

*LAPd as an Integrative Approach to Multiple
Myeloma and Non-small cell lung cancer:*

Evaluation of Two Case Studies

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LAPd: A Dietary Supplement

- Lipoic acid/palladium complex (LAPd) developed by Dr. Merrill Garnett Its main active ingredient LAPd is being considered by the pharmaceutical industry under several patents as “synthetic reductase”. LAPd complex has undergone extensive toxicology study

Multiple Myeloma

- MM is a relatively uncommon cancer
- The American Cancer Society estimates 16,000 new cases were Dx in 2005; expected to kill 11,000
- 1% of patients are <40 years of age, half of the people Dx are >71 years old
- 5 year survival rate is around 32%
- Despite claims of improved treatment, complete remission is uncommon and cure is rare

Multiple Myeloma

- Allogenic vs autologous stem cell transplant have similar 3-5 year survival
- Other transplant methods have not impacted relapse and survival rates
- High dose vs. conventional dose chemo (meta-analysis 575 patients) - no difference in long-term survival
- Some treatments may delay time to relapse - but not survival time

Multiple Myeloma

- Thalidomide, Velcade (Bortezomib), Thalidomide/Dexamethasone (Thal/Dex) are all commonly used - none of which extend survival time
- Vincristine, adriamycin, doxorubicin (VAD)
- Bisphosphates: help minimize bone damage
- External beam radiation - no data showing extension of remission or survival time
- No treatment has impacted the 3-5 year survival rates
- Chemotherapeutic agents are very toxic and can cause morbidity and mortality

Multiple Myeloma

- KW, a 67 year old male was Dx with advanced stage 4 MM 3/2001
- CT scan (chest) revealed multiple rib lesions and osteolytic lesions of the thoracic spine consistent with osseous metastatic disease. His seventh rib lesion on the right side was 2 cm in transverse dimension and extended of 5 cm within the rib was appeared associated with pathologic fracture.

Multiple Myeloma

- His ninth rib had a lesion destroying the rib and was approximately 2 cm in maximum transverse diameter and extended over a segment 6 cm along the axis of the rib case. His ninth rib as it abuts the manubrium had a lesion of 2.5 cm transverse and it extended 5-6 cm within the rib. There were additional lesions from the rib into the lateral aspect of the T3 vertebra and other areas of lucency seen within the thoracic vertebral bodies that were also suspicious for osteolytic metastases.

Multiple Myeloma

- He was admitted into the hospital on 3/24/01 for diagnostic testing and was also found to have a markedly elevated protein (9.9g/l), with reduced albumin (2.3 g/dl), a very high gamma globulin (7.6 g/dl) and a high sedimentation rate (49 mm/hour) all of which are common with multiple myeloma. Serum protein electrophoresis showed a monoclonal protein band in the gamma region with decreased polyclonal immunoglobulins consistent with multiple myeloma.

Multiple Myeloma

- His monoclonal protein at time of diagnosis was 4 g/dl. He had a bone scan which found the left humerus suspicious for a metastatic lesion; several metastasis to the skull; suspicion of metastasis to the right femur with a lesion in the proximal cortex laterally; suspicion of metastasis to the left femur with evidence of two small lesions of the proximal one third of the proximal femoral diaphysis.
- Patient was offered VAD chemotherapy (vincristine, adriamycin, doxorubicin) to “hopefully” slow down progression

Multiple Myeloma

- KW was experiencing significant bone pain and Rx Aredia to slow down fractures every 28 days
- Patient adamantly refused chemotherapy (VAD)
- Oncologist told him he had 3 months to live, get affairs in order, enter hospice and make funeral arrangements
- July 9, 2001 KW started taking LAPd 8 tsp/day

Multiple Myeloma

- At the same time agreed to take Thal/Dex at full dose (250 mg/40 mg) and stopped after two days due to severe side effects: rash, circulatory disturbance, severe bone & muscle pain
- After several weeks added back Thal/Dex on his own dose regimen: 50-100 mg/12 mg for 7-10 days each month
- Monoclonal proteins were used to assess progress, when to add Thal/Dex

Multiple Myeloma

- In November 2001 monoclonal proteins fell below 2 g/dl
- Oncologist considered this KW in complete remission, had never seen such a dramatic response in stage 4 MM
- December 2001 KW lowered LAPd to maintenance dose of 4 tsp/day
- Will add Thal/Dex when monoclonal proteins rise above 2.4 g/dl

Multiple Myeloma

- LAPd has allowed KW to survive on an unconventional dose of Thal/Dex with virtually no side effects
- From 3/2002 - 7/2002 KW stopped LAPd to confirm if LAPd was the cornerstone of his treatment
- He was on vacation and elected not to take it with him
- While off LAPd, even taking Thal/Dex his monoclonal proteins rise to 6

Multiple Myeloma

- Upon resuming 4 tsp LAPd per day his monoclonal proteins decrease to below 2.4
- KM took LAPd for more than one year and then took it less consistently
- Took LAPd 1-2 tsp - 2-3 times/week
- Monoclonal proteins start to rise again despite Thal/Dex
- Does not achieve of level <2.4
- Late 9/2005 KW resumes 8 tsp LAPd/day

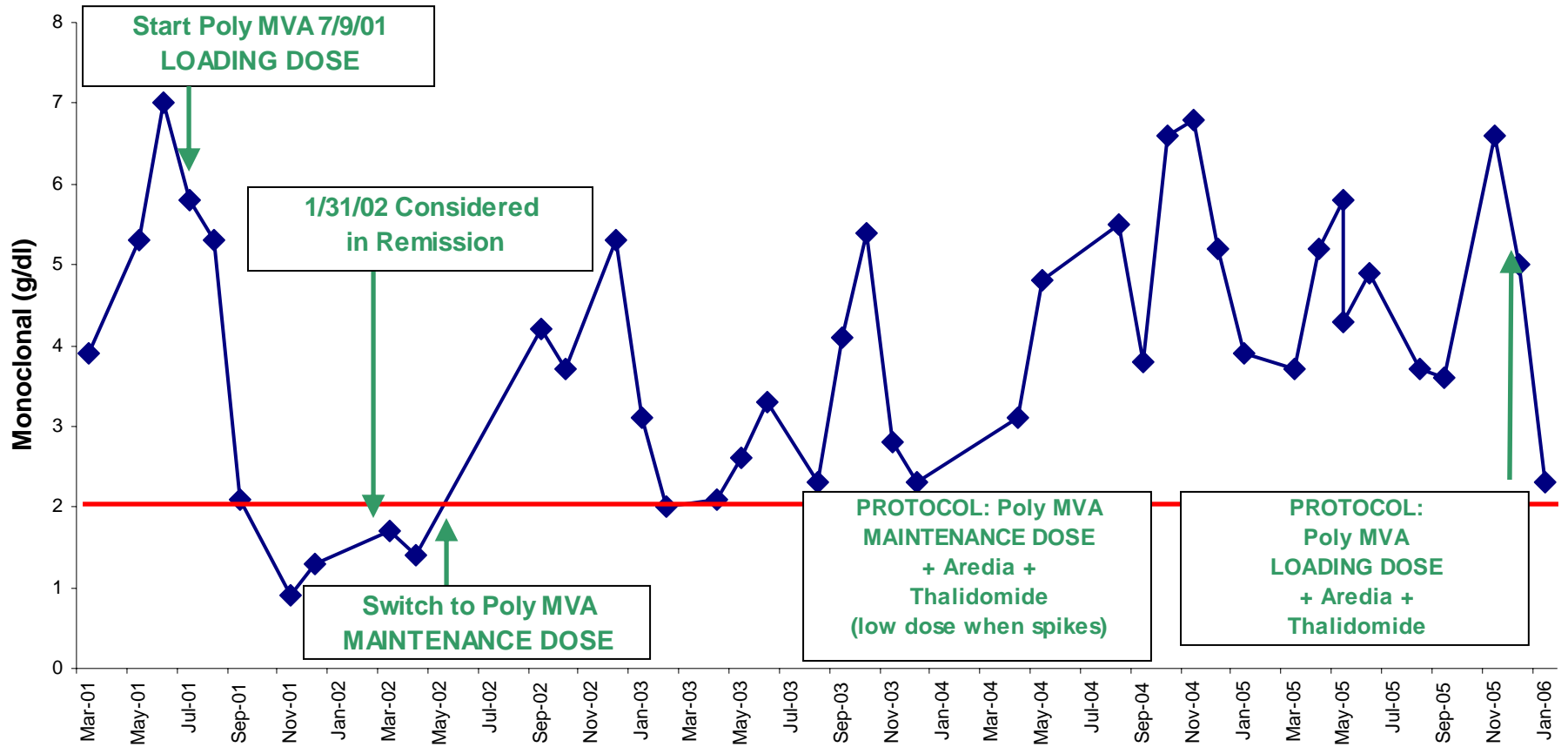
Multiple Myeloma

- KW decided to suspend all medication and to only take LAPd for one month
- Monoclonal proteins rise to 7
- Marked hemolysis of erythrocytes indicating end-stage MM
- Felt very sick and was admitted to hospital 11/28/05
- Continued Poly - was able to tolerate higher dose Thal/Dex in hospital
- He was told again to prepare for his funeral, and was visited by hospice

Multiple Myeloma

- He was released to go home
- He resumed unconventional dose of Thal/Dex plus 8 tsp LAPd
- Monoclonal proteins plummeted to 2.3 in 1/06!
- During visit with oncologist in 1/06 patient reported he felt “terrific” and that he had virtually no pain
- KW remains on current regimen

Multiple Myeloma



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LAPd as an Integrative Approach To The Treatment Of NSCLC - A Case Study

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Non Small Cell Lung Cancer

- Lung cancer is the leading cause of death worldwide
- In USA more than 170,000 new cases Dx/yr
- Annual death rate of 160,000
- 5 year survival is poor: 5-7%
- NSCLC accounts for 80% of all lung cancer
- Despite newer drugs - response and survival is the same

NSCLC

- Newer drugs may achieve a higher response rate - if you consider a 10% response rate (RR) as “significant”
- No change in survival data
- Taxotere (docetaxel) showed an 18% RR in older patients with advanced disease; 34% had minor response or stable disease
- Median survival time was 5 months
- One year survival 27%

NSCLC

- Another study compared 2 dose regimens of docetaxel to vinorelbine or ifosfamide
- “Greater progression-free survival” was claimed for docetaxel despite the fact that overall survival did not differ between groups
- Gemcitabine-cisplatin (GC) vs etoposide-cisplatin (EC) were compared in patients with advanced disease of various ages
- GC delay of disease progression 6.9 months vs. 4.3 months with EC

NSCLC

- No difference in survival time between groups
- “GC provides a significantly higher RR and a delay in disease progression”
- Iressa (gefitinib) was approved for advanced NSCLC despite no controlled trials or any demonstration of benefit
- Iressa was removed from the market
- Tarceva (erlotinib) approved without extensive clinical data
- 31.2% of patients alive with Tarceva at one year vs. 21.5% on a sugar pill

NSCLC

- No treatment has impacted 5 year survival statistics
- BA was Dx with advanced stage 4 NSCLC in 7/03 at age 62
- CT scan of lung and abdomen showed metastasis to the right adrenal gland, multiple bone sites and multiple pulmonary nodes
- Significant malignant left pleural effusion
- Tumor markers: CEA 27.3 (< 3.1 ng/ml) and CA 19-9 22 (<30 μ /ml)

NSCLC

- Low dose (70 mg/m²) Taxol (paclitaxel) each week starting on 8/03 for 3 months
- CEA was 25 in 9/03
- Oct 2003 CEA 19
- To achieve better result switched to etoposide and carboplatin (EC) in 11/03
- Took EC every 3 weeks until 1/04
- 1/04 CT scan showed no improvement, left pleural mass and nodules were worse
- Did not live near oncologist - every 3 weeks was too much strain

NSCLC

- Jan 04 switched to Iressa (250 mg/day) plus 8 tsp LAPd
- Developed rash, diarrhea from Iressa - but was low grade and manageable
- Continued LAPd and Iressa for 6 months
- May 2004 CEA 15
- June 04 LAPd 4 tsp/day (maintenance) plus Iressa
- Sept 04 CEA 24, info had surfaced that Iressa was ineffective and being pulled from the market

NSCLC

- Nov 04 Iressa was stopped, continued 4 tsp/day of LAPd
- March 05 CEA 37.2 while receiving no chemotherapeutic agent, only on LAPd
- Despite rise, patient felt well and traveled to Hawaii for vacation
- Some shortness of breath and mild fatigue
- April 04 developed pneumonia and hospitalized for one week
- During hospitalization CEA 55.2; CA 19-9 38

NSCLC

- Added Tarceva 3/05, by 7/05 CEA was 25.2 and 19-9 was 57 (first time 19-9 up and CEA down)
- July 05 stopped Tarceva - had bad reaction: anorexia, shortness of breath, severe fatigue, total loss of energy
- Continued LAPd 4 tsp/day
- July 05 started on older chemo regimen: fluorouracil (5 FU) and mitomycin-C (MMC) every two weeks

NSCLC

- Used older regimen due to multi-drug resistance
- Instead of giving full dose in one day - 1/2 dose given back to back for two days in a row
- Minimized side-effects, well tolerated
- July 05 CEA was 43, by 8/05 CEA was 14.3 and CA 19-9 was 19
- Nov 05 CEA was 8.8; CA 19-9 was 16.7
- Received last chemo in Nov 05

NSCLC

- Excellent performance scale score 90%
- Some mild shortness of breath, still travels
- No residual bone pain, no liver mets
- Jan 06 Metabolic Panel is normal; WBC slightly low 4.7 (4.8-10.8 thou/cmm); RBC 4.01 (4.2-5.4 mill/cmm); MCV 33.5 (27 -31 pg) - B12? Folic Acid?
- CEA was 5.5; CA 19-9 was 16.7
- Continues to be closely monitored
- Remains on 4 tsp LAPd/day

NSCLC

- “There has been interval clearing of the diffuse infiltrate involving the right upper lung. The extensive pleural disease in the left chest has improved, with improved aeration of the left upper lung. The soft tissue mass is left posterior costophrenic sulcus is also smaller, measuring approximately 3 cm as compared to 3.5 cm in its longest dimension. Tiny peripheral lung nodules in the right lung are unchanged. Bronchiectatic changes in right lung are seen, along with small bullous emphysematous changes”.

NSCLC

- Again, there is no apparent hilar or mediastinal lymphadenopathy. A low density, 2 cm right adrenal gland lesion is again seen showing no change in size. This is likely a benign adenoma”. The impression was as follows: “Interval clearing of the right upper lobe infiltrate, interval shrinkage of the extensive pleural disease involving the left lung, with improved aeration of the left upper lobe. Stable 2 cm right adrenal gland adenoma”.
- She remains well at 2.5 years after diagnosis and leads a full and active life

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Discussion

- Compelling case reports of a successful integrative approach to MM and NSCLC using LAPd along with conventional care
- Survival rates for MM and NSCLC are poor and conventional treatment can cause morbidity and mortality, poor quality of life
- Prior case reports on 3 prostate cancer patients who used LAPd as sole treatment with compelling results
- Two cases are stable; one in remission; 2 sexually active; all 100% on Performance Scale

Discussion

- More cases need to be documented to elucidate the best possible outcome using LAPd
- Compelling cases using LAPd alone and along with conventional treatment
- Mechanism of action is clearly defined (Dr. Frank Antonawich)

Discussion

- High dose vitamin C (IV or oral) should be given at least 6 hours after taking LAPd
- Loading or maintenance dose can be taken in the morning
- Alpha-lipoic acid should not be taken while on LAPd
- CoQ10 is synergistic with LAPd
- Other supplements, antioxidants can be taken