Robotic Prostatectomy—A Race to Failure?

> *"There is currently no convincing evidence that early screening, detection, and treatment improve mortality. Limitations in prostate cancer screening include potential adverse health effects associated with false-positive and negative results, and treatment side effects."* **ACPM Policy Statement, American Journal of Preventive Medicine, February 2008**

THERE WERE AN estimated 50,000 robotic prostatectomies performed in 2007[1]. It is projected that the number could double in 2008. While incredibly sad, even higher numbers are projected over the next 20 years and beyond! Robot assisted laparoscopic prostatectomy (RALP) is now accepted by Urology as the "gold standard" of curative treatment for Prostate Cancer. Robotic surgery is possible due to some amazing technology. One excellent example is the "da Vinci" system manufactured by Intuitive Medical, Inc. The device is remotely operated by the surgeon. Television cameras inserted into the abdomen provide multiple views and simulate three-dimensional vision. The robot consists of small, articulating arms which can perform multiple

tasks, tools include suture, scalpel, cauterizing tool, etc. This is a laparoscopic surgical process and is considered to be minimally invasive. Promoters of robotic prostatectomy routinely use the term "promising" in their expectation that this device and procedure will eventually demonstrate improvement in the cure rate for prostate cancer. Their enthusiasm is generated by the awareness that other curative treatments have a poor track record to cure prostate cancer, accompanied by other negative side effects. **The reality is that robotic prostatectomy has yet to deliver any results or evidence that it will provide any improvement over other treatments to cure prostate cancer.** Granted, the technology and the procedure are still relatively new, but there is as yet nothing dramatically different in performing the procedure and in the results from the traditional laparoscopic surgery. Armed with hope for improved results, the urology community has increased the rate of these surgeries at an alarming rate. In 2000, there were 1500 robotic prostatectomies performed. In 2007, it was estimated that 50,000 robotic prostatectomies were performed.[1] The rate of procedures is still climbing, with upwards of 80,000 procedures performed in 2008. The number is staggering when you add robotic surgeries to all other curative procedures performed which include open prostatectomy, conventional laparoscopic prostatectomy, radiation in all forms, radiation seed implantation, cryosurgery, thermometry, high intensity focused ultrasound ablation (HIFU), etc. Additional economic pressure is applied due to the significant cost of the robotic system. A typical robotic surgery device costs $1.2M with annual maintenance of $120,000.00 per year.[2]

A great number of urologists and academic centers promote early detection and early curative treatment, citing a better cure rate. Nonetheless, the facts speak for themselves.

> *"These technical improvements would lead one to believe that improved results with continence, potency and oncologic outcomes should logically follow. Ultimately, long-term outcomes and possibly financial impact will determine the role of robotic-assisted laparoscopic prostatectomy."*[1]

Published results of several studies simply do not support this . . .

> *"Cancer cure rate, measured by presence of cancerous cells at the surface of the removed prostate, and by PSA levels following surgery, was nearly identical for all three procedures (open, laparoscopic and robotic prostatectomy)."* [2]

Concurrently, the leadership associated with Urology and academic institutions have for several years expressed concern regarding "over treatment" of prostate cancer. Retrospective studies have revealed that a very high percentage, (30-56%), of surgeries were performed for "insignificant" cancers.[3] In addition, physicians promote cure rates for robotic prostatectomy using statistics with only five years of data. **The failure rates become quite significant (40-60%) for all treatments by 7 to 10 years. Without any evidence for improvement in the rate of cure, surgeons are wagering on the hope that this new approach will deliver better results.** As the numbers of treatments escalates, so will increased numbers of treatment failures and the devastating side effects that accompany them. A seemingly incongruous announcement in a policy statement recently released by the American College of Preventive Medicine recommended against routine prostate screening. Does this announcement have any connection to the alarming escalation

of treatment? Their policy statement details concern regarding the PSA blood test as cause for false positive and false negative diagnoses. However, it also recognizes concern over the inability to improve outcomes, to cure cancer predictably, or improve upon the negative side effects.

A conservative estimate is that 1,000,000 men are currently living as treatment failures as defined by a rising PSA result. A much greater number of men and their families suffer from debilitating side effects—incontinence, erectile dysfunction, diseases of the bowel, bleeding, infection, etc. At the current escalating rate of detection and treatment, notwithstanding, the associated needle biopsy issue, the number of failures could easily double within a few years. **Unfortunately, the sensationalism associated with robotic technology has been the driving force behind the escalation of treatment.**

Quality of Care

At what point does treatment go beyond quality of care and begin to cause greater harm than the disease itself? **Studies have already concluded that curative (radical) treatment of prostate cancer has provided no improvement in rate of cure and life expectancy when compared to doing nothing.** How can physicians ignore the facts, while noting the implications and continue to increase the rate of radical, so-called, curative treatments? Many surgeons now report that they "treat all cancers," even though a high percentage of cancers are determined to be insignificant or beyond treatment. Urologists generally diagnose, stage and grade the cancer according to location, extent and aggressiveness (Gleason Score) based on random 'blind biopsies'. Failure rates for Gleason 8 and above are very high within the first 5 years (≥ 85%). Unfortunately, alternatives

are presented to the patient in fewer and fewer cases leaving prostatectomy as the only option. **The goal, to cure cancer, is weighted with a higher degree of urgency and importance than a discussion of risk, loss of quality of life and outcomes.** In some cases, urologists present only one alternative, "watchful waiting," to the "curative" solution, i.e. radical treatment. Watchful waiting as it suggests, is watching PSA rise as we do nothing. Watchful waiting is a legitimate alternative, only due to the reality that all treatment approaches, including robotic prostatectomy; have yet to significantly improve upon doing nothing. Of course, a great majority of patients want to act with urgency, to have an enhanced chance to remove the cancer from their body before it has an opportunity to spread outside the prostate. Despite this thought, very few patients understand the need to insist on imaging with a 3 Tesla MRI scan to determine this. **Are urologists using this alternative as a "selling tool," to influence the patient to accept the physician's attempt at curative treatment?** Treatments, driven by robotic prostatectomy virtually doubled in 2008. The rate of needle biopsy has already doubled as well. [4]

> *"Our results suggest that tumor cell spillage and less frequently hematogenous dissemination may be associated with operative manipulation of the prostate during radical retropubic prostatectomy and may potentially represent mechanisms of failure after radical retropubic prostatectomy."* [5]

The patient and his urologist need to know that high PSA is driven primarily by non-bacterial prostatitis. Non-bacterial prostatitis is treatable and should be ruled out prior to any potentially harmful diagnostic testing, like random biopsies. A patient with an elevated PSA is typically referred by his general

practitioner to a urologist. In almost every case, the urologist recommends exploratory needle biopsy. In 2007, the number of tissue "cores" taken from the prostate for an initial needle biopsy ranged between 6-8 cores. In 2008, the number of tissue samples taken in the initial biopsy has more than doubled, from 12-20 cores. **Exploratory needle biopsy is an extremely inefficient diagnostic procedure. Only 20-30% of needle cores return positive for prostate cancer, a failure rate of 70-80%.** Patients intuitively are suspicious of the invasive nature of needle biopsies. It is well documented, but rarely accepted by urologists, that needle biopsy spreads prostate cancer cells outside the prostate, a phenomenon termed "needle tracking." Additionally, needle biopsy inflicts trauma causing inflammation in prostate tumors. Inflammation has been documented to lead to prostate cancer and may cause prostate cancer tumors to metastasize. There is only one common denominator to all treatment methods that uniformly fail. It is prostate needle biopsy. To read more about needle tracking, review our article, *"Prostate Biopsy Spreads Prostate Cancer Cells.*[4]

Why are Surgeries Escalating?

Setting the Bar Too Low? Failure to cure cancer may be defined in different ways. The debate to define failure to cure is influenced by growing concern over increasing numbers of the failures, marked by a return of PSA following radical prostatectomy. **As the failures increase, the definition will become increasingly vague.** Urologists are encouraged that the five year rate of cure for robotic prostatectomy is "very good." **A PSA of 0.2ng/ml and above is defined as "biochemical failure."** Considering that all treatments perform well in the first five years, a 5 year cure rate of 84% for robotic prostatectomy does not sound very encouraging.[6] Other studies may report higher rates of cure.

Nevertheless, free from PSA elevation for five years is too short a time-frame to determine the effectiveness of any curative procedure.

Following radical prostatectomy (robotic surgery included), the body no longer has a prostate gland. **Any increase in PSA blood levels can only represent one reality; prostate cancer continues to exist and is growing in your body.** In medicine the debate is whether to treat regionally (pelvis) with radiation and globally with chemotherapy, or to do nothing but watch for a rise in PSA. Radiation and chemotherapy may, or may not be effective, can result in negative side effects and cannot be applied repeatedly. Some physicians, urologists and oncologists, recommend monitoring of the "PSA doubling time" as a logical representation for the growth of metastases. Others choose to go by the statistics, stating that it may take up to eight years for metastases to be detected on a bone scan. [7] While this may be true, a bone scan is notoriously poor in its detection of metastases while delivering a hefty dose of radiation. **With a PSA of 20 following curative treatment, a bone scan still can only detect metastases in 1 of 1000 cases.** [8]

> *Referencing a bone scan" In patients with a PSA <10.0 ng/ml, the chance of a positive scan is approximately 1:1000. While a bone scan may be used as a baseline study, 30-50% of bone mass being studied must be replaced for it to be positive."* [8]

> A statement difficult to accept by most patients, *"On average, it took eight years from the time a man's PSA first went up until he developed metastatic disease—which suggests that there is no need to panic at the first sign of a rise in PSA."* [7]

Brady Urological Institute, Johns Hopkins

"Even after developing metastatic cancer (detected by bone scans and other imaging techniques), men still lived an average of five years—." [7]

"It could be argued that by 40 months after radical prostatectomy, obtaining an optimal outcome ***in just over half of patients*** *is not as favorable a result as would be hoped from a widely practiced localized prostate cancer therapy."* [9]

If the patient did not accept "watchful waiting," why should he be asked to accept "waiting" as prostate cancer metastasizes in his body? The patient should know that if prostate cancer metastasizes to the point it can be discovered on a bone scan, it is already too late. In this scenario, patients typically have between 3 and 5 years to live. There is promising new technology in development to detect metastases at a much earlier stage. Additionally, there is research into improved ways to treat prostate cancer metastases.

Over-treatment of Prostate Cancer?

"I treat all cancers" *the same, states a Urologist to a Wall Street Journal Blog* [10]

"Twenty nine out of 40 T1 stage histological cancers (67.5%), had tumor volume less than 1cc. The highest volume tumours were those of intermediate and high grade (Gleason scores of 5 through 8). Among tumours with volumes of less than 1 cc, 96.55% were confined within the prostatic capsule. According to our findings, there ***is possibly a high over-treatment rate*** *in many patients with clinically insignificant PC."* [11]

". . . the majority of impalpable prostate carcinomas are low volume, well differentiated tumours corresponding to ***clinically insignificant*** *neoplasms, and that similar characteristics could be attributed to most of the impalpable carcinomas detected after prostatectomy for BPH in clinical practice. With such a high number of clinically insignificant PCs among T1 prostatectomy specimens, and with an extraordinarily slow tumour doubling time, there appear to be substantial consequences for therapeutic decisions."* [3]

> *"In the literature up to 31% of all non-palpable prostate cancers (stage T1c) diagnosed with needle biopsy and treated with radical prostatectomy are potentially insignificant tumors"* [11]

> *"Cancer-free status with full continence and potency was achieved in 30% of men at 12 months, 42% at 24 months, 47% at 36 months, and 53% at 48 months postoperatively."*[9]

> Has Urology evolved to seek out smaller cancers, previously described as "insignificant?" One surgeon from a prestigious medical university advocates repeated biopsies to determine extent and grade of cancer. He also advocates aggressive treatment as best chance for cure. [12]

How can we predictably cure a man when we have spread prostate cancer cells with a biopsy? I guess this one surgeon (and many more) has not kept up with their reading! **This is the reason men must know their options and remain well informed if they want to avoid conveyor belt medicine!**

"Patients with significant, curable prostate cancer, e.g. those with at least 3 mm of Gleason 6 cancer, or any amount of Gleason 7 or greater tumors are probably best treated (radical prostatectomy or HIFU) rather than deferring treatment with active surveillance." [12]

"The Definition of a "clinically insignificant" tumor is Gleason 6 or less and less than 0.5 ccs volume."

"The arbitrariness of this is concerning. If the clinically significant prostate cancer rate was set at 4%, the clinically significant prostate cancer volume would be closer to 1 mL; conversely, if it were set at 12%, the clinically significant prostate cancer volume would be 0.2 mL. Nonetheless, this pathologic definition of clinically insignificant disease is widely used" [13], *thereby, confusing many, if not all of us!*

When is radical or curative treatment appropriate? A growing number of urologists believe when cancer is found, it should be treated. Their rationale, to discover and treat cancer in its earliest possible stage "is the best opportunity for cure." Of course, a great percentage of these cancers are called "insignificant" in retrospective studies. That is, the cancer was not expected to develop to a stage that it would be dangerous or life threatening. What of the dangerous or "aggressive" cancers? Prostate cancer is graded (Gleason Score) as a result of tissue analysis from needle biopsy. It has also been shown to be graded effectively with an MRI scanning sequence. Three categories emerge regarding the aggressiveness of prostate cancer. Cancers graded as "Gleason 6" and below are considered to be slow-growing and do not pose

an immediate threat to most patients. An exception would be cancer location when it is near the capsular edge. Considering the poor outcomes of treatment, there is a strong argument that these cancers should not be treated radically. Gleason 6 cancers are believed to become weakened or less aggressive when inflammation associated with prostatitis is controlled. [14]

Cancers graded as "Gleason 8" and above are considered to be aggressive cancers. It would seem logical that these cancers be treated immediately in the hope that cancer has not yet escaped the prostate capsule and ventured into the body. Unfortunately, it has been demonstrated that these patients have an *85%* chance of cancer returning within 7-10 years of treatment (Biochemical Failure). Finally, you have the middle ground, the "Gleason 7" cancer. Are these cancers appropriate for curative treatment? The high percentage of failures within 7-10 years for these cancers may not appear to justify the excessive negative side effects. **A top physician representing a prestigious medical school in the U.S. presents in detail on his website that he treats all grades of prostate cancer with robotic prostatectomy. This is a disturbing trend.**

Robotic Prostatectomy is Still Surgery

Curative Intent

"The overly hasty and widespread adoption of this technique could set the field of early prostate cancer detection and treatment back 15 years as did the early application of ineffective open brachytherapy techniques in the 1970s." [15]

> *"... there is no evidence that the procedure (robotic prostatectomy) improves cure rates"* [2] **Frankly, there is evidence, it does not!**

There is a steep Learning Curve for Robot Assisted Laparoscopic Prostatectomy. *"If you have to choose between someone who hasn't performed many robotic surgeries and a person who has performed many open procedures—take the open procedure," says Peter G. Schulam, M.D., Ph.D., a urology professor at the David Geffen School of Medicine at UCLA.*[2]

Robot Surgery is better due to potentially "fewer positive margins:" *"Several large studies have demonstrated that a positive surgical margin increases the chances that the prostate-specific antigen (PSA)—a protein produced by the cells of the prostate gland—will rise after surgery, and increase the chances that the disease will reoccur and progress." "Therefore, any intervention or technique to lower positive surgical margins,* ***we think,*** *will translate into a better long-term cure rate."* [16]

Fewer "Positive Margins" relates to the Experience of the Surgeon. *". . . positive margin rates in several laparoscopic prostatectomy series are concerningly high . . . Atug et al. reported a positive margin rate of 45.4% in the first 33 of 100 consecutive robotic prostatectomies . . . Baumert pointed out in an editorial comment, "the positive margin rate of the first group of patients is difficult to accept in this day and age. All surgical teams, new to robotic or laparoscopic surgery should initiate their programs with mentors to avoid 'sacrificing' the first (group) patients."* [15]

"Biochemical Failure"—Your Cancer has returned!!

When is surgery appropriate?

You need to know the potential outcomes of surgery. Gleason Score and PSA play an important role in determining the best opportunity to cure cancer. According to Johns Hopkins, James Buchanan Brady Urological Institute, **Biochemical Recurrence Probability after Radical Prostatectomy** was charted based upon Gleason Score and PSA. **According to the tables generated from the research, a Gleason 7 cancer with a PSA between 4.1 and 10 ng/ml, presents a 33% chance of biochemical recurrence (malignancy) in 10 years. For organ-confined Gleason 8-10 cancers with PSA between 4.1 and 10 ng/ml, there is a 43% probability of biochemical recurrence within 10 years. For non-organ confined disease, a Gleason 8 and above with PSA between 4.1 and 10 ng/ml, there is an 85% probability of failure within 10 years.** [17] For most radical prostatectomies, prior to surgery, it is unknown whether the disease is organ confined. **This is further reason that a 3 Tesla MRI scan must be performed prior to surgery.**

A study published in the Journal of Urology in 1996 revealed that in 92% of cases, prostate cancer cells were present in blood suctioned during surgical prostatectomy.[5] Authors of the study expressed concern and proceeded to speculate as to why this phenomenon existed. Robotic prostatectomy is promoted among physicians as having a lower rate of "positive margins." [16] Positive margins is an indication that not all of the cancerous tissue was removed during the surgery. The procedure may be promising, but it remains there is no evidence that robotic prostatectomy improves curative outcomes. It is still surgery and prostate cancer cells are still released into the blood stream.[5]

> *"In an attempt to understand the paradoxical observation of disease progression after radical*

retropubicprostatectomyinmenwithpathologically confined carcinoma several mechanisms have been hypothesized, including aggressive biological behavior with unrecognized metastases, ***local and possibly distant dissemination associated with the surgical procedure****, faulty pathological assessment, and perhaps an antecedent event, such as multiple independent* ***puncture biopsies****"* [5]

Another advantage claimed by robotic surgery is the improved ability to perform the surgery while allowing the patient to retain sexual function. This is described as "nerve sparing" surgery. The robotic technology in theory has greater precision to separate the prostate gland from the delicate nerves and vessels of the neurovascular bundle from prostate glandular tissue. Unfortunately, the numbers have not yet demonstrated improved results over any other treatment method.[9,15,17] This surgery continues to be described as "extremely difficult" by the top surgeons in the country. They have good reason. In addition, it is now accepted that robotic surgery has a significant learning curve for surgeons. Some publications cite a requirement that as many as 200 surgeries must be performed before proficiency is achieved.

"Nerve Sparing," but what about Curative Intent?
"I try not to touch the nerves at all," said (urologist), a warm man with a gentle manner. He is, of course, limited by how far cancer has advanced. In 80 percent of cases he is able to perform maximum nerve-sparing, resulting in a return to continence for 97 percent of patients and sexual function for 87 percent, within 6 months." [18]

*Is **Open Radical Prostatectomy** a Better Method for Nerve-Sparing Surgery? "For any surgeon, this procedure—technically, the anatomical radical retropubic prostatectomy—is a bumpy, treacherous road. There can be extreme blood loss. It takes years of training before a surgeon can handle the unexpected bleeding without panicking—and also without inadvertently damaging the fragile nerves. An experienced surgeon, too, **can tell much by tactile sensation**—literally, feeling the tissue for hardness, adherence, or other signs of cancer, and deciding how best to remove it."*[19]

The benefit of a shorter hospital stay does not offset the high cost of the equipment or the procedure. [2] *"It is costly. (Urologist) performs three robotic prostatectomies a day. His team nurse jokes that "we're heading for drive-thru surgery in this country" to cut down on hospital time. But the price can still reach $45,000.00 to more than $70,000.00 depending on who does the surgery"*[18]

Has Robotic Prostatectomy Delivered on Its Promise? *"Prostate cancer patients' biggest concerns—after cure—are the possible side effects of surgery, including urinary incontinence and sexual impotency. Data on these side effects from robotically assisted prostatectomy were sketchy at best, and no evidence was available to indicate that any surgical method emerged as better than another for these side effects."* [2]

> *"Although they may ultimately decide on treatment, there is no apparent gain to making this management decision quickly with the belief that a delay will compromise cure. Second, when selected carefully by use of criteria that suggest the presence of small-volume, lower-grade cancer*

and then monitored with a rigorous protocol for disease progression, these patients appear to have the same risk of non-curable prostate cancer ***for at least 2 years after diagnosis*** *as those patients who received immediate prostate cancer surgery. Our data thus suggests that this expectant management approach (like CDM) should be used more frequently, given that approximately 50% of men today are diagnosed with low-risk prostate cancer."* [20]

Summary

The increasingly aggressive search for cancer by repeated needle biopsies will inevitably lead to more and more unnecessary surgeries, more failures to cure and a growing number of men and their families suffering from the devastating side effects of incontinence and sexual dysfunction. There exists no compelling evidence at this time that robotic prostatectomy will deliver any improvement whatsoever over the current poor rate of cure for all other radical, curative treatments. What is truly alarming is that the effort to find more cancers by more than doubling the rate of biopsy, will only serve to increase the devastation that exists today. **Ironically, increasing numbers of insignificant cancers included for treatment, will only serve to (falsely) indicate better cure rates for robotic prostatectomies.** Of course, this will only incentivize urologists to treat even more cancers. Additionally, urology is trending to treat more aggressive cancers, Gleason 8 and above, without confirming prior to actual surgery that the cancer is organ-confined with a 3 T MRI scans. The number of failures, exceeding 1,000,000 men, could easily double in the near future. What of these men and these families? The only

reasonable conclusion is to discontinue curative treatments such as robotic prostatectomy, for the majority of positively diagnosed men until proof exists that these treatments can successfully cure prostate cancer. When will the cure become more dangerous than the disease? I think we have already reached that point!

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