

Everything You Ever Wanted to Know About Chronic Prostatitis

"A CRITICAL UPDATE ON PROSTATITIS _
AS A CAUSE OF PROSTATE CANCER"

INTRODUCTION:

CHRONIC PROSTATITIS (INFLAMMATION or infection of the prostate) is common to virtually all adult men. Not surprisingly, ***Prostatitis* is associated with virtually all cases of prostate cancer and present in nearly every prostate biopsy, regardless of other findings.** According to Drs. Krieger and Berger, Urologists at the University of Washington, in Seattle, "All men either have ***prostatitis*** or will get ***prostatitis*** in their lifetime." ***Prostatitis*** has received some unexpected, but welcomed, publicity with the movie, "The Green Mile", starring Tom Hanks as the Prison Warden who suffered with ***prostatitis*** as well as the revelation that the now deceased former leader from Iraq, Saddam Hussein had an attack of ***prostatitis*** while incarcerated. Interestingly, and notwithstanding the above comments, ***prostatitis*** has been termed the "trucker's disease", based on the fact that truck drivers sit on their backsides, (better stated, prostates), all day long, while driving a truck. While I can't change the historical reference, truckers manifest the signs and symptoms of ***prostatitis*** by virtue of sitting all day, driving mile after mile. The sitting position does not create the disease, but rather allows the disease to be readily identified clinically. Just for the record, all men are equally likely to contract ***prostatitis*** regardless of job description.

Chronic *prostatitis* may not cause significant symptoms in many men, but in others it can be a devastating disease that severely affects the quality of life of those afflicted. For many Professionals, *prostatitis* is difficult to diagnose and even more difficult to treat. A wide variety of therapies are available but few actually work in more than a small percentage of men. While none of the standard treatments available is able to improve the health and wellness of the prostate long-term, a proven approach, with a patented formula, may be your best first step. We'll review the current knowledge about chronic *prostatitis*, your treatment options, and the science linking an inflammatory disease to prostate cancer.

THE PROSTATE:

All men are born with a prostate that grows and enlarges throughout life based on various forms of stimuli. The prostate gland (in health) is a spongy, walnut sized, mucus-producing organ that lies just below the urinary bladder and superior to the rectal wall. The prostate surrounds the urethra, a channel through the prostate, which carries urine from the bladder to the outside. The most significant growth of the prostate, associated with an increase in the number of cells (hyperplasia), begins in the early to mid 40s and is believed to be related to Dihydrotestosterone production. Inflammation or growth of the prostate commonly causes difficulties in urination that should be addressed at the earliest sign. The only known function of the prostate is to produce a secretion that nourishes and protects sperm during reproduction. It has no other known proven purpose.

THE DEFINITION:

Prostatitis is defined as inflammation or infection of the prostate. **Simplistically, *prostatitis* can be divided into two groups; bacterial and non-bacterial.** Bacterial may be divided into acute and chronic while non-bacterial *prostatitis* is generally recognized as chronic. The National Institute of Health developed and accepted the latest definition of *prostatitis* primarily guided by the presence of chronic pelvic pain associated with the more traditional acute and chronic clinical presentation. While I refer you to the formal paradigm presented by the NIH for a complete understanding, the most common presentation is Type IIIA or non-bacterial, inflammatory *prostatitis*. While *prostatitis* may be acute, (associated with systemic findings of fever, chills and rigors (shakes), most cases of *prostatitis* are chronic and tend to be incurable, with relatively frequent recurrences despite optimal, yet ineffective traditional treatment. Unfortunately, traditional therapy involves the use of antibiotics, which are effective in less than 5% of cases, as a remedy for non-bacterial *prostatitis*, although, antibiotics may improve symptoms temporarily secondary to an anti-inflammatory mechanism.

THE CLINICAL PRESENTATION:

Symptoms of *prostatitis* (also common to [EP, enlarged prostate] or [BPH, benign prostatic hyperplasia]) are the number one reason that men seek the advice of their primary care physician or Urologist. The most significant symptom of chronic *prostatitis* is pelvic pain, followed by various voiding symptoms, impotence and/or infertility. Referred pain from

prostatitis is commonly located in the groin, testicles, lower back, penis, an area circumferentially around the rectum, the perineum and/ or in the suprapubic area above the bladder. Additionally, pain is not uncommonly associated with ejaculation. Typical urinary symptoms produced by *prostatitis* include getting up at night to void (Nocturia), frequency of urination, urgency of urination, incomplete voiding, decreased force of the urinary stream, intermittency of the stream and a need to push or strain to void.

Prostatitis is a troubling disease that remains a health risk to most of the adult male population for far longer than is necessary. Frequently, men don't realize they have prostatitis, requiring a Prostate Specific Antigen (PSA) blood test to be performed to prove it. A PSA of >1 ng/ml indicates prostatitis, based on research presented at the NIH in 2000. Historically, men under 50 years old, with voiding symptoms or pelvic pain, had *prostatitis* until proven otherwise. Men over 50 years old, with the same symptoms, were assumed to have had an enlarged prostate (EP) or BPH. A study presented at the NIH in 1999 has shown that most men with voiding symptoms, regardless of age, actually had *prostatitis* when properly tested. In a trial of 235 consecutive men who exhibited even mild voiding symptoms, greater than 80% were found to have chronic *prostatitis*, regardless of their age based on an evaluation of the expressed prostatic secretion (EPS).

THE DIAGNOSIS:

Prostatitis has been termed "the waste basket of clinical ignorance" by prominent Stanford University Urologist-Emeritus Dr. Thomas Stamey because of the difficulty it presents in diagnosis and treatment. *Prostatitis* is usually identified or suggested by the symptoms it produces and the

findings of a sore or tender prostate when a digital rectal examination is performed, albeit not very successfully. Prostate Specific Antigen (PSA), a blood test designed to identify patients at risk for prostate cancer, will also be increased in most cases of *prostatitis*. The presence of a specific urinary tract infection, together with pelvic pain, fever, chills, rigors, voiding symptoms and a sore or tender prostate on rectal examination, will identify the 5% of patients with acute bacterial *prostatitis*, a true infection. Chronic bacterial *prostatitis* is also quite common, but devoid of the acute symptoms including fever. While it would not be surprising to identify men with chronic *prostatitis* who have no symptoms at all, the PSA provides a virtual 100% sensitivity to predict the diagnosis when the PSA number is > 1.0 ng/ml.

While obtaining an EPS requires some knowledge and skill on the part of the Care provider, the ability to perform this procedure is critical to the ability to obtain representative outcome data as well as judge the benefit of a treatment plan. To be sure, one should not expect a Urologist or Primary Care Physician to perform this test with any degree of accuracy or skill if they rarely perform it. If you have concerns about *prostatitis*, you must go to a physician who understands the importance of the EPS and understands how to get the specimen to be evaluated. Unfortunately, most Urologists do not understand the disease or the diagnostic principles with significant clarity to assist you. When patients ask me how to find a doctor who performs the EPS procedure, I suggest they call the office and ask if the doctor(s) perform the test. If the receptionist hesitates with the response, they likely do not.

The prostatic secretion (fluid) is commonly obtained by gentle to moderate massage of the prostate during the digital rectal examination (DRE). The secretion is obtained from the tip of the urethra, if performed accurately. When the secretion is examined under the microscope, a finding of >10 white blood cells per microscopic field (400X) is considered

definitive proof of non-bacterial inflammation or *prostatitis*. Additionally, a histological examination of a prostate biopsy (a tissue sample) can also show definitive signs of inflammation and diagnose *prostatitis*. Unfortunately, inflammation tends to be under-diagnosed when prostate biopsy specimens are reviewed by the Pathologist, based on its presence in virtually every tissue sample. Ultrasonographically, the presence of enhanced blood flow (seen commonly with color flow, power Doppler) in combination with calcium deposits herald the diagnosis of *prostatitis* as well. Despite the fact that examination of the prostatic fluid or EPS makes the definitive diagnosis, the rare family physician and fewer than 10% of all Urologists perform it because of difficulty in obtaining a proper sample, lack of interest, test complexity, lack of time, inadequate testing equipment, uncertainty of treatment or a lack of knowledge. In the busy world of a medical practice, uncertainty of treatment and a lack of time are likely the two most common reasons physicians prefer not to deal with this vexing disease.

Based on challenges inherent with obtaining an accurate EPS, many physicians (including Urologists) have resorted to an evaluation of the post massage urine (VB-3) for the diagnosis of *prostatitis*. This concept has been popularized by Curtis Nickel, M.D. (Member of the **NIH Prostatitis Collaborative**) and others as an acceptable diagnostic alternative to the EPS. In an effort to validate the post massage urine as a surrogate diagnostic marker, a direct comparison of EPS and VB-3 was performed on 49 men believed to have *prostatitis* based on any degree of urinary symptoms and PSA (Reference the EPS/ VB-3 Comparative Study in the my book, *Men at Risk*). In this study comparison, all 49 men had *prostatitis* based on a diagnostic EPS with a median white blood cell count of 145 WBC's/HPF (High Power Field) or (400X). The post massage urine (VB-3) performed

immediately following the collection of the EPS noted a non-diagnostic median white blood cell count of 5-6 white blood cells/HPF. Using 10 WBC's, as diagnostic for *prostatitis*, the VB-3 (post massage urine) missed 61% of patients with *prostatitis*. In other words, a test that was heralded as an acceptable alternative for the EPS missed almost two thirds of patients with the disease that it was intending to diagnose.

For this reason, patients and physicians should be discouraged from using the VB-3 (post massage urine) as a definitive screening test for *prostatitis*. To restate, there are too many false negatives to suggest that this test has any redeeming diagnostic clinical value. On the other hand, if the pre-massage urine (a typical urinalysis) is compared to the post massage urine quantitatively for white blood cells, there is value to the test technique from a relative point of view. In my opinion, any increase in the number of white blood cells per high power field from one specimen to another will identify *prostatitis* patients definitively when the PSA is > 1.0 ng/ml. Unfortunately, the mere diagnosis does not provide an adequate and dependable marker for follow up based on variability of massage technique from one office visit to another. Acceptance and clinical application of flawed test procedures by physicians merely underscores the ignorance and confusion that trickles down to the suffering patient. With a clear understanding of the above, patients empowered with this knowledge will be able to take a more active role in treatment decisions with their physician while ultimately improving their outcome. While nearly everyone recognizes that medicine is an inexact science, physicians are obligated to separate fact from fiction. In other words, if a test fails significantly to identify the disease it is intended to find and cannot be reliably repeated, we should not use the test. Failure to understand this principle from a professional point of view merely widens the chasm

of ignorance between the educated and the under-educated masses allowing confusion to remain rampant.

In *prostatitis*, any combination of pelvic and urinary symptoms are possible, individually or concomitantly as well as the common presentation of an individual (with a PSA blood test result of >1.0 ng/ml), who is without pain, discomfort or urinary problems, yet still has prostatitis, based on an abnormal assessment of the prostatic fluid or EPS. In other words, it is not unusual to have *prostatitis* without signs and symptoms common to the disease. Our data shows conclusively that the PSA blood test is the most convenient marker to identify the presence of *prostatitis*. Furthermore, our research demonstrates the Sensitivity and Specificity of PSA as a diagnostic tool to be 100% when the PSA is > 1.0 ng/ml. This fact was pointed out to the audience of experts at the NIH in 2000.

TREATMENT OPTIONS:

Treatment of *prostatitis* has been anything but a sure proposition. According to noted *prostatitis* expert Dr. Curtis Nickel of Kingston, Ontario and the NIH, "there is widespread frustration, discomfort, and lack of knowledge in both primary care physicians and urologists' ability to manage *prostatitis*. A truer statement has never been made!

Those patients who truly have an identifiable bacterial infection of the prostate (culture proven) will certainly benefit from antibiotics. Antibiotics may need to be continued for 2-6 weeks; while in rare cases, long-term or indefinite antibiotic suppression therapy may be necessary. We don't have any data that looks at recurrent disease over many years, but, it is believed by this author that bacterial *prostatitis* may

transition to non-bacterial prostatitis. This fact, however, was later proven by the AACR and Michael Karin PhD at University of California at San Diego.

Campbell's Urology, the Urologist's most authoritative reference text, identifies only about 5% of all patients with *prostatitis* as having a bacterial component, which can be cured, at least in the short term, by antibiotics. In other words, **95% of men with prostatitis have little hope for a cure with antibiotics alone since they don't actually have any identifiable bacterial infection.** As a male, it is wise to request a culture & sensitivity (proving bacterial *prostatitis*) of either the urine or EPS, before consenting to the use of antibiotics. While antibiotics are overused, if your doctor insists on an initial trial of antibiotics, despite your concerns, it may be most prudent to follow his instruction as he likely has your best interests in mind, albeit repeated trials of antibiotics are discouraged based on concern for suppression of the immune system and the possibility that a super-resistant organism may result, not to mention the needless expense.

In the treatment of *prostatitis*, physicians have traditionally recommended everything from doing nothing to multiple and extended courses of antibiotics, synthetic drugs and lifestyle changes. **It is not unusual to hear a doctor tell his/her patient that he needs to learn to live with it;** referencing *prostatitis*. Among the various treatment options; alpha blockers (Hytrin®, Rapaflo, Cardura®, Flomax® and Uroxatrol®) are designed to relax the muscle tension at the junction of the *prostate* and bladder neck region (like a hammock) to improve urinary flow. This class of drug does tend to improve voiding difficulties by relaxing tension at the bladder neck region (space between the prostate and the bladder); but are expensive, need to be taken indefinitely, may have significant side effects and don't cure the underlying problem or prevent prostate growth.

Finasteride (Proscar®) or Dutasteride (Avodart®), synthetic drugs that block the conversion of Testosterone to Dihydrotestosterone, can shrink prostate tissue but there is no proof it helps in the treatment of *prostatitis* as defined by decreasing white blood cells found in the prostate secretion. Allopurinol, a drug that reduces uric acid levels in the body, has been used to treat *prostatitis*, based on the theory that uric acid crystals may form in the prostate secondary to refluxing urine and cause inflammation. Most clinicians, who have tried Allopurinol for *prostatitis*, report disappointing results from this therapy. Anti-inflammatory agents (Motrin®, Alleve or Advil®) and hot sitz baths have been helpful in treating the discomfort caused by *prostatitis* in many patients, but neither of these treatments actually cures the disease and the benefits wear off rapidly. Irritative voiding symptoms may be relieved by a myriad of bladder relaxing agents such as oxybutynin (Ditropan®) or solifenacin succinate (Vesicare®), while anti-depressants such as amitriptyline (Elavil®) have been helpful in various chronic pain conditions such as *prostatitis* associated with depression. Nanobacterium (one hundredth the size of an E. Coli bacterium) has been postulated as a cause of prostate stone formation. Unfortunately, there is no definitive data to suggest that this microbe is problematic, much less a concern for *prostatitis* evolution. Biofeedback, behavioral therapy, referral to a pain clinic, and/or psychological treatment has been recommended for patients with *prostatitis* and occasionally offers some relief to selected individuals. For the most part, current treatment methods for *prostatitis* are generally rather disappointing.

Prostatic massage plus antibiotics deserves further review. Proponents of prostate massage (championed in the Philippines) have little reproducible data to support their enthusiasm. My personal experience with prostate massage

demonstrates only temporary results with transient prostate size reduction and relief from congestion. Unfortunately, long-term benefit for the resolution of *prostatitis* based on prostate massage (as measured by EPS), over time, is unrealistic and is not likely to occur. Other drawbacks include intense discomfort/pain at the time of massage, the need for accurate cultures of the prostatic fluid and a dependence on antibiotics to ultimately affect the cure.

Dr. John Krieger, noted Urologist at the University of Washington and member of the Prostatitis Collaborative at the NIH, appropriately points out the following multiple factors preclude accuracy of the culture technique involving urine, semen or prostatic secretion for diagnosing or treating *prostatitis*:

1. The presence of inhibitory substances
2. The unknown effects of many previous courses of antibiotics
3. The fact that most bacteria from the prostate do not readily grow on conventional culture media
4. The high number of uncharacterized bacteria that infect human prostate tissue
5. There is inherent difficulty in obtaining a pure specimen from the prostate, which has not been contaminated by possible infectious organisms of the urethra or urinary passage
6. The fact that most cases of *prostatitis* are not infections in the first place.

PROSTATE SPECIFIC ANTIGEN (PSA) AND PROSTATITIS

Prostate Specific Antigen (PSA), referenced earlier, was originally designed as a bloodtest for prostate cancer surveillance. Historically, PSA blood levels of 0-4 were designated as "normal", but this range was arbitrarily selected and never meant to become gospel for normalcy; therefore, does not necessarily indicate a healthy prostate. ***Prostatitis* represents the number one reason that PSA elevates.** Additionally, we know that up to 30% of all prostate cancers occur in patients with PSA levels less than 4.0 ng/ml. Since prostate cancer obviously cannot be considered normal, this suggests that the original "normal" PSA range of 0-4 ng/ml is much too high. It's been suggested that any PSA level greater than or equal to 1.0 ng/ml indicates an unhealthy prostate, with active *prostatitis*, as confirmed by an NIH presentation in 2000 (R. Wheeler). Data from a Johns Hopkins white paper from 2002 corroborates the importance of PSA to prostate cancer. **Based in part on the Baltimore Longitudinal Data, Ballentine Carter and colleagues confirmed a 3-4 fold increased incidence of prostate cancer development in men aged 40-60, when the PSA level was in excess of 0.6-0.7 ng/ ml. Peter Gann and colleagues have shown through their research that a PSA between 2.0-4.0 ng/ml is associated with a 5-9 times increased incidence of an aggressive cancer within the subsequent 10 years. This is sobering data that predicts disease and must be understood; even though many men choose to be unknowing and/or ignorant regarding prostate disease markers rather than choosing a proactive or preventative course of action.**

As noted earlier, it's well known that *prostatitis* increases the PSA level. In fact, it is much more likely that any unexplained increase in PSA level is due to *prostatitis* than to BPH or prostate cancer. A few Urologists commonly treat their patients with high PSA levels with 4-6 weeks of antibiotics and repeat the PSA level before recommending a biopsy when the DRE (digital rectal exam) findings are non-diagnostic. In this scenario, only if the second PSA level remains elevated will a biopsy be ordered. My approach to this clinical scenario would be to recommend imaging for all patients, thereby replacing biopsy. Moreover, instead of antibiotics (unless a bacterial infection is isolated); I would recommend the formally patented *prostatitis* formula Peenuts®. A minimum of 6-12 months on this nutritional formula would be required to adequately make an impact on a disease that may be worsening at the time the patient is first evaluated.

I believe that a significant percentage of any elevation in PSA level in the blood (associated with a normal digital prostate examination) should be considered prostatitis until proven otherwise. This is based on the fact that 70-80% of all biopsies are negative when an elevated PSA is encountered. While prostate cancer is certainly a concern and should be considered carefully and appropriately, prostatitis is much more likely from a statistical point of view. PSA can serve as a very useful marker or indicator of the degree of prostatic inflammation present and help determine the effectiveness of prostatitis therapy through comparative testing.

THE LINK BETWEEN CHRONIC PROSTATITIS AND PROSTATE CANCER:

Virtually all men will develop *prostatitis* at some point in their adult lifetime. This has been shown in several studies including one done in 1979 by Drs. Kohnen and Drach who found 98.1% of 162 prostates removed surgically (for prostate cancer) had evidence of inflammation (prostatitis). **Dr. Timothy Moon, Urologist at the University of Wisconsin, and many others, report that virtually 100% of the biopsy and surgical prostate specimens they examine show evidence of *prostatitis*.**

Compounding the issues, virtually all men eventually get prostate cancer if they live long enough. In 2018, according to the American Cancer Society (ACS), 32,000 men died from prostate cancer; while over 202,000 new cases were diagnosed. Prostate cancer is the most common malignancy to affect men and the second leading cause of cancer death in men (lung cancer is first). In the United States, one in four men who undergo prostate biopsy will be found to have prostate cancer, but all of them will have *prostatitis*. **These findings have led Dr. Timothy Moon and others to suggest that prostate cancer is always associated with *prostatitis*.**

Young men in their thirties typically are quite prone to *prostatitis* and are not generally thought to be at risk for prostate cancer. But a study from Memorial Sloan-Kettering Cancer Center, in New York, found that 30% of 525 American men aged 30-39 actually had microscopic prostate cancer. Is it postulated then that chronic *prostatitis* may increase the risk for and/or promote the growth of prostate cancer? There is evidence that suggests this may be so. The importance of this data is confirmed by the Detroit Autopsy Study, headed up by Weil Sakr, which corroborated that 30% of 30-year-old men had *prostatitis* and prostate cancer.

It is well known that chronic inflammation of several other organs is associated with various cancers. Examples include but are not limited to: the inflammation of the lower esophagus (Barrett's Esophagitis), which leads to esophageal cancer, hepatitis may lead eventually to hepatic cancer and ulcerative colitis, which often develops into colon cancer. Since chronic inflammation causes cancer in other organs, it is not unreasonable to suggest that chronic prostate inflammation (*prostatitis*), if left unattended, may ultimately lead to prostate cancer. This concept has been demonstrated more clearly by the American Association of Cancer Research (AACR) and corroborated independently by David Bostwick, M.D., world-renowned Pathologist. **Specifically, the AACR has shown that prostatitis (an inflammatory disease) represents cellular oxidative stress resulting in cellular dysplasia, proliferative inflammatory atrophy, subsequent cellular mutation associated with changes in DNA (Deoxyribonucleic Acid), prostatic intraepithelial neoplasia (PIN), and ultimately prostate cancer.**

Prostate cancer is always found together with *prostatitis* while all men will probably get both diseases if they live long enough. Both prostate cancer and *prostatitis* raise Prostate Specific Antigen (PSA) levels and occur most often in men in their 60s. Both conditions are currently at epidemic, if not pandemic levels. While prostate cancer and chronic *prostatitis* are clearly associated, further research and epidemiologic studies are required to add additional clarity to the exact nature of the relationship, if disbelieved.

Based upon the now well-recognized association between *Prostatitis* and Prostate Cancer, *prostatitis* resolution is a key component to a Chronic Disease Management (CDM) strategy. CDM is a competing option to more traditional therapies that allows men to live with their cancer, while preventing Impotency, Incontinence and the stigma of failure to cure. **Living with prostate cancer is realistic and is**

analogous to living with Arthritis or Diabetes. Living with prostate cancer becomes more attractive when it is realized that successful intervention for cure (replete with the negative side effects) adds only 3 years to the life expectancy of a man in his 50s, 1.5 years to a man in his 60s and 0.4 years to a man in his 70s. This data comes from the elegant work of Michael Barry and colleagues at Harvard. For many prostate cancer patients, the risk of treatment failure is often too big of a gamble to take. Thus, as the male becomes better informed through prediction nomograms (statistical clinical models) and up-to-date treatment outcome data, an attempt at formal therapy may lose some of its luster, as quality of life takes center stage and becomes the dominant issue for our remaining years.

THE LINK BETWEEN PROSTATITIS AND INFERTILITY:

The inflammatory process of *prostatitis* has been shown to affect sperm quality primarily by decreasing the motility of sperm. Couples who are trying to conceive a child should look at the very real possibility of *prostatitis* treatment as the most cost effective and best "first step" to improving sperm quality. While the identification of >10 white blood cells in the prostate secretion is sine qua non for the diagnosis of *prostatitis*, the presence of any white blood cells in a sperm sample (ejaculate) would also herald the presence of concurrent disease in most cases. Additionally, my clinical acumen suggests that a PSA blood test result of > 0.5 ng/ml may also be associated commonly with *prostatitis* and decreased fertility. (Please review data regarding my patented natural remedy Peenuts® for resolution of signs and symptoms consistent with *prostatitis* on the Nitritonals page of this website).

CONTEMPORARY RESEARCH:

Present research dollars in *prostatitis* are so few, that at our present pace generations will come and go with countless innocent men suffering and possibly dying needlessly (related to prostate cancer developing from inflammation) before the true answers are known. A reflection of the paucity of academic support to *prostatitis* research is noted with the 1998 National Convention of the American Urological Association, (attended by American and International Urology experts). Specifically, 51% of all the papers and studies presented involved prostate cancer, while only 3% addressed prostatitis. The trend has not changed since then. While a few studies relevant to antibiotics as a treatment for bacterial prostatitis are underway (funded largely by a pharmaceutical industry that manufactures antibiotics), there is virtually no other significant research currently being done in the United States on this disease. **Clearly, there is no disease topic more worthy of research and research dollars than the number one health risk that men face. Whether we are speaking about *prostatitis*, enlarged prostate (EP) or prostate cancer; these diseases are individually and collectively epidemic while individually and collectively equally germane to male health and wellness.**

To state further, practically every man alive has *prostatitis*, making it one of the world's most common diseases, if not the most common. Diagnosis is difficult and current treatments are frequently inadequate. The association between *prostatitis* and prostate cancer is irrefutable. With all this in mind, it is particularly disturbing that *prostatitis* research has been so significantly under-funded for years. Leroy Nyberg, M.D., associated with Urology Research for the National Institutes of Health (NIH) has stated: "It's amazing to me that we can't reliably treat the majority of men with *prostatitis*. The NIH has organized a research arm that expects to bring a fresh

look to chronic *prostatitis*, but the results of this research are not expected for many years, if ever. Today, chronic *prostatitis* for many represents an enigma, but clearly qualifies as the single most under-diagnosed, misunderstood and inappropriately treated medical disease in the world.

In an effort to demonstrate the impact of *prostatitis* resolution to the evolution of prostate cancer, I have proposed the "ProCap" (Prostate Cancer Prevention) Trial. This is a randomized, double blind, placebo controlled, age matched study that is intended to prove the patented Peenuts@ prostatitis formula can prevent prostate cancer by resolving prostatitis. This study, intended to underscore the importance of inflammation resolution to an avoidance of prostate cancer, is the most ambitious effort to date to establish validation for prostate nutrition in men's health. As noted earlier in this article, the American Association of Cancer Research, Pathologist, David Bostwick, M.D. and others have shown that prostatitis evolves into prostate cancer. While this study seeks funding, the concept grew out of clinically significant results from a Prospective Prostate Cancer Study that showed benefit of diet and nutrition on men with moderately well differentiated prostate cancer (Gleason 5/6). Specifically, 90% of men enrolled in the study (n=23), noted suppression of their PSA (the marker of disease activity) over a surveillance period in excess of 40 months. The remaining 10% noted stable disease. While the study findings suggest that 50-60% of all prostate cancer cases (consistent with a Gleason scores of 5 or 6) are being over treated with traditional treatments, the Prospective Study was a designed effort to prove that prostatitis resolution (partial or complete) with the Peenuts@ formula would have an impact on prostate cancer. In this study, the improvement in the white blood cell count associated with the EPS (the most significant biological representation for prostatitis resolution) was noted to be 73%

which mirrors the 66% reduction in white cells (based on previous clinical research) presented to the US Patent & Trademark Office regarding the patent application which was granted in 2001.

THE PROSTATE BIOPSY REVOLVING DOOR:

The inability to maintain a normal PSA (less than 4.0 ng/ml for most labs) will put you (the patient) in a unique group of men asked to consider a biopsy of the prostate. Men unique to this group who fail to stabilize the PSA (less than 4.0 ng/ml) will become the hunted. Once the biopsy scheduling (merry-go-round) begins, it is difficult to prevent subsequent biopsies! It is PSA anxiety that drives repeat biopsies in the absence of a cancerous result. As doctors, it is important to find disease, seemingly at any cost, in men who will benefit the most from our therapies. If your PSA is high (2 4.0 ng/ml), your prostate will become the target of a biopsy needle with virtually any Urologist you meet, except me. Therefore, your only defense is to be proactive and know your PSA number! If your doctor says it is fine . . . ask what the number is and take a copy of the PSA with you for your records. To be healthy, your PSA must be minimally less than 1.0, while preferably less than 0.5 ng/ml; like mine! For the record, my PSA has been flat-lined for more than 10 years at 0.3 ng/ml, consistent with a healthy prostate (0.2 ng/ml is the same as 0.00 statistically speaking)!

While my thought process might be an exception to the traditional urologist, there are basic principles that need to be

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applied when a clinical scenario presents itself as concerning for prostate cancer. In my clinical practice, men with a non-cancerous digital prostate examination can defer the biopsy and definitive imaging when prostatitis is identified and the PSA

value is less than 5.0 ng/ml. Conservative management is the preferred and recommended treatment course, when added to proper diet, appropriate nutrition, adequate exercise, stress reduction and education. Obviously, the Peenuts@ prostate nutritional formula is an integral and proven part of the program. The inability to resolve the disease as determined by a normalized or stable PSA will put us back at square one where the biopsy becomes the diagnostic choice of most urologists! For me, a 3 T MRI scan is the best objective marker to a diagnosis of prostate cancer.

A classic example of a patient's experience in the traditional doctor's office involves a 65-year-old man from Lubbock, Texas who had noted a PSA of 18 ng/ml. His 'traditional' Urologist appropriately offered and performed an ultrasound examination and prostate biopsy. The biopsy result noted chronic prostatitis with no evidence of cancer. Antibiotics were ordered despite the lack of a positive culture and sensitivity, with no other therapy considered. Remember that less than 5% of cases of prostatitis are actually caused by bacteria; potentially curable with antibiotics. His PSA was repeated after 6 months and found to be unchanged. The patient underwent a second prostate biopsy, at the doctor's insistence, which again showed only chronic prostatitis. When the patient asked his doctor what he could do, the urologist offered to repeat the PSA in another 6 months and consider an additional biopsy at that time. This is a clinical scenario that is all too common across the United States every day, whereby, men are given no alternative in an attempt to avoid a future biopsy. Clearly, this patient would have benefited with an MRI scan using a 3.0 Tesla magnet. I believe, as physicians, we must become better educated regarding relevant scientific concepts that may radically change the diagnostic or treatment course of any patient. Far too many men are asked to return to the biopsy arena over and over, without a well thought out, patient-friendly strategy or "master plan". In this case, the

patient was aware enough to research prostatitis on the Internet. Eventually, he discovered a nutritional product that improved his urinary symptoms substantially and reduced his PSA by almost half in only 3 months. This was accomplished by merely using Peenuts®, the advanced nutritional therapy for the prostate, which he was able to purchase without a prescription! While this patient's response was outstanding, not all patients respond identically. The use of the Peenuts® formula is not intended to replace the advice of your doctor but your thoughts (as a patient) will play a role in the physician's decision.

Another equally riveting case involved a 75 year old male who had experienced five previous biopsies (all negative) associated with a PSA of 22.6 ng/ml. Using only Avodart® (Dutasteride) and the Peenuts® prostate nutritional formula, his PSA dropped to 7.88 ng/ml by the end of 11 months and 5.1 ng/ml at 24 months. Without the presence of prostate cancer, Avodart® would have been expected to cut the PSA in half (11.3 ng/ml). The improvement to 5.1 ng/ml is exceptional and validates further the benefit of the Peenuts® nutritional formula related to the resolution of prostatitis. Furthermore, his EPS decreased from 400 WBCs to 130 WBCs in only 9 months. While this approach likely shows the benefit of Avodart® and Peenuts® in combination, the need for additional biopsies is now gone as the patient's prostate health status has improved markedly. While further studies with this treatment protocol are encouraged, the expectation remains high that similar results will be forthcoming.

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CLOSING THOUGHTS:

To declare your prostate healthy, your PSA must be less than 1.0 ng/ml with a complete absence of urinary symptoms; To Check your PSA (as a screening test only) in the comfort of

your home, call today for your PSA "Diagnostic Home Kit"—
Toll Free: 1-866-PSA-CHEK (772-2435).

A PSA of 2.1 indicates an unhealthy prostate. It is obvious that the lower the PSA, the lower the risk of prostate cancer. Anything you can do to lower your PSA level will likely reduce your risk of eventually getting prostate cancer.

Keep track of your PSA level for your own records. The risk is too high if you do not! Never accept the words from a doctor that your PSA is normal or nothing to worry about unless it is truly less than 1.0 and stable. If your PSA is 1.0 or higher, your brain must not accept what you have just heard, because most doctors do not know the real facts and do not keep up. You must know the number!!! If your PSA is between 1.0-4 ng/ml, there is a 20-30% chance prostate cancer exists. Likewise, if your PSA is between 4.1-10.0 ng/ml, there is a 20-30% chance that prostate cancer is present. Given this data, the healthiest number for you is a PSA of less than one; remembering that prostate cancer has been reported with a PSA of less than one, as well, but the odds of not having cancer with such a low number are in your favor.

Have your PSA and digital rectal examination performed regularly, usually at least every year for men aged 30 or older. Get the PSA on your birthday so you can remember! You must know that 30% of 30 year old men have prostate cancer. This is referenced in the research from Memorial Sloan-Kettering and Weil Sakr's work with the Detroit Autopsy Study! Men at greater than average risk for prostate cancer, such as men of African-American descent and men with a positive family history of prostate cancer should be checked yearly starting at age 30 with a PSA blood test minimally. Men with known elevations in their PSA levels and those with inconclusive or "suspicious" previous biopsies may need to be checked more often.

Don't be afraid to ask questions of your physician or get a second opinion about your prostate health. A true professional

will take the time to answer your questions and be open to suggestions about alternative therapies as well as be willing to follow you clinically.

Research from the American Association of Cancer Research (AACR) and others indicate the link between prostatitis and prostate cancer is real! Practically all men with prostatitis will eventually get prostate cancer (if we live long enough) as the diseases are commonly found together. Remember, understanding prostatitis is your best first step to helping yourself.

Learn all you can about prostatitis and treat it as aggressively and effectively as possible. Peenuts@ may be your best and least expensive initial opportunity to establish and/ or maintain prostate health and may delay or even prevent the development of prostate cancer. Validation will be identified by any combination of biologic disease marker improvement, as determined by a decrease in PSA, a decrease in EPS and/or a decrease in Urinary Symptoms.

Be aware that your physician may not be an expert on the treatment of prostatitis. Ask him about the various validated diagnostic tests and therapies available and which ones are appropriate for you.

For more information on Peenuts@ and other nutritional products for the prostate, call SunVita™ at 1-888-733-6887 or log onto the Peenuts@ website at www.Peenuts.com. Also, check out the National Institutes of Health (NIH) Website (www.nih.gov).

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www.nih.gov) for more general information on prostatitis and prostate cancer research.

EDITORIAL COMMENT:

By Stephen W Leslie, MD FACS (Urologist and Chairman of the Department of Urology at Creighton Medical School)

The widespread incidence of prostatitis is well known to urologists and other doctors, but its association with prostate cancer has previously been considered incidental. In this chapter, Dr. Wheeler has suggested that prostatitis may actually cause prostate cancer based on evidence supportive of inflammation leading to cancer consistent with a number of other organ cancers, the research of the American Association of Cancer Research, David Bostwick, Michael Karin, PhD and others. While the association alone between these two conditions may fall short of being considered definitive, it is certainly plausible and deserves more study. Even a limited causative link between prostatitis and prostate cancer would cause a dramatic change in our attitude and approach to prostatitis.

Currently, prostatitis therapy consists primarily of antibiotics, alpha blockers and other drugs. This chapter correctly points out that these remedies are often inadequate. Dr. Wheeler recommends considering nutritional agents in the absence of successful definitive therapy. Although nutritional therapy has been widely used and studied in Europe, it is not routinely recommended by many U.S. physicians for a number of reasons. Nutritional therapy is not taught in most U.S. medical schools and many American physicians are unfamiliar with the available scientific research on the subject. Published studies on nutritional therapy are criticized for using different preparations and dosages, having too small a sample size with limited numbers of participants, being of inadequate duration, and bias in the selection of patients to be tested. Commercially available nutritional therapies are usually not manufactured to a pharmaceutical grade standard, which means each bottle, even from the same company, may have different biological effects. There is no universally accepted dosing schedule for many of these natural remedies and their mechanism of action is often unknown. Further, no specific combination nutritional product

for either prostatitis or symptoms of prostate enlargement has ever been properly tested in a well-designed, scientific study.

Dr. Wheeler describes a study he performed at the Diagnostic Center for DiseaseTM on a unique combination nutritional therapy called Peenuts®. He reports outstanding objective and clinical results, but the scientific details of his research need to be carefully reviewed and his findings duplicated by other medical experts. If further research indicates he has indeed found a safe and highly effective therapy for the signs and symptoms of prostatitis and prostate enlargement, this would be a major contribution to the health and wellbeing of American men while saving the health care system tens of millions of dollars. Further elaboration of the prostatitis to prostate cancer model would qualify as a major medical breakthrough. Minimally, Dr. Wheeler's research offers a unique patented formula with little downside with a potentially tremendous upside for motivated men.

CHARTS

NIH Classification of *Prostatitis*

- I. Acute bacterial prostatitis: acute infection of the prostate
- II. Chronic bacterial prostatitis; recurrent infection
- III. Chronic nonbacterial prostatitis; chronic pelvic pain syndrome (CPPS)—no demonstrable infection
 - IIIA. Inflammatory CPPS: WBCs in semen/EPS [voided bladder urine (VB3)]
 - IIIB. Non-inflammatory CPPS: No WBCs in semen (EPS or VB3)
- IV. Asymptomatic inflammatory prostatitis: no subjective symptoms; detected either by prostate biopsy or presence of WBCs in prostatic secretions (EPS) during evaluation for other disorders

SIGNS & SYMPTOMS ASSOCIATED WITH CHRONIC PROSTATITIS:

Perineal Discomfort/ Pain	Inguinal Discomfort/Pain	Lethargy
Penile Discomfort/Pain	Ejaculatory Discomfort/ Pain	Epididymal/Testicular Swelling
Burning on Urination	Hematuria (Microscopic)	Scrotal Discomfort/Pain (Including testicular)
Blood in the ejaculate	Voiding Symptoms	Dysuria (Pain/Stinging on Urination)
PSA 2 1	Irritability	Decreased Sexual Performance/Impotency
Depression	Hematuria (Gross)	

THE ETIOLOGY (CAUSE) OF PROSTATITIS:

	—Idiopathic (Unknown) Factors
—Bacteria, Nanobacterium, Mycoplasma, Chlamydia	—Stress and Psychological Factors
—Yeast	—Immune System Related Disease (Including Auto-Immune Diseases)
—Dietary Factors	—Social, Genetic or Environmental factors
—Crystal Deposition and Biofilms	—Any Combination of the Above

CHRONIC NON-BACTERIAL PROSTATITIS OPTIONS:

	EFFECTS ON LUTS (lower urinary tract symptoms) VOIDING SYMPTOMS	EFFECTS ON PSA	EFFECTS ON EPS	ABILITY TO CURE	IMPROVED SEXUAL PERFORMANCE
Antibiotics	Possible	Yes	No		No
Avodart/Proscar	Yes	Yes	No	No	No
Alpha-Blockade (Hytrin, Rapaflo, Cardura, Flomax and Uroxatral)	Yes	No		No	No; also causes retrograde ejaculation common
PEENUTS® (All natural Patented Formula)	Yes	Yes	Yes		Yes; secondary to prostatitis resolution
Sur e	Yes	Yes	Possible	Possible	

Chronic Prostatitis is non-bacterial in >95% of all cases.