

PART I - 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 2007¹. It is projected that the number could double in 2008. Robot assisted laparoscopic prostatectomy (RALP) is now accepted by Urology as the “gold standard” of curative treatment for Prostate Cancer. Like conventional laparoscopic surgery to remove the prostate gland, “robotic” prostatectomy is presented and described as a “minimally invasive” procedure. 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 is still fairly 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. Last year, 2007, it is estimated that 50,000 robotic prostatectomies were performed.¹ The rate of procedures is still climbing, with projected 80,000 procedures 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, focused ultrasound ablation, 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.

“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 in 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, exceeding 30%, 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 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 released by the American College of Preventive Medicine last year 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. 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 treatment and with it the rate of needle biopsy, this number 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 not know this, understand the implications and increase the rate of radical, 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 diagnose, stage and grade the cancer according to location, extent and aggressiveness (Gleason Score). Failure rates for Gleason 8 and above are very high within the first 7 years. 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 much higher than a discussion of risk 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, to have any chance to remove the cancer from their body before it has an opportunity to spread outside the prostate. 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, can potentially double in 2008. The rate of needle biopsy already has doubled and more.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. 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

PART II: *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 report higher rates of cure. Nevertheless, freed from PSA elevation for five years is too short a time-frame to determine the effectiveness of this 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 of 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. With a PSA of 20 following curative treatment, a bone scan still can only detect metastases in 1 of 1000 cases.⁸

“Bone Scan. In patients with a PSA <10.0 ng/ml, the chance of a positive scan is approximately 1:1000. May be used as a baseline study. 30-50(%) of bone mass 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.” Urologist to Wall Street Journal Blog ¹⁰

“Twenty nine out of 40 T1 stage histological cancers (67.5%), had volume less than 1cc. The highest volume tumours were those of intermediate and high grade (Gleason sums 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 overtreatment 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 nonpalpable 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

“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) rather than deferring treatment with active surveillance.” ¹²

“Definition of a “clinically insignificant” tumor is Gleason 6 or less and less than 0.5cm 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

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. 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 the patient. Considering the poor outcomes of treatment, there is a strong argument that these cancers should not be treated radically. Gleason 6 cancers become weakened 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

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 teams new to robotic or laparoscopic surgery should initiate their programs with mentors to avoid ‘sacrificing’ the first patients.”¹⁵*

Part III: “Biochemical Failure” – 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.

A study published in 1996 revealed that in 91% of cases, prostate cancer cells were present in blood taken 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. Prostate cancer cells are released into the blood stream.⁵

*“In an attempt to understand the paradoxical observation of disease progression after radical retropubic prostatectomy in men with pathologically 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 has been 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.”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 noncurable prostate cancer **for at least 2 years after diagnosis** as those patients who received immediate prostate cancer surgery. Our data thus suggest that this expectant management approach 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 number 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. The number of failures, exceeding 1,000,000 men, could easily double within the next few years. 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?

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