Avoiding Prostate Biopsies is now 'State of the Art'

PROSTATE BIOPSIES HAVE long been sacrosanct when it comes to diagnosing prostate cancer, with little to no open criticism for a procedure that has become obsolete, if not a public health risk. No longer do patients need to depend on a crude application of a traumatic procedure that lacks precision and accuracy to make a diagnosis. Unlike other organ cancers, diagnosed through excellence in imaging utilizing a 3.0 Tesla Magnetic Resonance Imaging scan, the prostate biopsy procedure relies on a less sophisticated system allowing for poorly detailed images generated by acoustic sound waves (ultrasound) to serve as the primary device to locate the organ in question. **Ultrasound is neither sensitive enough nor specific enough to allow clinicians to predictably isolate a region of interest, let alone hit a region of interest with a biopsy needle.** Better stated, ultrasound cannot accurately locate regions of interest independent of far more sophisticated scans like the 3.0 T MRI scan, with or without spectroscopy. While ultrasound diagnostics will continue to play a role in the medical diagnostic arena, a 20-30% yield for prostate cancer suggests there has to be a better system of prostate imaging that allows a more in depth evaluation of an often maligned organ, while tied to a higher yield for cancer. Currently, 10 men with a PSA (prostate specific

antigen) value between 4.0 ng/ml and 10 ng/ml are designated to undergo an invasive procedure that yields 2 or 3 cancers. Better stated, 7 or 8 of the men had a procedure they did not need to have. In a time when cost effectiveness and efficacy of technology is critical to disease diagnoses and management, the health system does not have the luxury of spending in excess of two billion dollars a year guessing about a disease status based on a hit or miss proposition.

Performing prostate biopsies is somewhat analogous to throwing darts with a few exceptions. In darts, you can see the bull's eye or target. Interestingly, despite the fact that you see the target clearly, one rarely hits it. In the case of a prostate biopsy, doctors rarely see or have a target; so in effect, we shouldn't be too surprised that they uncommonly hit a target. **Unlike a dart game, where there is no major consequence to missing the target, data out of the University of California at San Diego validates that needles puncturing the prostate promote inflammation that may ironically, 'hasten the progression of metastases' when cancerous or precancerous tissue is hit. 'In effect the proteins produced by inflammatory cells are the 'smoking gun' behind prostate cancer metastases'.** In a review of the literature, additional concerns are revealed that are noteworthy regarding a process called, 'needle tracking'. Simply stated, 'needle tracking' takes place when a biopsy needle punctures the prostate capsule. The process becomes more sinister when thousands of cells exiting the prostate include prostate cancer cells. According to Katsuto Shinohara at the University of California at San Francisco (UCSF), "needle tracking" is rarely seen. **I would agree with Dr. Shinohara in principle, however, the fact remains that "needle tracking" is rarely seen because it is rarely investigated.** The fact that we rarely see this phenomenon does nothing to diminish the frequency of

the event which must (minimally) coincide with the frequency of cancer detection. In my opinion, the phenomenon of 'needle tracking' is universally noted and obvious to every patient who is biopsied, while grossly understated by nearly everyone within this 2 billion plus dollar per year industry. Patients will have no difficulty understanding how this happens as it is quite intuitive to even the most untrained among us that a puncture wound allows cells to escape consistent with the organ punctured. A simple prick of the finger gives most of us the necessary visual.

The most graphic representation that validates "needle tracking" is noted in a case study from University of California at San Francisco published in the Journal of Urology in 2002. The case demonstrates a large lesion within the rectal wall, 3.5 years following a previously established biopsy needle tract. When this mass was subsequently biopsied, the findings revealed the cells to be consistent with prostate cancer. For those less familiar with the anatomy or how cells function, prostate cancer cells cannot grow in the rectal wall without being planted there. This graphic image confirms without equivocation, the validation, that the "needle tracking" process, in fact, does exist and that the rectal wall or perineum (the space between the anus and the scrotum) provides a excellent breeding ground that assists the incubation process equally well. This case presents a plausible explanation for how cancer of the prostate can return more than 10 years after surgery when the inked margins of the prostate capsule show no evidence of cancer extension.

While additional research on this topic is suggested, we should never describe a prostate biopsy as a simple, innocuous procedure with minimal side effects. There are consequences which patients must understand and accept including 'needle tracking'; a previously described process that allows cells to drain from mini-tunnels by the hundreds of thousands. **What happens**

to these cells is anybody's guess, but to assume that the cells will die and be of no consequence, as some 'experts' suggest, has been proven wrong, is overly simplistic, optimistic and reckless to say the least. As a patient, you must remember that you are the responsible participant who will bear the scars of your indiscretion or lack of forethought; not the doctor.

The 'Traditional' Rationale for a Biopsy

A tissue diagnosis represents the most valued, definitive and venerable piece of scientific evidence that a disease exists. Every other diagnostic test intends to make the point that validates the need for tissue confirmation. Prostate disease is no different in that there are multiple surrogate markers that predict when a biopsy should be considered and/or performed. While imaging dominates the diagnostic milieu throughout the human body, the PSA blood test has proven to be the most reliable and predictable marker of prostate cancer. Unfortunately and ironically, notwithstanding the lack of specificity, physicians, nonetheless continue to encourage a biopsy in virtually every male with an elevated PSA, regardless of the disease present. Success is defined by a cancer diagnosis while a lack of cancer on a biopsy does nothing to deter a subsequent biopsy with more cores. Historically, physicians are reticent to embrace inflammation as the number one cause of PSA elevation and treat proactively the disease process of prostatitis.

Who Qualifies?

According to research from Johns Hopkins, when a PSA blood test result rises above 0.70 ng/ml, the risk of prostate cancer increases by 3-4 times in men aged 40-60 years, when compared to the normal population. When a PSA is noted to be at least 2.5 ng/ml, there are Urologists and Family Practice Physicians who

will recommend a biopsy while others will spare you the trauma of a potentially risk laden and often needless procedure until your PSA reaches a number of 4.0 ng/ml or higher. Additionally, men who experience a progressive rise in PSA of 0.75 ng/ml in two consecutive years will be challenged to get a biopsy as the next best step or recommendation based on PSA Velocity change. Only men who maintain a PSA number less than 2.5 ng/ml without evidence of a bump or nodule on digital rectal exam will be allowed to live another day without the threat of a biopsy being discussed or performed.

Traditionally, the identification of cancer requires confirmation with a tissue sample obtained by a Urologist and reviewed by a Pathologist. Unlike most other cancers where imaging of an organ dictates the target from which cells will be obtained, Urologists have taken the liberty and initiative to look for a cancer without a formal "roadmap". Instead, a relatively unsophisticated review of the prostate with ultrasound technology serves to identify this organ's location for random blind biopsies. Unfortunately, despite many years of experience with ultrasound, physicians continue to randomly place biopsy needles into an organ where a visual target is rarely seen. The result is a procedure that lacks the sensitivity and specificity to predictably find a cancer. Efforts to improve the biopsy by using 'microbubbles' and blood flow to create a target or region of interest has not panned out. Early studies from dedicated research centers like Jefferson Medical Center have been disappointing to say the least. Notwithstanding a lack of direction based on current research, most Urologists target the prostate using a traditional sampling pattern or grid. Depending on the Doctor, 6-80 or more biopsies will be performed commonly in one or more biopsy sessions. Until a better marker is established, PSA remains the most important biological marker that dictates who

qualifies for a biopsy despite the fact that it also lacks specificity; in other words . . . creating a need to look for something that is not there; therefore, a false positive. Ironically, the number one reason PSA rises is prostatitis, a non-bacterial event in more than 95% of cases; not prostate cancer. This explains in part why only 20-30% of biopsies performed yield a cancer, our current 'gold standard'. To be certain, we are using the wrong marker to identify which men would benefit most from a biopsy. It would be far better to understand that PSA represents a health marker, noting that any PSA number greater than 1.0 ng/ml represents a diseased prostate, minimally associated with prostatitis. **Therefore, using this model, if patients fail to respond to prostatitis treatment with a lowering of PSA common to inflammation resolution, we now have an appropriate group of men who have qualified for a biopsy. Why this concept is not universally accepted, is beyond me.** My early pilot research shows that biopsies performed on men who fail to lower their PSA with our patented prostatitis formula Peenuts®, to less than 4.0 ng/ml, will note a 92% yield for prostate cancer. **While additional studies are encouraged, in the interim, men who see a significant decrease in their PSA, using this diagnostic exercise to reduce inflammation will avoid an unnecessary biopsy.**

What to Expect from the Biopsy

Side effects commonly associated with a biopsy are numerous but include: pain, bleeding from the bladder and bowel, scarring, blood in the ejaculate, bacterial infection, as well as less commonly noted complications of incontinence, impotency and hospitalization secondary to sepsis where an individual experiences high fever, chills and uncontrollable shaking (rigors) including death and 'needle tracking'!