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IS IT ALWAYS NECESSARY TO CURE PROSTATE CANCER WHEN IT IS POSSIBLE?

(Understanding the role of prostate inflammation resolution to prostate cancer evolution)

RONALD E. WHEELER, From the Prostatitis & Prostate Cancer Center, Sarasota, Fl

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ABSTRACT

Objective – Definitive therapy with radical prostatectomy, cryotherapy or radiation therapy generally follows the initial diagnosis of prostate cancer, particularly when men have at least 10 additional years of life expectancy. There is growing concern regarding the optimal conservative treatment for patients who decline or do not otherwise qualify for such definitive curative treatment. For those patients who choose a watchful waiting approach, it would be beneficial to know what specific dietary and nutritional methods could potentially slow the progression of their disease. In this prospective study, it was our goal to analyze the efficacy and safety of treating prostate cancer conservatively using the principles of a Mediterranean diet in association with a specific prostate nutritional supplement.

Method – 23 men aged 43-74 (median age: 64) with biopsy proven, organ-confined prostate cancer who had already declined immediate hormonal therapy and attempts at a curative cancer treatment agreed to participate in a Chronic Disease Management (CDM) protocol highlighted by diet with a specific prostate nutritional supplement. The diet recommended was a modified Mediterranean diet while a patented nutritional prostatitis formula (Peenuts®) was the supplement common to all patients. PSA, a recognized marker of prostate disease and prostate cancer activity, was the primary indicator to validate exacerbation or suppression of disease. All men were followed with serial PSA testing, a digital rectal exam, an International Prostate Symptom Score index (IPSS-Index) and an expressed prostatic secretion (EPS) examination. The primary Gleason sum/score represented in this study was 6 (n=11), while Gleason sum patterns 5, 5/6, 6/7, and 7 were also evaluated. Referencing the Partin Tables, organ confinement was predicted to be 66%.

Results – 87% of men (n=20) noted a 58% reduction (range of improvement: 13-90%) in PSA over an average of 38.5 months (range: 13-84 months). The remaining 13% of men included three men who experienced a mild elevation in PSA of 0.3, 0.7, and 0.9 ng/ml over 14 months, 42 months and 34 months, respectively. 15 men had completed an initial and secondary IPSS-Index while 14 men had undergone an initial and secondary EPS. The mean percentage reduction in IPSS-Index was 61% (range: 20-100% with a median of 55%), while men evaluated with EPS examinations noted a mean percentage reduction in white blood cells of 77.5% (range: 33-99% with a median of 82%). These results were evaluated using the t-Test, Wilcoxon Analysis and the Null Hypothesis and found to be statistically significant.

Conclusion –Clearly there is a need to develop effective alternative conservative therapies for the increasing numbers of prostate cancer patients who will not tolerate definitive curative measures or simply choose a conservative approach. Although this prospective study had no control arm, was of limited duration and included only 23 participants, it did appear to show significant benefit to the majority of prostate cancer patients treated with selective nutritional and

dietary therapy alone. Such treatments may provide a safe and effective long-term treatment alternative for some patients. Further study is encouraged.

Prostate cancer is the most commonly diagnosed malignant neoplasm among men in North America.(1) Notwithstanding the strides that have been made related to diagnosis and treatment, prostate cancer still poses a significant health risk. In 2005, the incidence of prostate cancer was noted to be in excess of 232,000 new cases while prostate cancer death currently ranks as the second most common male cancer death with approximately 32,000 men dying from the disease. (2) According to the SEER (Surveillance, Epidemiology & End Result) data and the age specific population projections in association with the United States Census Bureau, it is estimated that 99,000 men will die from prostate cancer in the year 2045. (3) Besides the health risk, there is also concern about the best way to pay for expensive prostate cancer treatment in the future where an aging population is expected to exhibit high rates of prostate cancer detection. (4) Despite our best efforts to cure, failure rates for prostate cancer may be as high as 40-60% in high-risk cases. (5)

Epidemiological studies suggest that diets rich in grains, specific vitamins, fruits and vegetables are associated with lower prostate cancer rates than high fat diets associated with red meat, dairy product intake and high dose calcium. (6-11) High temperature cooking and/or well-done or charred meat contains heterocyclic amines, nitrosamines and polycyclic aromatic hydrocarbons that have been shown prospectively to increase prostate cancer risk in the Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial. (12) Dairy products and diets with high calcium content have also been found to increase the risk of prostate cancer possibly through an increase in phytanic acid levels which are also elevated in high meat (protein) diets. (13, 14) A number of studies have found an association between saturated fat and prostate cancer although the precise mechanisms are not clear. (15-17) We, therefore, selected a modified Mediterranean diet which includes a high intake of cereals, grains, vegetables, fruits, virgin olive oil, beans, garlic, fresh herbs and seafood or poultry (white meat) with an avoidance of red meat and dairy products. (18, 19)

We know that many prostate cancer patients; up to 73% in one study, will take nutritional supplements on their own and the typical patient averages about three separate supplements daily. (20-23) Animal studies, epidemiological data and other evidence suggests that plant-based dietary supplements providing indoles, isothiocyanates, phenolics, monoterpenes, flavonoids, phytosterols, lignan precursors, lycopenes, and soy proteins as well as zinc, selenium, Vitamin E and various other anti-oxidants may serve as natural inhibitors of prostate carcinogenesis and growth. (24-29) The “Peenuts®” product is a standardized, certified and patented nutritional supplement that contains appropriate levels of these ingredients from plant-based sources. (30) The formula has been shown to suppress and help resolve non-bacterial prostatitis in randomized, placebo-controlled double blinded studies and is readily available commercially. (30, 31) Reductions in white blood cell count in the expressed prostatic secretions of prostatitis patients were reported at 66-77% using only this nutritional supplement. (31)

A number of recent studies have suggested that nutritional therapies alone could possibly lower the aggressiveness of prostate cancer and prevent its progression but randomized clinical trial data so far is very limited and no prospective studies have yet identified an optimal combination of dietary measures and nutritional supplementation that can effectively control prostate cancer growth.

There are many experts who question whether we are over treating prostate cancer. The poignant words of the late Willet Whitmore, M.D. may prove most prophetic. To paraphrase, his oft-quoted rhetorical question asks, “Is it possible to cure prostate cancer when it is necessary” and “Is it necessary to cure prostate cancer when it is possible”? If we accept that a cure is not always possible or even desirable in some cases due to complications, surgical risks, side effects, morbidity, cost and patient choice, this leads us to the next logical question, “Is it possible to significantly suppress or slow prostate cancer growth for prolonged periods using only nutritional and dietary measures”? The goal of this study was to attempt to begin to answer this important

question by prospectively treating prostate cancer patients exclusively with conservative measures including optimal dietary modification and standardized complex nutritional supplementation to determine the feasibility and effectiveness of such an approach as a possible alternative in prostate cancer treatment.

METHODS AND MATERIALS:

Between 1998 and 2004, 23 men (mean age: 63 years) with biopsy proven prostate cancer who had declined attempts at curative cancer treatment and hormonal therapy, were given full informed consent and offered the opportunity to try a strictly dietary and nutritionally oriented conservative protocol. The diet used was a Modified Mediterranean Diet (Prostate Diet) while a patented prostatitis formula (Peenuts®) was the nutritional supplement common to all patients. By study design, none of the patients had ever been exposed to anti-androgen therapy, a Luteinizing Hormone-Releasing Hormone (LHRH) analogue, LHRH antagonist or definitive therapy with surgery, radiation, or cryosurgery. All men were followed at varying time intervals with a PSA (prostate specific antigen) blood test, while many of the men were also followed with the International Prostate Symptom Score (IPSS) Index and the Expressed Prostatic Secretion (EPS) examinations. With the exception of two men with Gleason 6/7 components, three men with Gleason 5/6 components and one male with a Gleason 7 pattern, all men exhibited either a Gleason 5 (n=6) or a Gleason 6 (n=11) pathological pattern. All men were clinically diagnosed as T1c (n=15), T2a (n=2), T2b (n=2), or T2c (n=4). Interestingly, all of the men who met the entry criteria outlined above except one, enthusiastically chose to treat their disease through a dietary and nutritional supplement protocol represented by the term Chronic Disease Management (CDM) rather than undergo definitive therapy. The one male who initially qualified dropped out after 7 months, opting for a radical prostatectomy. CDM therapy is a unique cancer concept, but not dissimilar to the conservative holistic treatment of diabetes, hypertension, or arthritis whereby patients learn to live with the disease based on lifestyle changes consistent with improved diet, nutritional supplementation, stress reduction and exercise.

While the PSA level is a recognized marker of disease activity, it is noted that PSA levels may rise based on any combination of prostatitis (non-bacterial inflammation in ≥ 95% of cases), BPH (benign prostatic hyperplasia), and/or prostate cancer. The IPSS- Index is a recognized marker associated primarily with BPH and prostatitis, while the EPS (expressed prostatic secretion), represents the diagnostic biological marker for prostatitis. All men were evaluated at varying intervals of surveillance ranging from 13 months to 84 months (mean: 38.5 months). Three study subjects had a slight increase in their PSA levels of 0.3, 0.7 and 0.9 ng/ml at 14 months, 42 months and 34 months, respectively. Excepting these three patients with a small rise in PSA, the remaining 20 patients (87%) decreased their PSA levels during the study period an average of 58%.

Statistical Analysis

A performance analysis of these 23 patients relevant to any change in PSA noted statistical significance using the Null Hypothesis, t-Test and Wilcoxon Analyses. There was a significant decrease in PSA levels (ng/ml) after treatment with dietary modification and the specific herbal supplement taken at 2 capsules daily. The P value ($T \leq t$) one-tailed T test is 0.000068.

The null hypothesis can be postulated from the population of 23 patients. The first observation, u_1, is the initial PSA value taken. The second observation, u_2, is the follow-up PSA taken after treatment with the herbal supplement and dietary change. H0: $u_1 - u_2 = 0$. The null hypothesis postulates that the mean value of the difference is zero. There will be no significant difference in PSA levels after herbal supplementation and dietary change.

In the alternative hypothesis, the mean is different using the observed values; therefore, a two-tailed test is utilized.

t-Test: Paired Two Sample for Means
Alpha Significance level = 0.05

	Initial PSA	*Follow-UP PSA*
Mean	6.83	3.36
Variance	8.76	6.34
Observations	23	23
Pearson Correlation	0.43	
Hypothesized Mean Difference	0	
df	22	
t Stat	5.65	
P(T≤ t) one-tail	0.000006	
t Critical one-tail	1.717144	
P(T≤ t) two-tail	0.000011	
t Critical two-tail	2.073875	

Statistical Assessment: There was a significant decrease in PSA levels (ng/ml) after treatment with dietary encouragement and herbal supplementation, 2 capsules daily. Therefore we do not accept the null hypothesis that the mean difference is zero.
These nutritional variables had a significant effect in reducing PSA levels in this subject group.

An additional non-parametric test was calculated. The results of the Wilcoxon Matched-Pairs Signed-Ranks Test are as follows:
W+ = 269.50, W- = 6.50, N=23, p<= 6.769e-05 or p<= 0.000068.

t-Test: Paired Two Sample for Means
5-alpha Reductase Inhibitors (5-ARIs)

	Dx. PSA (ng/ml)	*F/U PSA*
Mean	6.38461538	2.6153846
Variance	10.2680769	1.1214103
Observations	13	13
Pearson Correlation	-0.05984581	
Hypothesized Mean Difference	0	
df	12	
t Stat	**3.95697795**	
P(T≤ t) one-tail	0.00095184	
t Critical one-tail	1.78228674	
P(T≤ t) two-tail	**0.00190367**	
t Critical two-tail	2.17881279	

The P value is statistically significant at 0.0019.

t-Test: Paired Two Sample for Means
Non-5-alpha Reductase Inhibitors (Non-5-ARIs)

	Dx. PSA	*F/U PSA*
Mean	7.06	4.64
Variance	8.987111111	8.707111111
Observations	10	10
Pearson Correlation	0.891877977	

Hypothesized Mean Difference	0
df	9
t Stat	**5.529914009**
P(T≤ t) one-tail	0.000182887
t Critical one-tail	1.833113856
P(T≤ t) two-tail	**0.000365774**
t Critical two-tail	2.262158887

The P value is statistically significant at 0.00037.

RESULTS:

All men within an age range of 43-74 years with a diagnosis of prostate cancer (Gleason Score: 5, 5/6, 6, 6/7,7) who declined standard curative and hormonal therapy were offered an opportunity to participate in a conservative quality of life protecting study with the understanding that diet and nutrition could play a significant role in disease proliferation or control. With the exception of the Gleason Score (excluding men with a primary Gleason Score of 8, 9, or 10) as a qualifying category of prostate cancer, there was no bias inherent in the entrance process. Twenty three men qualified for study evaluation using the PSA levels from the date of diagnosis (biopsy date) or the initial clinic appointment date (whichever was higher) as the reference PSA value for the starting point for data collection. 20 of 23 men experienced a positive response (decrease in PSA levels) relevant to the conservative therapy while 3 men noted a mild increase in their PSA values. Specifically, 87% of men (n=20) noted a 58% reduction (range of improvement: 13-90%) in PSA levels over an average of 38.5 months (range: 13-84 months). Using a mean PSA starting point of 6.8 ng/ml, 87% of men in the study experienced a mean reduction in PSA of 3.93 ng/ml (range: 0.9-12.5 ng/ml) over the identified time frame, while the median reduction was 3.45 ng/ml. The three men, who experienced a mild elevation in PSA, noted an increase of 0.3 ng/ml, 0.7 ng/ml and 0.9 ng/ml over 14 months, 42 months and 34 months, respectively. Overall, the effectiveness of Chronic Disease Management therapy to suppress prostate cancer was 87% using the PSA level as the disease activity marker.

A urinary assessment with a voiding symptom score (IPSS-Index) and prostatitis evaluation utilizing the expressed prostatic secretion (EPS) examination was conducted at the time of baseline (initial visit) and follow up evaluations on the majority of the participants. 15 men completed an initial and secondary IPSS-Index while 14 men had undergone an initial and secondary EPS. All men reduced their voiding symptom score with an average 4.9 points (range: 3-11), while noting an average starting score of 9.1 points (range: 2.5-19.5 with a median of 8.5). The mean percentage reduction in IPSS-Index was 61% (range: 20-100% with a median of 55%). Relevant to the EPS, an average starting point of 283 white blood cells (WBC's) per high-powered field (HPF) (400X) demonstrated an average decrease to 65 WBC's/HPF. To state further, a mean reduction was noted in the prostatitis marker of 218 white blood cells (range: 70-495) with a mean percentage improvement of 77.5% (range: 33-99% with a median of 82%). The reduced number of white blood cells on the EPS examinations as well as the improvement in urinary symptoms as documented by the average reductions in IPSS-Index scores in this group of men treated with nutritional means alone was statistically significant.

STUDY ANALYSIS AND DISCUSSION:

The possibility of treating prostate cancer conservatively has always been intriguing to the patient and a concern for the clinician. Previous studies have commonly grouped Gleason 7 scores with Gleason 5 and 6 scores within the designation of moderately well differentiated cancers. Ostensibly, this would give patients with Gleason 7 scores improved odds for cure while decreasing the chance for success in patients with Gleason 5 and 6 scores. This assumes the higher the Gleason score, the lower the chance for cure. (5,32) Increasing evidence through analyses now suggests that Gleason 7 prostate cancer responds better than a Gleason 8-10 but not as well as a Gleason 5 or 6. (5) Additionally, it is believed that Gleason scores of 5-7 may comprise almost 90% of all cancers encountered as 35-62% of men in most study groups analyzed are identified in the Gleason 6 category (5).

Qualification for this study included men with the diagnosis of prostate cancer who had not been exposed previously to anti-androgen therapy, LHRH therapy or any other definitive process of prostate cancer manipulation. Of the twenty three patients evaluated, 11 men were diagnosed with a Gleason 6 score, 6 men had a Gleason 5 score, 3 men had a Gleason 5-6 score, 2 men were noted with a Gleason 6-7 score, while one man had a Gleason 7 pattern. The clinical stage assessment noted 15 men with a T1c, 4 men with a T2c, 2 men with a T2b and 2 men with a T2a

stage classification. Pathologically, the biopsy diagnosis ranged from T1a – T2c. (*Refer to Patient Performance chart*) While the number of biopsy cores positive for cancer and the percentage of cancer per core varied widely, the percentage of cores positive for cancer (identified at the biopsy procedure) ranged from 12.5%-73% (mean: 33%; median 20%) associated with a range of biopsy samples from 2-18. This suggests the presence of significant disease in the study group.

In a unique study, Dean Ornish and colleagues at the University of California-San Francisco evaluated the ability of the Vegan Diet (n=44) to alter the PSA in a comparative analysis with a non-restrictive diet (n=43) in men documented with a Gleason 6 prostate cancer over a one year time period. (33) All of the men in this study, as in ours, had declined definitive curative treatment and hormonal therapy. While the merits of the Vegan Diet cannot be disputed as a benefit in heart disease prevention, it was less clear what effect this diet would have on men with known prostate cancer. An average decrease in PSA of 0.25 ng/ml (4%) identified in the Vegan group was statistically significant when evaluated in concert with a 0.38 ng/ml (6%) rise in the placebo group. While statistically significant, the difference was nonetheless modest at one year. This study result does not suggest a lack of benefit to the Vegan Diet, but rather demonstrates that the impact of diet alone on prostate cancer may be modest.

In our prospective study, we evaluated the benefit of a modified Mediterranean diet on known prostate cancer patients with Gleason scores of 5-7. The Mediterranean diet is recognized worldwide for its health benefits systemically but more specifically its promotion of cardiovascular health and cancer avoidance (colorectal, breast, pancreas, prostate and endometrial) properties. (18-19, 34-35) By design, men were asked to avoid red meat and dairy products including eggs in an effort to decrease saturated fat. It is commonly recognized that animal fat and dairy fat may play a role in prostate cancer proliferation. (6-17, 36) Unlike the Ornish cohort, men did not use soy in their diets. Fresh fruits and cruciferous vegetables belonging to the brassica classification were highlighted while the oil of choice was virgin olive oil.

Beyond the modified Mediterranean Diet, our study group used a complex nutritional supplement called Peenuts® that was originally developed to treat prostatitis. This formula represents a unique, synergistic blend of vitamins, minerals, amino acids and herbs. These ingredients have been shown individually to affect cellular oxidation, inflammation and immune function, while less clearly offering additional potential benefits from beta-sitosterols. (37-38) While using this formula, previous clinical investigations have shown an improvement in the expressed prostatic secretion (EPS) and voiding symptoms. (31) The EPS is the recognized diagnostic marker for prostatitis as shown through the historic work of Stamey, Meares, and others (39-43), while voiding symptoms are common to the diagnosis of benign prostatic hyperplasia and prostatitis.

The concept of looking at prostatitis within this study group was prompted by previous research from the American Association of Cancer Research (AACR) that supports a role for prostatitis in the evolution of prostate cancer. (44-46) It is postulated that the cellular oxidative stress associated with a chronic inflammatory process leads to proliferative inflammatory atrophy with subsequent evolution of free radicals through oxidative change eventually resulting in DNA alteration (cellular mutation), prostatic intra-epithelial neoplasia (PIN) and cancer. (44, 46) While it is beyond the scope of this article to review these findings in greater depth, it is well known that the process of inflammation is commonly associated with organ specific cancers including but not limited to cancer of the esophagus, colon, stomach, liver, lung and cervix. (45,47-48)

Within our study group, the mean PSA at the time of diagnosis was 6.8 ng/ml (range: 2.1-14.4 ng/ml). A statistically significant reduction in mean PSA of 3.4 ng/ml was validated using the t-test, Wilcoxon analysis and the null hypothesis. (*Refer to statistical analysis*) The mean percentage reduction in PSA was 50% while the likelihood for organ confinement in this group was 66% referencing the Partin Prediction tables. (49, 50)

While the topic of prostatitis and its role in prostate cancer evolution is likely to remain controversial for the immediate future, the topic's relevance may be best left for the health care provider and the patient to decide. Based on an average percent reduction in the white blood cells (a universal marker for inflammation) of 77.5% associated with the EPS, there appears to be sufficient clinical indication to support the addition of a scientifically validated prostatitis therapy to any long- term prostate cancer management protocol. The relative failure of the Vegan diet in the

Ornish study to significantly suppress prostate cancer (based on PSA analysis) supports this hypothesis.

Additionally, it is not unreasonable to suggest the noted reduction in PSA in our study is based mainly on the improvement in prostatitis, as it is well known that prostatitis is a common cause of PSA elevations. However, the long average duration of the reduction in PSA levels at over 3 years in patients with known prostate cancer receiving no other therapy would suggest that the treatment is acting directly on the prostate cancer. Only further study will be able to determine if this conclusion is accurate. At the very least, we can say that the nutritional component complements the diet and may well enhance the durability of response seen in the study patients.

There is a clear indication that the nutritional treatment evaluated had an impact on voiding symptoms, as there was a mean percentage reduction in the International Prostate Symptom Score Index (IPSS-Index) of 61%. This is consistent with findings from a previously performed randomized, double blind, placebo controlled study (31). This response exceeds that of any prostate or prostatitis nutritional formula such as saw palmetto described in the world medical literature suggesting a synergistic effect from the particular blend of nutrients selected. (51)

One gentleman aged 54, who had initially qualified for the study decided on a radical prostatectomy despite performing quite well at 7 months. Importantly, the delay in surgery had no adverse effect on the outcome, as his PSA was 0.0 ng/ml, 1 year post-prostatectomy. While further research could evaluate the potential benefit of this protocol to any ultimate outcome, the delay in definitive treatment allowed for improved awareness and decision making on the part of the patient and his family. Alternatively, research may demonstrate the use of the Peenuts® formula or similarly validated supplements to be a reasonable first step in avoiding additional biopsies in patients where prostatitis is present.

While the use of the modified Mediterranean diet and a prostate nutritional supplement has been shown to be effective, additional ingredients and/or products may be added to enhance the collective benefit in the prostate cancer disease suppression process. Beyond the modified Mediterranean diet and the Peenuts® nutritional formula that were used by all patients, 17 patients used an active form of vitamin D, 13 patients used an anti-cholesterolemic agent, 14 patients used omega-3 fatty acids, 13 patients used a 5-alpha reductase inhibitor (5-ARIs), 7 patients used a COX II inhibitor and 4 men used an alpha-blocker. When the men using 5-ARIs were studied versus the men who didn't use them, there was a 52% reduction in PSA in the 5-ARIs group (n=13) over 32 months versus a 43% reduction in the cohort not on 5-ARIs (n=10) over 48 months. This suggests a relatively insignificant benefit in PSA reduction relevant to the men on the 5-ARIs at this point in the study. Interestingly, when the nutritional supplement formula was evaluated alone (n=4), a reduction in mean PSA of 53.8% over 41.3 months of surveillance was noted. While this finding is potentially quite significant, it would be premature to draw any conclusions from such a small sampling size and a larger study with additional patients would need to be completed before the issue can be properly addressed.

CONCLUSIONS:

Prostate cancer is recognized as the number one male cancer health risk with a new case diagnosed every 3 minutes. With baby boomers aging and health care costs rising (52), an opportunity to examine novel concepts for the care of patients diagnosed with prostate cancer could not be more relevant. When a radical prostatectomy is successfully performed for a cure, consideration should be given to the potential average benefit of adding 3 years, 1.5 years, and 0.4 years to the life of a typical man in his 50s, 60s or 70s, respectively. When this benefit is weighed against the possibility of failure to cure and the associated morbidity, pain, surgical risks, complications, side effects and costs, an effective dietary and nutritional protocol may present a reasonable alternative. (53)

When all of these factors are considered in our aging population together with the risks of a significant decrease in the quality of life even in successful cases of definitive, curative therapy, a conservative approach may be welcomed as a viable first choice in Gleason 5 and 6 prostate cancer patients by Governmental agencies such as Medicare, the Health Care Insurance Industry,

and patients alike. Critical to research regarding the concept of living with the disease is to locate and allocate funding to study this protocol and similar programs in greater depth with additional patients followed over a longer period of time. This study has perhaps provided the first step in our improved understanding of the concept of nutritional therapy of prostate cancer. Beyond the issue of prostate cancer treatment is the potential role of prevention. Ultimately through this research effort and that of others, the landscape of prostate cancer treatment will become better defined.

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CHRONIC DISEASE MANAGEMENT PROTOCOL NOTING PSA RESPONSE TO 5–ALPHA REDUCTASE INHIBITORS (5-ARIs) VERSUS NON 5-ALPHA REDUCTASE INHIBITORS (August 2005)

5-ARIs

Dx.PSA (ng/ml)	Gleason Score	F/U PSA	Surveillance Months	Percent change
8.5	5	3.1	72	64%
5.4	6	2.1	41	61%
2.1	5	2.8	42	+33%
7.3	5/6	4.5	40	38%
3.2	6	2.0	21	38%
4.4	6/7	1.7	39	61%
6.8	5	1.7	49	75%
8.4	6	1.8	18	79%
4.4	6/7	4.7	14	+7%
14.4	6	1.5	29	90%
4.1	6	1.6	15	61%
6.1	5/6	1.3	13	79%
8.6	7	2.9	17	66%
Avg. Starting PSA 6.44 ng/ml	5.9	2.44	32 Months	52%

Average Reduction in PSA = 4.0 ng/ml

Non-5-ARIs

Dx.PSA (ng/ml)	Gleason Score	F/U PSA	Surveillance Months	Percent change
7.0	5	2.4	62	66%
11.7	5/6	5.8	60	50%
4.7	6	1.7	72	64%
6.9	6	5.1	19	26%
6.9	6	6.0	38	13%
9.1	6	5.5	58	40%
3.0	5	0.8	24	73%
6.2	5	4.1	84	34%
11.4	6	12.3	34	+8%
6.6	6	1.8	24	73%
Avg. Starting PSA 7.35 ng/ml	5.65	4.55	48 Months	43.1%

Average Reduction in PSA = 2.8 ng/ml

PATIENT DATA FOR PROSPECTIVE PROSTATE CANCER STUDY

AGE	INITIAL PSA	FOLLOW-UP PSA	% PSA DECREASE	TIME WITH DISEASE	GLEASON SCORE	CLINICAL STAGE	BIOPSY STAGE	IPSS-INDEX
61	8.5 ng/ml	3.1 ng/ml	64%	72 months	5 (3+2)	T2c	T2c	5.5-2.5 = 3
68	7.0 ng/ml	2.4 ng/ml	66%	62 months	5 (3+2)	T1c	T2a	19.5-8.5 = 11
43	5.4 ng/ml	2.1 ng/ml	61%	41 months	6 (3+3)	T1c	T2a	4-0 = 0
65	11.7 ng/ml	5.8 ng/ml	50%	60 months	5(3+2)/6(3+3)	T1c	T2b	
64	4.7 ng/ml	1.7 ng/ml	64%	72 months	6 (3+3)	T1c	T2a	
55	2.1 ng/ml	2.8 ng/ml	+33%	42 months	5 (3+2)	T2c	T2c	6.5-2 = 4.5
56	7.3 ng/ml	4.5 ng/ml	38%	40 months	5(2+3)/6(3+3)	T2a	T2b	10.5-6 = 4.5
70	6.9 ng/ml	5.1 ng/ml	26%	19 months	6 (3+3)	T2c	T2a	11.5-7.5 = 4
68	6.9 ng/ml	6.0 ng/ml	13%	38 months	6 (3+3)	T1c	T2a	4-0 = 0
56	9.1 ng/ml	5.5 ng/ml	40%	58 months	6 (3+3)	T1c	T2a	11-7 = 4
61	3.0 ng/ml	0.8 ng/ml	73%	24 months	5 (3+2)	T1c	T2a	
48	3.2 ng/ml	2.0 ng/ml	38%	21 months	6 (3+3)	T2a	T2b	9.5-2 = 7.5
69	6.2 ng/ml	4.1 ng/ml	34%	84 months	5 (3+2)	T1c	T1a	15.5-10 = 5.5
56	4.4 ng/ml	1.7 ng/ml	61%	39 months	6(3+3)/7(3+4)	T2c	T2c	8.5-1.5 = 7
74	11.4 ng/ml	12.3 ng/ml	+8%	34 months	6 (3+3)	T2b	T2b	
63	6.8 ng/ml	1.7 ng/ml	75%	49 months	5 (3+2)	T1c	T2a	5.5-2.5 = 3
71	6.6 ng/ml	1.8 ng/ml	73%	24 months	6 (3+3)	T1c	T2c	7.5-6 = 1.5
64	14.4 ng/ml	1.5 ng/ml	90%	29 months	6 (3+3)	T1c	T2a	
70	8.4 ng/ml	1.8 ng/ml	79%	18 months	6 (3+3)	T1c	T2a	
72	4.4 ng/ml	4.7 ng/ml	+7%	14 months	6(3+3)/7(3+4)	T2b	T2c	
55	4.1 ng/ml	1.6 ng/ml	61%	15 months	6(3+3)	T1c	T2c	2.5-0 = 0
72	6.1 ng/ml	1.3 ng/ml	79%	13 months	5(3+2)/6(3+3)	T1c	T2c	
71	8.6 ng/ml	2.9 ng/ml	66%	17 months	7(4+3)	T1c	T2a	14.5-7 = 7.5
TOTALS:	**157.2 ng/ml**	**77.2 ng/ml**	**802**	**885**				
	Mean Starting PSA	Mean PSA Change	Mean % Decrease	Mean Months				
	6.8 ng/ml	3.4 ng/ml	50%	38.5				

EPS=Expressed Prostatic Secretion (An Indication of Prostate Inflammation)
PSA=Prostate Specific Antigen
IPSS-Index=International Prostate Symptom Score
TNTC=Too Numerous to Count
Gleason Score: 2-10 (Primary Cancer Grade + Secondary Cancer Grade) with 2 being the most favorable and 10 being the worst

Ronald E. Wheeler, M.D.

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