

***Prostate***  
ONCOLOGY SPECIALISTS

## ACTIVE SURVEILLANCE FOR PROSTATE CANCER

Overview and Answers to Common Questions



Active Surveillance is rapidly gaining acceptance as viable treatment for prostate cancer. The lifestyle of living with prostate cancer is not particularly attractive since it requires periodic blood tests, prostate scans and doctor visits, not to mention the feeling of uncertainty of living one might have with untreated cancer. However, Active Surveillance shines as the most attractive alternative compared to the collateral devastation caused by surgery or radiation.

## A BETTER FUTURE REQUIRES WAITING

When choosing the right treatment, patients are faced with several bad alternatives. Presently, there is no treatment option that is both effective and nontoxic. However, techniques and technology for prostate imaging are steadily improving. In the future, doctors will be able to target the cancer rather than the whole prostate. Someday, treatments like surgery and radiation that destroy the whole gland will become antiquated. Choosing Active Surveillance enables the patients who wait for future technological advancements to escape the present no-win situation.

## WHAT ABOUT THE MEN WHO DIE FROM PROSTATE CANCER?

Understandably, monitoring cancer rather than treating it sounds radical. We would lose all credibility if we glossed over the potential dangers of cancer. Prostate cancer can indeed be deadly. However, prostate cancer behaves very differently than most cancers.

To get a rough idea of what we are talking about let's briefly compare prostate and colon cancer.

	Prostate Cancer	Colon Cancer	Difference Factor
Deaths Annually	28,000	26,000	1 : 1
New Cases Diagnosed	241,000	73,000	3.5 : 1
Mortality Rate	8.5%	35.5%	4.2 : 1
Average Survival if Relapse Occurs	13 Years	13 Months	12 : 1

As summarized in the table, men with prostate cancer are three-and-a-half times less likely to die from the disease. The minority who die, do so *twelve times more slowly*. Sadly, almost all cancers—lung, pancreas, stomach, gallbladder, kidney, brain, bone, etc.—behave like colon cancer rather than prostate cancer. People with colon cancer, or practically any other common cancer, are at far greater risk of early mortality.

So it's completely logical for the general population to be terrified by cancer. It's the second most common cause of death after heart disease. And when someone dies from prostate cancer, it's "Big News," because the media knows there are 2.8 million prostate cancer survivors living in the US that personally relate to having prostate cancer.

The fact is that 91.5% of men with prostate cancer live a normal life expectancy and die of natural causes. The 8.5% who will die, live an average of 13 years after diagnosis. This is why people say, "The worst possible prostate cancer is better than the best type of any other cancer." In our book, *Invasion of the Prostate Snatchers*, we stated there are two distinct types of prostate cancer: "One grows slowly and the other that grows extremely slowly."

## DISTINGUISHING BETWEEN "GOOD" AND "BAD" PROSTATE CANCER

Since only a small percentage of men with prostate cancer die, the real question is, "Can doctors predict which types of prostate cancer will behave more aggressively?" The answer is an unequivocal yes. Distinguishing the "aggressive" type of prostate cancer from the extremely low-grade type is based on the extent of the disease as reflected by PSA, biopsy findings and imaging studies. In addition, the tumor grade of the biopsy specimen is highly important. Table 2 provides some general guidelines for selecting the men who are eligible for Active Surveillance.

	Favorable	Unfavorable
PSA	Under 8	Over 15
Percentage of Biopsy Cores	A third or less contain cancer	Over half contain cancer
Imaging	Tumor < 10 mm max dimension	Tumor > 18 mm max dimension
Gleason Grade	Grade 3 + 3 = 6 or less	Grade 4 + 3 = 7 or higher

The decision to pursue Active Surveillance is based selecting cancers that have been detected at such an early stage that *even if they grow while under observation, they will still be curable*. This is the beauty of Active Surveillance. The men who end up getting treatment have the type of prostate cancer that really needs intervention. All the other men are spared from destructive treatments. The good news is that Active Surveillance is not simply an attractive theory; it is a scientifically proven fact.



## ACTIVE SURVEILLANCE VERSUS THE “GOLD STANDARD”

Ten years ago surgery was regarded as the “Gold Standard,” the treatment to which every other kind of treatment should be compared. Now you rarely encounter the Gold Standard argument to bolster surgery as the preferred treatment approach. What scientific studies led to this change in perspective and why has it taken so long for it to come about?

## FINALLY, A CLEAR ANSWER

The final nail in the coffin of the “Gold Standard” argument occurred in 2012, when the *New England Journal of Medicine* published a study by Dr. Timothy Wilt comparing the long-term outcome of surgery versus observation alone.<sup>1</sup> Between 1994 and 2002, seven hundred and thirty-one men volunteered to undergo either surgery or observation *based on a coin flip*.

## NO BENEFIT FOR “GOOD” CANCER, MODEST BENEFITS FOR “BAD” CANCER

The average age for the whole group of men was 67. The median PSA was 7.8. The study ultimately concluded that after ten years there was no difference in prostate cancer mortality with either approach. Mortality was within the expected range of statistical variation (5.8% died in the surgery group and 8.4% died in the observation group). A small survival benefit for surgery was seen in men with a PSA over 10.<sup>1</sup> (Mortality was 12.8% in the observation group and 5.5% in the surgery group.) Dr. Wilt also reported the side effects of surgery (See Appendix).

Even before Dr. Wilt’s report was published, Active Surveillance had been gaining mainstream acceptance in the medical community. Multiple, independently-published studies reach the same conclusion: Active Surveillance is safe. Some of these studies are briefly summarized in the next few paragraphs. The link to the full abstracts are posted on our website at [www.keepmyprostate.com](http://www.keepmyprostate.com).

## DO ALL MEN HAVE PROSTATE CANCER?

One of the most compelling arguments for avoiding radical treatment is based on the fact that prostate cancer is simply too common in the general population to represent an imminent threat to life. Studies of prostate glands removed from men dying of unrelated causes show that by the time they die, most men have prostate cancer.<sup>2</sup> The fact prostate cancer is incredibly common in the normal male population is also supported by another report from the *New England Journal of Medicine* where 4,692 healthy men over age 50 with a normal PSA (average 2.7) volunteered to undergo a simple six-core prostate biopsy. The resulting biopsies showed that one-fourth of the men had cancer.<sup>3</sup>



## MANY STUDIES, SAME CONCLUSION

Additional research has compared Active Surveillance with surgery. For example, a study from Johns Hopkins Hospital reported that life expectancy is only extended an average of 1.8 months by having immediate surgery.<sup>4</sup> Another study in the *Journal of Urology* confirms that the grade of the tumor is an excellent method for determining which type of cancer is safe to monitor, because prostate cancer mortality was almost nonexistent in 12,000 men with Gleason grade score of six or less who were monitored for 12 years after surgery.<sup>5</sup>

Additional studies reporting the long-term outcome of Active Surveillance have been published: In a ten-year study of 1,000 men undergoing observation at Johns Hopkins Hospital, not a single man has died of prostate cancer or developed metastases.<sup>6</sup> In another study of 450 men undergoing observation in Toronto that included some men with grade 7 disease, only five out of 450 men died of prostate cancer.<sup>7</sup>

## THE DARK SIDE OF TREATMENT

The idea of living with cancer may not seem at all attractive, but once the side effects of surgery are factored in, Active Surveillance starts to look really good. Unfortunately, the side effects of radical treatments like surgery are universally underemphasized by doctors and patients alike. Doctors downplay the effects of surgery because their years of working in the field accustom them to impotence and incontinence in their patients. The patients who have undergone treatment and are lucky enough to have had a good outcome, sing the praises of that treatment because they took a radical step to remove their cancer and were fortunate enough to avoid bad consequences. The patients with negative outcomes are frequently too embarrassed to talk about their diapers and sexual incapacity. They minimize the bad effects of the treatment and emphasize their gratefulness about “having been saved from cancer.”

The fact is that surgery and radiation both cause permanent side effects with astounding frequency. In a study of 475 men, four years after having surgery or radiation, less than 20% of men described their sexual function as returning to normal.<sup>8</sup> In another study of 785 men, three years after surgery or seed implantation, less than 20% of men who had surgery and less than 50% of the men who had seeds, described their sexual function as returning to normal.<sup>9</sup> Unfortunately, to many people, all these statistics are an abstraction. Nevertheless, the tragedy of *unnecessarily* destroying even one man’s sexual identity cannot be calculated.

## AT FIRST, NEW THINKING ALWAYS SEEMS RADICAL

Let me close by acknowledging that Active Surveillance involves a totally new way of thinking. The very first conference to review the science of Active Surveillance was convened in San Francisco in 2007. At that time two hundred prostate cancer experts laid down the basic guidelines for Active Surveillance. Doctors around the world are still being introduced to the idea of Active Surveillance. Believe it or not, some doctors have not even heard about it. Inevitably, it takes time for people to change. Even so, that’s no reason for any of us to be trapped in outdated thinking.

## COMMON QUESTIONS PEOPLE ASK ABOUT ACTIVE SURVEILLANCE:

### Why do many doctors who treat prostate cancer still act lukewarm toward monitoring?

1. Historically, all cancers have been treated, almost always with surgery. As recently as five years ago, most experts believed that all types of prostate cancer need treatment.
2. Delaying treatment risks a malpractice lawsuit if cancer were to spread. So far, no doctor has been successfully sued for recommending surgery or radiation.
3. The doctors who manage men with prostate cancer are surgeons (urologists). Obviously they tend to favor surgery. The old saying bears repeating, “If you are a hammer, everything looks like a nail.”
4. Prostate cancer experts specializing only in prostate cancer are extremely rare. Considering the complexity and rapidly changing nature of prostate cancer, it’s no surprise that keeping up with the latest studies is difficult.
5. Educating frightened patients about Active Surveillance takes time. It’s even more time consuming for doctors to be explaining something complicated when they don’t get practice doing it.
6. Most doctors have not studied the issue thoroughly enough to be totally convinced themselves that Active Surveillance is really safe.
7. If all things are equal, doctors prefer to give patients what they want; whenever “cancer” is in the discussion, patients naturally are biased toward treatment. Population statistics are cold and removed. Doctors sitting across the table from frightened patients want to satisfy their patient’s passion for getting a cure.
8. Doctors are humans and are influenced by financial incentives just like anyone else. Treatment happens to pay far better than observation.

### Why are many patients biased toward treatment?

1. In their frightened state they don’t fully understand the implications of being saddled with lifelong irreversible side effects from surgery and radiation.
2. They don’t have a doctor who whole-heartedly supports the concept of Active Surveillance. Therefore they don’t receive any emotional support for doing Active Surveillance.
3. Good statistics and probabilities don’t provide enough reassurance. With cancer everyone wants 100% certainty. Preconceived ideas about the deadliness of cancer are hard to overcome.
4. Resolution and closure feel good. Cutting out cancer sounds very attractive. Families and friends are frightened as well and they often insist on treatment.
5. Forgoing treatment might frighten business partners (or voters) who would conclude that you have terrible judgment or perhaps you are in total denial. (Warren Buffett and John Kerry are examples).

## Why come to Marina del Rey for Active Surveillance?

1. We have substantially more experience with Active Surveillance than anyone else in Southern California.
2. We are internists (with subspecialty training in medical oncology), rather than surgeons or radiation therapists.
3. We are impartial about whether or not a treatment is administered or withheld. We simply want our patients to be managed according to their specific needs.
4. We only treat prostate cancer. For urologists and radiation therapists, prostate cancer patients represent only a small percentage of their medical practice.
5. We are skilled at radiographic imaging with Color Doppler Ultrasound and Multi-Parametric MRI. Quality imaging is essential for optimal Active Surveillance.
6. Our philosophy is to educate and empower patients so they can intelligently participate in decisions about treatment.
7. We use biopsy as sparingly as possible because of concerns about side effects. When biopsy is called for, we rely on targeted techniques (rather than random biopsies).
8. If during Active Surveillance the determination is made that treatment will be required, we are the leader in deciding which treatment is best and which doctors are the most skilled performers. We refer hundreds of men every year to radiation and surgical experts when their prostate cancer is of the more serious type.

## What is the Active Surveillance Protocol?

1. PSA tested every three months.
2. Color Doppler Ultrasound imaging performed once a year.
3. Multi-Parametric MRI imaging performed once a year at a selected facility.
4. Avodart and Proscar are occasionally employed.
5. Targeted biopsy is used to evaluate suspicious changes noted with imaging.



## APPENDIX: SIDE EFFECTS OF SURGERY

In Dr. Wilt's study, during the first 30 days after surgery, there were a number of very serious side effects including one death. Additionally, there were two men with blood clots in their legs, one stroke, two with blood clots in the lungs, three heart attacks, one man with renal failure requiring dialysis, ten which required additional corrective surgery, six who required additional blood transfusions and six who still had urinary catheters more than 30 days after surgery.

Forty-nine men (17%) who had surgery compared to 18 men (6%) who underwent observation "have a lot of problems with urinary dribbling, some losing larger amounts of urine than dribbling but not all day," others who "have no control over urine," and the remainder "have an indwelling catheter."

231 men (81%) who had surgery compared to 124 men (44%) who underwent observation had erectile dysfunction defined as the inability to attain an erection sufficient for vaginal penetration.

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