PROSTATEFORUM

Active Surveillance To Proactive Growth Arrest Solutions

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INSIDE:

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Puzzle Points

- Active surveillance is widely recognised as an option that appears to be safe if done according to established guidellines.
- Before choosing active surveillance, iit is important to obtain a color Doppler ultrasound, Dynamic contrast-enhanced MRI, or Endorectal MRI.
- Once on a program of active surveillance, you should be sure to get your PSA done every 3-4 months and further imaging studies on a timely basis.
- At AIDP we take active surveillance several steps further. My Growth Arrest Program attempts to slow or arrest prostate cancer with several proactive solutions included on page two of this newsletter.

In Volume 11 # 3 of this newsletter, I reviewed two recent clinical trials that evaluated prostate cancer screening. In that issue, I briefly addressed the concerns that prostate cancer may be over diagnosed and over treated. In this issue, I'm going to delve into those two issues in greater detail.

While there are many controversies within the prostate cancer field, there now seems to be nearly universal agreement that many men with newly diagnosed prostate cancer do not need either surgery or radiation therapy. There is even an emerging consensus on how to identify these patients (Table 1).

At present, patients with cancer that matches the criteria in Table 1 are often offered an approach that involves measuring their PSA every 3 months, rectal exam every 3-6 months, and

Table 1. Characteristics of Candidates for Active Surveillance

Gleason total	*6 with no pattern above 3*
PSA	*At or below 10 ng/ml*
Proportion of cores positive	*One third or less*
Proportion of a core involved	*No more than half*
PSA progression	*Stable PSA*

transrectal ultrasound with or without biopsy every year or two. As will emerge later in this discussion, you'll find a surprising large proportion of the leaders in urologic surgery have reported favorable results using this approach.

My approach is radically different. I am a medical oncologist who largely sees men with cancer that was metastatic at diagnosis or is growing after surgery or radiation therapy. In those patients with more aggressive cancer, I will often try to kill as many cancer cells as possible first. Then I will work hard to arrest or slow the re-growth of their cancer. In the last issue of this newsletter, I recounted a number of patient histories in which I was able to dramatically slow or arrest the growth of the man's cancer.

As a result of that experience, I know of a group of drugs and supplements that slow prostate cancer progression. As I outlined in that issue, these agents come from three areas of research. The first area is on how to reduce PSA doubling time. The second area of research focuses on how cancers can be made dormant. The third area focuses on agents that act as differentiation induces.

When I see a patient who is a candidate for active surveillance, I recommend that they make the changes listed in Table 2 in addition to the usual surveillance measures mentioned above. For want of a better term, I call this growth arrest because that is the intent of the program. As you will no doubt note, the agents listed are not only nontoxic, but are likely to improve a man's general health.

Since I do not expect these patients to die anytime soon of prostate cancer, I also look carefully at other causes of illness and death common in prostate cancer patients. The common other causes of death in this patient population include heart disease, stroke, diabetes, lung cancer, and colon cancer. With this in mind, I strongly discourage cigarette smoking. I recommend a Mediterranean heart healthy diet and exercise. If that does not lead to adequate control of cholesterol and blood pressure, I strongly recommend patients start prescription drugs for cholesterol and blood pressure. If the patients are obese, I recommend they try to lose weight. Finally, I strongly recommend patients have a colonoscopy done at appropriate intervals.

Table 2. Moving from Active Surveillance to Growth Arrest

Avodart or Proscar (finasteride)
Mediterranean heart healthy diet
Exercise aerobically 30 minutes a day with resistance exercise three times a week.
Reverse vitamin D deficiency
Pomegranate juice or extract capsules
Lycopene
Soy isoflavones
Fish or fish oil
Antioxidants*
Aggressively treat hypertension, high cholesterol and elevated blood sugar
Reverse obesity
Colonoscopy on a timely basis

**I have traditionally recommended selenium and vitamin E. I'm now evaluating more potent antioxidants like resveratrol and curcumin.*

Now, I'm going to answer some of the questions *Prostate Forum* readers submitted about active surveillance.

How successful is active surveillance? [I've been highly impressed by the success indicated by the Klotz series (started in late 1995) at Toronto, Dr. Carter's Hopkins series, Dr. Scardino's Memorial Sloan Kettering series, Dr. Fritz Schröder's series (Netherlands), the MD Anderson series of Dr. Babaian, and the Peter Carroll series at UCSF. I believe it's important for men to realize that AS success is documented in results from independent, major, highly respected institutions treating prostate cancer.]

This reader is clearly a student of this disease. As this question outlines, active surveillance has been looked at by many widely recognized leaders in urologic surgery. The answer is that somewhere between 20-35% of men on active surveillance need to subsequently undergo surgery or radiation therapy. At the time of treatment, the evidence strongly suggests that these men are not at higher risk because they delayed treatment. So, I think it is proper to conclude that active surveillance is a prudent approach to newly diagnosed prostate cancer patients that fit the criteria listed in Table 1. This should be the standard approach to men in this setting.

Why do some leading doctors oppose active surveillance?

I think there are many different reasons leading doctors oppose active surveillance. First, some really excellent surgeons and radiation therapists strongly believe in what they do for a living. They believe that they can cure prostate cancer patients and can do so with almost no damage. Of course, studies have shown that such physicians routinely underestimate just how much damage they do to patients. Part of this is because patients are not always completely frank with physicians about how much harm they have experienced. Part of this is because many physicians minimize the harm they cause. Some of these physicians do not believe the published results that delayed treatment does not create a danger for the patient. Finally, some of these physicians think that the value of active surveillance should be tested in randomized controlled trials before it becomes standard therapy.

After prostatectomies, many biopsies determine low grade aggressive, small volume prostate cancers are found to be more dangerous. What additional diagnostic tests should be done before opting for active surveillance?

This is why it would be ideal to be able to visualize each cancer within the gland and follow its size. As you so correctly point out, it is fairly common to find in radical prostatectomy specimens prostate cancers that were missed using routine transrectal ultrasound.

Right now, the gold standard for detecting all of these cancers would be a saturation biopsy where between 40-100 biopsy cores are obtained. This is traumatic enough to require general anesthesia. Most patients are reluctant to go through this procedure. I am also not enthusiastic, as I have seen patients damaged by this procedure.

In my experience, the next best approach is color Doppler ultrasound. Unfortunately, this is not widely available and is apparently a difficult technique to master. As a result, I prefer to send my patients to Duke Bahn in Ventura, California, who seems the best at this business.

Endorectal MRI has also been mentioned as a possible tool. This is a rapidly advancing technology. At present, it seems quite reliable as a means to detect when the cancer is invading the capsule surrounding the prostate gland. I have seen it commonly miss cancers within the prostate tissue. Dynamic contrast-enhanced MRI appears to be an important advance in this technique and does a much better job in detecting cancer within the gland. Because of the inherent advantages of MRI imaging, I suspect this will eventually replace color Doppler in my clinic.

I should also mention the serum prostatic acid phosphatase. This is an older blood test, but is still of value as it increases as the cancer leaves the prostate gland and establishes metastases. If I am concerned that a patient might well have

much more of a problem than was previously suspected, I will get this blood test. If it is elevated, active surveillance is out of the question and we move on to looking for spread to lymph nodes or bone.

What are the chances that an apparently low-risk cancer will spread undetected during active surveillance and become a more serious, harder to treat, less likely to cure cancer?

As I mentioned earlier, the studies published to date strongly support the idea that the cancer does not become harder to treat or less likely to be cured. And as I mentioned above, this is the reason I send many patients to Duke Bahn in Ventura, California for a color Doppler ultrasound. In all fairness, I think it is easy for the disease to become wide spread and incurable if patients with more aggressive disease proceed with active surveillance. In Volume 11 # 9, I recounted the histories of several patients who should not have done active surveillance, but nevertheless have done so successfully. In general, I think active surveillance is quite risky if you have a large cancer, are Gleason 7, or have a PSA greater than 20 ng/ml or a rapidly increasing PSA.

How can anyone stand the idea of living with prostate cancer when you could get it all out and be done with it?

Well, many men have no trouble with this. I think there are several key factors men need to keep in mind if they go on active surveillance. First, men who have surgery or radiation therapy are never the same as they were before treatment. At the very least, even if they remain sexually active, sexual function will be altered in some way. Most will also have some problems with their urinary tract function. Even in the best of hands, some patients will experience complete loss of sexual function or severe compromise in urinary tract function. There is no reason to accept these limitations on your quality of life if the cancer is not a serious risk to your life and if delaying treatment does not place you at higher risk from prostate cancer.

I also think many people have an inappropriate fear of cancer. Newly diagnosed low-grade prostate cancer is much less a threat to your life than newly diagnosed diabetes or a systolic blood pressure of 140 mmHg or more. An even better example is an elevated LDL or bad cholesterol. A LDL cholesterol above 200 poses a serious risk of a heart attack. Yet, I have had men with a LDL cholesterol in this range refuse statins, yet choose to proceed with surgery for a small Gleason 6 cancer. That shows a profound defect in their ability to assess relative risk.

The fact is that most men over age 65 already have whatever disease is likely to kill them, even if it has not been diagnosed yet. Somehow, in many men low-grade prostate cancer triggers a fear that is out of proportion to the threat the cancer actually poses.

Can you be too young for active surveillance? I've heard that some well-known surgeons only want older men, near 70, in their active surveillance programs.

Well, age can be a factor. Men with newly diagnosed prostate cancer are unlikely to start dying of the cancer for at least 6 years. If you have other serious illnesses and are not likely to survive them for five years, there seems little reason to screen for prostate cancer, let alone treat it. In the same vein, low-grade prostate cancers do not usually cause any clinical problems for 10-20 years. In selecting men over age 70 for active surveillance, the surgeons are selecting a group of men at increased risk of dying of something else.

However, it is also true that I frequently run into surgeons who strongly object to active surveillance in young men. This is true for some radiation therapists. This objection seems more emotional than logical to me. At the present point, the studies have shown that delaying treatment of low-grade cancer does not put the patient at increased risk for potentially curative treatment.

Of greater concern, there is no randomized controlled trial showing a survival benefit to surgery or radiation therapy in low-grade prostate

cancer at any age. So, these surgeons and radiation therapists are pushing a treatment that is potentially damaging when they have not demonstrated the need for the patient to subject themselves to the risk of damage.

I would turn this issue around. If you are 45 years old and have surgery, you might face an additional 45 years of urinary incontinence and pay a big price in terms of sexual function. You should be sure you need to pay that price. The current evidence suggests that there is more than a 50% chance you do not need to pay that price. Furthermore, current best evidence suggests that you will not pay a price for avoiding surgery or radiation therapy until you need it.

My stance is sure to trigger controversy and anger in some quarters, but I think the evidence clearly supports what I have said.

Should a patient considering active surveillance have a color Doppler ultrasound or other extraordinary staging imaging? Most or all of the major active surveillance programs do not seem to go that far. [I sure would want it. I'm wondering why the major active surveillance programs have not moved in that direction. Maybe they are. Maybe they figure the benefit is just not worth the cost or potential discouragement of men from entering their programs, considering the travel, etc. involved.]

You are correct: most of the major active surveillance programs do not use extraordinary imaging studies. However, I have often sent my patients for endorectal MRI. Most of my patients also have a color Doppler ultrasound done by Dr. Duke Bahn in Ventura, California. Over the past few years, I have been very impressed with the results he has obtained. In patients who would otherwise be candidates for active surveillance, Bahn has identified more aggressive disease in 15-20%. I have therefore been able to steer these patients with more aggressive disease to surgery or radiation therapy. The results with endorectal MRI have been less impressive, but that may well be because this is a technology in rapid evolution.

If I go on active surveillance, should I be taking finasteride or Avodart to improve my chances of success?

Finasteride and Avodart work by preventing testosterone from being converted to dihydrotestosterone. Clinical trials have now shown that dihydrotestosterone plays a major role in the development and progression of prostate cancer. Administration of either drug reduces the risk of new prostate cancers by close to 25%. Of interest, these drugs increase testosterone levels by 20-50%, yet still decrease the risk of prostate cancer!

Men on active surveillance are not only at risk for progression of the cancer that has been diagnosed, but are also at risk for the appearance of new cancers that may well be more aggressive than the cancer they already have. For this reason, I think finasteride or Avodart make an important contribution to any active surveillance program.

Both drugs are very safe. The only significant side effect is that about 20% of men have a reduction in sex drive that resolves if they stop the drug. The opposite is also true: some men report an increase in sex drive, perhaps as a result of their increased testosterone levels. Nevertheless, the loss in sex drive is a rational reason for a patient not to elect to use either drug.

Since the goal of both drugs is to suppress dihydrotestostone, I make it a practice to monitor dihydrotestosterone blood levels to ensure they are in fact suppressed. Finasteride is the less expensive of the two drugs, but is not effective at suppressing dihydrotestosterone in many patients. If I find finasteride lacking, I will switch patients to Avodart. Again, one Avodart a day is not sufficient for some patients and effective suppression of dihydrotestosterone in those patients may require two to four pills a day. Many physicians think they can manage these drugs without measuring dihydrotestosterone. How they think that remains a mystery to me. It is the equivalent of using statins to treat high cholesterol without ever

bothering to measure if the statin dose used is sufficient to suppress cholesterol. Of course, many will also not measure testosterone during hormonal therapy, a practice that again appears to be completely irrational.

I was diagnosed in May 2009. My PSA was 4.4 and I had a Gleason 6. (My PSA in Oct. 2008 was 4.2 and in Dec. 2008 3.5.) 2 cores out of 12 were positive. Another biopsy in July 2009 showed 2 cores positive (Gleason 6 for one and Gleason 7 [3+4] for the other). I am on active surveillance. My question is: what tests (blood or otherwise) would you recommend to gather information as to the state of activity of the cancer.

First, you have a Gleason 7 cancer, so I would not recommend active surveillance for you. Gleason 7 cancers pose too high a risk to make this a prudent course of action. As I outlined in Prostate Forum Volume 11 # 9, I have a handful of patients who have done so successfully, but most men experience progression and will have cancer that passes beyond surgical management fairly quickly. In those patients who proceed along this path against my recommendations, I measure the following blood tests:

Total and % free PSA
Total testosterone
Dihydrotestosterone
25-hydroxyvitamin D (to ensure the patient is not deficient)
Prostatic acid phosphatase.

In a case like yours, I would have you visit Duke Bahn periodically because such cancers can progress to the inoperable stage without showing much of a PSA increase.

If you are not willing to proceed to surgery or radiation therapy, you would be better suited for my growth arrest program rather than active surveillance.

But again, I think you need to carefully review what you are doing and make sure you fully understand the risk you are taking.

I was tested with a PSA of 4.4 and a Gleason of 4 in December 1998 at age 64. I went on an active watchful waiting program (with a full exercise program), and had a PSA test and DRE every 6 to 12 months. I ate a healthy diet with many supplements that I studied and selected myself. I do a poor man's regression to track PSA and doubling time. My current PSA is 3.2 and my doubling time estimate is negative after 11 years. The DRE shows a smooth round gland but slightly enlarged. I have no negatives at age 75. My question is with negative doubling: am I right to believe that my mode of operation and results show that I am actually shrinking the tiny tumor I started with?

This is an interesting program. So, congratulations, active surveillance has worked so far. However, I think you are seriously overestimating the value of PSA in your case. No, I do not think the PSA changes you list reflect any change in the size of the tumor. I could be much more definitive if you had listed your prostate size and the estimated size of the cancer at the time you started active surveillance. The truth is that most men on active surveillance have cancers far too small to cause any impact on the serum PSA.

So, the change in your PSA almost certainly reflects the amount of PSA produced by your noncancerous prostate tissue. Most men with newly diagnosed low-grade prostate cancer have chronic prostatitis that elevates their PSA because of inflammation. Many of the supplements used by patients for prostate symptoms act by reducing prostate inflammation and this reduces their PSA. With Duke Bahn, I carefully follow the size of a patient's tumor during active surveillance. Despite the fact that I often see a decrease in PSA in my patients, it is rare for their cancers to shrink without specific treatment or powerful drugs like hormonal therapy.

In terms of the surveillance aspect of your program, you mention PSA and rectal exam, but do not mention transrectal ultrasound. All of the successful active surveillance programs specify repeated transrectal ultrasounds, most often yearly. Many would also mandate repeated biopsy of the cancer to confirm no change in pathology.

This is because the cancers can shift to high-grade disease and these lesions can make little or no PSA.

To summarize, I congratulate you on your success so far, but I am concerned you may place too much emphasis on PSA as a method to monitor your cancer.

Can you recommend a comprehensive list of tests (blood and otherwise) that men on active surveillance should have (and the frequency of the tests)? Also, what do you suggest to overcome the reluctance of local doctors to request those tests?

First, I think there is a broad consensus that testing should include a PSA every 3-4 months. Clearly, every 6-12 months is not sufficient as patients can have significant progression in that time frame. In many patients, I include a total and %free PSA because a dropping %free PSA can indicate progressive disease or the appearance of a more aggressive cancer. Because vitamin D deficiency is so common in men with prostate cancer (close to 50% of the men who visit our clinic), I measure vitamin D levels with every PSA and adjust the vitamin D dose to prevent vitamin D deficiency. Since I also often use finasteride or Avodart, I also then monitor testosterone and dihydrotestosterone. The prostatic acid phosphatase remains a useful marker of cancer escaping the prostate gland so in patients with potentially aggressive disease, I will often include this test. The major problem is that Medicare and some other insurance companies will not pay for it. As I mentioned in the previous question, I also typically recommend transrectal ultrasound, preferably color Doppler ultrasound every 6-18 months, depending on the nature of the case. My dependency on color Doppler ultrasound is controversial. Endorectal MRI may also be of use because it seems particularly good at identifying cancers about to invade through the prostate capsule.

If your local doctors do not seem to understand the principles of active surveillance, I recommend you travel to a center experienced in this approach. Re-read the first question in this newsletter: the reader actually listed some excellent urologic surgeons whom I strongly recommend. If you would like to pursue growth arrest rather than active surveillance consider making an appointment with me here in Virginia. As far as I know, AIDP is the only center with a comprehensive growth arrest program.

What is the biggest mistake you see being made by patients on active surveillance?

The surveillance aspect of active surveillance is key. It is your insurance that your cancer will not progress too far before effective treatment starts. After several years of good results, patients can get over confident and think they do not have a problem. They stop getting PSA levels done every 3-4 months; they may stop getting PSAs altogether. They then also forget to get rectal exams and do not have transrectal ultrasound evaluations. Instead of practicing active surveillance, they practice “passive neglect”. These patients will not know if their cancer is progressing until it is too late to render them disease-free. As a physician, I find it heartbreaking when a patient returns after some years with metastatic cancer.

For this reason, I think patients need to realize that active surveillance means that you can never forget about your cancer, never turn your back on your opponent. You should not try active surveillance if you think you do not have the persistence and discipline needed to stay the course.

Now, there were a number of patients who did not understand what I meant when I asked for questions on active surveillance and sent me questions having to do with the treatment of prostate cancer recurrent after surgery or radiation. I'm saving most of these for a later newsletter devoted to questions on more advanced disease, but I have elected to answer several of them here because they touch on some of the points I've already made.

I am 63 and was diagnosed with prostate cancer on March 20, 1998. My PSA was 4.6 and

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Maxine Hey, Medical Assistant, Option #4

I had a Gleason 5. I had a prostatectomy on May 14, 1998. The pathology showed T3a Nx Mo tumor with a Gleason 7. I have had no treatments since, rather relied on active surveillance. My PSA became detectable at 0.06 on May 6, 2002 and doubled two months later at 0.12. It doubled again, 0.29, 33 months later. My last PSA was 0.57 in August 2009. I spoke with my urologist who felt treatment was appropriate at this time and referred me to a radiation oncologist. He plans to schedule a Prostascint scan to ensure that recurrent disease is confined to the prostate bed. He recommends 2 months of androgen deprivation therapy followed by radiation therapy (66 Gy in 33 fractions). My question is: should I continue with active surveillance or proceed with the recommended treatment? I am otherwise in good health except for a diagnosed lumbar stenosis. A facet nerve denervation has reduced my pain significantly. I exercise regularly. I take daily supplements: selenium-200mcg, vitamin D-5000 IU, vitamin E 200IU, 4000 mg fish oil and daily tomato and pomegranate juice. I eat a Mediterranean diet.

The guidelines for active surveillance listed in Table 1 exclude patients with Gleason 7 cancers. The presence of a T3a lesion at surgery makes you high-risk for recurrent disease. Despite all of these negative factors, your cancer has progressed very slowly. Now twelve years after surgery, you do not have detectable metastatic disease and your PSA is less than 1 ng/ml. You have already started many of the elements I list in Table 2. My recommendation would be to put in place the rest of the program, especially the addition of either Proscar (finasteride) or Avodart. I would also be sure that your vitamin D levels were within the normal range. Supplements differ markedly in quality and dose is also important. So, I would make sure that the other aspects of your program included supplement sources of known quality and that the doses used were appropriate. I think it likely that with some effort, the progression of your cancer might be arrested.

Do I need to be concerned about "rising PSA?" If so, what to do?

Here's my personal data: I'm 68 years old,

and in reasonably good health. I'm taking low doses of blood pressure (Altace) and cholesterol meds (lipitor), and have a slight kidney deficiency.

My PSA at diagnosis was 2.4 and has been steady at that level for several years.

I was diagnosed in August 2001. I had an RP in February 2002. (The results were clear margins and lymph nodes. I lost no functions.) My Gleason on biopsy was 7. (I asked for a biopsy on a hunch; my Uncle had had prostate cancer and mother had had breast cancer.)

I know that PSA doubling time is important. Here are some recent PSA values to help you determine my doubling time.

Feb 2002 to May 2006 = "less than 0.1" (Older test.)

March 2007 = 0.02 (new more sensitive test)

January 2008 = 0.02

November 2008 = 0.03

August 2009 = 0.03

Here is another case of possibly recurrent cancer that presents with interesting issues. You have a PSA that is advancing very slowly. At this pace, even without any treatment, your cancer is not going to cause you problems for a long time. Surgery was close to 8 years ago and your PSA is not yet 0.05 ng/ml. You have several options.

First, you have a decent chance of going into complete remission with salvage radiation therapy. However, radiation therapy after surgery very frequently worsens incontinence. Additionally, if you are potent after surgery, the odds are high you will experience some loss after radiation. You have hypertension and elevated cholesterol, both additional risk factors for loss of potency.

The second approach is to do nothing. You would avoid the side effects of radiation therapy. At your current rate of PSA increase, it could take more than a decade before you are pressed to do aggressive treatment. On the other hand, you are only 68 and appear to be aggressively treating your other medical problems. With any luck, you can still be doing well into your 80s. So, you may well live long enough for the cancer to cause a problem.

The third approach would be to adopt some version of my growth arrest approach. If you can significantly slow your PSA doubling time, it becomes more likely that you will avoid the need for radiation therapy or other potentially toxic treatment options.

The Bottom Line

Active surveillance has been tested in a number of the leading urologic centers and appears to work well. This approach offers men a chance to avoid damaging therapy, such as radiation or surgery. In the studies to date, an appropriately done trial of active surveillance does not appear to put a man at increased risk for incurable disease. This makes active surveillance an appropriate response to the problem of over diagnosis.

At AIDP, I don't recommend active surveillance, but instead use an approach designed to slow or arrest cancer progression. This approach was developed in my attempt to slow the progression of cancer recurrent after surgery, radiation therapy or even after hormonal therapy or chemotherapy. My goal is to slow your cancer, while improving your general health.

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