

Immune Enhancing Effects of a Patented, Plant Based Formula on the Compromised Immune Function in Four AID's Patients

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Abstract

This study used a patented formula of natural phytochemical plant compounds and herbal extracts known to have a positive effect on individual lymphocyte cell lines, to stimulate the debilitated immune systems of HIV positive patients with AIDS. These plant products include: chrysin, resveratrol, green tea extract, quercetin, curcumin, and coriolus versicolor. The patented formulation also contains L-Selenium Methionine. All of the constituents are carried in a liposomal base.

After baseline lab tests and complete histories and physicals, patients were started on the herbal formula; 30cc orally, 3 times daily.

This paper reports the lab data and patient findings over the first four months. During that time HIV-1(RNA) dropped an average of 70% within 38 days, with 3 out of 4 of the patients averaging a 93% drop in an average 38 days. Absolute lymphocyte count increased an average of 445 cells/ml. CD3+ increased an average of 344 cells/ml. CD4+ increased an average 168 cells/ml. CD8+ increased an average 175 cells/ml. CD4+/CD8+ increased an average of 0.12. Interestingly, average glucose levels dropped from 109 to 95 and average cholesterol dropped from 231 to 200.

There were neither reported complaints nor side-effects related to taking the LifeOne formula.

Introduction

Many current therapies for AIDS are both cost prohibitive to many people, and have many undesirable side effects. The purpose of this small pilot study was to explore the effects of a proven patented natural formula on AIDS patients and compare it to current treatment methods.

Highly active antiretroviral therapy (HAART) in the treatment of HIV-1 is associated with a decrease in viral replication, often to undetectable levels, with an increase in CD4-T lymphocytes (helper T-cells).

Unfortunately residual HIV-1 replication recurs with incomplete recovery of CD8-T lymphocytes (cytotoxic, natural killer cells). (1) The initial increase in CD4+ cells is accompanied by a proportionally larger drop in CD8+ cells.

The CD8+ cells are an essential factor in inducing CD4-T cells to increase production of Interferon gamma and FAS-Ligand. These two molecules are critical to long term CD8+ function in the killer cell mode in HIV-1. (2)

This patented herbal formula, a natural phytochemical immune system booster therapy increased absolute lymphocyte cell counts, increased CD3+, increased CD4+, and increased CD8+ while decreasing HIV-1 viral load 70% in 42 days. (3) see table.

Normally CD3+ cells are mature T-cells and natural killer cells. In HAART studies CD3+ levels drop or are not measured, according to Willard-Gallo, K et al (4). HIV-1 retrovirals incapacitate their T-cell host by interfering with the CD3+ antigen activation pathway. The herbal formula users CD3+ lymphocyte counts increased an average of 1895 cells/ml in 42 days.

SIDE EFFECTS

Recently many serious side effects of HAART have been recognized. In particular, a syndrome of Lipodystrophy (peripheral fat loss and/or abdominal obesity) and Hyperlipidemia occurs in 60 to 80% of patients treated with HAART. (5, 6)

Hyperinsulinemia, insulin resistance, and impaired glucose tolerance have all been observed. This chronic and progressive disorder can lead to diabetes mellitus Type 2. Increases in triglycerides and VLDL associated with HAART are very disconcerting and the impact on cardiovascular disease is a very serious matter.

On the other hand, the side effects of this patented herbal formula and dietary changes appear to be beneficial. It improved the lipid profile and lowered average serum glucose levels. Glucose dropped 10%, cholesterol dropped 30% and triglycerides dropped 40% in an average of 42 days.

This herbal formula synergistically combines a patented and proprietary blend of herbal extracts and phytochemical compounds with a liposomal delivery system in an easy to administer suspension. The phytochemical compounds include: Chrysin, Coriolus versicolor, 3, 3' Diindolylmethane, Resveratrol, Tumeric Extract, Green Tea Extract, Quercitin, and L-Selenium Methionine.

Michael Farley, N.D. developed this herbal formula as a primary tool in treating diseases of immunodeficiency. As such, life threatening diseases such as cancer and AIDS have routinely responded to this herbal formula, literally bringing those patients from a bed-ridden state back to normal function.

Method

Detailed case histories and physical exams were performed by Dr. Alessandrini. Baseline levels consisting of a metabolic profile, lymphocyte subset panel, HIV-1(RNA) viral load, and complete blood cell counts were drawn and evaluated at independent laboratories. Patients were counseled in the importance of diet and nutrition, and explained the purposes of future laboratory tests. After the baseline tests were completed, patients began to take the herbal formula (1 ounce orally three times a day).

Laboratory tests were repeated every thirty days to accurately monitor remission or progression of the disease, as well as any clinical changes that may have gone unnoticed. Clinical notes concerning general health status, compliance with the herbal formula and diet regime were taken every two weeks for the first thirty days and every thirty days thereafter.

Dietary recommendations were the following:

When possible all simple sugars and simple carbohydrates were asked to be eliminated from the diet. The diet recommended consisted of large amounts of fresh vegetables, fish, poultry, lean meats and fruit. Breads, white flour, corn, white potatoes, white rice and most dairy products were asked to be eliminated to aid in the control of glucose levels. Protein intake should be 50-80 grams per day. This should be supplemented with whey isolate protein. The diet should also include large amounts of distilled water; one fluid ounce per two pounds of body weight per day. It is extremely important to keep the body flushed with pure water (a 180 pound man should drink 90 oz. of water per day).

CLINICAL HISTORIES

Patient #1 9/28/02 Initial Consultation

This 24 year old male was diagnosed with AIDS in December 1996 when he was admitted to Bajanor Hospital with acute pneumonia, severe respiratory insufficiency, and in an extreme state of cachexia. Earlier, in 1977, a right submaxillary biopsy had confirmed pulmonary tuberculosis and the patient was treated with three antibiotics consisting of Ethambutol, Rifampin, and Streptomycin. His condition improved and he did relatively well until 1998 when he complained of severe fatigue. In February 1999 he began treatment with HIV anti-retrovirals consisting of Efavirenz, Zidovudine and Zalcitabine. His primary complaints were of severe bouts of diarrhea and fatigue.

The patient contracted HIV-1 Virus through passive, promiscuous homosexual contact.

Physical Exam- Wt. 164lbs. Ht. 5ft. 4in. B.P. 120/80 P.76 R.R.20

A male patient, calm and cooperative, appears his chronological age.

Head- Normal cephalic, without protuberances or indentations, with a full head of hair.

Eyes- P.E.R.L. Eyelids- Open and shut with no problem.

Ears- No trace of bleeding or hearing loss. No adenopathy: retroauricular or submandibular. Tympanic membranes normal.

Pharynx- Well hydrated mucosa and no discomfort in swallowing.

Nostrils- Normal mucosa, septum centered and intact, slightly atrophied.

Neck- Trachea centered and mobile, with scar from previous lymph node biopsy; carotid pulse present without signs of jugular distention; no lymphadenopathy.

Thorax- Normal respiration with normal expansion and contraction, with normal breath sounds, without unusual exudates in both lungs.

Cardiac- Rhythmic cardiac sounds with no unusual blowing or gallops.

Axilla- Negative for lymphadenopathy.

Back- There is a tattoo in the central lumbar region.

Abdomen- No scars or bruising, slight abdominal pannus, without visceromegaly or palpable masses, Peristalsis is present.

Extremities- There is no evidence of deformity, or edema or purpura.

Rectal- Digital examination showed empty ampulla. Sphincter tone normal, without fissures or anal lesions.

Clinical plan-

Patient is scheduled for a lymphocyte subset panel on 9/28/02 with BHC and SMAC 24 and a viral load level. He is to start the herbal formula, 1 ounce 3X daily, orally. His diet is to be limited in sugars and he is to be physically active, daily.

11/8/02 Progress note- B.P. 90/60, Pulse 78, Resp. 20, Temp 36.9 C.

Initially the patient reported constipation in the first few days. His bowel movements are now regular. He feels much more energetic, which he attributes to the herbal formula. He reports having had a dry cough with irritation around the opening of the pharynx for the last 4 days. He has had no fever or other symptoms accompanying the cough.

He is unstable in his work (he changed jobs because he became angry).

He has been given specific instructions to eliminate sugars and maintain physical activities and exercise daily.

Lab studies for control to be done 11/9/02.

12/8/02 Progress note- B.P. 110/70, Pulse 87, Resp. 24, Temp 36.5 C

Marked increase in energy. No secondary manifestations of HIV or adverse reactions. The preliminary clinical studies show improvement in relation to CD4+ and viral load.

Today he presents with an injury to his left ankle. He sustained a closed fracture without distal displacement of left fibula and a separation of lateral malleolus from falling from an escalator. This required surgical repair (plate with three screws). He was hospitalized for three days and will be unable to work for three months.

01/8/03 Progress note- B.P. 120/80, Pulse 70, Resp. 20, Temp 37.2 C.

He seems calm, complains of a slight pain around his surgical wound which is found to be clean without signs of bleeding or infection. The stitches will be removed at the end of the month. Current blood work results are pending. There are no secondary or adverse effects manifested – so there are no other clinical signs to report.

Patient #2 10/3/02 Initial Consultation

This 26 year old male was diagnosed with AIDS in September 1999. He initially presented with pulmonary tuberculosis which was treated for 6 months with INH and ethambutol. He also had prophylaxis with trimethoprim sulfamethoxazole after presenting with meningitis the same year.

Physical Exam- Wt.186, Ht. 5ft. 5in. B.P. 125/85, P.68, R.R.22, Temp 36.7 C.

This is a calm and cooperative male patient with an athletic constitution who appears his chronological age.

Head- Normal cephalic, without protuberances or indentations, with a good head of hair.

Eyes- P.E.R.L.

Ears- Tympanic membrane intact, no signs of lymphadenopathy - retro auricular or submandibular.

Pharynx- Well hydrated mucosa with good color.

Nasal cavity- Septum centrally located with intact mucosa.

Neck- Trachea central and mobile, no tenderness, no palpable lymph nodes, no scars. Carotid pulse present, without evidence of jugular distention.

Thorax- Normal respiratory movements with normal expansion and contraction, with normal vesicular sounds, without unusual exudates. Clear breath sounds at bases.

Cardiac- Rhythmic cardiac sounds without blowing sounds.

Axilla- Both axillary regions without presence of lymphadenopathy

Abdomen- Athletic appearance without the presence of visceromegaly or palpable masses, slight tympanitic sound of the ascending colon; peristalsis present.

Extremities- There are no signs of ecchymosis or edema, no tender spots, no lymphadenopathy.

Rectum- Manual exam shows empty ampulla with intact sphincter with normal tone.

Clinical plan-

Patient started treatment with the herbal formula, 1 ounce 3X daily.

Patient sent to laboratory for blood test as per protocol.

10/24/04 Progress note- B.P.120/80, Pulse 78, Resp. 22, Temp.36.7 C.

Patient relates having had slight diarrhea which now is under control. He complains of persistent abdominal distension. He says he has a great deal of energy, his daily activities are increased and his hours of sleep are deeper and longer.

His general appearance is adequate and he appears well hydrated. There is no sign of lymphadenopathy in the submandibular region, the neck, or axillary regions. Cardiopulmonary exam without pathology to report; abdomen has slightly less distension than previous exam. The rest of the exam is unremarkable. His next appointment is in two weeks.

11/8/02 Progress note- B.P.120/80, Pulse 73, Resp. 19, Temp. 37.1C

He claims to feel very well, with higher energy levels. Intestinal movement is normal. He tolerates his diet well, without any problems. His only complaint is occasional frontal headaches. He is involved in an active physical program in a gymnasium.

Thorough physical examination is normal. Cardiopulmonary exam is without pathology. Abdomen is normal with added abdominal muscle tone due to the exercise.

11/18/02 Progress note-

Laboratory studies show increase in CD4+ from 150 to 225. Also his CD8+ increased from 150 to 326. The HIV-1 viral load decreased from 67,400 to 4,010.

11/26/02 Progress note- B.P. 120/70, Pulse 72, Resp. 20, Temp. 36.8

His symptoms are under control, with high activity and energy levels. He continues physical exercise and his diet is good.

Clinically, the cardiopulmonary and abdominal exams are normal without pathological signs.

He continues on 1 ounce of LifeOne, three times daily.

12/5/02 Progress note-

All is normal, and patient continues with the diet and the herbal formula. The patient has not manifested any undesirable or adverse secondary signs or symptoms. He continues to enjoy high energy levels. He is alert and vital. Follow-up lab results are pending.

Patient #3 10/14/02 Initial Consultation

This 48 year old male patient who carries the HIV-1 virus was diagnosed in 1997 after his wife died of complications of pneumonia and AIDS. The patient is heterosexual and became infected through his wife who had been infected by a previous partner.

At this time this patient has no manifestations or symptoms of immunosuppression OR incapacitating infirmities related to HIV-1. He presents having been treated with anti-retrovirals as follows:

Norvir- Ritonavir 2 every 12 hours
Crixivan and Indinavir 2 every 12 hours
Videx- Didanosine 2 in the morning
Retrovir 1 q 12 hours
Sustiva and Efavirenz 3 at night
Novavir and Zidovudine 2 every 8 hours

He also takes multi-vitamins once a day. The patient presents with previous lab tests revealing an elevated CD4+ and a non-detectable viral load. Our baseline tests, however, showed a depressed CD4+ of 117 cells/ml and a viral load of 2900.

Physical exam- B.P. 140/90, Pulse 82, Resp 23, Temp 36.9 C

Male patient looks his chronological age, is cooperative, forthright, but slightly anxious in his answers.

Head- Normal cephalic, without protuberances or indentations, slightly graying, thick hair.

Eyes- P.E.R.L.

Nose- Slightly atrophic mucosa, septum midline.

Mouth- Well hydrated mucosa, without hyperemia or edema, complete loss of teeth.

Neck- Trachea is midline and mobile without tenderness, with a contracted scar from previous surgery. Carotid pulses are present, no evidence of jugular venous distention. No palpable lymphadenopathy.

Thorax- Elongated and there are no scars, blotches or ecchymosis present. Normal respirations with normal expansion and contraction with normal breath sounds. No exudates or spasms noted.

Cardiac- Rhythmic cardiac sounds are normal with no blowing or gallops. Slight splitting of second heart sound.

Abdomen- Mildly globular abdomen, with scars from umbilical hernia repair. No visceromegaly or tumor masses palpable. Slight distension with tympany of stomach with normal peristalsis.

Rectum- Empty rectal ampulla, sphincter tone normal without fissures or anal lesions.

Extremities- Slight discomfort flexing left knee. No lymphadenopathy, edema, ecchymosis, blemishes or signs of pathology.

Clinical plan-

Patient was given precise medical instructions on diet, exercise, and dosage of the herbal formula, one ounce 3X daily. He is to return to get further lab tests in 10 days.

11/22/02 Progress note-

Patient reports he feels more capacity to work and his work load is very demanding. He feels his vitality has increased by 100%. Patient notes a discrepancy with another lab's previous results, compared to our recent lab tests. This caused him so much concern that he stopped his treatment for 15 days. He restarted his treatment. He says he feels much better. The laboratory results show improvement over previous laboratory tests.

Patient #4 10/15/02 Initial Consultation

This is a male patient 35 years old who has had HIV-1 since 1996. His HIV manifested with pneumocystis carinii and Karposi's sarcoma. He is homosexual and got the virus from sexual contact. Presently, he is physically asymptomatic. He has taken retrovirals since 1996.

Physical exam- Wt.190, Ht.5ft.9in. B.P. 120/75, Pulse 68, Resp. 18, Temp 36.7 C

Patient looks his chronological age, is forthright and cooperative.

Head- Normal cephalic, without protuberances or indentations, with abundant hair.

Eyes- P.E.R.L.

Nose- nasal septum intact and central, with well-hydrated mucosa.

Mouth- oral mucosa intact with no hyperemia, there is evidence of dental caries.

Ears- tympanic membranes intact.

Neck- Trachea midline, mobile and non tender, no palpable lymph nodes, no jugular regurgitation nor distention.

Thorax- Clear lung fields, without exudates or rhochi present, vesicular sounds normal, with rhythmic cardiac sounds-regular without murmurs.

Abdomen- Slightly rounded without visceral enlargement or palpable masses, peristalsis present.

Rectum- Empty rectal ampulla and adequate sphincter tone.

Extremities- Fully mobile without tenderness or distal edema or adenopathy.

Clinical plan-

Referring to previous studies from three months ago, CD4+ fluctuates between 526 and 867. Viral load is 43.600. His weight is presently 180lbs. He will start treatment with the herbal formula, one ounce 3 times daily. Immediate lab results for protocol were ordered. Follow-up appointment is scheduled in two weeks.

10/24/02 Progress note- B.P. 120/80, Pulse 78, Resp. 18, Temp 36.7 C

Patient feels increased energy, is sleeping longer and is more productive at work. He had hiccups the first day. He tolerates the formula well and has four bowel movements daily. He augments his diet with fruit and vitamins.

Cardiopulmonary unchanged; abdomen unchanged. He is to continue to take one ounce of LifeOne three times a day and will return in one month.

11/22/02 Progress note-

Patient says he feels much better and recounts about his work. Clinically presents without changes from previous visits. Cardiovascular and abdominal exam is normal. Lab studies ordered. He continues with a diet low in sugars. He was supplied with LifeOne.

12/08/02 Progress note-

Patient says he feels well. He has no secondary undesirable or adverse effects. The preliminary clinical results show a significant reduction in his viral load and an increase in CD4+. He is supplied with LifeOne to take 3 ounces daily.

Discussion

The immune system is amazingly complex. For ease of description, it can be divided into 2 parts, humoral immunity, concerned primarily with production of antibodies, and cellular immunity, involving the interaction of multiple cells that process information, recognize "self" and "other", and effectively destroy foreign invaders. With regards to HIV infection, we are primarily concerned with immune cells and proteins coating the outside of the cells which are the target of the HIV virus. This protein is named CD4. It is found on several cells of the immune system. The cell with the highest concentration of CD4 is named the CD4+ T cell. The CD8+ cell is also rich in CD4 protein.

- The CD4+ T cell is the primary target of HIV but all other cells exhibiting the CD4 protein are also adversely affected.
- The primary function of the CD4+ cell is as a helper cell that facilitates the functions of many other cells of the immune system.
- CD8+ cells are the NK, natural killer cells that recognize and destroy cells presented to them that are coated with foreign proteins. They may also suppress immune responses. Initially, in the acute HIV infection, CD8+ cell numbers increase as the immune system is activated. Also acutely, the numbers of CD8+ T cells may remain elevated or return to normal levels. But apparently overwhelmed by the sheer numbers of viral particles, large populations of CD8+ cells simply disappear followed by a decrease in absolute numbers of CD8+ T lymphocytes as the disease enters the chronic phase.
- CD16+/CD56+ cells are another subpopulation of NK cells with the function of destroying foreign invaders.
- Arrest of development or failure of function of one or more of these T cell subsets may result in immunodeficiency or autoimmune diseases.
- Normally, the immune system remains in a state of equilibrium, becoming active when presented with an invading organism. When the threat is cleared by an intact immune system, it returns to a state of normalcy.
- The HIV infected immune system, however, is chronically activated. Chronic exposure of the immune system to a particular viral invader over an extended period may ultimately lead to an inability to sustain an adequate immune response to that invader. Furthermore, the ability of the immune system to respond to a broad spectrum of viruses and other threats may be compromised if the immune system is in a state of chronic activation.

Synergism

Many natural compounds require synergism with other compounds to be most effective against cancer, AIDS, and other immunodeficiency diseases. Dr. Farley has used several natural compounds together in a proprietary formula to enhance the synergistic action of each compound. Some known compounds in the herbal formula that have synergistic effects are: Curcumin (Turmeric Extract), Green Tea Extract, Quercetin, and Resveratrol. It is apparent from this small initial clinical trial, that this herbal formula accomplishes this goal by effectively reversing the destructive capacities of HIV, and offers the possibility of having similar effects on other immunodeficiency diseases.

Liposomal Delivery System

The unique property of a liposomal delivery system is a higher cellular uptake and a prolonged circulation of chemotherapeutic and phytochemical agents, as well as aiding in bypassing the digestive system. Therefore, this herbal formula utilizes a liposomal delivery system to maximize the actions of each of its compounds.

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