

"Poly-MVA for Treating Prostate Cancer" A Report on Three Cases

**Shari Lieberman, Ph.D., C.N.S., F.A.C.N., and
James W. Forsythe, M.D., H.M.D.**

According to The Prostate Cancer Institute (Eden Prairie MN), an organization that maintains one of the leading websites on prostate cancer information and treatment, this disease: * Is the single most common form of solid tumor in humans * Is newly diagnosed every 2.6 minutes * Is present in more than 9 million men * Kills 1 man every 13 minutes * Afflicts 1 in 6 men in their lifetimes * Is second only to lung cancer in annual cancer deaths of U.S. men * Is high risk for black men (they have incidence and mortality rates as much as 50 percent higher than other racial or ethnic groups) * Strikes as many men (and causes almost as many deaths annually) as breast cancer does in women but lacks the national awareness and research funding breast cancer currently has * Is nearly 100 percent survivable if detected early.

Us TOO Inc. (Downers Grove, Illinois; www.ustoo.com), an independent network of support group chapters for men who have the disease, recommends annual testing for prostate-specific antigen (PSA) and digital rectal examinations for all men 45+ years old (and men at greater risk beginning at 40). And, while one can argue the accuracy of at least some of these statements, such as "is nearly 100% survivable if detected early," any man reading this information would certainly be scared to death or at least scared into immediate treatment.

Cancer, in general, is rarely detected early because we simply do not have the technology to do so and is it generally asymptomatic. And there is little evidence to confirm that early prostate cancer detection will confer "100 percent" survival. This statement can give a false sense of security because it does not include the prognosis of hormone refractory prostate cancer, which is more difficult to treat and has a poorer prognosis.²

It is also misleading in that it could be argued that, because most prostate cancers are slow growing (as evidenced in autopsies of older men who did not die from prostate cancer and were untreated) that the progression time evidenced in 10, 12, or 15 years after treatment would be expected if left untreated.

While there are some limitations on the use of serum PSA to monitor patients after treatment for prostate cancer, this agent remains the "gold standard" for conventional treatment.³

Bio-chemical failure definitions in patients treated with radiation therapy appear to provide a 6-18 month lead time to clinical failure but there are only limited published data to suggest that early intervention of any type (androgen deprivation, radiation therapy, surgery, etc.) affects survival.

Conventional Treatments

What are men being told about the available treatments? A good deal of the information on the Prostate Cancer Institute's website represents the conventional approach.

According to The Prostate Cancer Institute's article on treatments, radical prostatectomy is said to have a "success rate" of 70-85 percent. However, a very recent review revealed biochemical recurrence-free survival rates of 71 percent at 5 years and 63 percent at 7.5 years.⁴ So, clearly, the survival rate decreases with years more distant from diagnosis.

What appeared most predictive of biochemical recurrence was a PSA level of > 10 ng/ml and the highest grades on biopsies, positive margins, perineural invasions, and Gleason score. But the side-effects of radical prostatectomy include incontinence (in about 10 percent of cases) and impotence in 79.6 percent of men reported at 2 years after the procedure.

The Institute also reports that laparoscopic prostatectomy that is "less invasive" but still carries the risks of incontinence and impotence associated with the radical procedure. 1

Watchful waiting is described on the Institute's website as the option for "a man who has chosen not to have immediate prostate cancer treatment. During the watchful waiting period, the physician keeps the cancer under close watch." However, watchful waiting is appropriate for men who meet one or more of these criteria: short life expectancy; significant other illnesses; small tumors; low Gleason score; and low PSA level.

The article on the site goes on to say that "the major risk of watchful waiting is that without treatment, cancers can grow and spread quickly (metastatic cancer) so the cancer may escape the prostate capsule between doctor visits." Finally, this section of the article concludes: "Even slow-growing tumors may suddenly become rapidly growing tumors if left untreated." This message is clear: treat the prostate cancer early regardless of the side-effects of treatment.

The site also describes cryotherapy for prostate cancer eradication. This procedure was noted as conferring a major risk for impotence but the data show that 97.6 percent of patients are still cancer-free at 12 months.

There is also a section on the site on hormonal therapy that describes surgical castration, luteinizing hormone-releasing hormone therapy, and combined androgen blockage. 1 All three types of therapy can cause the following side-effects: impotence; loss of sexual desire; hot flashes; weight gain; fatigue; reduced brain function; and loss of muscle mass.

External beam radiation therapy (EBRT) is also described. The article states that "EBRT can be curative if the cancer has not gone beyond the prostate gland." However, an actual study is quoted on the website that states that, "after 5 years 67% of men with a pre-procedure PSA of 4.1 to 10.0 were still disease free when treated with EBRT alone. To improve success rate EBRT is often used in conjunction with other therapies." The "other therapies" referred to are often hormonal blockades. Once again, some of the information seems a bit inflated compared to the actual data. The website correctly discloses the potential side-effect: "If the radiation damages nerves that control erections, the patient may lose his ability to get or keep an erection. . . . the probability was about 45 percent.

"Finally, brachytherapy is described as a minimally invasive procedure that implants small radioactive pellets. . . . into the prostate." And, once again statistics are given: "Long term clinical data supporting the use of brachytherapy has shown that over 87% of men are still free of cancer 10 years after brachytherapy treatment." However, what is omitted is that high-dose brachytherapy is often combined with EBRT (or hormonal blockade).

A more recent study shows a lower survival rate of 79 percent and suggests using EBRT with brachytherapy. Impotence rates are listed as 6-30 percent on the website but it says that this is the case "although patients receiving brachytherapy often report similar levels of impotence before treatment. The risk of impotence increases with age; impotence after brachytherapy can often be treated with prescription drugs such as Viagra (Pfizer, New York City),

There does not appear to be any conventional therapy for prostate cancer that does not carry an increased risk of impotence. According to a study on minimizing destruction of vessels that govern erection,⁶ what actually causes impotence is radiation to the corpus cavernosum and the internal pudendal artery causing some vessel destruction. This study demonstrated that using coronal, sagittal, and axial magnetic resonance imaging data allows superior definition of the prostate apex so the radiation dose to critical erectile structures can be limited. However, this is rarely if ever done because this approach is costly.

The reasons why prostate cancer treatment is often delayed are fear, anxiety, and depression. I was personally depressed after reading the Institute's website. 1 Although the website has nurses that one can consult with and an oncologist referral base—and complies with the HONcode (Health On the Net Foundation; www.hon.ch/HONcode)—there is *no* mention on that site of the hazards and risks associated with any radiation therapy (e.g., a secondary cancer) or the fact that all radiation is cumulative.

Nor was there any link to, or mention of, any alternative or complementary prostate cancer treatment resources on this website although several reports confirm that the prevalence of alternative and complementary medicine use by patients with cancer range from as little as 7 percent to as much as 64 percent.^{7,8} Most patients who have cancer combine some form of alternative or complementary therapy with their conventional treatment while only 37.5 percent of patients with cancer surveyed in two studies expected complementary and alternative therapies to cure their disease.⁸

Poly-MVA: An Alternative Treatment

However, because of the overwhelming side-effect of impotence, some men refuse conventional treatment and seek safer, nontoxic alternative treatments instead such as garlic (*Allium sativum*), soy (*Glycine soja*), lycopene, Haelan 951 (Haelen Products Inc., Woodinville, Massachusetts), or Poly-MVA® (see section called About the Product). In 1990, Larry Clapp, Ph.D., J.D., was diagnosed with prostate cancer and refused conventional treatment. Instead he embarked on a lifestyle program of nutrition, natural products, spirituality and detoxification.⁹ He remains in remission today.

Large-scale human studies on many of these natural treatments for treating cancer are simply cost-prohibitive. It costs at least \$300 million to bring any cancer drug to market. This makes the "gold standard" validation for many of these therapies as a sole treatment impossible. However, well-documented case studies can serve as an excellent vehicle to explore the potential cancer-ameliorating effect of a natural agent when used as the primary treatment.

Three cases of patients using a proprietary product called Poly-MVA indicate that it may be a good alternative treatment for prostate cancer. The remainder of this article focuses on these cases.

About the Product

Poly-MVA contains a lipoic acid/palladium complex (LAPd) developed by Merrill Gamett, D.D.S. (founder and chief executive officer of Garnett McKeen Laboratory, Inc. Islip, New York). The formulation is sold as a dietary supplement under the trade name Poly-MVA and is distributed by AMARC Enterprises, San Diego, California. The formulation's main active ingredient LAPd is being considered by the pharmaceutical industry under several patents as "synthetic reductase."¹⁰

The initials "MVA" stand for "minerals, vitamins and aminoacids." The product is a proprietary formulation that contains palladium, alpha-lipoic acid, thiamine, riboflavin, and cyanocobalamin, formyl-methionine, and acetylcysteine. LAPd is the main active ingredient in both Poly-MVA and in synthetic reductase.

LAPd complex has undergone extensive toxicologic study.¹¹ The study was conducted both intravenously and orally. Mice were given doses of 5000 mg/kg (a typical human dose is 20 mg/kg). No deaths or signs of organ damage occurred in the test animals. It was concluded that the LD₅₀ of LAPd exceeds 5000 mg/kg. The Ames Test was conducted by the same independent laboratory and yielded negative results. LAPd was also studied for its effectiveness in halting the growth of glioblastoma cells in vivo.¹² Tumors were allowed to grow in mice. The animals were then divided into 8 groups of 10 mice each. Four (4) groups were given daily intravenous (IV) doses LAPd or placebo. Another 4 groups were given intraperitoneal doses of 0.05, 1.0, or 2.0 mg per mouse for a total of 4 weeks and tumor volume was measured throughout the study. Compared to the controls who received no LAPd, mice receiving the test material orally or IV at 0.5, 1.0, or 2.0 mg had a significantly reduced growth of the glioblastoma (a 50 percent or greater reduction in tumor size).

Mechanisms of Action

There are two proposed mechanisms of action of Poly-MVA.¹³

The formulation is an irreversibly-bound trimer of lipoic acid and palladium with a thiamine core and thus exists as a polymer rather than a single molecule. The product can therefore provide a unified redox (accept charge and donate charge) reaction. When glucose enters a cell it is broken down, in the absence of oxygen, into pyruvate, which subsequently enters the mitochondria and is quickly oxidized to acetyl-coenzyme A (acetyl-CoA). In aerobic respiration, acetyl-CoA is then channeled into the Krebs/citric acid cycle to create nicotinamide adenine dinucleotide (NADH). NADH is then oxidized to the electron transport chain. The electrons entering the chain are used to drive the phosphorylation of adenosinetriphosphate (ATP). The energy needs of the body are supplied by splitting ATP into adenosine diphosphate (ADP) and a free phosphate molecule.

Dr. Garnett created LAPd to shunt electron energy from itself to DNA and thus replace the electrons lost in normal cells as a result of the oxidative damage associated with radiation and chemotherapy.¹⁰

Further studies have demonstrated that the excess energy LAPd provides to the mitochondria, which travels down the electron transport chain, cannot be accepted by cancer cells. Because malignant cells function in a hypoxic environment, a local generation of free radicals occurs at the mitochondrial membrane. This activates apoptosis by facilitating cytochrome C release and activating caspase enzymes that destroy malignant cells. Given that healthy cells are richly oxygenated, LAPd is nontoxic to them and they actually benefit from the energy boost.

Another hypothesized mechanism of action is that LAPd can target tumor cells selectively by modulating pyruvate dehydrogenase (PDH). PDH is the bridge between anaerobic and aerobic metabolism. During anaerobic metabolism, glucose is broken down to pyruvate which nets 2 ATPs. The pyruvate molecule is then channeled into aerobic metabolism. Cellular metabolism results in the generation of 38 ATPs.

Because 2 ATPs are needed to initiate glycolysis, each glucose molecule will net 36 ATPs. Thus the vast majority of ATPs are generated during aerobic metabolism. Without PDH, aerobic metabolism cannot take place and the cells shift primarily to an anaerobic metabolism. While PDH activity is altered in cancer cells, LAPd may also affect it. This would eliminate the primary means of ATP production in tumor cells (aerobic metabolism) and in doing so effectively kill cancer cells.

Data from Human Studies

Case reports have been cited by Milne and Block,¹⁴ appeared on the website polymvasurvivors.com and have been presented at several conferences. For example, a large case study was presented in 2004 at the American Academy of Anti-Aging Medicine.¹⁵ This study followed patients who had stage IV cancer with multiple origins including breast, sarcoma, colon, lung, brain, bladder, stomach, and prostate for 3-9 months.

In this large case study, there was a complete response rate of clinical remission in 14 of 66 patients (21 percent); a partial response rate of 39 of 66 patients (56 percent), and a progressive disease rate in 15 of 66 patients (23 percent) all of subjects who received conventional therapy together with LAPd. A partial response was defined as a 50 percent tumor mass or tumor marker reduction. The combined response rate (clinical remission + partial response) of patients who only received the formulation with other supportive nutrients was reported to be 10 of 24 (42 percent). I have colleagues who have also reported success using the formulation either alone or as an adjuvant to conventional cancer treatment. This product is sold for oral ingestion only. In order to give it IV, it must be filtered with a Millipore filter to remove any impurities such as parasites or bacteria.

Poly MVA in Three Case Studies

Patients gave written and verbal consent for the use of their medical records in the preparation of this report. *Case 1: R.Z.*

R.Z. is a 73-year old man who was diagnosed with stage 4 adenocarcinoma of the prostate in January 2001. His biopsy revealed a Gleason score of 6. Tumor involvement was 25 percent of the right lobe and 15 percent of the left lobe. His PSA at the time of diagnosis was 7.8. His bones can showed 7th rib bone metastasis. A computed tomography (CT) scan of his abdomen and pelvis showed possible liver metastasis and liver cysts. He also was diagnosed with a dilated left ureter with tumor nodules around his ureter. His urinalysis was negative. R.Z. was getting up to urinate at least 4-5 times each evening and had difficulty in urinating (dysuria) because he had a partially obstructed ureter.

R.Z. adamantly refused any conventional treatment, including chemotherapy, radiation, or surgery. He was started on multivitamins, multiminerals, and an herbal supplement (PC-RES) similar to PC-SPES, which is a Chinese herbal combination. He adhered to this regimen from February 2001 to May 2004. Initially, his PSA started to decrease and by June 2001 it was 5.

However, close monitoring revealed that his PSA levels were erratic, with the levels going up and down over the course of time. In 2004 his PSA rose steadily. His highest PSA level was 11 in May 2004. R.Z. was given LAPd to add to his regimen in May 2004. He took 2 teaspoons of the formulation, q.i.d., for 6 months and then decreased the dose to 2 teaspoons t.i.d. His PSA levels came down progressively, reaching 8.7 in February 2005. This was the first time he experienced a consistent decrease in his PSA levels.

This patient has stage IV prostate cancer and has been stabilized on LAPd for the past 11 months and he remains physically, mentally and sexually active. During the 11 months he has been taking the formulation, his sexual function and libido have been good. As oft his writing, he is now waking 2-3 times each evening to urinate and no longer experiences obstructed urine flow. His performance scale results have been 100 percent perfect. He is also being treated for hypertension, which is under control with Diovan and Lotrel. His comprehensive metabolic panel has shown normal results.

Case 2: J. C.

J.C. is a 59-year-old man who was diagnosed with adenocarcinoma of the prostate with a Gleason score of 6 in September 2004. His left lobe was moderately differentiated and his right lobe was negative.

The lesion on his prostate was measured at 10 mm x5mm with a pelvic ultrasound and was palpable. A CT scan of the chest, abdomen, and pelvis showed no lesions and his virtual CT colonoscopy also showed no lesions. A bone scan and urinalysis also yielded negative results. His comprehensive metabolic panel results were also normal. His lymphocytes were very low at 3.9 (normal range is 24-44). He presented with dysuria and hematuria.

J.C. adamantly refused any conventional treatment, including chemotherapy, radiation, or surgery. He was started on IV LAPd initially, beginning on November 11, 2004. He then received the following treatment:

- *Week 1*—For 5 days, he received 20 mL of LAPd IV and took an additional 20 mL (two teaspoons b.i.d.) every day of the week including the non-IV days.
- *Week 2*—For 5 days, he received 30 mL of LAPd IV and took an additional 10 mL (2 teaspoons) every day of the week including the non-IV days.
- *Week 3*—For 3 of 5 days he received 40 mL of LAPd IV and took 40 mL orally (2 teaspoons q.i.d.) on non-IV days.

He now remains on the oral dose he took during week 3. His PSA was 5.6 in November 2004 immediately after receiving the formulation.

It is unknown whether this elevation was the result of the biopsy he had or the possible tumor killing effect of the product. His PSA level decreased to 4.01 by December 2004. His last PSA in March 2005 was 2.8 and his prostate nodules were no longer palpable. His dysuria and hematuria completely resolved after he took the formulation and he scored 100 percent on a performance scale. He was also diagnosed with chronic Epstein-Barr virus (EBV) and gastroesophageal reflux disease that has also improved during this time. Prior to starting the formulation, he was taking a multi-vitamin and multimineral supplement, fish oil, and a multiherbal supplement. None of these decreased his PSA level before starting the LAPd. His lymphocytes were 19.3 in January 2005. As of this writing, he remains mentally, physically, and sexually active.

Case3:M.O.

M.O. is a 77-year-old man diagnosed with stage 4 adenocarcinoma of the prostate in October 1996. At the time of diagnosis, his PSA was 69.2 with a Gleason score of 3. His bone scan revealed multiple bone metastases to various sites and he complained of back pain.

M.O. adamantly refused chemotherapy, radiation, or surgery but agreed to hormonal blockade treatment. He took Lupron and Casodex for 18 months. His PSA level decreased to 15.3 by November 2001. It then went up to 27.9 by December 2003. M.O. Stopped the hormonal blockade because he developed gynecomastia and continued to have back pain. He agreed to take Zoladex intermittently for approximately 1 year and, by January 2002, his PSA was 32 and he decided to stop all hormonal treatment. He then sought an alternative treatment.

His PSA on December 2003 was still high at 27.9 after he had stopped all hormonal treatments. He had been taking a multivitamin supplement, a multimineral supplement, fish oil, and an herbal supplement for at least 1 year before he was started on the LAPd formulation.

He began taking the product in February 2004 and took 2 tea-spoons q.i.d. for 6 months and continued to take 2 teaspoons b.i.d. there after. His PSA level decreased to 0.4 in July 2004 and rose to 0.5 in September 2004.

He was last seen in February 2005 and his PSA had risen to 9. During this last visit, it was noted that, despite the rise in PSA level, his back pain had resolved and his performance scale was 100 percent. His comprehensive metabolic panel showed normal results. However, his gynecomastia did not resolve.

As of this writing, he has been instructed to reinstate his oral dose of 2 teaspoons of the formulation q.i.d. and is being treated for mild hypothyroidism with synthroid. He is mentally and physically active but has not been sexually active for some time. He refuses further bone scans and ultrasounds.

Discussion and Conclusions

Conventional prostate cancer treatment carries significant risks for impotence, incontinence, and loss of sexual desire. While other side-effects are associated with these treatments the afore-mentioned side-effects appear to create the greatest fear and anxiety in men and cause them to refuse conventional treatment.

Toxicology studies of the LAPd formulation have demonstrated that it is extremely safe and an LD50 was not induced even at extremely high doses that are far above what any human could take in via oral or IV administration.^{13,14} Poly MVA's mechanism of action appears to be a result of a crystalline polymer structure that promotes a more powerful redox than alpha-lipoic acid alone and induces apoptosis in cancer cells only.^{15,16} Therefore, the product does not affect normal healthy tissue the way that radiation, chemotherapy, brachytherapy, or cryotherapy would. The formulation also does not make an impact on the hormonal system as does hormonal blockade.

It appears unlikely that the use of this formulation would lead to the significant risks associated with conventional treatments.

These three case studies indicate that the product may stabilize prostate cancer and mitigate the very side-effects that may be caused by conventional treatments or that may present at the time of diagnosis.

Two of these patients continue to have no intention of combining any conventional treatment along with LAPd and one subject refused further hormonal blockade as well as any testing other than for PSA. All of these men appear to be completely satisfied with their treatment, continue to be closely monitored by their physicians, and are willing to continue treatment with the formulation.

M.O. (Case 3) has reinstated his initial loading dose of LAPd (2teaspoons q.i.d.) to see if he can reduce his PSA level. Two of these cases appear to be stable and one case appears to be in remission at this time.

The most compelling feature of the treatment appears to be that all men scored 100 percent on a performance scale. J.C. was initially diagnosed with EBV and also appeared to have improvement in this condition as evidenced by his performance scale rating.

What is more, these three men remain physically and mentally active. Two (2) of the 3 men remain sexually active at ages 59 and 73. The third man (age 77) had not been sexually active for sometime. R.Z. (Case 1) had significant reductions in nocturia and dysuria while taking the formulation. J.C. (Case 2) had complete reversal of dysuria and hematuria while using LAPd. It is feasible that this is the result of the hormonal blockade that he had previously received. However, according to his physician, the prior treatment is not an issue at this time.

While these cases are moderate in duration (7-12 months) they provide compelling evidence that this formulation may be a worthwhile alternative treatment for men who refuse any conventional treatment.

Other case studies are presently being gathered on a number of patients with cancer who have used the formulation, including but not limited to breast cancer, non-small-cell lung cancer, glioblastoma, and sarcoma. The goals of these case studies are to provide a clear protocol for the best dosing of the product and best route of administration of (IV versus oral), to determine which types of cancer are the most responsive, and to develop a timeline for the length of remission or stabilization of disease.

These and other cases will continue to be followed. Updates to published cases will be reported as addendums in case studies to be published in the near future.

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Shari Lieberman, Ph.D., C.N.S., F.A.C.N., is a research scientist and industry consultant based in New York City and Pompano Beach, Florida. She is also the Founding Dean of New York Chiropractic College's (Seneca Falls, New York) MS Degree Program in Clinical Nutrition.

James W. Forsyth, M.D., H.M.D., is the medical director of the Century Wellness Clinic, Reno, Nevada, and an associate professor of medicine and pathology at the University of Nevada Medical School, also in Reno.

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