

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

Lieberman S, Forsythe J  
*Alternative & Complementary Therapies 2005;11(4):203-7*

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## Prostate Cancer

- Is the single most common form of solid tumor
- 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 lifetime
- Second only to lung ca in annual deaths of men
- Strikes as many men and causes as many deaths annually as breast cancer
- "Is nearly 100% survivable if detected early"

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## Prostate Cancer

- Early detection is rare - we do not have technology and it is asymptomatic at early stages
- Hormone refractory prostate cancer has a poorer prognosis, more difficult to treat
- Most prostate cancer is slow growing as evidenced by autopsies of older men who were untreated and did not die of PC
- Untreated - progression time is 10- 15 years in older men

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## Prostate Cancer

- Treatment with radiation appears to provide a 6-18 month lead time to clinical failure
- There are only limited published data to suggest that early intervention of any type improves survival
- Some studies demonstrate survival time may be higher if left untreated (by conventional treatment in older men)

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## Treatment - What Men Are Told

- Radical prostatectomy is said to have a "success rate" of 70-85%
- A recent review revealed recurrence-free survival rates of 71% at 5 years, 63% at 7.5 years
- Clearly, survival rate decreases with years more distant from Dx (or conventional treatment??)
- PSA >10 ng/mL and highest grades on biopsies, positive margins, perineural invasions, and Gleason score are most predictive of recurrence

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## Conventional Treatment

- Side-effects of radical prostatectomy include:
  - Impotence 79.6%
  - Incontinence 10%
- Laparoscopic procedure considered "less invasive" - but still carries same side-effect risk as radical procedure
- Watchful waiting is an option for "a man who has chosen not to have immediate prostate cancer treatment. During this period the physician keeps the cancer under close watch."

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## Conventional Treatment

- “WW is appropriate for men who: have a short life expectancy, significant other illness, small tumors, low Gleason score, low PSA level”
- Major risk of WW is: “without treatment cancers can grow and spread quickly (metastatic cancer) so the cancer may escape the prostate capsule between doctor visits”
- Scared to death into treatment? Are the risks truly exposed or discussed?

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## What Men Are Told

- “Even slow-growing tumors may suddenly become rapidly growing tumors if left untreated”
- The message is clear - treat the prostate cancer early REGARDLESS of the side-effects of treatment (or efficacy)
- Cryosurgery promoted as “97.6% of patients are cancer free at 12 months”
- Cryo still carries major risk for impotence

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## What Men Are Told

- Hormonal therapy: surgical castration, luteinizing hormone-releasing hormone therapy, combined androgen blocking
- All can cause: impotence, loss of sexual desire, hot flashes, weight gain, fatigue, reduced brain function, loss of muscle mass
- External beam radiation “can be curative if cancer has not gone beyond prostate gland”

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### What Men Are Told

- The research shows: after 5 years 67% of men were still disease free (PSA 4.1-10)
- To improve "success rate" it is combined with hormonal blockades
- "If the radiation damages nerves that control erections the patient may lose his ability to get or keep erection... probability is 45%"

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### What Men Are Told

- Brachytherapy (radioactive pellets): long term clinical data show that 87% of men are still free of cancer after 10 years"
- However, what is omitted is that it is often combined with EBRT and/or hormonal blockade
- More recent study shows a 79% survival rate along with EBRT
- Impotence rates 6-30%

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### Conventional Treatment

- Remember - usual progression of prostate cancer 10-15 years if left untreated
- Almost all conventional treatments carry an increased risk of impotence
- The only way to minimize risks is to use coronal, sagittal and axial magnetic resonance imaging data
- This allows superior definition of the prostate so the radiation dose to critical erectile structures can be limited
- Rarely if ever offered, too costly

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## Conventional Treatment

- Treatment is often delayed due to fear, anxiety, depression
- No mention on of hazards and risks associated with any radiation therapy (e.g. secondary cancer)
- No mention that ALL radiation exposure is cumulative
- No link, mention of alternative/complementary cancer treatment
- [www.prostate-cancer-institute.com](http://www.prostate-cancer-institute.com)

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## Alternative & Complementary Therapy

- Most patients use some form of altern/comp therapy with their conventional therapy
- Because of the overwhelming side-effect of impotence, some men refuse conventional treatment and seek safer non-toxic treatments such as garlic, soy, lycopene, Haelen 951, and Poly-MVA

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## Cost of New Drug Approval

- Large-scale human trials are cost-prohibitive for dietary supplement companies
- Cost at least \$300 million to bring any new cancer drug to market
- FDA will NOT APPROVE an arm of an IND for the natural product only
- Validation as sole treatment according to "gold standard" is impossible

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## Case Studies

- Case studies are an accepted protocol for to help validate a treatment
- Record keeping: scans, biopsies, lab analysis, tumor markers, physical exam
- Informed consent and other pertinent forms
- Patients must be informed about all available treatment including risks and potential side-effects, efficacy

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## Poly-MVA (LAPd Complex)

- Developed by Merrill Garnett, D.D.S.
- Poly-MVA contains a lipoic acid palladium complex (LAPd)
- LAPd (the main ingredient) is being considered by the pharmaceutical industry under several patents as "synthetic reductase"
- MVA stands for minerals, vitamins, amino acids which include: Pd, ALA, thiamine, riboflavin, cyanocobalamin, formyl-methionine, acetylcysteine

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## LAPd Complex

- Extensive toxicological study orally and IV
- LD50 study: mice given 5000 mg/kg (human dose 20 mg/kg) no deaths or organ damage occurred in any of the animals
- LD50 exceeds this dose
- Ames Test negative
- Glioblastoma tumors allowed to grow in 80 mice
- Groups divided to receive LAPd daily: IV, orally or placebo for 4 weeks (.05, 1.0, 2.0/mg)

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## LAPd

- Mice receiving test material orally or IV had a significantly reduced growth of glioblastoma (50% or greater reduction in tumor size)
- Poly-MVA is a irreversibly-bound trimer of lipoic acid and palladium with a thiamine core and exists as a polymer rather than a single molecule
- It is a powerful redox molecule
- ORAC (oxygen radical absorbance capacity) of ALA = 2,400 (trolox equivalent per gram)
- ORAC of Poly-MVA: 9,605

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## Case 1: R.Z.

- R.Z. is a 73-year old man Dx with stage IV adenocarcinoma of prostate 01/01.
- Gleason score 6, PSA 7.8
- Tumor involvement 25% right lobe, 15% left lobe
- Bone scan: 7th rib bone mets
- CT scan abdomen/pelvis: possible liver mets, liver cysts
- Dilated left ureter, tumor nodules around ureter

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## Case 1: R.Z.

- Nocturia: 4-5 times each night
- Difficult urination (dysuria) due to partial obstruction
- Was informed about all treatment options - adamantly refused all conventional treatment
- Started PC-Res (similar to original PC-Spes), multi-vitamin, multi-mineral from Feb 01-May 04
- PSA initially decreased to 5 by June 01 but after then levels were erratic and continued to rise - the highest level was 11 in May 04

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### Case 1: R.Z.

- May 04 Poly-MVA added at loading dose of 2 tsp q.i.d. for 6 months
- After 6 months dose reduced to 2 tsp t.i.d.
- PSA decreased progressively reaching 8.7 by Feb 05
- First time he experienced a constant decrease in PSA
- Is stable, remains physically, mentally and sexually active
- Sexual function and libido are good
- Nocturia down to 2-3/night

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### Case 1: R.Z.

- Dysuria completely resolved
- Performance scale results 100%
- Patient continues to be stabilized with Poly-MVA
- Comprehensive Metabolic Panel is normal
- Also being treated for hypertension with Diovan and Lotrel

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### Case 2: J.C.

- 59-year old man Dx with adenocarcinoma of prostate, Stage II, Sept 04
- Gleason score 6, PSA 3.8
- Left lobe moderately differentiated, right lobe negative, lesion was 10 mm X 5 mm and was palpable
- CT scan chest, abdomen, pelvis neg
- Met Panel normal, Lymphocytes low 3.9(24-44)
- Dysuria, hematuria

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### Case 2: J.C.

- He adamantly refused all conventional treatment after being informed about options
- Started on IV administration (note - Poly-MVA is not sold or prepared for IV administration - must be put through millipore filter) on Nov 11, 2004
- Week 1: For 5 days received 20 ml via IV and 20 mL orally (2 tsp b.i.d.) daily
- Week 2: For 5 days received 30 ml via IV and 10 mL (2 tsp) every day
- Week 3: For 3 of 5 days received 40 ml IV and 40 ml orally on non-IV days

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### Case 2: J.C.

- At time of Dx PSA was 3.8
- Immediately after receiving Poly his PSA rose to 5.6 in Nov 2004 (tumor kill or biopsy?)
- PSA decreased to 4.1 by Dec 2004
- Last PSA March 2005 was 2.8
- Prostate nodules no longer palpable
- Dysuria, hematuria completely resolved
- He continues on 2 tsp q.i.d.
- Mentally, physically and sexually active
- Performance scale 100%

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### Case 2: J.C.

- Prior to Poly he was taking nutritional supplements, none of which impacted his PSA or tumor load
- His lymphocytes returned significantly increased to 19.3 by Jan 2005
- Also Dx with EBV, gastroesophageal reflux disease which also significantly improved

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### Case 3: M.O.

- 77-year old man Dx: stage IV adenocarcinoma of prostate Oct 1996
- PSA 69.2, Gleason score 3
- Bone scan: multiple bone mets to various sites, complained of back pain
- He adamantly refused all conventional treatment except hormonal blockade
- Took Lupron & Casodex for 18 months
- PSA decreased to 15.3 by Nov 2001
- PSA rose to 27.9 by Dec 2003

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### Case 3: M.O.

- Stopped hormonal blockade due to gynecomastia and continued to have back pain
- Agreed to take Zoladex intermittently for 1 year, by Jan 2002 PSA was 32
- Refused all further conventional treatment
- Dec 2003 PSA was 27.9, he had been taking multivitamin, multimineral, fish oil and herbal supplement for one year

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### Case 3: M.O.

- Feb 2004 took 2 tsp q.i.d. for 6 months and continued 2 tsp b.i.d. thereafter
- July 2004 PSA 0.4, Sept 2004 PSA 0.5
- Feb 2005 PSA 9
- Despite rise, back pain resolved Performance Scale 100%, Comprehensive Metabolic Panel normal, gynecomastia did not resolve
- Instructed to resume loading dose of Poly (8 tsp/day)

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### Case 3: M.O.

- Also being treated for mild hypothyroidism with Synthroid
- He is mentally and physically active
- He has not been sexually active for some time
- Refuses bone scans, ultrasounds

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### Latest Results

- RZ - PSA 10.1 9/20/05, sexual function normal, no palpable tumor, 6/05 pelvic ultrasound neg - no mets, prostate remains the same (slightly enlarged), still no symptoms, takes 8tsp/day
- JC - PSA 3.3 6/05 - physician talked him into proton beam despite low PSA and no symptoms, continues 6tsp/day, no symptoms
- MO - went off Poly in Israel for several months, PSA 4.3 in Oct 05, back on 8tsp/day, no complaints, no bone pain

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### Conclusions

- Toxicology of LAPd Complex has demonstrated it is extremely safe and LD50 was not induced even at extraordinary high doses far above what any human could take orally or IV
- It is a powerful redox polymer, induces apoptosis in cancer cells only
- Does not have any adverse effect on normal healthy tissue

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## Conclusions

- May be synergistic with chemo, radiation and other therapeutic interventions (Forsythe ongoing case studies)
- May protect normal healthy cells against tumor invasion and adverse effects of chemo & radiation
- More case studies needed to determine which specific cancers respond the best and most effective maintenance dose (or is it based on individual response?)

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## Conclusions

- These case studies provide compelling evidence for the use of Poly-MVA:
  - 2 of 3 men remain sexually active
  - All men are physically, mentally active, 100% Performance Scale
  - Resolution of nocturia, dysuria, hematuria
  - Are still being closely monitored by oncologist
  - Other case studies being documented: NSCLL, multiple myeloma, glioblastoma among others

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## Conclusion

- All men continue to adamantly refuse any conventional treatment
- All men are satisfied with results and continue using Poly-MVA
- All men continue using Poly-MVA under their informed consent
- They can stop Poly or continue Poly with or without conventional treatment at any time they choose

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## Vitamin C Update

- Scientists from the NIH, NCI and FDA collaborated in ground breaking research on intravenous vitamin C (IVC) as a natural chemotherapeutic agent
- Cell death in 10 cancer and 4 normal cell lines were chosen to determine if VC kills cancer cells selectively
- Normal cells were unaffected by 20 mM
- 5 cancer cell lines had a 50% decrease in cell survival (EC<sub>50</sub>) of < 4 mM - a concentration easily achievable via IV
- 10 g IVC produces plasma levels of 6 mM which are 25 fold higher than levels achieved with an oral dose

• PNAS 2005;102(38): 13604-9

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## Vitamin C Update

- Pharmacological concentration of ascorbate of 0.3- 15 mM are only achievable via IV
- Plasma ascorbate concentrations from maximum oral dose cannot exceed 0.22 mM because of limited intestinal absorption
- Extracellular, not intracellular ascorbate mediated cancer cell death
- Cell death due to apoptosis, pyknosis (contraction of nuclear contents), necrosis
- Cell death independent of metal chelators

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## Vitamin C Update

- Cell death absolutely dependent upon H<sub>2</sub>O<sub>2</sub> generation
- Cell death from hydrogen peroxide added to cells was identical to that found when it was generated by ascorbate treatment
- H<sub>2</sub>O<sub>2</sub> targets can be intra or extracellular since it is a membrane permeant
- It may target DNA, DNA repair proteins or mitochondria due to diminished SOD activity in cancer cells

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## Vitamin C Update

- IVC generated hydrogen peroxide has a therapeutic potential in infections in addition to cancer treatment
- Has been shown *in vitro* to be toxic to Hepatitis C (influenza? avian flu?)
- H<sub>2</sub>O<sub>2</sub> is a potent antimicrobial mammalian defense system against viruses and bacteria
- "Deserves rapid exploration"

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## Vitamin C Update

- More than 100 patients described without glucose-6-phosphate dehydrogenase deficiency who have received IVC at levels of 10 g or more without symptoms other than tumor lysis
- Altern/Comp. medicine practitioners worldwide use IVC at levels as high as 70 grams over several hours
- Phase 1 safety trial in advanced cancer is justified and under way
- Also see: Lieberman S. Intravenous Vitamin C Therapy: A Natural Agent for Treating Cancer" *Alternative & Complementary Therapies* 2005;11(2):58-62.

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## Vitamin C Update

- Poly taken first - leave 6 hours for high dose oral or IVC - taken in am (can energize if taken in the pm)
- Can take loading dose of Poly-MVA at one time
- At 10 hours - 1/2 dose of IVC can remain
- High levels of ascorbate interfere with Poly-MVA

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