have either T1 or T2 disease, consistent with most contemporary clinical trials of the PSA era. Clinical stage was not identified in 25 patients (while not classified in our database they are assumed to be T1c or favorable). Baseline testosterone was available in 97 patients and is 388 ng/ml.

All men were treated with TAB for an average of 13 months (range 13-29 months); 5 early patients were treated with greater than 20 months of therapy (20, 22, 24, 24, and 29 months, respectively). TAB consisted of standard Lupron® or Zoladex® therapy, an antiandrogen (bicalutamide 50 mg daily, or flutamide 250 mg every 8 hours, or bicalutamide 150 mg daily), and finasteride 5 mg daily. Since 1998 we have con-

sistently recommended and preferred bicalutamide 150 mg daily. If men are not able to afford bicalutamide we use standard dose flutamide. We do not recommend bicalutamide 50 mg daily. All men in our series have remained on finasteride 5 mg daily as maintenance after completing their 13 months of TAB.

At a median follow-up of 5 years (range 14-140 months) the mean PSA is 1.97 ng/ml. The mean testosterone for the entire group is 438 ng/ml (n =146). Median follow-up over time is listed with concurrent PSA values in Table 4. Comparable PSA values for the first 40 men versus the first 80 men show us stable PSA levels, even with additional prolonged follow-up. All of these men have an intact prostate and normal level of testosterone; as testosterone recovers it will stimulate the cells of their normal prostate gland to make PSA. Therefore at least some of their PSA is coming from benign, healthy prostate cells. In men *without* prostate cancer, PSA levels increase with age; keeping that in mind, our results look even better.

Median Follow-up	PSA ng/ml	Count
60 months (5 years)	1.97	130
72 months (6 years)	2.02	80
78 months (6.5 years)	2.20	40

As of May 2003, only twelve patients have required a second cycle of ADT. All twelve of these patients presented with high risk PC. No patients with low or intermediate risk disease have required a second cycle of ADT. The baseline prognostic factors for these twelve men who required a second cycle of ADT are noted in Table 5. The characteristics printed in red identify their high risk prognostic factors.

Only one man has died of prostate cancer. His original pathology (reviewed by a community hospital) showed adenocarcinoma with a Gleason score (3+3) but subsequent review of his pathology at Johns Hopkins diagnosed his disease as **ductal carcinoma** of the prostate. Also known as ‘endometrioid’ prostate cancer, this form of PC is rare and distinctly different than the more common adenocarcinoma. Ductal carcinoma is more aggressive, usually androgen independent, and locally advanced or wide-spread at the time of diagnosis. Overall prognosis for ductal

PC is far worse than standard adenocarcinoma of the prostate⁷. Surgical results for ductal carcinoma treated with prostatectomy reveal PSA recurrence in more than 90% of men within 5 years of surgery. The 5 year prostate cancer specific survival for our series is 99.4%.

Patient	Age	Original PSA	Gleason Score	Clinical Stage
A.D.	59	22.8	7	T1c
B.B.	55	51.3	8	T1c
D.E.	54	4.5	8	T3
W.O.	77	43	9	T3
G.R.	69	19.2	8	T2a
N.W.	68	11.4	8 ‘Endometrioid’	T2a
J.O.	65	59.8	7	T3
J.W.	70	36.5	6	T1c
D.H.	70	18	10	T3
J.S.	69	4	6 → 8 *	T2a
T.M.	62	8.7	9	T2a
W.M.	68	18.6	9	T2a

* Original community pathology was (3+3); at recurrence, a repeat biopsy was obtained showing (4+4) from Johns Hopkins, however review of the original pathology failed to identify any malignancy! The patient likely had focal areas of GS 8 at diagnosis. Items in red designate high risk prostate cancer.

All of our patients experienced the predictable and almost always reversible side effects from ADT. For a comprehensive review of the potential side effects and methods to minimize toxicity, we recommend the excellent review⁸ by Dr. Celestia Higano. We have never needed to discontinue TAB because of side effects. All men who reported ‘good’ sexual function (libido and erections) prior to TAB have regained ‘good’ function. We recommend aggressive supportive care, both as needed and preventively, for problems from ADT such as; bone loss (pamidronate⁹ or zoledronate¹⁰ therapy), anemia⁸ (erythropoietin, Procrit®, Aranesp®), and Viagra® or other measures for erectile dysfunction. In our opinion, one of the single best ways to combat the fatigue and lassitude associated with ADT is strength training exercise. Even walking 20 minutes daily can help prevent fatigue and elevate mood. Currently, we are doing clinical trials to assess quality of life and the treatment of anemia in men on TAB therapy. Upcoming trials will assess Zometa® for the prevention of bone loss for men on TAB.

Now that some high risk men have required a second

cycle of ADT we have modified our treatment recommendations for patients presenting with high risk disease. In addition to the traditional high risk factors (PSA>20, or Gleason 8-10, or clinical stage T3) we believe that more than 50% core biopsy involvement or more than 50% positive biopsies also define high risk disease¹¹. We have always felt that patients with a Gleason score (4+3)¹²⁻¹⁴ rather than (3+4), any primary Gleason 4 or 5, lymph node positive disease, or metastatic bone disease are high risk. Another high risk category is men with PSA recurrence after failed prostatectomy or radiation. In these men a PSA doubling time of less than 12 months indicates more aggressive disease^{15,16}.

Our strategy for all of these high risk categories is to utilize 12-15 doses of low dose, weekly chemotherapy with Taxotere®, estramustine, and carboplatin. We have been successfully using weekly Taxotere based therapy for advanced PC for the past 6 years. We know it can be given with easily tolerated side effects and certainly **none** of the side effects classically associated with chemotherapy. Like so many other treatments in oncology, what works effectively for patients with advanced disease works even better in earlier disease. Our philosophy is to use the best treatments now, never saving your most effective treatment for later. We would rather treat when the cancer is at its weakest and the patient is at his strongest, not the other way around. We will further discuss the details of chemotherapy for high risk and recurrent PC in forthcoming issues of *Prostate Cancer Communication*. Additional information on chemotherapy for high risk and metastatic PC can be ordered from our office directly.

In summary, Triple Androgen Blockade followed by finasteride maintenance is an excellent treatment choice for previously untreated PC. We would not recommend any form of radical local therapy with attendant, permanent side effects¹⁷⁻¹⁹ and far too many of these men will experience PSA recurrence²⁰⁻²². Subsequently, these men will require treatment with ADT. Instead of saving ADT for later, use it up front. The earlier ADT is used the better the response and even survival. For men with high risk disease, the likelihood of PSA recurrence is so overwhelming and the permanent side effects of radical therapy so enduring, that PADT is now being given to 48.2% of patients². We would recommend that all men with high risk disease be treated with TAB followed by

finasteride maintenance but also consider use of neoadjuvant (upfront) or 'preventative' Taxotere® based chemotherapy. We applaud the increasing use of PADT which we believe will result in men living better and living longer.

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PROSTATE CANCER: MY SIDE OF THE STORY!

By Richard G. Ward
Prostate Cancer Survivor

Ten years ago, my life was nearly perfect. I was divorced after a marriage of 30 plus years. During the first 20 years there were some great times for my wife, our children, and myself. Unfortunately, the last 10 years had not been pleasant. I was the managing partner of a 50-man law firm and a litigation attorney specializing in the defense of civil litigation lawsuits. Over the years, I had worked with a number of great clients and attorneys around the country who referred trial work to me. In my judgment, it was a perfect career.

At that time, I did not realize how important my family's medical history would be to my future. My father had died 30 years earlier. He had been treated for an upper respiratory disease for two or three years. He never seemed to get any better and he never seemed to get any worse. During my father's illness I went into the Army. I was stationed at Fort Sill, Oklahoma, when I received a phone call from my brother, Bus. He advised me that dad's condition had taken a turn for the worse. After a brief discussion, it was decided that Bus would take Dad to the emergency room of a major, near-by hospital. Dad was admitted to the emergency room. Abdominal surgery was performed and extensive cancer was found. One week later he was discharged. My mother and my three brothers were able to keep dad comfortable. Unfortunately, being comfortable was not enough. Dad died three weeks later.

My brother, Bus, died 17 years after my father. Bus had been treated for a number of ailments several years before his demise. The cause of death was not determined until the autopsy was performed. Prostate cancer!

Ten years ago, when life was great, I was away on a business trip when I called the office to pick up messages. There was a message to call my doctor. Two weeks before receiving this message, I had my regular annual physical. At the conclusion of the physical the doctor told me everything was fine and he would let me know if the blood work and tests showed anything different. The message to call the doctor did not concern me. I had been healthy all my life, and I had not yet connected the cause of death for my father and brother.

The doctor called to advise me my PSA (prostate-specific antigen) was 20. At the time, PSA did not mean a thing to me, nor did the fact that the reading was 20. The doctor indicated to me that a PSA of 20 strongly suggested that I had prostate cancer. My first question was "What is prostate cancer?" He gave me a brief explanation over the

telephone and suggested that I should see an urologist. At the time, I was not even sure what an urologist was. Needless to say, over the next few months I became very familiar with the specialties of the urologist and prostate cancer.

On the trip home I shared my bad news with the man sitting next to me on the plane. He was 60 days ahead of me. His doctor had advised him of an elevated PSA two months earlier on his fifty-first birthday. I was pleased that my prostate cancer had not been discovered as early as his had. (Later on, I learned that I probably had the cancer for 10 years before it was diagnosed.) At the time, I was sixty-two. It was helpful for me to have talked to a layperson early on. He had seen an urologist and a radiologist. The urologist told him to have surgery. The radiologist told him to have radiation. He said he had talked to several other doctors none of whom suggested any other option or provided any insight as to which of the two was the better option.

When I said good-bye, I was concerned for him, and for myself. He was not sure what he would do and I knew I also had big decisions to make in the near future. When I left my newfound friend, I had decided I would become the best-educated prostate cancer patient I could be.

All my life I have been an optimist. Even when I was told I had cancer, I had no immediate concern for my life. It was going to be a tough battle but in the end I fully expected to be on the winning side.

One of the first decisions you must make when you are told you have cancer is; whom do you tell? When do you tell them? What do you tell them? It is my impression, having gone through this that your loved ones will never agree that you took the right course of action in advising them of your cancerous condition.

When I received the news that I undoubtedly had prostate cancer, my thoughts went immediately to my son and daughter. Both of my children were living out of state. My son, Mark, was living in Florida and my daughter, Susan, was in North Carolina. I decided to delay telling them until I had more information and had seen at least one specialist.

Immediately I decided on two courses of action. I would see at least two specialists who treated prostate cancer, and I would start the education process.

Our law firm had defended hospitals and doctors for a number of years. As a result, we had a reasonably complete medical library. I consumed those books and everything in them having to do with the prostate gland and prostate cancer. In addition, I visited the medical libraries

of two notable universities (the University of Michigan and Wayne State University) located close to our office and relatively close to my home. My search did not end with libraries and medical texts. I sought out information from the United States government, The American Cancer Society and pharmaceutical companies. In addition, I sought out every member of the medical profession who would talk to me about prostate cancer.

In seeking out a treatment plan, I talked to several urologists and radiologists. At that time, as I believe it still is today, if you talk to an urologist he or she will recommend surgery, if you talk to a radiologist he or she will recommend radiation. My research convinced me that radiation was not a permanent fix. And, I was not convinced that surgery, with all the problems associated with prostate cancer, was the best solution either.

When you are told you have cancer, your immediate concern is for your life and your life style. I did not realize at first that the conditions associated with the treatment could be so devastating to your life style if you did survive. Incontinence. Impotence. WOW. I was not exactly sure what these terms meant, let alone how they could affect the rest of my life.

Throughout the next few months, I learned more than I ever wanted to know about incontinence and impotency. My continued research gave me even more information on the prostate gland and prostate cancer. In terms of treatment, it provided no additional information other than the two options of surgery and radiation, unless you include "watchful waiting." My research did provide good background information about the anatomy, the function of the prostate gland, and the surgical procedure. This was all advantageous in my subsequent conversations with the urologist and the radiologist. When I began to speak with the specialists, they knew immediately that I was knowledgeable about prostate cancer and its many related issues. As a result, I believe they went into more detail, provided me with more complete explanations, and were more attentive to my questions.

Before I made the decision that I wanted to go ahead with surgery, I met with three urologists and a radiologist. My internist recommended the first urologist that I visited. He was a good choice. This kind, patient, and extremely helpful doctor was ready to retire and was not performing surgery any longer. I was impressed that he had not seen many prostate cancer patients. When I met with him he examined me, asked many questions, explained prostate cancer to me, but did not give me any options or make any recommendations. He told me that he believed as result of my elevated PSA and based on his examination, which included a digital examination, that surgery was appropriate.

In the next couple of weeks, I visited two other urologists and a radiologist. As I expected, the urologists recommended surgery and the radiologist recommended radiation. I was still disappointed and surprised that there were no additional options. I understand better today than I did then, that in fact, options for treating prostate cancer were limited. Based on my subsequent experience and continued research, I'm not convinced that a third option should not have been offered.

Not only did I research the prostate gland and prostate cancer; I also sought information on the experience and background of urologists throughout the country. I finally decided to go ahead with the surgery utilizing the services of an urologist close to home.

In practice with the urologist was a radiologist who specialized in diagnosing and treating prostate cancer. This radiologist was himself a prostate cancer survivor. He had been self-prescribing medication for a number of years. He indicated he experienced some difficulties but those difficulties were very minor when he considered the alternatives. The radiologist had a good bedside manner and a persona that I immediately liked, giving me confidence in his observations and recommendations.

The radiologist performed the ultrasound and the biopsies. At the conclusion of the tests including a PSA, he gave me his observations. His first remark was that the prostate cancer had been present for at least 10 years. Secondly, he said the prostate cancer was outside of the prostate gland. Lastly, he advised me that my chance of surviving more than five years was less than 50 percent.

At that point, I must confess my optimism began to wane. I was taken back and had no immediate response. The good doctor waited for me to collect my thoughts. I'm sure he knew from his past experience that I had a number of questions to ask. The problem was that the questions were coming to mind faster than I could ask them. How can you be sure? How do you know it's outside the prostate gland? How do you know it's been there 10 years? And finally, how can you tell how long I will survive?

The doctor was very patient. He answered my questions by telling me of his past experience in working with prostate cancer patients. It was obvious when listening to him that he was not only telling me about his life's work but also his life's passion. He had been working with prostate cancer patients for many years. He had studied the subject and knew it well. When he completed his explanation and answered numerous additional questions, I was convinced that he was giving me the answers I needed to hear, even if it was difficult news. The doctor indicated to me that there are always exceptions, and that the right attitude and

possibly a change in lifestyle could slow the expected outcome.

The next step was to discuss the surgical procedure with the urologist. My meeting with him convinced me I made the right decision. He was compassionate, patient, and was more than willing to give me all the time that I required to understand the procedure and follow-up care. We also discussed in detail the downside to the surgery including the possibility of being both impotent and incontinent. The cancer was outside of the prostate gland. He explained that the nerves, veins, and arteries associated with being potent and being continent would likely be compromised during surgery. He further explained that making a judgment as to what and how much should be removed during the surgery would be a difficult decision.

The doctor then explained the importance of having "clean edges." He said that during the surgery, the prostate gland and other parts of the anatomy in the area that were removed would be sent to the pathology lab during the surgery. They would examine the tissue that had been removed to make sure the surgeon cut beyond the cancerous areas to ensure that all of the cancer had been removed. The edges around the cancer had to be clean. No cancer! He further advised me that during the surgery they would remove several lymph nodes. He explained that if the cancer had spread it would go to the lymph nodes first. My later research and discussions with doctors indicated that when prostate cancer metastasizes it shows up first in the bones. This would most likely occur in the spine.

The doctor indicated that prior to surgery he would put me on hormone therapy. Up until this point, I was not familiar with hormone therapy. The doctor explained that my prostate gland was more than twice the normal size, the normal size being about the size of a walnut. Putting me on hormone therapy would likely reduce the size of the prostate gland. The surgery, he explained, would be easier with the reduced-size prostate gland. The field, as he called it, would then have less mass. The recommended time for this hormone therapy was six months. The hormone therapy would require a shot every month and taking a pill daily. The intent of the hormone therapy was to stop the production of testosterone. Testosterone, in lay terms, is the food that feeds the cancer. The doctor further advised that I would be unable to have an erection two weeks after starting the therapy. There are several possible side effects to hormone therapy — this is the major one. Since I decided to go ahead with the surgery, I went ahead and received the first shot and a prescription for the pills.

It was obvious that having the surgery was not just a major surgical procedure. The number of potential problems and disadvantages seemed to be multiplying. The surgery

is difficult because of the structure and location of the prostate gland. The gland is located below the bladder and in front of the rectum. The prostate surrounds the urethra, the tube through which a male urinates.

It was now time to talk to my children, Mark and Susan. I felt I had all of the information I needed to fully inform them of my condition and what might be expected from the surgery. My future did not look as rosy and bright as it did several months earlier.

After leaving the doctor's office and I made immediate plans to see Mark and Susan. Within the next few days I would see Mark in the Florida Keys, and visit Susan in Asheville, North Carolina. I decided to fly to Florida first, talk to Mark and then work my way back north, stopping in Asheville.

My son was a fishing guide working out of Naples, Florida. During the last two weeks of May and the month of June, he was in Islamorada located in the Florida Keys, fishing for tarpon. It was the perfect place for tarpon fishing during the summer months.

When I arrived in the Keys, Mark was expecting I would be there for a week or ten days. Obviously my discussion with him about cancer was not expected. I gave him all the details about my condition and my discussions with doctors. I also told him I was very optimistic and while I was not looking forward to surgery, I was not at all concerned about my life expectancy.

It was my intention to arrive in Florida, drive to the Keys, talk with Mark, and head back north that evening. Mark insisted that we fish that afternoon. Mark worked very hard to make sure I caught a tarpon. It was a 90-pounder. The practice back then was to remove a scale as a souvenir. For Christmas that year, Mark gave me several pictures along with the scale, all handsomely framed.

Early the next morning, we had breakfast together and I prepared to head north to see Susan. As I got in the car we hugged and said goodbye. Mark said he would be with me at the time of the surgery and added "Don't worry Dad, everything will be ok." As I closed the door, he added, "It may be time for us to get back to church."

When I arrived in Asheville, Susan knew that something was up. Susan and I spoke frequently on the telephone and if I was going to Asheville it was usually discussed in detail, well in advance of the trip. It was difficult to evade Susan's questions at the airport but I didn't want to discuss my problem until we arrived at her home. After getting into her condo, the questions started before I sat down. Susan knew me well enough to know there was a problem.

My discussion with Susan was pretty much the same as my discussion with Mark. I was able, based on my talk with Mark, to anticipate several questions and answer those before they were asked. As with Mark, the most difficult part was trying to give answers to those questions to which there were no answer. At that time, the words of the radiologist were still ringing in my ears. Was his estimate of my life expectancy valid, or could I beat the odds...?

My discussions with both Susan and Mark, covering my conversation with the radiologist, were quick and maybe not as forthright as they should have been. Now ten years later, maybe they'll forgive me for not telling them all of what was said about my life expectancy.

Susan, like Mark, had a great number of questions. All the questions were either questions that I had asked the doctor or had pondered since seeing the doctor. As I answered their questions as best I could, I realized that there were still many unanswered questions. Those questions would be answered in the months and years ahead.

Susan and I discussed whether she should come to the hospital for the surgery or whether she should be home with me after the surgery. It was decided that since Mark and a number of friends would be with me in the hospital, having Susan home with me after the surgery would be best. I was beginning to be concerned about my own mental state after the surgery and going forward into the future. I knew that she would be a great comfort. When I left Susan, we were both in tears. We hugged and kissed. She held me so tightly I felt sure she was trying to protect me from the future.

When the doctor told me about the hormone therapy, he had suggested that I stay close by for the first few weeks. He said he did not anticipate any difficulty with the treatment but there were possible side effects. I decided to head to northern Michigan for a long weekend. A close friend offered the use of his home on a lake near Petoskey, Michigan.

I recall being home in the afternoon packing for the trip. Running through my mind was all the information that I had gathered about prostate cancer in general and more specifically, the life expectancy information received from the doctor. It seemed overwhelming. I remember first sitting down on the bed, then lying back trying to put it in perspective. Life had been good and I was still confident it would be good in the future. Yet, there was a great deal to consider, not only my life but also the lives of my family and friends.

Many things ran through my head... My sex life had been better the last few months than at any time during my

adult life. In two weeks, this would end, and after the operation it might be gone forever. I wondered again, how serious was it that the cancer was outside of the prostate gland? This question would not be answered until after the surgery. My children had lived in other states for a number of years. There was no real way to change that, but I realized that I missed a great deal by not having them close by. There were no grandchildren at that time but I fully expected that would change in the future.

I was hospitalized in mid-December. The surgery, according to the doctor, went very well. The pathologist reported there were clean edges and the lymph nodes looked good on gross examination. (Note from Surgical Pathological Report: "Microscopic Findings: The index tumor present is present in both right and left peripheral zones. It involves both seminal vesicles and penetrates the capsule in the left lateral portion near the base. Surgical margins are free of neoplasm.") The usual stay in the hospital for prostate cancer surgery is three to four days; however I was confined for 10 days as result of a very persistent staph infection that I developed while in the hospital.

While being in the hospital was painful and uncomfortable, the attention that I received from my family and friends was overwhelming. My son Mark being with me was special. One of my best friends had also traveled from Florida. My daughter was in constant touch and told me she would be arriving the day I was discharged from the hospital. Many local friends visited and I received a great number of cards, flowers, and other remembrances.

Although the time in the hospital was only 10 days, it seemed like an eternity. I was continually on medication including pain medication and antibiotics. As a result I was not able to get up and move around until just before I went home. It was my impression that the doctor felt I should stay in the hospital a couple more days but felt compelled to send me on my way as I had reached my allotted number of days.

I felt absolutely drained of all energy as I prepared to go home. I did walk the halls of the hospital for a day before leaving, but it did not give me much confidence that I would be able to move about after arriving home. In addition, I realized just before going home that I would be going home with a catheter. The catheter that was inserted during my hospital stay was very painful and I fully expected that pain would continue after I arrived home.

The day arrived. I left the hospital in the usual fashion: in a wheelchair pushed by an attendant, into a private car, and a very long drive home. The drive home and the short walk from the driveway to my bedroom were exhausting. It did feel good, however, to be home and I looked forward to being in my own bed.

Susan was very attentive. She looked after my every need. Other friends helped out. The pain was constant and I was very uncomfortable.

My arrival home was just a few days before Christmas. Susan and I had talked from the time I got home about how nice it would be to go to Christmas Eve church service. I was looking forward to the service and tried to make myself mentally and physically ready.

As Christmas Eve approached, Susan and I talked about whether or not it was going to be possible. We talked about what I would wear, how I would get into the car, how I would get out of the car, and how I would walk to the pew. It looked like a real possibility and I began to believe it was going to happen. Late in the afternoon of December 24th, we began to prepare. Susan got herself dressed then helped me get dressed. The major concern that I had all along was the catheter. It was very painful despite the fact that I used Vaseline to lubricate the tube and was very careful about my movements.

In the end, it was the catheter that did me in. Susan had warmed the car and she was helping me get to the car when the pain of the catheter became overwhelming. We decided that Susan would go on to the service alone. She helped me back to bed. By the time I was under the covers, I thought I would faint, the pain was so severe. Finally I fell asleep. When I awoke later Susan was there to tell me about the beautiful service.

After three days, I was beginning to feel stronger and the pain was considerably less. The catheter was still causing a problem but I would be going to the doctor soon to have it removed. At this point in time, there was no way to tell whether I would be continent and potent. Only time would tell.

On the fifth day after arriving home, we went to the doctor's office for the purpose of having the catheter removed. I had no recall of the catheter being inserted since it occurred during surgery. Having it removed, however, is something that I will never forget. When inserted, the catheter has a balloon that is situated in the bladder. (Note from the Surgical Report: "An 18 gauge French Foley Catheter was placed in the bladder and 20 cc. put in the balloon.") I kept wondering, before going to the doctor's office, what would be the procedure for removing the catheter? Without explanation, it was removed. The procedure is for the doctor to put his thumb and forefinger on top of the penis, and pull. The pain is instant and unbelievably severe, but the relief knowing it is no longer present helps you forget the pain very quickly.

The doctor advised me at this visit that everything looked good. He cautioned, however, that he had not received the

final pathology report and also did not know whether I was going to be continent and potent. When I left the doctor's office, I left with a catheter and several diapers. The doctor indicated that in the immediate future I would likely have one of two difficulties. There was a possibility that I would need to utilize a catheter to drain my bladder. There was also a possibility, that for a short period of time, I would be incontinent and it would be necessary to wear diapers. I learned very shortly that this was the good news.

Neither of these two possibilities was something that I was looking forward to. As it turned out, I had difficulty draining my bladder without utilizing the catheter for several weeks. As I got stronger, I returned to work and using the catheter three or four times a day became routine.

If you walk into the men's room in a large office or a plush hotel and see someone at the sink washing out a catheter, a good guess would be that he is a prostate cancer survivor. For me, it was routine and also very interesting to watch the other men in the men's room looking over their shoulder or looking at me sideways to try and figure out what I was doing. The catheter was about 12 to 14 inches long. In order to insert the catheter you needed a little Vaseline, in order to clean it, a little soap. For carrying the catheter my preference was a sandwich bag. The insertion and draining of the bladder took only a few seconds. Cleaning the catheter took only a few minutes. All in all, the process was very efficient and not at all embarrassing. Within a very short time, however, the whole process completely changed. I was incontinent. Wearing diapers was not nearly as efficient as utilizing the catheter to drain the bladder.

When you're incontinent, there are critical times. For example, as long as you're sitting down or lying down, there is no problem. But, as soon as you stand up, the bladder begins to drain and it would be best if you were wearing a diaper. Where and how you carry the diapers, where you change the diapers, how you change the diapers, and how you excuse yourself, all become very routine. It was not enjoyable but it had to be done. All these things I learned very quickly. It is also one of those things that appear to be considerably more difficult than it really is. I learned to cope and cope I did for about 18 months.

When I went to the office, it was quite easy to carry the diapers in my briefcase. When out for dinner or to the symphony, it was a different thing. I carried a little black bag. In this little black bag I carried three diapers and the necessary paraphernalia to strap them on. When out to dinner I would pay the bill, go to the men's room, and make the change. After the change, I picked up my lady friend at the table and headed out to the car. At the symphony, it was a little different. At intermission it was nec-

essary to make a change. The diapers only hold a limited amount. When I stood up at intermission I had better be moving toward the men's room. Depending upon who asked the question and how it was asked, answering questions about the black bag could be a challenge. Whenever a lady asked if it was my make up kit, I was always left with my mouth wide open.

During the diaper period, there were several instances that were embarrassing at the time but give me a good laugh now. One incident did not give me a laugh then, and it still embarrasses me when I recall it. If you are a Detroit Red Wings fan and have been to Joe Lewis Arena, you know how crowded the rest rooms are between periods. Changing diapers without using a stall is possible but certainly not desirable. If you are fortunate enough to get a stall at a Red Wings game, you better get in and out in a hurry. In my haste, I didn't realize I had put the diaper on inside out. The diaper is very absorbent on the inside but plastic on the outside. As I started walking back to my seat, I knew something was wrong. It was a very exciting game, third period, with the score tied. The Red Wings were playing Colorado and it was a need-to-win game... and it was running down my leg. Diaper bag empty. I got back to my seat and said, "Let's go. This game stinks." That day, I almost lost a couple of friends.

During the 18 months that I was wearing diapers, the urologist suggested several possibilities to improve my continence. The first possibility was to retrain the muscles. This may sound easy, but it is not. To retrain the muscles, you pretend you are urinating and then contract and release the muscles that you use when urinating. Unfortunately, after a number of weeks working hard at this exercise program, it was determined that it would not fix the problem.

The next possibility was to inject collagen into the urinary tract. Up to this point in time, I thought the only use for collagen was for face-lifts. The urinary tract had expanded as a result of the drastic surgery. If the inside diameter could be reduced, then maybe the exercise program would work. The downside is that injecting the collagen is major surgery. Two additional major surgeries to inject collagen did not help.

Finally, there was a solution. One last major surgery was done to implant an artificial sphincter. The artificial sphincter is truly an engineering marvel. It includes a cuff that fits around the tube through which your urine passes. This cuff has a liquid solution in it. The user has a pump in the scrotum. When the pump is pressed it releases the fluid in the cuff and the urine flows. The solution goes to a reservoir where it remains for a short time then reverses and returns to the cuff clamping down on the tube. The surgery was relatively easy. There was a six-week wait to

see if it was a success. It WAS a success and is still working today, after seven years. After 18 months in diapers, it was one of the best things that ever happened to me. Sometimes I joke with my friends by asking them if they still do it the old-fashioned way.

Within 30 days after the surgery, the urologist advised me that he had received the pathologist report. At the time of the surgery and immediately thereafter, both the urologist and the pathologist examine the lymph nodes. They determine whether or not they are distended, discolored, or show a possibility that they have been affected by cancer cells. In my case, this initial examination by both of the doctors indicated that the lymph nodes were normal. The later report was different.

After surgery, the pathology department freezes the lymph nodes and then slices them in very thin slices. The slices from one of my lymph nodes showed cancer cells (Note from the Surgical Pathology Report: "Microscopic Findings and Diagnosis: Lymph Nodes R. Pelvic Carcinoma of Prostate in one lymph node.") The next question to be answered was, "Are these cancer cells in a transient state or did they indicate the cancer had metastasized?" At the time, there was no answer and even today there is no answer. My bone scans are clear so my assumption, or hope, is that the cells are still transient.

As a result of the evidence of cancer in the lymph node, the doctor suggested that I return to the hormone treatment. This was based on a very cautious assumption that the cancer may have metastasized. At the time, I was not convinced that this was the right course of action. If the cancer had not metastasized, I was looking at the possibility that I would be on hormone therapy for the rest of my life. While I did not experience any side effects before (if you consider not being able to get an erection a side effect), there was no assurance I would not have side effects over a longer period of time.

The possible side effects from hormone therapy include impotence, weight gain, osteoporosis, and loss of muscle mass, anemia and induced male menopause with hot flashes.

After hearing about the cancerous lymph node, I sought out additional medical advice. While the possibilities did not change, I was glad that I had an opportunity to speak with other experts in the field. I finally reached a decision, based upon my discussion with the urologist and other experts that I would not return to hormone therapy. The theory was that if my PSA began to climb, we would know there was still cancer in my system. If the PSA did not begin to climb, I could reasonably expect that I was cancer-free.

It was also decided that I would have a PSA test every 30 days. Everything looked good for the first 60 days and then the PSA began to climb. When the PSA reached 2.8 I was still not sure what to do. I again talked to several other doctors including an urologist and an oncologist. The new urologist I spoke with said that if I went on the hormone therapy I might eventually reach a point where it would not be effective. He then said, very casually, "Why not wait until it gets to the bone then start the therapy?" This was a real curve ball. Was he suggesting I wait until the cancer gets in the bone before I do anything? That was exactly what he was suggesting.

My next visit was to the oncologist. When I gave him the background and told him what the urologist said he was also taken back. He said, "You always want to attack the cancer as soon as possible that's the reason we stress the importance of early detection. If you let it spread you may never get it in check. Yes, you may reach a point where the therapy is not effective but what if you wait until it is in the bone and it is not effective at that point...?" With this doctor's advice, I started back on the hormone therapy.

There are a few rules of thumb that I've heard from various doctors and throughout my readings. One is that when your PSA reaches seven and you have not received any treatment; it's time to start. The other is that if you've had your prostate gland removed and your PSA climbs to four, it's time to take some action. These, of course, are only rules of thumb and your doctor is the one whose advice you should follow.

As I indicated, I spent a good deal of time researching prostate cancer. After my surgery, I continued this research. The sources that I have found most helpful are newsletters published by either doctors or organizations concerned with curing prostate cancer. There are several doctors that are very helpful in writing articles for these newsletters. I began to see articles or tidbits in articles suggesting that if you stayed on hormone therapy continuously there was the possibility that the hormone therapy would no longer be effective. There also appeared to be suggestions that if you wanted to remain on hormone therapy for a period of time and then discontinue the program for a period of time that might extend the length of time that the hormone therapy would be effective.

As a result of this very inconclusive information, I decided to change my treatment program. I suggested to my then-treating oncologist that I stay on the hormone therapy for one year and then discontinue the therapy until my PSA began to rise. The doctor told me there had been no scientific studies to suggest that this type of treatment would be successful in extending the effectiveness of the hormone therapy. Part of the basis, though, for my starting this pro-

gram was a further discussion with the doctor. I asked the doctor if I stayed off the hormone therapy for a short time, would it really affect the growth of the cancer. His answer was that no one knows, but in all likelihood it would have very little effect.

After these discussions, I started my new program. I would remain on the hormone therapy for twelve months and then discontinue the therapy. After twelve months of the hormone therapy, I stopped. The plan suggested by the doctor was to have my PSA checked every 30 days. After 30 days, it started to climb slowly, but it started. After eight months, it was 3.8. Back on the therapy.

This hormone treatment program was followed for six years. The program became very consistent and very predictable. Twelve months on the hormone therapy, then eight months off. The one other side effect from the therapy was the shrinking of my penis and my testes. When I went on the therapy prior to my surgery, the prostate shrunk dramatically, but I do not recall my penis and testes shrinking at that time.

As I mentioned earlier, prostate cancer impacts not just your health, but also your way of life, with impotency being one of the biggest challenges. In my judgment, if you are married or in a close relationship it is easier to deal with becoming impotent than if you are single. If you are single, the dating scene is very difficult. While many of the younger people in our society believe sex loses its appeal for those over sixty, I'm a firm believer that it actually becomes more important. Many of the hang-ups you may have had as a younger person are no longer a problem. Your parents do not care, your children do not care, and it is time to make up for all you missed when you were younger.

If you are single, impotent, and dating, you are confronted with a whole new set of problems. There are several ways to get around the problem: pills, penile injection, penile implant, and several other tools or devices that can be used. The first problem is when do you tell your lady friend and what do you tell her? The first consideration is what do you tell her about your prostate cancer? This may depend on what stage you are in and whether you are receiving treatment. If you are on hormone therapy, your sex drive will be reduced or maybe non-existent. If you are cured, it may not be a problem, but anywhere in-between may require an explanation.

There are many challenges as you deal with your impotence. If you are going to use pills, there are several variables. Drinking and eating could affect the effectiveness of the pill. This apparently is not a problem with the injection, but with the injection, there is a whole new set of problems. First, you need to mix the solution (no, you

cannot do it ahead of time). Then you need to extract the correct amount from a very small bottle into a syringe. In all likelihood this will need to be accomplished while your lady friend is waiting in bed and you are in a strange bathroom with poor lighting, sitting on the edge of a bathtub, bare naked, with your bifocals sliding off the end of your nose. When that is all done, then you are required to select a location on the tenderest place on your body and stick in the needle and inject your self. You cannot just stick it in a little ways, the directions state "up to the hilt." After all this is done, with a little luck, in five to twenty minutes, you will have an erection. But, will your lady friend still be awake! The use of all of these pills and devices require help and patience from your partner.

During the six years when I did my 12-months-on-hormone-treatment and eight-months-off, I continued to stay abreast of developments in the prostate cancer field. I continue today to read newsletters, websites, and newly published books in an attempt to keep abreast of the expanding field of medical research having to do with prostate cancer. The newsletters, newspapers, medical papers, and several books begin to mention other possibilities for either controlling or preventing prostate cancer. There were references to tomatoes, green tea, vitamin E, selenium, broccoli and other foods, and supplements. Consideration was also being given to stress and exercise. There was also reference to the genetic factor.

There is presently a study underway (SELECT - Selenium and Vitamin E Cancer Prevention Trial - begun in 2001, by the National Cancer Institute) involving 35,000 males in the United States. This study was instituted based upon smaller studies that indicated the combination of Selenium and Vitamin E might prevent prostate cancer.

In my research, I came across a book by Robert Arnot, M.D. entitled *The Prostate Cancer Protection Plan*. Dr Arnot had previously written a book entitled, *The Breast Cancer Prevention Diet*. This book was widely read and suggested that diet and changing your way of life may have an effect on the development of breast cancer. After reading Dr Arnot's book, I decided to change my diet and my way of life. I had always exercised and considered myself to be in reasonably good shape. My blood pressure and cholesterol have always been low and I've had very few illnesses throughout my life. My plan was to give up red meat but to continue to eat fish and fowl. I also decided to eat as much ocean salmon as I could possibly find. The original must-eat items on my list included: Selenium, Lycopene, green tea, vitamin E, broccoli, and a high concentration of green vegetables and fruit. In the past, I had been a juicer and I returned to juicing. My juice recipe includes broccoli, carrots, asparagus, apple, orange, pineapple, green beans, and usually one additional fruit.

I also started to take supplements. For instance, Lycopene is found in tomatoes. I drank a good deal of tomato juice but also took a Lycopene supplement. I did the same for green tea and broccoli. Over the years I supplemented this program. Eventually I added calcium and fish oil concentrate. It had been my practice in the past to take vitamins but I have since increased the quantity, particularly of vitamin E.

Eventually the newsletters started to recommend Proscar (a prescription drug) with the hormone therapy, which I also added.

Did all this help? I think so. The first thing that occurred is that I felt better that I was actively doing something to fight the cancer. I was intrigued that the doctor was interested. We were not just sitting by and waiting for a change that may very well be for the worse. We continued to check my PSA every thirty days. The PSA reading when everything is OK is less than .1. My PSA stayed less than point one for three months. Then it started to climb but climbed very slowly. In the past, my PSA was about 3.8 after eight months. This time it took twenty-six months to reach 3.8. Does this mean my approach is a cure? Certainly not. But it does in my judgment mean it is effecting the cancer. Of course I went back on the hormone therapy. Then, another surprise, after 60 days my PSA was only .2. After 90 days another surprise PSA was .082. With that good news I decided to stay off the hormone therapy and continue to check the PSA every 90 days. As I write this article I'm 60 days post my last PSA. I fully expect it will be 26 months plus before my PSA gets back to 3.8. Luck will surely be with me!

The medical issues surrounding the diagnosis of prostate cancer are very challenging to deal with as you do research, meet with doctors, and make major decisions about your body and health. During this time when you are educating yourself, you will also be confronted with many lifestyle issues. There is a possibility that your life will not be the same after this is all over. There are many daunting possibilities and you must consider all of them.

Keep in mind that this paper is about the past. There has been a great deal of research in the past ten years on prostate cancer and prostate surgery. Many of the studies under way now will help prostate cancer patients in the near future. In the next ten years, we may very well find a cure.

As we wait for a cure, realize that we are moving towards more options to treat prostate cancer. One of my frustrations, as I began my research, was that the only options were surgery, radiation and "watchful waiting," all of which have drawbacks. My own experience suggests that hormone therapy should be added to the list of options. As I mentioned, when I was on hormone therapy prior to the

surgery, my prostate gland was reduced in size by fifty percent within 30 days. I do not recall getting a PSA reading during that time. My past experience tells me it would have been less than 0.1. If someone had given me the option at that time and told me of the possible side effects for both hormone therapy and the surgery, I may very well have selected the hormone therapy. Just think...if I had started hormone therapy I would have missed all the fun that I had with the catheter, diapers and the surgery and the recovery process. Not to mention the three additional surgeries involving the collagen and the artificial sphincter. It is my understanding that doctors around the country are now offering hormone therapy.

To me the biggest advantages to hormone therapy are the options it offers. Keep in mind there **are** side effects with hormone therapy, but if the side effects are a major problem you can make a change. Your PSA will be down during the trial period, which suggests the cancer is not active. And keep in mind the treatments for erectile dysfunction are continually improving. Another advantage to hormone therapy is the fact that there are many studies going on right now working on a cure and the treatment of prostate cancer.

No matter what options have been presented to you, if you've been diagnosed with prostate cancer, be pro-active. Do your research. Ask questions. Go to meetings. Try new things. It's your life and you want to be making informed decisions about how you live it.

The Specifics

My Hormone Therapy Program

Lupron one shot good for three months
Casodex one tablet every day - 50 mg
Proscar one tablet every day - 5 mg

The Proscar is not part of the hormone therapy but is recommended as part of the prostate cancer treatment regime. I take Proscar even when I'm not on the hormone therapy.

My diet and food supplement daily program

Green tea Supplement 450 mg
Vitamin E 400 I.U.
Broccolive Plus one per day
(Three capsules equal 1 pound of Broccoli)
Lycopene 10 mg
Selenium 200 mcg
Calcium 1000 mg
A good multi-vitamin

Keep in mind there is some thought that while you are on the hormone therapy you might lose some calcium from the bone.

Newsletters

Prostate Cancer Communication

In Care of Patient Advocates for Advanced
Cancer treatments, Inc
PO Box 141695
Grand Rapids, Michigan 49514
616-453-1477
Fax 616-453-1846

Prostate Forum

PO Box 6696
Charlottesville, VA 22906-6696
434-974-1303
Fax 434-974-9597
www.prostateforum.com

Prostate Cancer Research Institute

5777 W Century Blvd Ste 885
Los Angeles Ca 90045-9787
310-743-2116
Fax 313-743-2113
www.pcri.org

All three of these newsletters are good. The first one listed is published by an organization that was started twenty years ago by a prostate cancer victim. There are a number of doctors on the Medical Advisory Board many of whom contribute articles to its newsletter. Doctors publish the last two. Much of the information I have relied upon came from either the Prostate Cancer Communication or the Prostate Forum.

Helpful Web Sites

www.mdandersonn.org/diseases/prostate
www.oncology.com
www.prostate-cancer-info.com
www.cdc.gov/cancer/prostate/prostate.htm
www.cancerindex.org/clinks3b.htm
www.cancerresearch.org/prostatebook.html

Other Resources

American Cancer Society www.cancer.org
800-ACS-2345
Reference section of your public library
Gray's Anatomy
Physician's Desk Reference

Keep in mind that I am not a doctor. I'm just an ordinary guy that awakened one day and found out he had prostate cancer. If you have taken the time to read this article, I assume you have an intense interest in prostate cancer. If this is the case, I hope you realize the importance of being well informed. There is a lot of help out there but you must take the time to get the answers to your own questions. What do you need to know to make an informed decision? Do not rely upon information someone else

chooses to give you. Decide what information you need, and then find it. This will give you confidence you are doing the right thing for yourself and your loved ones. Remember you are your own best advocate.

**RANDOMIZED COMPARISON OF
NEOADJUVANT TREATMENT ARMS IN ORGAN
CONFINED PROSTATE CANCER USING PSA
NADIR AS THE END POINT**

Ronald E. Wheeler, Scott Yun, Jonathan Vukovich,
Charles Metzger, Ahmad Kassraean, Bradford Moss, Vic-
tor Ching, Durango, CO

Introduction and Objectives: Neoadjuvant therapy has become the state of the art methodology for tumor size reduction (downsizing) and alteration from one stage of disease to another (downstaging). Prostate cancer treatment has been enhanced by the timeliness and efficacy of neoadjuvant therapy. Regardless of the methodology used, the PSA (prostate specific antigen) has served as the biologic marker to gauge effectiveness of treatment response. Thus PSA is a surrogate marker to disease suppression or inactivity in the vast majority of cases. The concept of CAB (combined androgen blockade) is well known. This format remains the gold standard for patients with clinical stage C or stage D disease. The goal of such therapy is to provide stabilization of disease, maintain minimal side effects, provide minimal impact on quality of life issues while allowing patient compliance in a cost effective manner. Based upon the belief that an antiandrogen + Finasteride could reduce disease activity as effectively as standard CAB, a study model was designed to compare the two arms prospectively. In a randomized format, an LHRH-a + Flutamide arm was compared to a Flutamide + Finasteride arm. PSA nadir was the pre-selected end point to disease stabilization prior to definitive therapy. It is generally accepted that physicians recognize a low PSA as a marker representative of decreased cancer activity.

Methods: Seventy-six patients with organ confined prostate cancer were randomized to the LHRH-a + Flutamide arm or the Flutamide + Finasteride arm. Organ confinement was largely left to physician judgment and in concert with recognized diagnostic modalities. The initial PSA at disease verification was recorded prior to the initialization of the neoadjuvant treatment arm. Subsequent PSA testing was recorded weekly starting at week 4. PSA testing continued until the PSA nadired at less than 2 ng/ml. At this point, patients were scheduled to undergo definitive treatments including radical prostatectomy, brachytherapy, external beam radiation therapy, combination radiation therapy, or cryosurgery.

Results: Seventy-six patients representing 6 institutions

qualified for the study. Patient selection was based upon organ confined prostate cancer using recognized industry standards to validate within a randomized format. Twenty-nine patients were evaluated on an LHRH-a + Flutamide arm while thirty-five patients entered the Flutamide + Finasteride arm. Patient selection for this study was based on the likelihood that definitive therapy would be carried out. Defined treatment included radical prostatectomy, external beam radiation therapy, brachytherapy, and cryotherapy. The average PSA starting point for the Flutamide/Finasteride arm was 10.95 ng/ml (n=35), while the average PSA starting point in the LHRH-a/Flutamide arm was 9.3 ng/ml. The average PSA nadir was .59 ng/ml in the Flutamide/Finasteride arm while the average PSA nadir in the LHRH-a/Flutamide arm was .45 ng/ml. The average change in PSA in the Flutamide/Finasteride arm was 10.36 ng/ml while the average change in PSA in the LHRH-a/Flutamide arm was 8.85 ng/ml. The average days to nadir on the Flutamide/Finasteride arm were 60.06 while the average days to nadir with the LHRH-a/Flutamide arm were 59.83. Patients who failed to complete the neoadjuvant trial numbered twelve (six in each arm). Reasons given for study withdrawal included urinary retention, a positive bone scan, nausea and diarrhea, heart palpitations, hot flashes, history of previous prostate cancer treatment, triple hormone blockade, excessive medicine expense, inability to nadir the PSA or patient non-compliance.

Conclusion: While no one has criticized the ability of CAB to nadir cancer activity through the use of PSA, the use of an antiandrogen + Finasteride is a novel if not a new approach in the battle for prostate cancer suppression. While economic ramifications of this study are significant, both the physician and patient are given an opportunity to nadir disease activity with a very user friendly and cost effective methodology, heretofore not identified. Additionally, it would appear that the side effect profile would favor the novel Flutamide/Finasteride approach.

MEDIA RELEASE

**New, Less Invasive Test
May Help Detect Prostate Cancer**

From www.woodtv.com
Grand Rapids, MI

Often times, it's an elevated PSA blood test that has doctors ordering biopsies to detect whether cancer is present.

Now, scientists at City of Hope Cancer Center in Los Angeles are investigating a new test that could significantly reduce the number of surgical biopsies necessary for the detection of this disease.

This test involves monitoring the levels of a component of the enzyme telomerase in a patient's prostatic fluid. Telomerase is a protein that is present in 85% of cancers.

Dr. Timothy Wilson is an urologist at City of Hope Cancer Center. He says, "This test merely involves a standard, digital rectal examination, which all men should have anyway, with their annual history and physical. It's much less uncomfortable than having the prostate ultrasound procedure performed and there's no sharp pain involved, as would be with the prostate biopsy."

Statistics show that in 70% of cases, prostate biopsies come back normal. So, researchers estimate that the new test could effectively eliminate many of these invasive procedures.

Dr. Wilson says, "Currently, about 800,000 men per year undergo prostate biopsies because they have an abnormal PSA or digital rectal examination. The telomerase test potentially can eliminate 70% of those biopsies from being performed."

Because telomerase is so common to cancers, tests like this one have potential to one day become screening methods for a number of types of cancer.

For more information, you can call City of Hope Cancer Center at 1-800-888-5323.

NEW VIDEOTAPE/DVD

There is a new videotaped lecture available by Dr. Bob Leibowitz from his May 2003, Chicago lecture.

"Everyone is Entitled to Their Own (WRONG) Opinion."

In this tape you will learn:

1. Why continuous blockade is worse; intermittent blockade is better; but reveals the best way to use hormone blockade.
2. Updates our triple hormone blockade results.
3. Reports astonishing results using high dose testosterone for select prostate cancer patients.
4. How testosterone can sometimes stimulate but at other times inhibit the growth of prostate cancer. This lecture describes the type of patients most likely to benefit from testosterone replacement therapy.

Dr. Bob believes this is his best video ever!

There are also four other videos by Dr. Bob available:

1. Prostate Pearls "To Infinity and Beyond" – July 2001
 - a. Emphasizes the treatment choices and results for "early previously untreated prostate cancer, including our triple hormone blockade results.
2. Treating and Defeating all States of Prostate Cancer – August 2001
 - a. Describes how to avoid getting hormone resistant/refractory.
 - b. Reports on various new and effective treatment options including weekly low dose taxotere, emcyt, decadron, carboplatinum chemotherapy; thalidomide,; and many other choices.
3. Antiangiogenic Cocktail and Unrelated Associates – February 2002
 - a. PC Antiangiogenic Cocktail.
 - b. "Metronomic" schedule of very low dose chemotherapy.
 - c. Testosterone replacement therapy featuring new slides showing how testosterone can kill prostate cancer cells (in very select situations).
 - d. An update on Triple Hormone Blockade.
4. Challenging PC Treatment Biases – Is Nothing Sacred??? – October 2002
 - a. "Testosterone and CaP – The higher the better?"
 - b. Treatment options for "localized prostate cancer.
 - c. Update results of triple hormone blockade as sole treatment of Prostate Cancer.
 - d. Update on PC Antiangiogenic Cocktail. Chemotherapy 2003 – highly effective with minimal side effects.

Videos are available from Compassionate Oncology Medical Group:

Cost: Video Tape \$20

DVD \$30

Refund (if video/DVD returned in good working condition)

Shipping \$5

There are also a limited number of Videos/DVD's available for loan from PAACT at no charge [These videos should be returned within a reasonable period of time (2 weeks), so that they may also be available for others to view].