

WHY SHOULD THE AFTER EFFECTS OF SOME PROSTATE CANCER TREATMENTS BE WORSE THAN THE DISEASE ITSELF?

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A great number of men who have completed a treatment for their prostate cancer are left without clear benefit from their choice of treatment and with considerable short-term and long-term after effects.

The after effects from a treatment for localized prostate cancer are relatively common, often severe, often lifelong, can impact a man's quality of life (QoL) and often can be worse than the prostate cancer disease itself.

The after effects or complications from treating prostate cancer can occur after any of the four main definitive treatment options for localized prostate cancer: high intensity focused ultrasound (hifu), cryoablation (freezing), various radiation options (external beam options, brachytherapy or seeds, proton beam) and various surgical options (conventional, laparoscopic, robotic). These four basic treatment options essentially are suitable only for truly localized prostate cancer. However, radiation, as it is somewhat imprecise, can also be used for locally advanced prostate cancer or cancer that is not organ confined but immediately outside the margins of the prostate.

Although the survival benefits of all four treatment options are similar, the incidence of their complications, and especially those of impotence and/or incontinence varies considerably between the treatment options. Therefore, men considering a treatment option for their localized prostate cancer should take extra special care in understanding the complications associated with that treatment as well as the potential negative impact on QoL.

Limp and Leaking

Let's look at the very important QoL issues concerning impotence and incontinence or "limp and leaking" after a treatment for localized prostate cancer, but especially so after radical surgical/robotic removal.

Seeing a man despondent and wearing diapers because he is no longer able to control his urine flow after his radical surgery/robotics treatment of his prostate cancer is a very, very sad sight. Sadder still is seeing his wife trying to support and console her man. Both are in despair, confused and wondering how this predicament came to be, was this necessary and where do they go forward with their lives from here? For him, trying to share his feelings with his surgeon and his prostate cancer support group is an empty and fruitless task.

Hardly is it surprising then to hear some of these men afflicted with these horrible complications tell me that "their" choice to have their prostate cancer removed through radical surgery/robotics was, "the worst decision of my life".

The worst decision, because not only was he left with the miserable after effects of urinary leakage, diapers and pads but he also lost his ability to have erections and sex and, if this was not enough, often as not, he was left also with a shortened penis.

Why is my Wife Affected by my Treatment?

Prostate cancer treatment complications are rather unique when compared to treatment complications for other diseases as the after effects of compromised sexual function and the shortened penis suffered by the man after prostate excision impact his wife, their union and their marriage. Because of the concern for complications and QoL issues associated with the various treatment options for prostate cancer, but especially so after radical surgical/robotic prostate removal, it is very important for men to bring their wife or partner to any pretreatment counseling sessions.

Your Journey

Let us consider the journey you are about to embark upon or the journey you completed with respect to your prostate cancer and attempt to address several concerns that may, or have already, impacted you along the way.

This journey encompasses your evaluation and consideration for one or more of the treatment options available. Unfortunately, this journey is affected by a preponderance of judgment issues, inaccuracies, varying definitions, a lack of objective information, assumptions, philosophies, egos, more egos and misleading statements cloaked under the guise of data which has been construed as fact.

Let us look at various aspects of the prostate cancer arena from PSA screening to prostate biopsies, pathology and treatment options, as well as their complications.

Screening for Prostate Cancer

How accurate are these blood markers such as the prostatic specific antigen (PSA) in screening and suggesting the possibility of a prostate cancer?

The most reliable way may be by determining the total PSA as well as the free PSA in order to determine your % free PSA and your estimated probability of having prostate cancer.

Abnormal laboratory results can be repeated to verify if they were really abnormal (remember not to do this blood test within 24 hrs of sex or a prostate examination as the PSA may be falsely elevated).

Although measuring your free PSA is sanctioned only for use in men with PSAs over 4 ng/ml, its real use is in estimating the probability of a prostate cancer in those men with a "normal" PSA of under 4 ng/ml. This fact is especially important as some 15-20% of men with a so called "normal" PSA of 4 ng/ml or less

are known to have significant prostate cancer. Men with these prostate cancers will be missed if they are screened without measuring the free PSA.

Not so reliable for suggesting the possibility of prostate cancer in men is the total PSA on its own or the digital rectal examination which both have a reliability of about 50% or the same as tossing a coin. This lack of reliability for detecting prostate cancer when just using the total PSA (without the free PSA) is underscored by the fact that men screened with total PSAs only, and with values between 4 and 10 ng/ml, had benign disease on biopsy 70% of the time.

Generally, the higher the PSA, the increased likelihood of cancer. However, the aggressiveness of a prostate cancer cannot be inferred from the PSA level as some very aggressive cancers present with normal or slightly elevated PSAs, even in the elderly, and continued observation may in fact be harmful by delaying a prostate biopsy and potentially curative treatment.

Other markers or formats which are described as possibly useful are the PCa3 or using the total PSA density or velocity. Most of these determinations lack the reliability of measuring both the total PSA and the free PSA. It is important to remember that measuring these blood markers provide estimations of probability only and are not an absolute indicator of prostate cancer.

A prostate cancer can only be diagnosed through a well-conducted prostate biopsy. Furthermore, the monitoring of possible progression of a small area of cancer by simply following the PSA is unreliable and the possible progression of that cancer can only be determined through the analysis of serial biopsies. Most prostate biopsies are straightforward although there are some potential downsides.

However, the concern for possible spread or needle tracking of the underlying early stage prostate cancer through a needle biopsy is misguided and one of many myths in the prostate cancer arena.

My PSA is Low. Is that Good?

Another important issue relating to PSAs are the false and potentially harmful and misguided attempts to lower the PSA in the absence of a definitive treatment, thinking that this will lower your chance of prostate cancer or even arrest an early cancer. Also, men who have been diagnosed with small areas of cancer and elected active surveillance should not be lulled into thinking that lowering their PSA (through medicines or supplements) controls the cancer or even treats it. I have seen several men fall into this trap only to have more advanced cancer on presentation to me when I could have offered a minimally invasive option much earlier with a potential to cure.

Furthermore, several common medicines have PSA lowering effects that can lead to a false sense of security. These medicines include the statins (cholesterol lowering drugs), NSAIDS (non-steroidal anti-inflammatory pain medicines), thiazide diuretics and 5 alpha reductase inhibitors like proscar and avodart. In addition, two large trials studying the use of these 5 alpha reductase inhibitors for possible prostate cancer prevention have helped fuel confusion as to PSA lowering and cancer prevention. A decrease was seen in low grade prostate cancers diagnosed but these cancers may not have impacted the patient anyway. In contrast, these studies suggested that the use of these medicines may have allowed an increase in incidence of high grade prostate cancers which is not ideal.

Again, prevention of prostate cancer and the lowering of your PSA through medicines or supplements with the thought that this will lower the chances of you having a significant prostate cancer is probably without protective benefit or merit and only gives you a false sense of security.

How Reliable is Your Prostate Needle Biopsy?

Let's look at how a diagnosis of prostate cancer is established along with multiple concerns about getting to that diagnosis.

A prostate cancer diagnosis can only be established from a well-conducted prostate needle biopsy and not from an MRI or any other imaging study. Whether or not these studies suggest an area or areas of possible cancer, a diagnosis offered without a biopsy is absolutely inappropriate and often false. In fact, I have performed several saturation as well as targeted biopsies of suspicious MRI findings of the prostate to find not even a micro focus of alleged cancer. Only a prostate biopsy can establish definitively the diagnosis and grade of the cancer.

The indications for a biopsy of the prostate include a prostate nodule, an elevated PSA and or an abnormal % free PSA. These markers allow early detection of prostate cancer usually way before the presence of symptoms and clinical findings. Currently, most prostate cancers now present as a T1c stage (discovered because of an abnormal PSA).

The technique for biopsying the prostate is another area in the prostate cancer arena where there is considerable subjectivity and room for error. For example, the standard 12-core office biopsies are conducted under a local anesthetic or periprostatic block and through an arbitrary sextant division of the prostate. It is very easy not to rotate the ultrasound probe enough resulting in sampling more of the middle and bulk of the prostate and not to be sampling in a systematic random fashion the six arbitrary regions of the prostate appropriately therefore missing possible areas of cancer, especially at the apex.

What about the reliability of the biopsy picking up a prostate cancer? For the standard 12-core biopsy, this reliability is in the order of about 70%. In order to improve on this reliability figure, I usually suggest a 24-core random sextant sampling with or

without margins under outpatient sedation. This is especially important when reevaluating for prostate cancer and/or determining margin status to ensure the cancer is organ confined. Evaluation with a 24-core sampling of the prostate (and extra cores for margin evaluation) provides a greater reliability for what is really going on in that prostate. Especially so since 75% of all prostate cancers are multi focal and, if a patient elects focal therapy, I want to be sure that we are going to be successful with that treatment option. In the past when I relied on the 12-core sampling, I was often misled, only to find a cancer that had been missed on the 12-core when reevaluating with a 24-core biopsy. However, the true significance of all of these cancerous areas in multi focal disease is unknown. We believe that one of them, the index lesion, may be more significant and possibly be responsible for progression and spread of the cancer but we are unsure if that ability resides with the satellite lesions also.

Also unclear is whether or not there is a variation in malignant potential for prostate cancers arising from different zones of the prostate such as peripheral, transitional or central. Although cancers arising in the transitional zone may be less aggressive, those situated in the apical area appear to be more problematic.

Are there other concerns about the prostate biopsy? In addition to possible side effects of infection and bleeding and incorrect random sampling of the sextant areas of the prostate, these concerns include inadequate biopsy core length, core contamination from other areas of the prostate already sampled, labeling errors of the specimen containers and handling errors and incorrect recording and reporting errors in the pathology laboratory. Hence, physician vigilance is paramount and these concerns are also the reason why some men undergo a buccal smear for DNA identification which is submitted along with their prostate biopsy to minimize errors in assigning a diagnosis.

How Reliable is Your Pathology Diagnosis?

Let's look at some pathology issues and the validity of those results. This issue was brought to my attention several years ago when a patient of mine submitted his biopsy slides to three different pathologists and got three different answers.

The diagnosis of prostate cancer by a pathologist is a situation associated with some concern for validity. This is because there is a certain amount of subjectivity involved by the pathologist in reading the biopsy specimens and coming to a diagnosis of whether the cancer is even present, the volume of the cancer and the grade of the cancer. This concern for accuracy and validity exists despite the aid of specialized stains to assist the pathologist and improve diagnostic accuracy.

Although these stains have been found to be important by many pathologists in coming to a diagnosis (but surprisingly not by all pathologists, probably because of cost) there is still a lack of concordance in the reading of prostate biopsy slides and different pathologists can come to different diagnoses on the same biopsy specimen. In fact, the same pathologist can come to a different diagnosis when presented with the same slides months later.

This is not an exact science and many pathologists will try to present these differences in interpretation as not being significant. This is certainly not true for all of the readings and if the readings of prostate biopsy slides were that easy they would not need the special stains to assist them.

Obviously, this concern for pathology interpretation is neither reassuring nor comforting to the patient nor the treating physician. Because of this concern for accuracy, I strongly recommend having the prostate biopsy slides evaluated also by a pathologist from a recognized independent reference laboratory experienced in diseases of the prostate. This referral

to a reference pathology laboratory can be important as most prostate biopsy slides in the community are interpreted by general pathologists. Such prostate biopsy validation from a higher authority not only reassures the patient about the validity of his diagnosis but also allows for counseling of the patient with reliable information. This of course, assumes that the patient underwent a well-conducted prostate biopsy in the first place as discussed previously.

Prostate biopsy information as to where the tumor was located (apical cancers deserve special attention), the volume of the various cancerous areas, the tumor grade and Gleason score as well as PSA are the basis for assessing the risk category of a man's prostate cancer. This information may also suggest if further evaluations are advisable before considering treatment options and whether any of them should not be offered.

Fortunately, many men will be found to have benign disease only. Although this benign reading is reassuring, periodic monitoring is advisable on the off chance that an area of prostate cancer was missed in the initial biopsy. On the other hand, some men will be diagnosed with possible precancerous areas such as high grade prostatic intraepithelial neoplasia (HGPIN) and/or atypical small acinar proliferation (ASAP) demanding additional biopsies at a later date. These diagnoses should also be validated by a pathologist experienced in diseases of the prostate. Men need to be aware but also understand that prostate cancer is not inevitable.

In addition to knowledge about where and how much cancer was identified, it is important to know the weight or volume of the prostate. It is believed most treatment options have better results with prostate volumes under 40gms. Prostate glands greater than 40gms are often downsized arbitrarily through medicines or by one of the outpatient vaporization techniques using laser or bipolar plasma button options.

Is the Cancer Within or Outside my Prostate?

How can we determine whether the prostate cancer was truly organ confined or localized and not immediately outside the prostate? We can evaluate the margins of the prostate through biopsy. The status of these margins can tell us fairly reliably whether or not the cancer is organ confined and suggest if the choice of radical surgery/robotics or any other definitive treatment option such as hifu or cryoablation is reasonable.

In addition to the sextant biopsy of the prostate, the very edge or margins of the prostate, those at the bladder neck and seminal vesicles, as well as those at the apical margin of the prostate adjacent to the sphincter that controls urination are biopsied. This process is considered rarely by proponents of radical surgical/robotic prostate removal let alone discussed with the patient. That is probably for fear of actually finding tumor outside of the prostate and then "losing" the patient (and his fee) to radiation.

These prostate margin biopsies should be considered especially for men who are found to have high volume and/or high Gleason score prostate cancer disease at the apex of the prostate as cancer at the margins means the cancer is no longer organ confined and therefore, not a candidate for radical surgery/robotics, cryoablation or hifu.

Admittedly, biopsying the base and apical margins of the prostate only clears these two regions and it is possible for these to be clear but for the patient to still have positive margins because of other margins that are involved. However, the base and apical margins are the most important margins as they are the ones most frequently involved by infiltration of the cancer.

Apical prostate cancer demands particular attention in terms of whether or not it is really organ confined. Some 80% of apical prostate cancers are close to the apical capsule and the cancers here are at risk of capsular penetration along apical nerve

branches entering the prostate allowing the cancer to infiltrate (perineural infiltration) along these conduits out of the prostate.

As an aside, this is not to say that all men who have clear base and apical margins to their prostate will remain free from disease forever as some 10-15% of men with localized or organ confined disease will develop spread of their prostate cancer after radical surgical/robotic removal. It is unknown if the manipulation from radical surgery/robotics actually contributes to this problem of cancer spread or whether there are other factors involved.

Do All Prostate Cancers Need Treatment?

I do not believe we can ever "over" diagnose a cancer, but we can certainly over treat cancers. Detecting and diagnosing should not necessarily follow with treatment. That is a patient's prerogative.

Does every man with a diagnosis of prostate cancer need treatment? No. Some may undergo watchful waiting or active surveillance.

Are all prostate cancers the same? No.

Are all four definitive treatment options suitable for every prostate cancer? No.

Is it possible to have "too little" or "too much" prostate cancer? Yes.

For example, you can be "over treated" if you have "too little" cancer as in the finding of a solitary micro focus of prostate cancer in one needle core biopsy only (5% or less of a Gleason 6 adenocarcinoma).

Despite many physicians steering men into immediate treatment on finding a solitary micro-focus, there is no evidence to support the benefit of such an approach in these individuals. Additional

support for this conservative approach comes from the study of the natural history of low grade and small volume tumors. These studies suggest an indolent nature of most of these cancers.

Men with a micro-focus or small volume and low grade cancers can be followed through active surveillance and re-biopsied a few months later to confirm the presence or absence or progression of a cancer. Often as not, the existence of a micro-focus of cancer cannot be confirmed even after an extended or saturation biopsy and the treatment of a man with a solitary micro focus of prostate cancer that cannot be confirmed at re-biopsy represents "over treatment". Such men unlucky enough to have been encouraged into an immediate treatment option such as a radical surgical/robotic prostatectomy by overzealous surgeons is misguided and represents a lack of patient advocacy.

Other men who can be over treated are those who do not have a 10-15 year life expectancy and/or, co-morbidities such as significant diabetes or significant heart disease. Many of these men can be followed with active surveillance and kept free from the potential complications associated with one of the definitive treatment options for prostate cancer. Should there be progression of the prostate cancer (this can only be determined through further biopsies of the prostate), these men may be treated with hormone manipulation or androgen deprivation therapy (ADT) such as lupron. Simply because radiation is less invasive than surgery does not make it a reasonable treatment option in men with a reduced life expectancy.

"Too much cancer". A prostate biopsy indicating a high volume and/or high Gleason score cancer, especially at the base or apex of the prostate represents a scenario where the cancer is highly likely to be outside of the prostate and not organ confined. Steering these men towards immediate radical surgery/robotic prostate removal can represent over treatment as the pathology results after surgery will likely indicate positive margins and, in this situation, the man is likely to also need radiation to deal with that positive margin.

Is the Radical Surgical/Robotic Technique Flawed?

How valid is the concept and technique for radical surgical/robotic removal of the prostate? The surgical approach for removing most cancerous organs is fairly straightforward. Separate it from its surrounding structures while preserving that which is not part of the involved organ and return the patient to his normal life and daily activities. However, for a few organs like the prostate, the situation is far more complex. Here the anatomy is not easily separated from its intimately and intricately associated adjacent urinary sphincter for urinary control and the closely adherent nerves for erection. Separation of the prostate from these structures, while trying to maintain integrity of these structures, is virtually impossible. This is despite high tech "optical magnification" and "motion control".

It is this fundamental act of cutting the prostate out from its location and its association with the sphincter muscle fibers and nerves, whether conventionally or robotically, in high definition or with any other "bells and whistles", that automatically gives rise to the common complications of impotence and incontinence.

High-tech methodology does not necessarily translate to high-tech results when it comes to prostate cancer treatment. The marketing of the high tech procedure for prostate cancer treatment as being associated with less impotence and incontinence compared to conventional surgery or any other

treatment option and therefore affording a better QoL, is unsubstantiated without support from scientific trials, and is simply medical as well as manufacturers spin. Although robotics have advanced the cause of surgery in many fields, there is little scientific evidence for their value or place in prostate cancer treatment.

Another marketing spin is using the term "minimally invasive" to advertise this surgery. There is nothing minimally invasive about this "high-tech robotic" procedure as the radical surgical/robotic removal of the prostate still requires hospitalization. Furthermore, use of the terms "reconstruction" and "nerve sparing", although well intentioned, are naive and misguided as is evidenced clearly by the propensity for impotence and incontinence after radical surgical/robotic removal of the prostate. Attaching the urethra to the bladder neck (as well as shortening the penis) after surgical removal of the prostate creates a "controlled" stricture and, as well as an absence of ejaculation, there is no return of the anatomy to a "normal" state after reconstituting the urinary channel.

It has been shown also that surgeons utilizing this radical surgical/robotic technique require considerable numbers of cases before they exhibit a modicum of proficiency. Therefore, in addition to the large number of cases required before a surgeon can claim experience, the sheer number of robotic machines in use in the US should be additional cause for concern for men considering the radical surgical/robotic option for treatment.

Radical Surgical/Robotic Treatment and Russian Roulette

How and why did the radical surgical/robotic treatment for prostate cancer achieve this "most favored" status as a treatment option for prostate cancer and, more importantly, is it deserved?

Unbelievably, the management of prostate cancer through surgical/robotic options has become so entrenched in the

mindset of treating physicians that they have given it the arbitrary moniker of being “the gold standard”. This term, when recited often enough, has some surgeons actually believing it. However, there are no well designed and scrutinized FDA (Food and Drug Administration) supporting scientific studies where the results following radical surgery/robotics (or after any other treatment option for localized prostate cancer for that matter) were evaluated by physicians truly independent from the study physicians. This elementary scientific principle has escaped, seemingly, the mindset of even the most seasoned of academic surgeons.

Although these complications of impotence and incontinence are common after surgery, their existence post-operatively is often dismissed (with feigned surprise!) by the treating surgeon as unusual. Even the most experienced surgeons have their share of these complications.

In reality, these after effects of impotence and incontinence (limp and leaking) from radical surgical/robotic removal of the prostate are seen as the “cost of doing business” not only by surgeons here in North America but by surgeons in prostate cancer treatment centers worldwide. Indeed, some surgeons are not shy about considering the radical operation as a possible staged procedure to be followed at a later date by surgeries to treat impotence and incontinence resulting from the prostate excision.

With the endorsement from some surgeons, the runaway juggernaut of surgical technology business and its support cast of financially motivated lobbyists have managed to “approve” for mainstream use, through very clever marketing, a very profitable but non-FDA scrutinized treatment option.

In addition, the medical technology manufacturing industry has not only encouraged and supported this high-tech assault on the prostate but the industry has spawned the development of a whole array of other surgical approaches and devices to treat

and attempt to correct the very complications and negative QoL created by the radical surgical/robotic removal of the prostate.

In fact, I believe that these surgical treatment options represent a direct assault on manhood, and men choosing this radical surgical/robotic treatment option for their prostate cancer are playing Russian Roulette with their QoL. Furthermore, I believe that the radical surgical/robotic treatment option has single-handedly increased the incidence of impotence and incontinence worldwide and physicians would do well to consider Hippocrates affirmation: "As to diseases, make a habit of things to help or, at least do no harm".

Are Prostate Cancer Treatment Complications Guaranteed?

Do all patients who undergo a treatment option for localized prostate cancer get complications which affect their QoL? Of course not.

Certainly, there are men who have had a lucky result from surgery for prostate cancer. In fact, at times, the result of a radical/robotic operation surprises even its most ardent of supporters, allowing the surgeon to gloat that he has achieved the "trifecta" because his patient came out of surgery with negative margins (all cancer removed), remained continent (dry) and retained his erections (was able to engage in sex). However, without the evidence and support of FDA trials, the perceived benefits of radical surgery/robotics appear to be vastly overstated, fueled both by the manufacturers along with the inflated egos of some surgeons.

As well, and leading to false promises, the complications and negative effects on QoL by the radical surgical/robotic option appear to be intentionally minimized and clouded by manufacturer marketing spin. In fact, a recent study of hospital websites showed that many sites overstated the benefits of robotic surgery, largely ignored the risks and were influenced

strongly by the manufacturer.

For other men, their complications of impotence and incontinence after radical surgery/robotics or possibly after one of the other definitive treatment options may gradually lessen and even resolve. Again, however, it is only after a man has had a radical surgical/robotic prostatectomy that I have ever heard him cry out in exasperation that his choice of surgery/robotics for prostate cancer treatment was “the worst decision of his life”.

Limp and Leaking Definitions

Let's look at how the common complications of impotence and incontinence (limp and leaking) are defined by various surgeons in their clinical studies. It is not what you expect!

Astonishingly, as if evaluating your own study (or even by someone in your own department, institution or by your supporting manufacturer) is not conflict enough, many surgeons have published treatment results with non-standard and made-up definitions of incontinence and impotence. The urological literature is replete with these non scientific and arbitrary definitions. For example, incontinence may be defined as needing to wear more than two pads per day while impotence has even been defined as being unable to engage in a sex act over a twelve month period. Consequently, if a post-surgery prostate cancer patient wears just one pad per day, or was unable to engage in a sex act for ten months, he is not considered incontinent or impotent in some studies. These ridiculous, self-serving definitions are designed simply to bolster the ego of the treating surgeon with favorable treatment results while intentionally misleading potential patients about the true incidence of impotence and incontinence. This very common practice of using made-up definitions for impotence and incontinence hardly places surgeons and their talk of patient advocacy in a good light. Furthermore, for colleagues to ignore such blatant manipulation of results and imply that the surgical option for prostate cancer treatment has "withstood the test of

time", is simply shameful and false.

Cancer Left Behind After Surgery (a Common Problem) with More Definitions and Mental Gymnastics

Let's look at how often the surgical procedure is truly successful at removing the total prostate and its cancer.

Here, we see the disturbing mental gymnastics undertaken once more with playing the "definition game". This time, how do we define the significance of cancer left behind after radical surgical/robotic removal of the prostate, and what if anything should be done about it?

This event is common and is seen only in men having undergone the surgical/robotic option. This issue is recorded on the pathology report as a POSITIVE MARGIN (all patients are encouraged to review all of their pathology reports and learn to understand their meaning). Although a few surgeons have suggested that some positive margins are simply artificial and a function of how the prostate was cut out, in most men, a positive margin means that cancer was left behind and their prostate cancer was more extensive.

Alternatively, in some other patients, this positive margin may have come about because of the surgeon's knowledge and fear that impotence and incontinence may result from his surgery; therefore he purposefully preserves the apex of the prostate to minimize the chance of these complications from occurring.

On the other hand, a residual or recurrent prostate cancer may be seen after any of the four treatment options. However, a positive margin, which is different from a residual or recurrent cancer, should be preventable in many men electing radical surgery/robotics if their prostate needle biopsy evaluation had been more complete.

Consider this. When you were first diagnosed with prostate cancer, you were immediately steered towards radical surgical/robotic prostatectomy. However, now after surgery, you have been found to have a positive margin and the same treating surgeon steers you towards radiation or some period of close monitoring also known as watchful waiting or active surveillance. Are they different prostate cancers? Of course not. Same man, same cancer, but where he was initially steered towards immediate surgery (remember, the arbitrarily anointed “gold standard” for this treatment), he is now steered towards radiation as being the preferred option! This radiation treatment option may well finally offer a cure but it also comes with its own set of potential after effects or complications. The worst of these possible complications from radiation are hemorrhagic radiation cystitis and hemorrhagic radiation proctitis. Both complications can lead to considerable bleeding and be life threatening, rarely.

So now the man has been subjected to radical surgical/robotic removal of his cancerous prostate, has some cancer left behind and is now being steered towards radiation. How commonly is this scenario played out? Unfortunately, some 20 to 40% of men who choose the radical surgical/robotic option to treat their "localized" prostate cancer have cancer left behind.

Too often this situation is justified by the surgeon after the fact, as a de-bulking procedure to attempt to remove as much of the prostate and cancer as possible. This proposition is meritless and this incomplete surgical removal of the prostate and cancer resulting in positive margins may have been forgone if these men had undergone a more detailed prostate biopsy evaluation.

FDA Proven?

What about FDA status?

The whole confusing issue of FDA status is another big quandary for patients reviewing prostate cancer information.

Surely, every treatment option for localized prostate cancer has been rigorously scrutinized through FDA controlled trials? Unfortunately, not so!

Three of the four definitive treatment options for localized prostate cancer: cryoablation, radiation options (including brachytherapy and proton beam) and radical surgical/robotics have never had the benefit of any FDA scrutiny through well-conducted scientific trials. These treatment options were simply arbitrarily “rubber stamped” with the FDA “approved” label. This process has allowed considerable grandstanding by the various proponents of radical surgery/robotics and radiation options but without the definitive support from blinded, independently evaluated studies that can verify both the worthiness of a treatment as well as its complication rate.

Amazingly, and a first in the treatment arena of localized prostate cancer, the FDA has now required treatment trial data for hifu. However, the trial data required from hifu (Sonacare) evaluation are not from virgin cases of prostate cancer, but from the men whose cancer has returned due to failure of their radiation treatment. This is a very difficult subset of prostate cancer patients to try to cure once more as well as keep complication free. At least, positive data from this study may provide further hope for cure in those men who have failed radiation instead of being relegated to long term androgen deprivation therapy (ADT) and all of its potential side effects including symptomatic as well as cardiac and bone risks.

Is it possible that the FDA might see the wisdom of having the other definitive treatment options for localized prostate cancer such as radical surgery/robotics, cryoablation and all of the radiation options undergo validation through rigorously conducted scientific trials? Astonishingly, despite the preponderance of complications with the various surgical/robotics and radiation options, the FDA has not seen the need for real trial data from studies that would be completely

devoid of conflicts of interest, philosophies and egos.

Post Treatment PSA Monitoring

Monitoring a man after any one of the four prostate cancer treatment options is a very important, lifelong process as some will fail treatment and need to be considered for an alternative option. Measuring the total PSA after prostate cancer treatment is an accurate way of determining the status of a man's response to his treatment option. However, men who have been followed for at least 10 years and continue to have a PSA <0.1 ng/ml can probably dispense with further follow up.

The very first sign of a residual or recurrent prostate cancer is a rise in the PSA from its lowest level after treatment or NADIR and represents the phenomenon of "biochemical recurrence".

Some 50% of men with a positive margin after radical surgical/robotic prostatectomy (remember, 20-40% will have a positive margin after their surgery) will develop a "biochemical recurrence". This term is meant to be reassuring but denotes a rise in your PSA after your cancer treatment, possibly from a positive margin but with no physical or imaging evidence for recurrence. However, what "biochemical recurrence" really means is that you have prostate cancer cells somewhere that the surgeon has yet to find and this term means, essentially, the very first indication of a prostate cancer recurrence or local spread.

The definition of a biochemical recurrence, how much of a rise in PSA is seen from your baseline and when this is meaningful depends upon which definition you use for a meaningful PSA rise. Here we see again, a variety of definitions in prostate cancer management and various organizations (ASTRO, PHOENIX and STUTTGART) have arbitrarily decided on different definitions for what defines a significant rise in PSA after prostate cancer treatment.

Also, in addition to using the standard PSA for follow-up, there is an ultra-sensitive PSA which attempts to detect the earliest of prostate cancer recurrences or residual disease so that these men can be evaluated and treated sooner with another definitive treatment option. For example, residual or recurrent prostate cancer after radiation may be treated with cryoablation or hifu.

Is Localized Prostate Cancer Treatment Expensive?

What about the costs for these various definitive treatment options for localized prostate cancer?

The costs vary considerably with the hifu option being the least costly at about \$25,000 and the other options of cryoablation (freezing), radiation (includes brachytherapy or seeds and proton beam and the various forms of external beam) and radical surgery/robotics costing two to four, or more, times that of hifu. Furthermore, when the purchase costs of the high-tech equipment for the surgical or radiation options, their maintenance costs as well as the cost of supplies or durables are added to the bottom line, it is obvious that the clear winner in this healthcare business is the high tech manufacturer. On the other hand, costs applied to the minimally invasive treatment options of hifu and cryoablation are much lower.

Yet, Medicare and the insurance companies will not reimburse the cost of outpatient hifu (though it is being performed successfully worldwide) as this procedure is undergoing FDA trials here in the US and for the moment, is considered experimental by the FDA. You will recall that, astonishingly, radical surgery/robotics, cryoablation, nor the various radiation options have ever undergone FDA trials here in the US yet all are Medicare approved and therefore paid for by insurance companies.

The costs for individual treatments can rise even more once the cost of treatment complications are factored in. After their radical

surgical/robotic treatment, some men will elect to undergo further surgeries to correct the complications from this treatment, while other men will add up the cost of their extra doctor visits, co-pays, evaluations and the thought of more surgery, and be induced to live in silence with their pads and devices. The need for these secondary corrective procedures is much less likely in the men who chose one of the other treatment options such as hifu, cryoablation or radiation for their prostate cancer.

Another cost that has been added to the overall financial outlay for many men, and which rode in on the back of the cancer label, has been the so called "prostate health" business and the pseudo-scientific drivel about "prostate health", nutrition, hydration and supplements. Aside from healthy living, ideal weight and moderate exercise, there is absolutely no scientific evidence to support the use of supplements, or even anti-cancer supplements. Complementary or alternative medicine through trained physicians, when used carefully and alongside traditional treatments and as long as not harmful, may be reasonable. However, injudicious use can lead to more harm.

Scurrilous and potentially harmful are the infomercials about health issues that purport to be factual and beneficial but are simply clever and persuasive marketing of medical myths. Myths and spin that sound plausible and hopeful but are knowingly and intentionally misleading. It is simply a business of taking advantage of gullible and vulnerable people and emptying their wallets for the sole benefit of the company's wallet.

Cure Rates and Medical Spin

What can we say about the marketing and talk of "cure rates" in the treatment of localized prostate cancer? In addition to misleading the public that radical surgery/robotics and the various radiation options were FDA scrutinized through trials when they were simply rubber stamped with the FDA "approved" label, there is also misleading talk about these treatment options and their cure rates for localized prostate cancer. These cure

rate numbers are seemingly reasonable but determined from treatments of groups of men with a hodge-podge of various amounts and grades of non-validated prostate cancer. Furthermore, all of this talk about cure rates is spurious and without merit, least of all because of the constant change in technology and software for the various definitive treatment options for localized prostate cancer. This constant evolution in software and technology makes the comparison of results from current treatments to those of even five years ago invalid as the technology is no longer the same.

Not only is this talk misleading for individual treatment options such as radical surgery/robotics and the various radiation options, but also for comparisons between the various treatment options as well as between so called data bases. This is another very common practice that involves considerable medical spin, arbitrary definitions and the use of the word data, which has again, been construed to mean fact when it is not.

Do Men Get Counseled Appropriately?

Are men with a new diagnosis of prostate cancer and their partners completely educated and informed about all of the possible treatment options open to them as well as the complications that may arise from these treatments? Not usually.

The counseling of men about the various definitive treatment options available for localized prostate cancer can be awkward for most surgeons and radiation oncologists. That is because most treating physicians have very little knowledge and no experience in the minimally invasive treatment options of hifu and cryoablation for localized prostate cancer. Therefore, the patient and his spouse are highly unlikely to receive an unbiased account of their true value. Because of this fundamental lack of knowledge on these options, most surgeons will “talk up” the believed benefits of radical surgical/robotic removal while the radiation oncologists will do the same for the various radiation options.

This so-called counseling of men about "all" prostate cancer treatment options is disingenuous, and reliable literature and Internet sites to find bona fide results on scientifically conducted trials for all of these options and comparisons between them, is wanting.

Egos and Opinions

With this background of judgmental issues in pathology, arbitrary definitions, assumptions, inaccurate information, lack of independent and FDA-conducted trial data for the various treatment options, rubber stamping of the FDA label to some treatments, lack of objective findings, philosophies of treatment as well as the very questionable talk of cure rates, medical spin, egos and more egos, it is obvious to all that there is a compelling need to address and establish real and truthful information regarding prostate cancer treatment options and their complications.

Currently, many of the treatment recommendations espoused by the various proponents of radical surgery/robotics or radiation simply represent philosophies of treatment. For example, rather than a definitive treatment option standing on its merits on the basis of rigorously conducted scientific studies, we now see radiation being "talked up", as combining ADT with radiation may give some extra months of survival.

Because of this need for real information, patients should be very proactive and independent in seeking as much information about their treatment options and probable complications as well as other opinions. Although this process is absolutely the prerogative of patients, many patients will be made to feel quite uncomfortable by their initial treating surgeon, physician or even pathologist when seeking these requests for other opinions.

Unfortunately, many physicians have not learned how to corral their egos. For example, I have encountered resistance from pathologists regarding the sending out of slides for validation. Also, instead of forwarding all slides for the second opinion I have had pathologists send only the slides "they" thought required a second opinion. Some pathologists even forward a copy of their own diagnosis along with their slides on the pretext of courtesy, but in reality, they are trying to influence the validation process along the lines of their own interpretation.

Similarly, when patients ask for recommendations on whom to seek second opinions in order to understand their disease state, options and potential complications, many physicians find it quite difficult to accommodate their patients. I have heard from numerous patients about their troubling experiences with surgeons when requesting from them the name of another expert in the field for a second opinion. In fact, some physicians were downright defensive, nasty and unprofessional while at the same time intentionally intimidating the patient for the sole purpose of retaining his/her role as the treating physician (and anticipated fee). Be prepared to dismiss any physician that does not provide you with a thorough explanation of your findings, all of your treatment options and possible complications.

Furthermore, many physicians in this medical business have become quite adept at persuading and insincerely coddling patients and purposefully fostering concern in order to manipulate the patient to follow a treatment path of no or marginal benefit to himself, but of every benefit to the doctor.

This lack of patient advocacy may be compounded by physician investments in various medical enterprises and can represent a huge conflict. In fact, many urology groups have been purchased already by radiation companies. However, with adequate homework, study of your particular prostate cancer (remember,

not all prostate cancers are suitable for every treatment option) as well as seeking additional medical opinions, these potential concerns may be offset.

The insatiable need for some surgeons to demonstrate their prowess and justify their radical surgical/robotic procedure as well as explain the endless positive margins, complications, negative QoL and patient dissatisfaction is disturbing. The superiority attitude among the surgical and radiation fraternities as well as their tunnel vision, especially when it comes to other definitive treatment possibilities is remarkable. Remarkable and embarrassing considering the apparent subjugation of some physicians by the manufacturers of their respective technologies.

Physician grandstanding with eloquent and convincing speak (spin) is no substitute for being a true patient advocate and providing honest counseling. Certainly, some in the medical fraternity are not above coupling inaccurate and misleading data with quasi counseling and medical spin. Much of the so-called data on prostate cancer management needs immediate review, overhauling and correction through rigorous study, as do certain medical review groups and committees who are themselves in need of review.

Can Physicians do Better?

Every man expects to return to his normal daily activities, be a cancer survivor, be free from residual cancer, and be complication free. That is their right. This ideal, however, may not always be achievable but absolute honesty and patient advocacy must prevail, always.

Samuel Johnson once wrote: "Expectations improperly indulged must end in disappointment".

Expectations based on questionable results derived from reviews of one's own treatment results, and bounded by spurious definitions and errors of judgment, brings about distorted

interpretations, beliefs and philosophies, not facts.

The lack of solid trial FDA scrutinized data, the unwillingness of prostate cancer treatment specialists to demand these trials as well as the lack of desire to challenge the validity of a treatment and management option is not too dissimilar from the sheep-like behavior of followers of the flat earth society.

Honest and reproducible FDA data regarding the success and complications of the various treatment options for localized prostate cancer are severely wanting, as is real data about their complications and cure rates. This data can be realized by designing the appropriate trials.

1. Designing FDA trials for all treatment options with virgin cases of localized prostate cancer for hifu, cryoablation, all of the various radiation options and radical surgery/robotics.
2. Have all prostate pathology validated by recognized independent prostate reference laboratories.
3. Stratifying patients to treatment options in studies according to prostate tumor volume, tumor location and Gleason score and based upon an extended prostate biopsy rather than based upon cancer stage after a 12-core biopsy.
For example, the T1c stage which is the most common stage with which men with prostate cancer present these days, varies not only in Gleason score but in tumor volume from one micro focus to involvement of every biopsy core, underscoring the huge variation in disease state for cancer of the T1c stage.
4. Scientific studies using only truly independent and blinded reviewers of treatment results and with absolutely no ties or conflicts to the study organizers, departments, institutions, committees or manufacturers.
5. Standardizing all definitions used in the study, particularly as to what constitutes impotence and what constitutes incontinence.

The lifetime risk of a man being diagnosed with prostate cancer is about 8% and some quarter of a million new cases of prostate

cancer are diagnosed in the US every year. On the other hand, only about 12% of men with prostate cancer die every year (second leading cause of male cancer deaths after lung cancer). The natural history of many low volume and low grade prostate cancer is generally for slow local progression and for these cancers not likely to impact survival.

Currently, apart from the PSA, some information on tumor volume, the Gleason score, as well as attempts to score risk, the true malignant potential for progression of an individual prostate cancer is not very predictable. In fact, the same Gleason score tumor can have different potentials for progression and what is sorely needed in the arena of prostate cancer management is being able to predict which of those tumors have the potential to progress in individual men.

Trying to identify those men that really need treatment in order to be saved and cured and also to prevent men from falling to unnecessary surgery and its probable complications is a quandary for many men and prostate cancer treatment specialists.

Empowering Yourself

How then do men and their partners go about empowering themselves to become informed about their disease and their treatment options? In addition to seeking out several opinions from physicians experienced in the field of prostate cancer treatment, men and their partners need to look to other sources for information.

Information on the treatment options for localized prostate cancer, for example, is readily available on the Internet. This information allows men and their partners to empower themselves about prostate cancer treatments in their own time and at their own speed. However, this process of information gathering needs to be tempered with the understanding that not all of this information is reliable.

Furthermore, not all prostate cancers are the same and not all treatment options are suitable for every man's cancer, as discussed previously. Despite many years of prostate cancer management, treatment and clinical studies, it is still not clear how many men are actually saved and cured by their treatment or which treatment option truly excels. Therefore, careful and thorough research of your options is important for every disease state and strongly advised.

Despite the unsubstantiated bias for surgical/robotic removal of a prostate harboring cancer, especially for younger men, this cancer can be cured without surgery, robotically or otherwise. Prostate cancer just does not have to be cut out to offer cure and cure does not have to come at the expense of QoL with impotence and incontinence (limp and leaking).

Weighing the benefits of the different definitive treatment options against their possible/probable after effects and complications is important. However, this should not be an excuse for excessively delaying or even forgoing treatment in many cases.

Totally understandable is the effect of the cancer label on your psyche with desperate, disbelieving and irrational thinking. Do not feel overwhelmed. Slow down, this is not an emergency. If you let yourself or others talk you into believing that your diagnosis is an emergency, you will be befuddled with misleading information which will invariably lead you to serious misgivings. Do your homework. Write your questions down. Get two, three or more opinions from experts. Empower yourself. You are your best advocate. You control the type of treatment that you believe is best for you as well as the pace of your treatment.

Patients should remain strong and persist in getting the counseling and information they need to make an informed consent. When considering their treatment options, patients

would do well to remember the old adage “caveat emptor” or buyer (of treatment advice) beware! This is particularly important due to the great amount of biased and unsubstantiated information available on localized prostate cancer treatment.

In the meantime, get your pathology validated. Get a copy of the report and study it. Study where your tumor was located. How many cores were involved? What percentage volumes of tumor did the various cores have? What were their respective Gleason scores? Do your prostate margins need biopsy? What was your prostate volume? What was your PSA at the time of biopsy? What is your estimated risk level for your disease?

Finally, there is no other operation like the radical surgical/robotic treatment where the downsides of the surgery are so problematic but well known by the proponents of this operation. In fact, so well known that many surgeons often employ preoperative counseling to counter the dissatisfaction rate of this surgical option as well as having men undergo preoperative "training" exercises with the vacuum device and Kegel's, for the anticipated erection and incontinence issues likely stemming from their surgical treatment. As well, these exercises are continued often postoperatively for some time.

No other urological procedure has proponents going to such lengths with counseling and exercises to minimize the known downsides of this surgical treatment approach yet continue to endorse the procedure as a viable option. This is especially troubling when it is well understood that other definitive treatment options for localized prostate cancer are available with equal survival, with less complications and after effects, as well as more positive QoL issues and without the need for counseling exercises or excuses.

Because many prostate cancer treatments are without clear benefit yet associated potentially with considerable short-term and long-term after effects or complications, the place of many of these treatments is in question. Especially so for the radical surgical/robotic option where this treatment often can be worse than the prostatic cancer disease itself .

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

Dr. Vorstman is a 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 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'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 for localized prostate cancer treatment 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 three websites, two of which highlight prostate cancer issues. One is the general urology site www.urologyweb.com while the other two are the prostate cancer advocacy network or PCan program www.pcadvocacy.com (in progress) and the resource site for the minimally invasive option hifu, www.hifurx.com

