

March, 2004

PATIENT POWERline from the desk of Marie Savard, M.D.

RE: Guidelines for Surviving Prostate Cancer

Dear Friends,

A friend and colleague, Dr. Roy Berger, has just published a new edition of his book - *Updated Guidelines for Surviving Prostate Cancer* by E. Roy Berger, M.D., F.A.C.P. and James Lewis Jr., PhD.

Many of us have a family member or friend who has been diagnosed with prostate cancer and therefore it is an important topic. Dr. Berger has given me an excerpt from his book dealing with the latest research and findings on the treatment of prostate. Please share this information with anyone you know who could benefit from this most up-to-date information presented in a clear way. The information seemed too important to summarize in my usually small newsletter so I have attached the entire excerpt.

Updated Guidelines for Surviving Prostate Cancer is available at all major bookstores and online at <http://ecpcp.org/books/> or by calling 516-942-5000.

Please visit www.MerckSource.com to download my most up-to-date forms for managing and monitoring your health care. This link will take you directly to that page, http://www.mercksource.com/pp/us/cns/cns_patient_resources_savard_form.jsp.

Please visit www.diabeteswatch.com and click on the blue box "Take Control of Your Health" to download your free Emergency Health Information Wallet Card.

Warm regards,

Marie
Marie Savard, M.D.

Marie Savard, M.D. is an internationally known internist, women's health expert and champion of patient empowerment. She is the founder of The Savard System, dedicated to teaching patients how to manage their own healthcare. She is the author of two highly acclaimed books, *How to Save Your Life: The Savard System for Managing-and Controlling-Your Health Care* (Warner Books, Inc. 2000) and *The Savard Health Record: a Six-Step System for Managing Your Health Care* (Time-Life, Inc. 2000). Dr. Savard is currently writing a book on women's health for Simon and Schuster about the importance of a women's body shape in forecasting their health destiny - and what they can do to reverse that course (Apples & Pears).

Is There A Correct Way To Treat Prostate Cancer?

From Updated Guidelines for Surviving Prostate Cancer
By E. Roy Berger, M.D., F.A.C.P. and James Lewis Jr., PhD.

Is there a correct way to treat prostate cancer? This is a question that hundreds of thousands of patients and their families are asking. The reason is because there is such enormous disagreement among the various subspecialties that treat the disease. I have been a student of prostatic carcinoma for more than 20 years and have participated in research studies that have helped advance the knowledge that is utilized today.

The answer to the titled question must be, “Yes, I am sure there is a correct way to treat prostate cancer.” However, no one who is currently treating it today can be sure that his or her treatment is the right one. The reason for this is that there has not been a significant number of randomized controlled studies to answer all of the questions related to the various treatment modalities. The current selection of treatment options for patients who have early stage disease include: radical prostatectomy, external beam radiation therapy, brachytherapy (seed implant treatment), cryotherapy, combination hormonal treatment and watchful waiting. In addition, there are a several new drugs that are currently undergoing clinical trials that appear promising to make the treatment of prostate cancer less invasive.

The treatment that is preferred by a given physician very much depends upon his or her training as well as biases that result from their own experiences and interpretation of the medical literature. Urologists are more apt to believe in radical prostatectomy as a curative treatment for early stage prostate cancer. Radiation oncologists frequently believe that radiation therapy, by either external beam, brachytherapy or a combination of both is equivalent to the radical prostatectomy results. Some urologists believe that cryosurgical techniques will be proven to be equally effective as the other two modalities.

CURRENT TREATMENTS:

Radical Prostatectomy:

A radical prostatectomy, the surgical removal of the prostate, is performed to treat localized prostate cancer. After prostatectomy, the patient's PSA should drop to an undetectable - or virtually undetectable - level. If it does not do so within a month or so after surgery, it is usually assumed that there is residual cancer in the prostatic fossa or elsewhere in the body. Frequently, this cancer is within the area where the prostate gland used to be, and external beam radiation therapy may be helpful. This will often decrease the PSA to an undetectable level.

Approximately 25 to 30 percent of patients whose PSA level is undetectable following radical prostatectomy will have a gradual rise in PSA within 4 or 5 years. This usually means that prostate cancer has recurred. Because no test will indicate with certainty where the recurrence is located, the recommended treatment is often external beam radiation to the area where the prostate used to be. If the physician believes that the recurrent cancer is elsewhere in the body, he or she may recommend external beam radiation, hormonal therapy, or both. The

goal with any treatment is to get the PSA level as close to undetectable as possible and to keep it at that level for as long as possible.

External Beam Radiation Therapy:

External beam radiation started in the 1970s with the use of box-like fields, which often did not give adequate doses to the prostate but gave a significant dose to nearby structures. This caused acute and long-term side effects. However, with the advent of 3D conformal radiation in the early 1990s, radiation oncologists were able to shape the radiation field much more precisely to the region of the prostate, allowing more radiation to be delivered to the prostate and less to the normal tissues nearby, improving not only the cure rate, but also reducing the side effects of the treatment. In the late 1990s, the advent of intensity-modulated radiation therapy (IMRT) increased this advantage, allowing clinicians to increase the radiation dose to the prostate to a level where cure rates approached or equaled those of surgery while reducing side effects to levels equal to or less than those of surgery. It allows for better control, lower side effects, increased flexibility of radiation delivery, and improved results.

IMRT is a three-dimensional conformal radiation treatment that combines the power of today's computers with advanced delivery devices to produce a highly focused radiation dose that conforms to the area of disease identified by the radiation oncologist and reduces the radiation received by nearby normal tissues. IMRT radiation beamlets are combined by the computer into a precise treatment delivery that results in a high dosage to the cancerous tumors and a lowered dose to the surrounding healthy tissues. IMRT is, without a doubt, the most updated technologically advanced external beam radiation method available.

The medical linear accelerator was first used in the 1950s, which revolutionized the way external beam radiation was delivered to treat prostate cancer. Linear accelerators accelerated electrons to produce radiation that could be aimed with greater precision. By using electromagnetic waves, the device accelerated electrons through a specially designed tube to generate X-rays. However, until the advent of digital diagnostic imaging capability, powerful computers, and specialized software, it was almost impossible for radiation oncologists to conform the external beam radiation to the shape of the tumor. Prior to the advent of CT-based treatment planning, it was actually possible to miss the target. Heavy lead blocks were used and constantly repositioned for each patient. In addition, the therapist had to leave the radiation room to change the direction of the machine and the field size and to insert a new block and any other field changes. The introduction of the multi-leaf collimator (MLC) and other devices has changed the dynamic role of external beam radiation in treating prostate cancer.

The advantages of IMRT include:

- ? Greater reduction of dose to surrounding healthy tissues, thus reducing side effects.
- ? Increased flexibility in treating difficult lesions surrounding critical organs.

- ? Improved conformal dose distributions around the cancerous area.
- ? Advanced approach to 3-dimensional radiation therapy.
- ? Improved potential for curing patients.
- ? Higher tumor controls and lower normal tissue toxicity.

With the more complex delivery of IMRT, there are now too many treatment parameters to be transferred by nonelectronic means; information must be sent from the treatment-planning computer to the delivery device using media such as a floppy disk or by direct network connection. Once delivered to the treatment machine, key parameters are verified by the clinic's medical physics staff to insure a correct delivery.

In the typical planning process, the radiation physicists and physicians design a treatment plan and make use of a computer to display the dose that would be received if the plan were delivered. This plan, which consists of a number of beams from several directions, as well as their relative weights, is changed until which time an adequate dose is achieved. IMRT takes a different approach.

Certain dose prescriptions and dose constraints are given to the computer, and the computer generates a plan that meets these dose goals. There are a number of optimization of types. Each one allows the computer to determine the "best" solution among millions of possible combinations of beam directions and weights. This particular process is called "inverse planning." The physician and physicist determine what doses to deliver to the tumor and what limits on dose should be applied to nearby organs, and the computer determines how to deliver that dose. The process is similar to the one used in image reconstruction in computed tomography (CT). The Corvus treatment planning system of NOMOS Corporation is the first inverse planning system to be used in radiation therapy. Currently, it is used by more than a hundred hospitals and clinics around the world to create complex treatment plans used with IMRT. However, other inverse planning systems are now in clinical use, and it is anticipated that soon all treatment planning for IMRT will be of the "inverse mode."

Seed Implantation and Cryosurgery:

In the 1990s, with the advent of new technologies and procedures, doctors began to return to the two treatments that had not been successful in the past: seed

implantation and cryosurgery. Although many physicians advised patients that these treatments were experimental and should be avoided, many patients chose to ignore them. Today, as a result of the ease of the operation, the minimal side effects, and lowered cost, these two approaches are getting a great deal of attention. In many cases, urologists are being trained to perform either cryosurgery or seed implantation. These physicians are at the forefront of what are potentially more acceptable and, hopefully, more effective therapies for prostate cancer. It is possible that radical prostatectomy and external beam radiation will become obsolete in the future because of the success of investigational treatments such as cryosurgery. Why? Because these treatments are getting results similar to or better than those for radical prostatectomy and external beam radiation. They have less morbidity, they can be used as salvage treatments, and they can be repeated. Patients can receive these treatments in less time, and they are less costly.

Cryosurgery, also called cryoablation surgery, is a technique in which six to eight cryoprobes, small tubes utilizing argon gas, are inserted between the scrotum and anus. They enter the prostate gland to freeze and thus kill prostate cancer cells. Freezing of the prostate was first done about 30 years ago; however, it was abandoned because of severe side effects. With the advent of transrectal ultrasound, it reemerged as a viable technique and an alternative to radical prostatectomy and radiation. During cryosurgery, a 2- hour procedure performed under anesthesia, the prostate is frozen with argon gas circulated in cryoprobes. The physician monitors the procedure using transrectal ultrasound and thermosensors to assure a killing temperature (-20 °C to -40 °C) at the site of the cancer.

Seed implantation is a medical procedure in which a team of physicians (a urologist, radiation oncologist, and radiation physicist) uses a radioactive source to irradiate prostate cancer cells, while minimizing radiation to the surrounding tissues. Patients with low to intermediate Gleason scores usually receive 1-125 seeds, which have a half-life of 60.2 days; patients with higher Gleason scores usually receive palladium-103 seeds, which have a half-life of 17.0 days. In addition, these higher-risk patients often receive hormonal therapy, external beam radiation, or both. The number of seeds delivered can vary from 50 to 120, depending on the anatomy of the patient and the size of his prostate.

Is seed implantation as effective as radical prostatectomy? Will it become the gold standard for treating prostate cancer patients? It is difficult to say. However, we do know this: many, many radiation oncologists who specialize in external beam radiation have become more proficient in seed implantation, as have many urologists. Although no one has taken a survey of the number of doctors "switching over" to seed implantation, we believe that it is gaining momentum. A 12-year study done by Dr. Haakon Ragde indicates that seed implantation is "as good or better" than radical prostatectomy. The Northwest Prostate Institute in Seattle has reported on 215 patients treated with brachytherapy and followed for

12 years. The overall control rate was 79 percent, which is equal to or better than the gold standard of 70 percent for radical prostatectomy. Radiation oncologists in Washington, D.C. (Cancer, July 1, 2000) found that 82 of these patients were considered at high-risk for cancer outside the capsule based on the size of the prostate nodule, Gleason grade, and PSA level; thus, they were treated with both seeds and external beam radiation. Obviously, not all patients should undergo seed implantation only. It appears that only low-risk patients are eligible for this form of treatment. Intermediate- and high-risk patients should get seeds and external beam radiation.

Seed implantation generally has fewer side effects than does radical prostatectomy or cryosurgery. In addition, the recuperation time for most patients treated with brachytherapy is much shorter than with radical prostatectomy, and the procedure is less costly as well.

Hormonal Therapy:

Hormonal therapy is being utilized much earlier in treating prostate cancer than in the past. Work done many years ago by Dr. Fernand LaBrie showed that a combination of two anti-androgenic agents was more effective than any single agent available at that time. This work had been expanded and a number of trials have shown an improvement in disease free and overall survival when an LHRH-Agonist (an injection to deplete the body of testicular male hormone) and an anti-androgen (a pill or pills which block the rest of the male hormone in the prostate cancer cell that is produced by the adrenal gland) are combined. This was first shown to be effective in advanced disease, and now more and more studies are showing that combined hormonal therapy (CHT), when utilized early on, is helpful in better controlling early stage cancer. A number of studies are currently ongoing, showing that patients who receive three months of CHT prior to radical prostatectomy show that about one-third more men have negative surgical margins, compared to patients who go directly to radical, without any hormonal therapy. At this time, there does not appear to be a difference in recurrence rates at 5 years when PSA is used to indicate recurrence. One of the main criticisms of these studies is that the time these patients were on hormones may have been too short to show a benefit. It will be several years before we know whether or not there is a survival advantage for the hormonal group. Other studies have been done utilizing hormonal therapy before, during and after external beam radiation therapy, and those studies have, thus far, shown an improvement in progression free survival and survival as well in some of the studies. However, since radical prostatectomies have been done after even six to eight months of hormonal therapy and the vast majority of patients still have prostatic cancer, hormonal therapy is, in my opinion, not sufficient in and of itself.

Metastatic prostate cancer may be either symptomatic or not. The best treatment at present is CHT. It has been clearly shown that CHT improves progression free survival. Patients with metastatic disease who are asymptomatic must consider whether to begin CHT immediately or delay it. A good way to understand these two options is by looking at the data from the NCI Intergroup Trial, which randomized patients with minimal

metastatic disease to monotherapy versus CHT. Results show that survival time appears to be much greater with CHT. Furthermore, the survival rate was much greater for the men with widespread metastatic disease using CHT. These two observations and other studies confirming the benefits of the early utilization of hormonal therapy, lead us to conclude that early treatment with CHT in patients with minimal metastatic disease will improve their survival time, compared to waiting until symptomatic metastasis occurs. In fact, there is now a trend in the oncologic and urologic communities to treat patients earlier, before symptoms develop.

Watchful Waiting:

In Scandinavia and a number of other areas in Europe, watchful waiting has been used for low-grade prostate cancer patients who have early stage disease. Watchful waiting, or observation-deferred treatment, is a strategy in which a patient is monitored periodically but receives no treatment. Generally this strategy is advised for older men with limited life expectancy, those with localized prostate cancer who do not want to experience the side effects of conventional treatment, and those who have cancers that are not likely to kill them. Although there are certainly arguments in this country regarding observation, the disease specific survival figures do support a place for observation depending upon the stage, grade, and age of the patient.

The question of whether to watchful wait or treat prostate cancer will continue to be asked until there are definitive answers from clinical trials, such as the Prostate Cancer Intervention Versus Observation Trial (PIVOT study). This multi-institutional cooperative study involves comparing early or clinical localized prostate cancer patients who undergo radical prostatectomy or watchful waiting alone (by a randomization process). This study will monitor and report patients in terms of progression-free survival, freedom from metastatic disease, disease-specific survival, and overall survival, as well as quality of life. The results will not be evident until approximately 2008, but 5 years into the study, no survival advantage has been noted in either arm.

THE FUTURE:

Provenge:

With the advent of gene therapy, scientists and researchers now believe it should be possible to create prostate-targeted vaccines that would cause an immune response to search for, locate, and destroy prostate cancer.

Provenge, also known as APC8015, is a prostate cancer vaccine currently in phase III clinical trials sponsored by the Dendreon Corporation. The first one of these phase III trials recently reported results. APC or antigen presenting cells are involved in the initiation and expansion of cellular immune responses to carrier and virus-infected cells. Dendritic cells, the most potent APCs, are trained to detect cancer cells by exposure to the target (Valone et al., 2001). Dendritic cells potentiate the effectiveness of the initiation of T-cell and B-cell (lymphocytes) mediated immune responses. Provenge

activates these cells to mount a more effective immune response against prostate cancer. APCs do not kill cancer cells; rather, they alert effector cells, like T-cells, to the presence of cancer. T-cells are the immune system's attack cells, and thus they attack and destroy the cancer cells. Provenge consists of autologous dendritic cells loaded with PA2024, a fusion protein consisting of human prostatic acid phosphatase (PAP) coupled to a targeting molecule, granulocyte-macrophage colony-stimulating factor (GM-CSF). PAP is a tissue-specific antigen that is expressed only by normal prostate cells and is in greater than 90 percent of cancer cells of the prostate. GM-CSF is a cytokine, which regulates the survival, proliferation, and differentiation of granulocyte (white blood cells) and macrophage progenitors (cells that destroy other cells by "eating" them) and which are a potent stimulator of dendritic cells (Rini and Small, 2001).

Provenge is a vaccine currently in two randomized double-blind, placebo-controlled trials for patients with asymptomatic metastatic hormone-refractory prostate cancer and patients with rising PSA after prostatectomy but no other signs of disease. Patients in the hormone refractory trial must have a pathology record stating that their original tumor was graded as a Gleason Score of 7 or lower. Patients are randomized to either the treatment or control group in a 2: 1 ratio. In the metastatic trial, approximately 275 patients will be enrolled in approximately 60 sites in the United States. The treatment group receives Provenge, which consists of APCs loaded with prostatic acid phosphatase. The control group receives placebo. At baseline, before the first apheresis (blood filtering for dendritic cells), the patient must undergo screening tests to determine eligibility. At weeks 0, 2, and 4, all patients undergo apheresis followed by an infusion 2 days later with either Provenge or a control. This is the active treatment phase. If a patient's disease progresses after the active treatment phase, further treatment is at the physician's discretion. If the patient is in the control group and progresses, he may have the option to join the open-label salvage protocol (i.e., receive the active vaccine).

Potential adverse effects can occur during the collection of dendritic cell precursors (leukopheresis) and during and after reinfusion of Provenge. During apheresis, patients may experience citrate toxicity (numbness and tingling around the mouth and hands) and, rarely, arrhythmias due to low calcium secondary to anticoagulants used during apheresis. In addition, hypovolemia (decrease in the volume of circulating blood) and low blood pressure may occur, as well as pain, bruising, and infection at the venous catheter site. Reinfusion can be complicated by chills, fevers, muscle ache, pain, and fatigue (Burch et al., 2000). In addition to apheresis or infusion-related incidents, there is the theoretical possibility that patients may experience prostatitis due to the induction of an immune response to PAP; therefore, the PSA may rise without disease progression.

Phase I and II

trials of Provenge at the University of California at San Francisco and the Mayo Clinic demonstrated that Provenge is generally well tolerated (Valone et al., 2001).

In the Mayo Clinic trial, patients received two doses of intravenous Provenge every 4 weeks, followed by three doses of PAP-GM-CSF subcutaneously every 4 weeks. The UCSF trial used Provenge only. Patients in the UCSF study had a

higher frequency of antibody responses and higher antibody titers. A substantial number of patients experienced disease stabilization and a longer than expected time to disease progression. Several patients had objective tumor regression on CT scan, and there was decreased PSA in about 20 percent. Both trials supported the efficacy, safety, and tolerability of Provenge in treating hormone-refractory prostate cancer patients.

A double-blind placebo-controlled, randomized, phase III trial was initiated in late 1999 and completed enrollment by mid-2001. A second phase III trial is currently in progress. In late 2002, the Dendreon Corporation announced the results of its first placebo-controlled phase III trial of Provenge: "In addition to delaying the time to disease progression, the investigational cancer vaccine delayed the onset of disease-related pain in patients with hormone-resistant prostate cancer with a Gleason score of 7 or less." For these patients, the probability of remaining free of cancer-related pain while in the study was over 2.5 times higher than for patients treated with placebo. In the same group of patients, median time to disease progression was 9.1 weeks among placebo patients compared to 16.1 weeks in the Provenge-treated group, with a highly significant p value of 0.001 and a treatment effect of 77 percent. In addition, after 6 months of follow-up, the patients receiving Provenge had a progression-free survival nine times that of patients who received placebo (35.9% versus 4%).

In the future, Provenge may be used to delay the need for androgen- deprivation therapy. This is being tested in another trial in patients with hormone-sensitive prostate cancer who have a rising PSA level as the only sign of disease recurrence after radical prostatectomy. Entry into this trial is not restricted on the basis of Gleason Score. In the future, it is hoped that Provenge will be given to prostate cancer patients at high risk of developing a recurrence or at the first detection to enhance the immune system's ability to eradicate cancer cells in the microscopic stage before development of a tumor.

Vitamin D and Taxotere:

Approximately 50 percent of all men diagnosed with prostate cancer will someday have metastatic disease. When metastatic prostate cancer progresses after initial hormonal therapy, it is referred to as hormone-refractory. Hormone-refractory metastatic prostate cancer is at the present time not curable, and all attempts at therapeutic intervention have been based on palliating the disease and reducing bone pain. Because there is no standard treatment for hormone-refractory disease, new therapeutic strategies are definitely needed. A recent strategy that seems to hold some promise, which is in a phase III clinical trial at the Oregon Health and Science University Cancer Institute in Portland, Oregon, under the leadership of oncologist Tomasz Beer, M.D., is the use of a blend or combination of vitamin D and a chemotherapy drug known as Taxotere (docetaxel).

"It's becoming increasingly clear that vitamin D has a host of effects in the body, especially on the growth of tumor cells," said David Feldman, M.D., of Stanford University at a seminar sponsored by the American Institute for Cancer Research in Washington, D.C., in 2002. Dr. Feldman and colleagues concluded that "Vitamin D is anti-proliferative and promotes cellular maturation." It seems clear, they add, "that vitamin D must be viewed as an important cellular modulator of growth and differentiation. Vitamin D has the potential to have beneficial actions on various malignancies including prostate cancer."

Taxotere is a drug in the taxane class of chemotherapy agents, which inhibits cancer-cell division by "freezing" the cell's internal skeleton, which is comprised of microtubules. Microtubules assemble and disassemble during a cell cycle. Taxotere promotes their assembly and blocks their disassembly, thereby preventing cancer cells from dividing and resulting in cancer-cell death. Taxotere can help destroy cancer cells in the body when cancer is discovered, or recurs, after previous therapy.

The following list summarizes what researchers and scientists have concluded from studies of Taxotere and its effects on prostate cancer.

- ? Docetaxel is a semisynthetic chemotherapy drug made from an extract of needles of the yew tree. It is used to treat people with some types of early- and late-stage cancer.
- ? Many chemotherapy drugs stop cancer cells from dividing by interfering with the cells' DNA, but Taxotere acts quite differently. Taxotere changes microtubules, vital structures involved in cell division.
- ? Taxotere, one of the most effective anticancer chemotherapy drugs available, is injected into a vein to treat various types of tumors by attacking cancer cells. It is approved by the FDA to treat locally advanced or metastatic breast cancer that returns after any prior chemotherapy and locally advanced or metastatic non-small cell lung cancer that recurs after prior platinum-based chemotherapy.

Taxotere is given intravenously every 3 weeks, with each treatment lasting about an hour. In worldwide phase II clinical trials, Taxotere demonstrated the highest tumor response rates ever reported for a single agent in men with hormone-resistant disease.

Taxotere with Other Drugs

Clinical trials have suggested even more activity for regimens based on Taxotere. This agent is commercially available and is approved in the United States for the treatment of lung and breast cancer. Many oncologists now offer this drug in various combinations as first-line therapy against hormone-refractory prostate cancer. In initial studies as a single

agent, Taxotere has demonstrated responses in nearly 50 percent of patients treated. Although Taxotere has significant side effects, studies with a weekly schedule of therapy have demonstrated significant activity and less toxicity.

Taxotere has been combined with estramustine in a number of clinical trials. These combinations have demonstrated the highest activity ever seen from chemotherapy against hormone-refractory prostate cancer. PSA responses have been seen in many patients. As many as 75 percent of patients receiving Taxotere-based combinations have had a 50 percent reduction in PSA, 43 percent have demonstrated a 75 percent reduction, and as many as 20 percent have demonstrated a complete normalization after therapy. In addition, patients receiving Taxotere-based combinations have also had a prolonged period before progression of PSA as well as significantly less pain.

Clinicians today are faced with the dilemma of which regimen to use. A recently concluded clinical trial compared the regimen of Novantrone plus steroids with Taxotere plus estramustine. These results should be available within the next several years. In the meantime, patients and physicians will need to consider the available clinical data and toxicities. From the patient's perspective, there are at least two effective chemotherapy regimens, both of which have shown the ability to delay disease progression and improve the patient's pain. Perhaps the sequential use of both regimens will lead to further improvements and perhaps an improvement in duration of survival as well.

Changing Your Mind about Chemotherapy

Developing hormone-refractory disease remains a serious complication for patients with prostate cancer. Recent clinical data do suggest a change in how these patients are treated. Prostate cancer is sensitive to chemotherapy with more than 50 percent of patients responding to newer combinations. Although patients with advanced disease have not been observed to live longer, it is reasonable to believe, based on other disease states, that earlier treatment might affect survival. Based on average survival rates of more than 20 months in hormone-refractory prostate cancer patients (whose average survival has historically been about 12 months), we are cautiously optimistic that a survival benefit will be seen in the randomized controlled trials that are being conducted. Ongoing trials are evaluating the role of chemotherapy in asymptomatic patients with increasing PSA level as well as earlier in high-risk patients before or after initial local therapy in patients with hormone-sensitive disease. Available clinical trials do show the following: high response rates, prolonged survival in responders, palliation of pain, reduction in analgesic use, and improvements in quality of life. Although the benefits of chemotherapy in advanced hormone-refractory prostate cancer appear modest, the 68% response rate compares favorably to those documented in breast (48%), lung (15.3%), and colon (39%) cancer patients where chemotherapy as part of care is the standard.

Conclusion:

As I stated earlier, no one really knows the “right way” to treat prostate cancer. In fact, currently there are probably several appropriate ways to approach this disease. Only time

and further clinical trials will help us decipher the best approach. Until that time arrives a multi-disciplinary approach seems the most reasonable. In other words, a patient should seek the opinion of a urologist, a radiation oncologist, and a medical oncologist before embarking on a definitive treatment plan. With advances in technology and some promising clinical trials there is cause for great hope in the fight against prostate cancer.

--From *Updated Guidelines for Surviving Prostate Cancer* by E. Roy Berger, M.D., F.A.C.P. and James Lewis Jr., PhD

Updated Guidelines for Surviving Prostate Cancer is available at all major bookstores and online at <http://ecpcp.org/books/> or by calling 516-942-5000.

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