

PROSTATE CANCER SURGERY? Lies, lies and more damned lies.

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"Choosing prostate cancer surgery was the worst decision of my life" patient

There is no creditable scientific evidence for significant curative life extension in men treated for prostate cancer through radical prostate surgery/robotics alone. In addition, this one surgery is associated with more permanent complications than probably any other operation ever, performed on humans. It's an operation that is often treated as an emergency, is without merit and is probably without equal in providing false hope. Unbelievably, this high-risk surgical technology for prostate cancer treatment was simply given a pass by the FDA without being rigorously and scientifically evaluated for risk or reward.

The current lack of progress towards a sincere and definitive resolution to determining which of the few prostate cancers demand treatment, and which treatment if necessary, is confounded by a preponderance of short term (5-15 years) clinical studies hopelessly jaundiced by treatment philosophies, egos and money. For many men, their small area of prostate cancer (which was never going to behave like a cancer we normally think of) never required treatment. For many other men, their prostate cancer treatment with surgery/robotics was a journey to hell and back.

The absence of any real significant scientific validation for prostate cancer surgery/robotics in bringing about curative life extension or reduction in prostate cancer-specific mortality, is an indictment against prostate cancer surgeons worldwide and should stop every man in his tracks.

Lost in all the years of so-called "data" gathering from a multitude of non-scientifically run clinical studies around the world since the radical surgery was first described by Young in 1905, has been **the most basic and fundamental issue of whether prostate cancer surgery/robotics actually extends the life of a man afflicted with prostate cancer in a curative manner**. That there is no evidence to support surgery for treatment of prostate cancer has not tamed the proponents of surgery from disseminating opaque prostate cancer information where sensationalism, half truths, downright lies, bias, obvious conflicts of interest, use of the word "data" to imply real results and use of marginal statistical significance to misconstrue real benefit has been spun, distilled and re-spun. Much of this so-called "scientific" prostate cancer surgery information now belongs in the category of junk science.

To date, we have no robust supporting scientific evidence from long term randomized trials using validated pathology and imaging (to diminish significant observer error) to say that radical surgery/robotics for prostate cancer results in curative life extension. In place of answering that most fundamental question of "are we doing any good at curing a man from prostate cancer with surgery?", we have countless articles on the ignorant preoccupation with PSA testing for prostate cancer, along with endless papers on the latest imaging techniques, each desperately attempting to show how they can identify even smaller, probably meaningless areas of prostate cancer. Along with discussions on other mindless trivia, we see a nauseatingly long list of "how to" articles on surgical technique for prostate cancer removal with each egotistical surgeon trying to outdo the previous "gifted" surgeon. **At the very pinnacle of these stupefying discussions however, is the apparently serious debacle questioning the relevance of positive margins (cancer left behind) in a prostate cancer operation! This is an unbelievable example of medical defensive posturing and pseudo scientific rationalization.**

As you begin your journey on understanding prostate cancer, you should ask to see internationally recognized, scientifically run, long term, independently validated radical surgery/robotics studies resulting in significant curative life extension for prostate cancer. See if this data exists.

WHEN TO GET YOUR PSA?

Because of the great potential for negative downstream effects of an abnormal prostatic specific antigen (PSA) resulting in severe and possibly permanent complications from testing and treatment for prostate cancer, full disclosure and consent should be obtained from a man before he agrees to this PSA blood test.

Fundamentally, the PSA test is a flawed screening test for prostate cancer as it screens more for benign prostatic disease. Its value, however, is in post prostate cancer treatment monitoring.

At what age should you get PSA tested? Does age, family history and race matter? New evidence suggests marginal, if any, race difference. **What type of PSA testing should one undergo?** What end point should we use and how often do we repeat the PSA to come to a consensus that it may suggest the need for a biopsy to determine if cancer is present? How do we determine which of the few cancers may be significant for a treatment to be considered? What is a proven treatment? What is a rising PSA after a definitive treatment for prostate cancer? Not surprisingly, there are almost as many "philosophies" on PSA management and prostate cancer treatment as there are urologists. A word of caution. Never take any action based upon just one abnormal PSA.

Once there is a reasonable concern for the possible existence of prostate cancer and there are no compromising medical or life span issues, a definitive determination on presence or absence of cancer can only be established through a prostate needle biopsy.

The complications resulting from all of this testing and treatment as a consequence of an abnormal PSA and the finding of some prostate cancer needs to be eyed with great circumspection. Only some 7% of men die FROM their prostate cancer and therefore, most men just live with their prostate cancer as most prostate cancers are not lethal. **Clearly, prostate cancer is NOT going to "spread" quickly while you empower yourself on your condition.**

Today, many, if not most, of the cancers detected through prostate biopsy after PSA screening would have gone undetected and would have remained silent and

without impact when the PSA was unavailable. The present fervor for PSA screening is sensationalism at best, without proven benefit, and has simply resulted in many men undergoing prostate cancer surgery/robotics that was neither indicated nor needed.

THE "C" WORD

The word "cancer" carries a very significant emotional charge producing considerable anxiety and leaving one quite overwhelmed. **However, the emotional charge on hearing the words "prostate cancer" is totally out of proportion to the slow growth and indolent nature of MOST prostate cancers.**

Your feelings of disappointment and "why?" and "how come?" and "is it true?" are natural and very understandable, but your first order of business is to take a deep breath, relax, and take charge. This "time out" is especially important for you to assure that your anxiety cannot be manipulated by some "well meaning" physician. There is no better patient advocate than you, yourself. You must take charge and be in total control of the slow and methodical information gathering and remember that treatment, if at all, is not an emergency. Also, understand that the words "prostate cancer" includes all grades and amounts of prostate cancer representing a huge mixed bag of prostate pathology so each mans' cancer is different.

The anxiety associated with this new diagnosis of prostate cancer, or even untreated prostate cancer, is totally unwarranted. There are cancers, and there are cancers, and the majority of prostate cancers are not deadly! Most folks are not too concerned about a little skin cancer and you are not going to cut off your arm for a little cancer on the hand. For most prostate cancers, a similar understanding is warranted. In fact, it may be high time for us to coin another term for the words "prostate cancer" as the majority of prostate cancers are slow growing with a cell dividing time of one to two years and unlikely to impact most men during their lifetime.

The words "prostate cancer", unlike some other cancers, rarely, if ever, demand an emergency solution to "do something before it spreads". Naturally, after

hearing the words "you have prostate cancer", one would think that a quick surgical removal, especially with a state-of-the-art sounding technique like robotic surgery is going to solve all of your problems. This belief is both false and potentially very harmful.

WHAT WILL YOUR SURGEON SAY?

During the normal and mind-numbing disbelief you feel after hearing the words "prostate cancer", you may hear many enticing words and terms during your cat and mouse interaction with your surgeon under the guise of counseling.

First, the dialogue will be filled with a liberal sprinkling of very hopeful terms designed to lend credence to the wishful concept of curative surgery. You will hear such terms and words as: "may benefit", "may reduce complications", "may cure", "curable", "curative intent", "curative treatment options", "curative intervention", "definitive treatment", "survival" (does not mean cure), "survival benefit", "survivorship", "excellent results" (this does not necessarily mean treatment was appropriate), "may reduce", "superior outcomes" and "probability of progression free". All of these terms sound very hopeful but are very misleading and just a play upon words. Surgery has never been proven to cure prostate cancer but continues to be implied or intuitively thought to be reasonable. Despite ongoing wishful attempts at surgical cure, in many men, metastatic disease can and often does present some 20-30 years later.

Second, you will hear terms flattering surgery and which seem plausible, but are absolutely unsubstantiated and simply self promotion. The term "gold standard" is a very unfortunate, self-anointed, self-serving term, which implies scientifically established and proven benefits for radical surgery/robotics when the truth is far from it. Surgery is simply the oldest treatment modality for prostate cancer and, because of this history, it was deemed "appropriate" by surgeons to anoint their treatment as the "gold standard" for prostate cancer treatment. However, the appropriateness of this label for surgery has never been proven with randomized, long-term scientific studies and, in addition, there were no other prostate cancer treatment modalities available for many years to challenge the use of this unworthy moniker. Similarly, the bold-faced claim of surgery being the "first

choice" of treatment for younger men, or men who have aggressive prostate cancer, also belongs in the fairy-tale bin.

Third, you will hear many misleading marketing terms used to glorify the robotic technology for radical prostatectomy by spinning this robotic surgery as some unbelievable miracle. These terms include, "state-of-the-art", "advanced" (high tech, robotics, minimized operative trauma, enhanced precision, decreased post operative pain, faster recovery time, nerve sparing, tremor control, optical magnification) and "minimally invasive" (but still requires hospitalization) as well as liberal use of the over-reaching superlative, "superior outcomes". **It should be appreciated that these impressive words and self-serving statements for robotic surgery have not resulted in any reduction of cancer-specific mortality for prostate cancer.** What the surgeons don't tell you is that prostate cancer surgery is solely responsible for the worldwide increase in urinary incontinence and impotence. Surgery is no panacea for prostate cancer and, rather than providing curative life extension, for most men it will leave them with one or more lifelong complications to remind them permanently of their foray with the surgical treatment. Often, this is for a cancer that did not even need treatment. Unfortunately, this unforgiving surgery is final and you cannot have your prostate back should you change your mind. All Prostate Cancer Awareness campaigns should underscore these concerns about the absence of benefits and the propensity for after effects and negative quality of life issues from radical surgery/robotics.

The absence of long-term curative life extension may also exist for the other definitive treatment modalities like the radiation options, hifu or cryoablation for localized prostate cancer after thorough review. But because the radical surgical treatment option for prostate cancer has been with us the longest, and it is unjustly glorified more than any other prostate cancer treatment modality and plagued more often by significant and permanent complications, that particular focus on this option is warranted. Currently, there is a total lack of evidence to support one treatment modality for localized prostate cancer over another. Therefore, men should focus on treatment options that result in less complications and better quality of life.

WHAT SHOULD YOU DO?

There are several moves you can undertake to become informed and empowered as well as to lessen the complications and negative issues associated with prostate cancer treatment. First off, you need to send your biopsy slides out to a nationally recognized reference laboratory so your diagnosis, benign or malignant, can be validated. Unfortunately, there is some discordance amongst pathologists at coming to the same diagnosis on the same specimens so you should only consider further actions on your prostate cancer diagnosis based upon a consensus of reliable pathology results.

You should always obtain copies of all of your test results and pay particular attention to the biopsy report, and to where and how much prostate cancer was diagnosed. If your biopsy report indicates cancer at the base or apex of the prostate, you should consider having further biopsy evaluation of these areas as significant tumor volume in these areas may suggest that there is tumor at the margins of your prostate and that your cancer is no longer organ-confined or localized to the prostate. The importance of determining the location and volume of tumor in your prostate is important especially for those men who are still sold on radical surgery/robotics as it is associated with about a 20-40% positive margin rate (particularly at the apex), meaning cancer left behind after the prostate has been removed. In some scenarios, when you add this percentage of positive margins to the 10% or so of men who develop spread of their cancer after surgery and who did not have positive margins, you can have a 50% chance of having recurrent cancer after this complication-ridden surgery. **This high rate of inadequate cancer control is a very important concern and should be researched before considering the invasive, irreversible, high-risk robotic surgical procedure.**

No imaging study, such as an MRI, can diagnose conclusively the presence or absence of prostate cancer. These imaging studies MAY suggest that there are areas of possible involvement or even that it is clear. However, ALL imaging studies are affected by observer error and associated with too many false positives and false negatives. Never, ever consider treatment based upon a

supposed cancer from an MRI study of the prostate without pathology confirmation through a combination of random and targeted (if suspicious areas are seen) prostate biopsies.

While you are in this stage of coming to grips with the words "prostate cancer" and attempting to understand your particular disease state, you can safely take a period of time for a course of active surveillance (AS). This is a great first step to adopt while empowering yourself with knowledge on localized prostate cancer. This process of AS is a course of periodic monitoring and examinations every few months with PSAs and additional prostate biopsies (usually annually or so) to monitor any possible prostate cancer progression. AS is a common course for men to follow who have a normal prostate exam, a PSA less than 10ng/ml, a small number of positive biopsy cores and a Gleason score 6 or less. This initial course (which may become permanent and lifelong) of close observation can be safely adopted by many men with a new diagnosis of prostate cancer. One micro focus of prostate cancer (less than 5% of a Gleason 6 in one core) should never be treated but simply monitored as not uncommonly, this cancer can not be confirmed on a future biopsy.

This period of AS is also the time when men should review all the possible complications associated with the various treatment modalities and especially those which may be permanent and negatively impact you and your wife's quality of life (QoL). Those men who are uncomfortable with a "watch and wait" policy may decide to abandon the process of AS and seek an alternative definitive treatment from the ala carte menu of treatment modalities. Men would do well to consider minimally invasive outpatient treatment options that offer fewer complications than surgery/robotics but with similar survival benefits.

It is absolutely the patient's prerogative as to what treatment modality he chooses, if at all, to treat his prostate cancer. After any diagnosis and especially a "cancer" label, it is imperative for the patient to empower himself and seek several opinions. Most of the information given by physicians will be skewed with bias, but often one is still able to work around this issue as well as the egos of those in the medical profession offering advice. Second and third or more

opinions can be important, however most surgeons offer surgery and most radiation specialists offer radiation. Do lots of research and reading as well as seeking the counsel of physicians who will give you time to digest the information.

Finally, **not all prostate cancers are the same** and you should be very wary of following the treatment adopted by a friend who may not have been treated accordingly or has a Gleason score, tumor location and tumor volume different from yours. **It should also be very clearly understood that most men will die WITH their prostate cancer and not FROM it.**

WHAT SORT OF COUNSELING SHOULD YOU EXPECT ?

Men given the prostate cancer label need to find the support of a very dedicated, sincere, empathetic physician who is experienced in the arena of prostate cancer. Choose one who has an understanding and ability to review your results with you in a slow, calm deliberate fashion, as well as work through your questions and concerns.

The initial approach to dealing with a man who has been given the cancer label is one of absolute support, sincere empathy and understanding, and to emphasize that time is on his side. All findings, doubts and concerns need to be addressed and discussed openly and with opportunity for questions from both patient and spouse. The patient should undergo an initial risk stratification based on his tPSA level, Gleason score, tumor volume and estimated stage of disease. Basically, three risk categories are recognized, Low, Intermediate and High. The Intermediate category has the following criteria, tPSA of 10-20 ng/ml, Gleason 7 with risk adjustment depending upon number of positive biopsies. The Low and High risk categories fall on either side of this Intermediate risk category with respect to tPSA and Gleason scores. However, these criteria are not absolute in predicting which of the few prostate cancers really need treatment and which prostate cancers do not need treatment.

The size of the prostate or prostate volume also needs to be reckoned with as treatment success can be compromised in large prostates and the prostate may need downsizing before considering a definitive treatment. There should be no

rush to "judgment" by the physician. **Treatment is not an emergency and a man should never feel coerced towards a certain treatment modality.**

Being able to discuss the various treatment modalities used in localized prostate cancer and with an ability to address fairly the many potential complications relative to the perceived benefits of treatment is a very uncommon quality for most prostate cancer specialists.

Men and their spouses should be given literature on prostate cancer treatment modalities (realizing that most if not all is biased towards the modality being featured) and given an opportunity to empower themselves regarding their disease state and return for follow up with their questions. In the interim, the specialist should have the patient's prostate biopsy slides sent to a nationally recognized reference laboratory for pathology validation so that when the couple returns with questions, there is a consensus with respect to the diagnosis, tumor grade and Gleason score and tumor volume. Because many men will fall into the favorable risk category, the subject of AS can be discussed. In those men who have a less favorable risk category, particular attention should be paid to volume of tumor in the apex and base of the prostate. Apical areas of involvement, as previously discussed, demand particular attention.

Unfortunately, some prostate cancer specialists are not above the deceitful practice of psychological manipulation of men diagnosed with prostate cancer by fear mongering and playing the "cancer card". By misleading them with inaccurate information (see above, "What your surgeon will say") some doctors may steer men to adopt a treatment regimen that is more for the benefit of the physician than to the patient. The manipulation and exploitation of someone in a vulnerable emotional state because of the "cancer" label is reprehensible.

WHAT DOES EVERY MAN EXPECT from PROSTATE CANCER TREATMENT?

Every man expects total curative life extension after treatment of his prostate cancer, no complications and a full return to normal daily activities and the QoL he had before the surgery. This happens rarely, if ever, after radical surgery/

robotics for localized prostate cancer, but it is a naive dream still pursued by many surgeons.

INACCURACIES/PROBABILITY ESTIMATES and a WORLD OF TREATMENT
"PHILOSOPHIES"

The prostate cancer arena is a world of inaccuracies and probability estimates.

When a man has been given the prostate cancer label, it is absolutely imperative that while he empowers himself about his disease, he fully understands that **virtually nothing in the world of prostate cancer is written in stone**, and, like the very questionable merits of prostate cancer surgery/robotics itself, prostate cancer information is a world bounded by treatment philosophies, misleading information, rampant self-serving speculation and inaccuracies caused by pervasive subjectivity. There is a preponderance of marginal and uninformative information misconstrued as data spiced with vague guidelines and hypothetical outcomes under the guise of scientific outcome.

Many men considering the surgical/robotic option are never cautioned on the fact that much of the information in the prostate cancer arena, and especially that on "surgical success" and "complications" is hopelessly clouded by bias and opinions (theirs and their colleagues) where doctors are really advancing their own treatment beliefs rather than management supported by strong scientific trial data which unfortunately, does not exist. There have never been long term scientifically run randomized studies comparing treatment in men with equal amounts of prostate cancer and Gleason score.

Because of this preponderance for "shaky" prostate cancer surgical information, it is absolutely naive to expect a man or even his internist/ family practitioner for that matter, to come to an understanding on all of the double-speak of "success", "complications" and "survivorship" for so-called "curative intent" radical prostate surgery/robotics. It must also be realized that the pre-surgical ritual known as "informed consent" is really nothing more than an exercise in futility leaving most, if not all men, hopelessly confused, more anxious or downright scared. Finally, it is even more naive to think that all doctors in the field of prostate

cancer have the patient's best interests in mind. For some physicians this could represent an oxymoron.

THE INCREDIBLE INACCURACIES in the field of PROSTATE CANCER

1. PROSTATE EXAM INACCURACY

The prostate exam or digital rectal exam (DRE) is extremely subjective (observer dependent) in terms of feeling an irregularity, lump or nodule. Generally the accuracy is about that of a coin toss, 50%. Some physicians however, can feel nodules in nearly every prostate they examine and employ the "cancer" or fear card to induce men to follow up with the next step, a prostate biopsy. This can then be a chance to treat an insignificant prostate cancer ("don't want to let it get away").

2. PSA INACCURACY

The total prostatic specific antigen (tPSA and PSA are the same) is NOT prostate cancer specific and generally, INACCURATE as a blood marker for EARLY prostate cancer. The tPSA can be normal and you can have cancer, and the tPSA can be high and you can have no cancer. Furthermore, there is no evidence to support the use of courses of antibiotics to try to "normalize" abnormal levels of tPSA.

The accuracy of the tPSA blood test generally, is about 50%, or like a coin toss.

Whereas only some 30% of biopsies done for tPSAs between 4-10ng/ml (some labs have different limits) show areas of cancer, some 15-20% or so of men with a "normal" tPSA under 4ng/ml, have areas of prostate cancer. Many of the small areas of prostate cancer detected from tPSA screening however, are simply due to serendipity and from the inherent fluctuations of the tPSA normally and NOT secondary to the small area of cancer that was detected.

The accuracy of the %free PSA, tPSA velocity, tPSA density, and tPSA doubling time as well as the PCa3 test, are somewhat more reliable for suggesting early prostate cancer. Sometimes, downward manipulation of the tPSA is tested with a 3 month course of proscar and if the tPSA drops by about 50%, it is thought that chances of a prostate cancer being present are diminished.

Also, there are many medicines and scenarios including laboratory error that can influence the tPSA level. Men with an abnormal result should ensure they remove or resolve those factors or issues that can affect the tPSA result, up or down, and track several tPSAs and %free PSAs before considering the merits of a prostate biopsy. In fact, it can be very challenging for both patient and doctor as to when a prostate needle biopsy to rule out cancer should be considered.

Sometimes tPSAs do not reflect accurately what is going on in the prostate as some of the rare **aggressive prostate cancers do not produce much PSA** resulting in a low PSA, or minimally elevated PSA, giving the patient and physician a false sense of security. This also happens on occasion after a definitive prostate cancer treatment and the residual or recurrent prostate cancer has upgraded into a more aggressive form of prostate cancer producing little or no PSA and misleading patients and doctors into believing their cancer is still under control when it is not. Aside from these few uncommon scenarios, post-operative PSA monitoring is a reasonably accurate method of determining treatment status.

The claim for generalized screening, detection and treatment of prostate cancer (unlike for cervical cancer) earlier rather than later with the tPSA has never been substantiated and, up until now, is considered another inaccuracy and misleading claim in the world of prostate cancer. **The perceived benefits of prostate cancer screening and subsequent treatment with radical surgery/robotics are far outweighed by its lack of curative life extension, propensity for complications and a negative impact on QoL.** Screening for prostate cancer often represents pure exploitation of men troubled by the undeserved fear associated with the words "prostate cancer". Having men tested and retested provides them with no apparent health benefits.

3. INACCURACY of XRAYs and other IMAGING TESTS

ALL imaging tests such as MRIs, x-rays, ultrasounds, CAT scans, bone scans, and Prostatecint scans are UNRELIABLE in determining the EXISTENCE of prostate cancer. **No imaging study to date (not even the MRI) can conclusively diagnose a prostate cancer.** These studies may SUGGEST an area or areas of cancer however.

The interpretation of all types of imaging studies (like the interpretation of all prostate biopsy pathology) are affected by "subjectivity" and "observer error" and/or bias, with different physicians "seeing" different things. Not only does physician observer error lead to inaccuracies in staging, but all of the imaging studies are prone to "false positives" (suggesting cancer where there is none) and "false negatives" (suggesting absence of cancer when it is actually present).

At times, one may be advised to biopsy only the areas of the prostate that appear to be problematic on an imaging study such as an MRI. Of course, this is naive because of the propensity for false positives and negatives associated with these imaging studies. Therefore, if one did have an imaging study suggesting possible areas of prostate cancer, evaluation should be through targeted biopsies in addition to performing random biopsies of the rest of the prostate to rule out cancers that "did not show up" on the imaging study. Sometimes, the "problem" areas on an imaging test show no cancer and a "normal" area does show cancer.

Other common imaging studies such as CAT scans and bone scans are absolutely valueless in detecting possible spread of cancer until the tPSA reaches about 15-20 ng/ml.

4. INACCURACY of the PROSTATE BIOPSY

The standard 12 core biopsy performed under local in the office or under outpatient sedation has about a 70% accuracy for identifying cancer (depending upon the pathologist) compared to step sectioning the whole prostate (when removed surgically). Biopsying the prostate is the only way one can determine the existence of prostate cancer. **There is NO EVIDENCE for the conjecture that the needle biopsy of the prostate spreads cancer, especially for early disease.**

For men considering minimally invasive options, their prostate margins should be biopsied to ensure that the cancer is indeed localized to the prostate or organ confined. For those men considering focal treatment of their prostate cancer, a 24 core biopsy under outpatient sedation should be considered to ensure that the prostate cancer is indeed focal or unilateral. The 24 core biopsy has a higher accuracy than the 12 core and because of this increased accuracy, a 24 core

biopsy is recommended for men who wish to follow a course of AS. Which of these areas of cancer are truly significant though, is another story and although a 24 core biopsy may diagnose more insignificant cancers, the 24 core is suggested for those men adopting the AS course in order to lessen the chances of underestimating his prostate cancer. As the needle core only samples about 0.015 ccs of prostate, increased sampling numbers may be reasonable for bigger prostates also, in order to minimize cancer underestimation.

Inaccuracies or mistakes in the taking of your prostate biopsy can come about through inappropriate prostate measurements, failure to identify prostate landmarks, failure to recognize possible pathology, improper random sextant sampling of the prostate usually through inexperienced trans-rectal ultrasound technique, inadequate prostate needle core length samples, core contamination, incorrect recording and labeling as well as transport errors. This long list of concerns is why some men insist on having their buccal DNA swab accompany their biopsies to confirm that the prostate biopsy belongs to him and no one else.

5. INACCURACY of PATHOLOGY

The diagnosis of cancer from your prostate biopsy is absolutely affected by "subjectivity" and dependent on which pathologist is looking down the microscope. The diagnosis of prostate cancer is NOT straightforward, and quite observer dependant. It is quite possible that you may even be given a diagnosis of cancer when no cancer exists or vice versa!

Not only is diagnosing the presence or absence of prostate cancer not straightforward, neither is interpreting the Gleason score, tumor volume and presence of precancerous lesions in the needle core. If the diagnosis of prostate cancer was straightforward, we would not find such a discordance between different pathologists reading the same slides. In fact, the difference in opinions between pathologists on the same biopsy slides is uncomfortably high. Furthermore, the same pathologist reading the same slides at a later date is highly likely to change his diagnosis.

Most prostates affected by cancer have several areas of involvement. About 75% of prostate cancers are multi focal, usually with about 4 distinct areas of involvement but often with one, possibly significant index lesion and several possibly insignificant satellite lesions.

In order to determine the existence of early prostate cancer, pathologists are using more and more special stains to aid in the diagnosis. These stains are diagnosing more and more insignificant prostate cancers and leading more and more men into unnecessary evaluations, treatments and, potentially, lifelong complications. Therefore, it is vital for men to seek validation of their prostate pathology from a nationally recognized reference laboratory to get a consensus on what's really going on before considering any further steps towards evaluation or even considering a definitive treatment.

Finally, if a small area of prostate cancer is verified, most men should simply consider a course of AS while they take charge and empower themselves. Most low risk, low volume prostate cancers will never impact your life. **Furthermore, we have yet to discover the ability to reliably identify those few prostate cancers that could benefit from treatment from the majority of prostate cancers that do not need treatment.**

6. INACCURACIES in defining COMPLICATIONS

There is absolutely no consensus on definitions of the various complications arising from radical surgery/robotics, and your risk from one or more complications associated with this radical surgery is very high. Trying to obtain real data on complications is virtually impossible owing to the fact that there is no standardization and that **nearly all, if not all, results on complications are clouded by self-serving spin to reduce the true incidence.**

a) death

The most severe complication in this most unkindest cut of all, is death. The reason for this is the fact that this surgery, until the early 80s was a primeval blood-letting exercise and many men died from blood loss. If we use a 30-day post operative period, the death rate (despite death certificates being unreliable),

as has been estimated by Dr. Anthony Horan in his book, "The Big Scare", becomes quite significant.

b) recto-urethral fistula

Another severe complication which mercifully occurs infrequently but more commonly after surgery than any other treatment modality for prostate cancer, and requires reconstructive surgery for repair, is the recto-urethral fistula where a hole was made into the rectum inadvertently during surgery. **When you understand that many men with small volume, low grade prostate cancers did not need this heavy-handed robotic surgical treatment, any death or complication becomes very significant, and especially when the surgery does not provide for curative life extension.**

c) cancer left behind

Another very significant and frequent complication associated with the radical surgical removal of a cancerous prostate is that of "residual cancer". This complication occurs in some 20-40% of men undergoing radical surgery. The prostate cancer therefore, was never totally removed. This is a complication so unbelievably common and contrary to the principles of cancer surgery that this fact alone should question the validity of radical robotic surgery for the treatment of prostate cancer. **This amazing fact, however, is trumped by the even more outrageous issue of some surgeons encouraging robotic removal of a prostate cancer that they know is not localized but locally advanced, and that they know will leave cancer behind.** This travesty goes under the guise of a "debulking" procedure, and like the "salvage" prostatectomy, is fraudulent as not only does the prostate cancer surgery alone not provide for extension of life, but a debulking or salvage procedure certainly does not extend life and only increases the odds for a host of permanent miserable complications.

d) limp and leaking

An area particularly beset with doublespeak and lies are the various interpretations of the words "incontinence" and "impotence". These are words that used to be self explanatory but are now hopelessly subject to self serving

physician interpretations and non-standard definitions, simply to keep these horrible after effects out of the usual and common complication column associated with radical prostate cancer surgery/robotics.

These two words, incontinence and impotence, are very troubling issues to deal with both for surgeons and patients. The surgeons want to pretend that these problems hardly ever occur after "their" surgery, while men, who now live with the problems as well as deflated feelings of manhood, simply want to forget about their disappointments. Men affected by the surgery in this way just don't feel complete anymore. This scenario is like a win-win situation for surgeons allowing them to exaggerate their "good results" and affected men, too embarrassed to admit to their disappointments and too dejected to challenge the so-called "good" results.

i) diapers and clamps

Urinary incontinence is a complication no matter how it is defined. Of course, surgeons have adopted less stringent definitions again to exaggerate their "good" results. The urinary leakage or urinary incontinence complication is extraordinarily common (but less common depending upon how you define incontinence) and varies in degree. The big problem is in understanding the difference between what the surgeon believes to be incontinence compared to the normal understanding of incontinence meaning even the spillage of one drop. Unfortunately, many surgeons have forgotten this usual and customary definition and have made up their own so that in their terms you can still spill, leak, use a clamp or use more than a pad or diaper per day and still be dry!

The fundamental reason why the prostate cancer surgery necessarily results in urinary leakage of some form is simply because of the two cuts required for removal of the prostate. The cuts, one close to the urethral sphincter level and one at the bladder neck level totally divides the smooth muscles at these levels. Some contiguity of these muscles is required for normal urinary continence. If either one of these areas is maintained, urinary control may be preserved normally but, as the whole prostate is removed in radical surgery, normal function and control is never possible. Irrespective of the surgical technique (conventional

or robotic) for prostate cancer removal, it is the fundamental act of cutting and disrupting these smooth muscle fibers that involve the bladder neck prostate and external sphincter that leads to urinary leakage. These smooth or slow twitch muscle fibers cannot repair or regenerate themselves to resume the normal urinary function and urinary control they had before radical surgery/robotic intervention.

After removal of the prostate, the urethra is joined to the area where the bladder neck existed, and a controlled scar or stricture is created. A scar never functions like muscle. This area or join, gives some men a semblance of control but it is not a normal return of smooth muscle sphincteric function as many men will leak on straining or sneezing, as well as leaking urine during an orgasm if lucky enough to have some return of erectile ability. Commonly, there will be incontinence post operatively but as the area of the join closes down an improvement in urinary control is often noted. However, if the scarring continues even further, urination can become difficult and urinary tract infections, bladder stones and even urinary retention because of bladder neck contracture, may occur. In order to treat this complication, this contracture or scar will need to be opened. After this, urinary leaking usually resumes. In a few men, urinary control may be better than anticipated because the surgeon has purposefully left the apex of the prostate (and probably some cancer) attached to the urethral sphincter to minimize the disruption of the muscle fibers.

ii) shorter, softer and less of a man

Another significant complication bragged about in clinical studies as "rarely" occurring is that of impotence, loss of erections, loss of sexual activity and loss of manhood. This definition too has undergone much self serving revision and the standard understanding amongst all men (except maybe prostate cancer surgeons) of getting a "hard on", being able to get it "in" and "come" now has a variety of meanings clearly designed to have the surgeons' results with so called "nerve sparing" and "preservation of function" appear more favorable than actually occurs.

For a normal, healthy, pleasurable sex life, genital/sexual anatomy needs to be intact. Clearly, the act of cutting out the prostate cancer through the radical surgery/robotics will not leave your anatomy intact and will impact your sex life, resulting in one or more of the following: lack of libido and spontaneous sex, penile pain or absence of penile sensation, loss of penile girth, loss of penile length, a decrease or loss of penile rigidity, lack of seminal fluid on ejaculation, sterility, altered orgasm or the discharge of urine during orgasm if by a stroke of good luck some erectile function is maintained. Surely, it is not surprising to discover that after their radical prostate cancer surgery, many feel less of a man.

The cutting and removal of the prostate is responsible for the loss of semen production as well as responsible for ejaculatory issues. The disruption of the adjacent nerves and blood vessels invariably impacts the quality of erections resulting in either incomplete or total loss of erections and impotence. This nerve damage resulting in loss of erections often occurs despite the laudable concept of "nerve sparing", an approach which is more academic and philosophical than real. In some men, however, there may be a resumption of erectile ability, not by surgical design or dexterity but because the nerves for erection took an atypical route and were therefore undamaged from the surgery. Invariably, however, most men will be left with a penis requiring medicines or devices to achieve some fullness of the penis post operatively and "stuffability" after radical surgery/robotics. This is certainly not the normal sexual function you had before the surgery.

An additional insult associated with the radical surgical procedure is the shortening of the penis by 1-2 cm. This is another complication that is said not to happen but it is obvious to all men (except prostate cancer surgeons) that when you remove a prostate of at least 2cm and attach the urethra to the bladder, you may lose some 2 cm of length.

e) what QoL?

This destruction of manhood and effective emasculation by the radical robotic prostatectomy under the guise of a cancer surgery is, not surprisingly, associated

with a basket of psychological issues that also affect the spouse, their partnership and QoL.

Clearly men will appreciate that you cannot possibly be "whole and normal" after surgical removal of an organ that was necessarily important in the first place for normal urinary and sexual function and why most will feel a loss of manhood after radical prostate surgery. The preponderance of papers discussing the fairy tale post operative management of "bladder and penile rehabilitation" leading men to believe that they will return to "normal" is quite astounding. Now, remarkably, surgeons have instituted preoperative counseling of men to prepare them for their disappointment postoperatively. Admittedly, there are some men who have, through a tincture of time, apparently "normalized" their urinary and sexual dysfunction after radical prostatectomy. However, this occurrence is often more from good luck than any great technical robotic expertise. Just like some can slip out of a hangman's noose and live to tell the tale, some men have reasonable erections and urinary control. This occurrence, along with a prostate cancer removed with clear margins, has allowed some surgeons to crow that they (the surgeon) have achieved the trifecta. This occurs rarely as the wife's interpretation of normal erectile and sexual function is often at variance with that of her husband after surgery. Radical prostate surgery/robotics is not the panacea surgeons would have you believe it is.

7. INACCURACIES in SURGICAL CLINICAL STUDIES

After receiving your tentative diagnosis of prostate cancer and while awaiting the validation of your pathology, you may well be subjected to the charming "spin" of your most capable and incredibly skilled and gifted surgeon. You will be led to believe that the clinical studies they quote to endorse their approach will have you "cured" and back to "normal" in a very short order. Like the previous paragraphs outlining the various inaccuracies and liberal use of self-serving definitions to minimize the true impact of all of the severe complications associated with the radical surgery on the prostate, we have a multitude of clinical studies full of self-serving definitions on surgical "complications" and "treatment success" and generally, pure fabrication.

Empower yourself and consider your next move while you follow the AS course. You should also realize that all of the definitive treatment modalities for localized prostate cancer have similar survival benefits generally, but any reading on how "good" and how "safe" they are, is generally unsubstantiated scientifically.

For example, what is "success", "treatment success", "cure", "cancer specific", "progression-free", which means you can have cancer but it's not identified, "biochemical recurrence", which means you do have a recurrence but we have yet to identify it, "cancer specific mortality", "survivorship" and "survivor rate"? Trying to understand each interpretation of these terms from the prostate cancer literature is an impossible exercise and again, hopelessly clouded by bias and inaccuracies. Furthermore, each word or term can have a different interpretation in a different paper with a different surgeon. Robotic technology marketing literature is what it is and just cannot be believed regarding rates of complications or the mythical "superior outcomes" for prostate cancer treatment.

Indeed, you rarely, if ever, see the term "cure rate" as most physicians in the prostate cancer arena finally realize this is a wishful and nebulous term for success in prostate cancer treatment. That is mainly because reliable results require 20-30 years of study and residual or recurrent prostate cancer, although common before this time, can take these longer time frames to present.

Not only can we not be 100% sure on how much and what Gleason score prostate cancer you have (because of observer error), but when it comes to staging, we are not sure exactly what stage you have. Again, all imaging studies, including MRIs, are subject to observer error and so-called misreads or over-reads and under-reads as well as the studies being associated with false positives and false negatives. Combining all the observer errors in pathology reading, along with errors in imaging reading, it is abundantly clear that the addition of all of these inaccuracies must lead to inaccurate staging of prostate cancer. For example, the T1c stage of prostate cancer, which comprises the majority of prostate cancers these days and is diagnosed on the basis of an abnormal PSA, is a large conglomeration of various prostate cancers differing in amounts and Gleason score. Because of limitless subjectivity and observer issues and lack of validation,

as well as the pooling of different amounts of cancer as well as grade in the same stage, it is clear we have no real handle on what we are treating. Basing prostate cancer treatment results and success on this much inaccurate information is farcical.

Even more farcical are surgeons quoting 98% 10 year "survivorship" data after radical surgery. **Note that the word "survivor" is NOT the same as "cure"**. A 10 year "survivorship" of 98% simply means that 98% of men are still ALIVE after radical prostate surgery AND, would likely be alive without having had surgery. What surgeons don't tell you is that many of these men in this "survivorship" group have residual or recurrent cancer as well as surgical complications and diminished QoL. Furthermore, prostate cancer recurrences can take 20-30 years to present. Survivorship is a common but deceitful play upon words.

Every man assumes a "survivor" is one who is cured totally and without residual or recurrent cancer. However, this is NOT so and if you are still convinced that you want to try and remove your prostate cancer through surgery/robotics, you need to appreciate how hollow the terms "cure rates", "survivorship", "treatment success", "complications" and "superior outcomes" are in the prostate cancer business. No man needs a daily dose of misery to be reminded of his misguided choice for surgery. Furthermore, no man expects the after effects of radical prostate cancer surgery/robotics to be worse than the disease he started with.

BAD HISTORY REPEATS ITSELF

For over 100 years, the conceited and self-absorbed proponents of this primitive assault called radical prostate surgery have obstinately remained entrenched in their irrational support of an operation **where curative life extension fails to occur**. This surgery was the first treatment modality offered for prostate cancer and has its origins in antiquity and in the same Baltimore halls of academia where the grossly mutilating radical breast surgery had its origins, and under the same misguided principles.

From the early 1900s and still performed up into the 70s, this primeval, mutilating and unscientific blood-letting catastrophe (under the guise of real cancer surgery)

called radical prostatectomy was still being practiced like there was no tomorrow. Astoundingly, this example of unadulterated human experimentation is still being given serious consideration despite this operation never having proven curative life extension. Recently, however, the nagging concern amongst many urologists regarding the preponderance of complications associated with the radical prostatectomy, more than the absence of curative life extension, brought about a painfully slow, virtual disappearance of this surgery in the 70s and 80s. But, like the Phoenix rising from its ashes, the development of every new surgical technology from laparoscopy to the current robotic technique was seen as a license to resurrect the radical prostate cancer surgical concept and continue this outright human experimentation. Apart from less blood loss, at times, than in conventional prostate cancer surgery, the incidence of all the other complications associated with the robotic technique remains about the same. These complications remained the same simply because, irrespective of the approach to total radical prostate removal, this organ cannot be removed without the cutting of the intimately connected and associated muscle fibers and nerves about the prostate. It is this basic fact that necessarily leads to many of the complications associated with radical prostate removal for cancer. **What seems to be correct intuitively, that cutting something out quickly, is necessarily beneficial is not always correct.** Furthermore, the natural instinct to assume that everything high-tech has to be an advance over a conventional treatment does not necessarily follow. Robotics has been a great advance for many things in surgery but not so for prostate cancer treatment.

This fact that surgical cutting is required to remove the prostate cannot be circumvented, no matter how advanced the technology, places continued experimentation with any technique for radical prostate surgery in a very questionable light. Despite these undeniable concerns, this shameless ongoing human experimentation with prostate cancer surgery is afforded in part by an indifferent urology hierarchy and exploited by the bio-tech industry. The situation was indirectly endorsed by the FDA when it gave the robotic technology for use in prostate cancer surgery a simple "pass" without this technology for prostate cancer treatment being validated by rigorous scientific scrutiny and long term

studies. **The question "what are we doing?" when it comes to radical surgery/robotics and prostate cancer treatment remains in force.**

CONFLICTS OF INTEREST (egos, treatment philosophies and money)

The prostate cancer arena is full of conflicts of interest from testing to treatment and, commonly, the money trail fosters these conflicts of interest. Today, the prostate cancer business is a multi-billion dollar industry with many money-making opportunities and all possible treatment options vying for a piece of the prostate cancer business pie. This addiction to the dollar in the prostate cancer business has led to a lot of misleading information, unnecessary testing and over-treatment as well as over-reaching claims of superior outcomes for robotic prostate surgery that just cannot be substantiated. Unfortunately, this prostate cancer business requires the involvement of physicians in addition to the technology companies: physicians working for financial incentives and bio-medical and bio-technology industries working for stock holders. **The "follow the money" trail begins with the misguided concept of prostate cancer screening and early diagnosis and ends with the fairy tale of amazing "curative intent" and "superior outcomes" robotic prostate cancer surgery.**

Repetitive testing is quite insincere and capitalizes again on the undeserved fear associated with the words "prostate cancer". However, since the testing is rewarded financially, like Pavlov's dog, we see more and more testing, more and more evaluation and more treatment. Many physicians have even lowered the tPSA threshold from 4 ng/ml to 2.6 ng/ml before suggesting a prostate biopsy. This means even more tPSA monitoring and more prostate biopsies using a blood marker that is not even prostate cancer specific.

More testing has resulted in more doctors offices purchasing tPSA testing equipment, more office ultrasound machines for more in-office prostate biopsies, more biopsies per prostate as laboratories are paid per core sample, more use of expensive specialized stains by pathologists to identify more and more insignificant prostate cancers. In addition, there exists more costly sophisticated imagery to detect equally more insignificant cancers. All of these abnormal areas found on imaging also require biopsy for diagnosis placing a man at risk of sepsis.

This complication can result in possible hospitalization, adding to overall costs in addition to downtime from work and loss of income. Couple this financial incentive for testing along with many physicians having financial interests in various equipment options and treatment centers as well as the hospitals wanting a return on investment in their expensive robots (cost, supplies and maintenance) and we have unabashed and shameless, very profitable ongoing surgical human experimentation for prostate cancer treatment.

NON CHALLENGERS

Incomprehensibly, many organizations such as various urology academic groups, the Veterans Administration, insurance payers, hospital ethics committees, prostate cancer support groups and even the FDA have failed in their role of stewardship to challenge the alleged benefits of this heavy-handed, high-risk, non-beneficial radical robotic prostate cancer operation with its inherent, long list of usually permanent complications. The opportunities to review and challenge the merits of this operation have presented themselves many times over many years. However, each opportunity was "tabled" because of the egos of the believers in surgery and the convenient occurrence of new "advances" in technology such as when the radical prostatectomy surgery morphed from conventional, to nerve-sparing, to laparoscopic and then to robotic approaches. This unadulterated human experimentation under the guise of real surgery was able to continue, because some academic "leaders" in urology had an unwavering but misguided belief in their ability for complication-free surgical removal and curative benefit, despite existing information to the contrary. However, these anticipated improvements and benefits have never materialized and robotic surgical "cure" remains unreachable as a treatment for prostate cancer.

UNCOMMON CHALLENGERS

There have been a few brave hearts like Dr. Anthony Horan who have had the testicular fortitude to challenge the so-called conventional wisdom of prostate cancer surgery and provide supportive evidence and references for its meritless place in the prostate cancer treatment arena.

Much more time and energy has been spent by surgeons comfortable with the confused status quo of prostate cancer surgery in discrediting the challenges to this misguided operation rather than working to develop the truthful long-term scientific data from which men can become truly informed. **Even some university physicians, conveniently cloaked by the gown of academia to imply authority, but an authority which can be hollow and not always tempered with real experience, honesty or ethics, have failed to rise and challenge the alleged benefits of prostate cancer surgery and its very questionable "gold standard" status with randomized long term scientific trials.** In fact, most surgeon believers of radical prostate cancer surgery/robotics have gone out of their way to intentionally cloud the pool of information on the known absence of long-term curative benefits as well as its propensity for lifelong complications.

The charade on the "benefits" for prostate cancer surgery continues and we really need nonmedical committees to audit and oversee the medical committees overseeing doctors. Many physicians appear to be both unable and/or ineffective at monitoring and auditing treatment test results without bias and these physicians do not deserve our trust. In fact, to underscore the circus phenomena in the world of prostate cancer, we have physicians who endorse the robotics procedure knowing that the procedure is associated with a multitude of complications and without life extension but dare to criticize and judge alternative prostate cancer treatment modalities that they do not "believe" in. These actions expose their flagrant bias and surgical treatment "philosophy" when true physicians should be unbiased, impartial and scientific in their review.

WORKING on MYSTERIES WITHOUT any CLUES

That prostate cancer surgical treatment is so controversial is hardly surprising when one understands it is mostly based on opinions, philosophies and consensus. **What is a mystery is that, after all of these years, surgeons are still trying to establish a case for the place of surgery in prostate cancer treatment.** Surprisingly, there may be a flicker of realization by some prostate cancer surgeons these days that there are real clues that their "gold standard" surgery may not be the panacea that they would have you believe. First, many urologists

now require a written consent from a man before having him tested for his PSA because of the potential for very significant negative downstream effects from testing and surgical/robotic treatment for prostate cancer. Second, there is some realization and acceptance now by some of these surgeons for significant, real and permanent surgical complications from treatment and along with an absence of curative benefit. Therefore, many men are now steered towards AS with monitoring and postponement of treatment of their prostate cancer. Third, there is a recognition by some robotic surgeons for significant disappointment in men post operatively because of the complications resulting from their prostate cancer surgery that these urologists have instituted a program of preoperative psychological counseling so patients can deal with their postoperative disappointment more effectively.

LIES, LIES and MORE DAMNED LIES

Yesterday's untenable dishonesty has become today's accepted standard practice of confusion and something far from the truth. Truth, honesty and integrity, even in medicine, appear to be fading. This clouding of physician trust and advocacy makes it even more imperative that each man given the diagnosis of prostate cancer take charge and take the time to become informed and ask many, many questions. Prostate cancer information generally, but especially for radical surgery/robotics, is a very thick soup of inaccuracies and fabrications but mostly, an epidemic of lies.

Finally, the obligation of physicians to endorse only those cancer practices that have been proven to benefit man is paramount and pivotal studies for prostate cancer curative treatment are wanting. Lies, opinions, philosophies, egos and hopeful-sounding rhetoric now trump information based upon proven facts and truth. **This appalling lack of established, real and reliable curative data for prostate cancer surgery/robotics, as well as a pervasive lack of sincere patient advocacy in the prostate cancer arena, is unconscionable, requires urgent remedy and makes a mockery of urology "best practice" guidelines.**

"physician, heal thyself"

Bibliography

Required reading for all men diagnosed with prostate cancer as well as all urology residents (especially those sections on radical prostatectomy). These books will serve as an antidote to the omnipresent misinformation about the alleged value of prostate cancer surgery/robotics.

1. The Big Scare-the business of prostate cancer, Anthony Horan, MD (this book contains over 500 supporting scientific references)
2. Surviving Prostate Cancer without Surgery, Bradley Hennenfent, MD (this book contains over 200 supporting scientific references)
3. The Male Lumpectomy, Gary Onik, MD
4. I Want my Prostate Back, L. Stains. Men's Health, March, 2010
5. Life After Prostate Surgery Worse than Expected, Fox News, July 1, 2011
6. Why Should the After Effects of Some Prostate Cancer Treatments be Worse Than the Disease Itself? Bert Vorstman MD, www.HIFURx.com, August, 2011
7. Prostate Surgery is Booming, but at What Cost?. Sun Sentinel newspaper, September 11, 2011

Other books, journal articles, newspaper articles, TV articles and web articles about the misery surrounding prostate cancer treatment, as well as articles detailing individual patient experiences are also available by searching the web.

About Bert Vorstman MD, MS, FAAP, FRACS, FACS

Dr. Vorstman is a Board Certified urological surgeon with some 30 years of experience. He is Fellowship trained in Pediatric and Adult Reconstructive Urology, a former NIH surgeon researcher and a former Urology Faculty Member at the University of Miami, Florida. He also earned the honor of a Masters of Surgery Diploma through Otago University, Dunedin, New Zealand for pioneering

research on urinary bladder reinnervation using nerve cross over techniques. These techniques could have possible application in patients with neurogenic bladders.

Dr. Vorstman is well published and has lectured nationally and internationally. He belongs to a number of organizations including the prestigious Societe Internationale d'Urologie.

Dr. Vorstman's passion and dedication is to help men and their partners fully understand the treatment options available to them as well as their possible complications when facing a diagnosis of prostate cancer.

He works to promote the acceptance and use of minimally invasive treatment options such as hifu and cryoablation for localized prostate cancer in appropriately selected men. In that regard he has developed a Center for Minimally Invasive Treatment Options for localized prostate cancer.

In addition, Dr. Vorstman has developed a leading urology practice, Florida Urological Associates, pa, was instrumental in developing the Coral Springs Surgical Center and developed websites highlighting prostate cancer issues including www.urologyweb.com