

A Significant Improvement in a Clinical Pilot Study Utilizing Nutritional Supplements, Essential Fatty Acids and Stabilized Aloe Vera Juice in 29 HIV Seropositive, ARC and AIDS Patients*

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ABSTRACT: It has been found that poor nutrition is one of the risk factors for progressing from HIV seropositive into ARC and into AIDS. By improving the patient's nutritional status the possibility of progressing into AIDS Related Complex (ARC) or Acquired Immune Deficiency Syndrome (AIDS) may be reduced or at least delayed, and the goal is to place the patient into long term remission.¹ To attempt to accomplish this end, a powdered nutritional supplementation was provided to study participants together with essential fatty acids and stabilized 100% pure Aloe Vera Juice for a study period of 180 days.¹ At the conclusion of the study, the participants had improved both clinically and functionally. Most patients who were symptomatic reported that within three to five days their symptoms had subsided and they had gained weight. This regimen of nutritional supplementation is cost effective and non-toxic and can be an important factor in halting the progression of the HIV virus by boosting the immune system, decreasing the P24 core antigen activity and improving the overall quality of the patient's life.

Introduction

The possible beneficial effects of a balanced nutritional supplementation,^{2,3} including essential fatty acids (EFA)^{4,5} and Aloe Vera Juice in

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**Used ALOE From our LAB - Dr Jui
(As did CARRINGTON LAB - inspiring glyconutrient research)*

HIV seropositive asymptomatic, ARC, and AIDS patients was studied in an open trial in 30 patients. In this study, which combined all three of these food substances, the specific objectives were to determine if this combined treatment regimen caused remission or regression or helped to prevent the progression of this disorder as evidenced by physical signs, laboratory measures and subjective reports.¹⁰⁻¹²

Patients and Methods

The study protocol and patient consent form were approved by the Dallas/Fort Worth Medical Center at Grand Prairie, Texas, Investigational Review Board (IRB). Reports were made to the IRB at three month intervals and at the conclusion of the study.

The study protocol required that an initial 30 patients be selected and studied for a period of 180 days. In order to enter the study the patients had to meet the following criteria: Ambulatory patients, age greater than 18 years; diagnosed as HIV seropositive asymptomatic, ARC or AIDS; sign a valid informed consent as approved by the IRB; demonstrate positive HIV antibody testing (ELISA) confirmed by Western Blot; T-4/T-8 lymphocyte ratio of less than 1; and Karnofsky Quality of Life Assessment score (KQLA) of 20 or greater.

There were no current exclusion criteria to entering this study except for inability or unwillingness to comply with the protocol, or sign the informed consent. Hypersensitivity to the food supplements would have precipitated immediate termination from this study. At the initiation of the study, patients were excluded if their T-4 count dropped below 12, since the disease was considered too advanced or if they were receiving treatments which might interfere with determining the effectiveness of the study protocol.

No chemotherapeutic agents or radiation therapy could be given simultaneously for the patient to remain an active participant. Immunization to tetanus, influenza (Fluzone 0.5 cc.), and pneumonia (Pneumovax 0.5 cc.), were to be current. The patients were allowed to continue with all other medication regimens, including AZT. (Table 1).

Patients entered into the study were asked to take the following nutritional supplements during the study: Essential Fatty Acids (EFA) Capsules, 2 capsules, 4 times a day; Aloe Vera juice, 5 ounces, 4 times a day and 1 level scoop of nutritional supplementation pow-

TABLE 1

Drugs the Study Participants Were Taking When They Entered the Study

Patient	AZT	Pentamidino	Zovirax	Other	None Dropped
1				INI//Ethambutol Daily (Military TID) Sulfepomyacin, 1 gm 2 x wk VZA, 1500 mg. Q.D.	
2	200 MG. Q 4 Hours	150 mg. Q 2 weeks	200 mg. TID (Chronic EBV)		
3		150 mg. Q 2 weeks		ETOI//Cigarettes	
4				Accutane; ETOI//Cigarettes	
5		300 mg. Q mo	200 mg. TID (EBV)	Completed CHOP/Liver chemotherapy for Primary Lymphoma	X
6					
7			200 mg. 5 caps Q 8 hr.		X
8					
9					X
10					X
11				ETOI	
12		300 mg. Q mo.		INI	
13	AZT induced anemia (J/c/d on start in study				
14		300 mg. Q mo			
15		300 mg. Q mo (AIDS dementia)		Nizoral 200 mg. Q D (Onychomycosis)	
16			200 mg. (EBV)		

TABLE I (Continued)

Patient	AZT*	Pentamidine	Zalcitabine	Other	None (Dropout)
17					X
18				Isoprinessine 500 mg, 2 p.o., TID	X
19	200 mg. Q 4 hr.			Mycelax; ETOII	
20	None, AZT failure	300 mg. Q mo			(Iud KS) P24 core antigen dropping from 9 to 4
21		300 mg. Q mo			
22				EFOIVCigarettes	
23					
24	AZT (Aug-Oct 88), did three months into the study	300 mg. Q mo.			
25				EFOIVCigarettes; + for Marijuana	
26		150 mg. Q 2 wk		Nizoral 200 mg. QD	
27		S/P PCP		EFOII; + for Marijuana	
28	100 mg. Q 4 hr	150 mg. Q 2 wks	200 mg. Q 8 hr.	Nizoral 200 mg; EFOIVCigarettes	
29				EFOIVCigarettes	X
30					
31				+ for Cocaine on Drug Screen	

TABLE 2

GLA/EPA Capsule Ingredients

Linoleic Acid (LA)	250 mg
Gamma Linolenic Acid (GLA)	80 mg
Eicosapentaenoic Acid (EPA)	45 mg
Docosapentaenoic Acid (DPA)	9 mg
Docosahexaenoic Acid (DHA)	30 mg
d'alpha tocopherol	15 mg

der, 4 times daily in water. (Tables 2-4) The patients were encouraged to continue to eat their regular diet, allowing the nutritional supplements and aloe vera to be the only change in diet. The powdered supplement exceeded the recommended daily allowance (RDA) by about 200%.¹²⁻¹³ However, the concentration of vitamin A was well below the theoretical toxic level of 50,000 units a day, and that of vitamin D was well below the projected toxic level of between 150 and 300,000 units/day.¹⁴ The protein source was adequate for all the essential amino acids and the supplementation as described in the study was found to be well within the margin of safety. Each patient received monthly supplies of the nutritional supplements. Medications other than the study nutrients were to be provided by the patient's physician and/or the study physician as the subject's condition appeared to require, with accurate record keeping of dosages and schedules. The patient's personal physician was kept fully informed. Patients were also asked to refrain from any other supplements or vitamins. They were also required to practice safe sex guidelines throughout the study, and were aware that they could withdraw from this study for any reason, any time.

The study of any individual was to be discontinued if it was obvious that there was rapid deterioration in the clinical condition.

Clinical Evaluation

Each subject was initially seen for a thorough medical evaluation and laboratory studies, and repeated at 30, 60, 90 and 150 days throughout the study. This consisted of a complete physical examination, lab-

TABLE 3
Powder Ingredients

Nutritional Information per serving					
Serving Size	48 grams	Fat	1 gm		
Calories	160	*Cholesterol	0 gm		
Protein	13 gms	Sodium	120 mg		
Carbohydrates	26 gms	Potassium	660 mg		
Percentages of U.S. Recommended Daily Allowances (U.S. RDA) per serving:					
Protein	30%	Vitamin E	50%	Copper	50%
Vitamin A	70%	Vitamin B ₆	50%	Biotin	50%
Vitamin C	50%	Folic Acid	50%	Pantothenic Acid	50%
Thiamine	50%	Vitamin B ₁₂	50%	**Chromium	23 mcg
Riboflavin	60%	Phosphorus	20%	**Selenium	23 mcg
Niacin	50%	Iodine	50%	**Manganese	2 mg
Calcium	25%	Magnesium	50%	**Fiber	3 gms
Iron	50%	Zinc	50%	**Octacosanol	2000 mcg
Vitamin D	50%				
Amino Acids per 48 gram serving					
Alanine	375 mg	Histidine	320 mg	Proline	1425 mg
Arginine	450 mg	Isoleucine	655 mg	Serine	700 mg
Aspartic acid	850 mg	***Leucine	1115 mg	***Threonine	510 mg
Cystine	65 mg	***Lysine	920 mg	***Tryptophan	145 mg
Glutamic acid	2640 mg	***Methionine	310 mg	Tyrosine	630 mg
Glycine	250 mg	***Phenylalanine	600 mg	***Valine	755 mg
Ingredients: Fructose, Nonfat Milk Solids, Calcium Sodium Caseinate, Natural and Artificial flavors, Cellulose, Corn Bran, Potassium Chloride, Lecithin, Maltodextrin, Carrageenan, Wheat Germ Oil (source of Octacosanol), Magnesium Oxide, Beta Carotene, Selenium, Ascorbic Acid, Ferrous Fumarate, d-Alpha Tocopherol Acetate, Chromium, Niacin, Aloe, Apple Pectin, Zinc Oxide, Manganese Sulfate, Vitamin A Palmitate, d-Calcium Pantothenate, Copper Sulfate, Pyridoxine Hydrochloride, Riboflavin, Thiamine Hydrochloride, Cobalamin Concentrate, Vitamin D ₂ , Folic Acid, Biotin and Potassium Chloride.					

* Information on cholesterol content is provided for individuals who, on the advice of a physician are modifying their dietary intake of cholesterol.

** No RDA established for these nutrients.

*** Essential Amino Acids.

TABLE 4

Aloe Vera Juice Ingredients

The Aloe Vera Juice is produced from the crystal clear gel of Aloe Barbadensis Miller fresh leaves by an extraction and purification process.

SPECIFIC GRAVITY:	1.00 - 1.002
SOLIDS:	minimum of 0.30%
pH VALUE:	3.5 - 5.0
CONSISTENCY:	slightly viscous
PATHOGENS:	none
CALIFORMS:	none
POLYSACCHARIDE CONTENT:	minimum 1200 mg/liter
PRESERVATION:	0.25% stabilized electrolytes of oxygen (non-toxic) 0.07% potassium sorbate

oratory studies, including chest x-ray, EKG, white blood cell count with differential and sedimentation rate. Blood pressure, temperature, pulse, and respirations, as well as weight were recorded at each visit during the study.

Episodic interval care, including any additional laboratory studies for other conditions which could have significant impact, if required, were recorded. (Table 5). A sexual practice questionnaire was gathered (Table 6). A Modified Walter Reed Clinical Evaluation was calculated at each visit.¹⁷ (Table 7). The modified version was selected because it contained more criteria and allows for evaluation up to 14; the standard Walter Reed scores only up to 6. The Modified Walter Reed score was ranked 1 for each parameter noted. A score of 6 or greater was equivalent to AIDS, while ranking 2 to 5 was ARC, ranking 0 to 2 was HIV positive, asymptomatic. In addition, any lymphadenopathy was recorded and a T-4 count less than 400 was noted. Delayed skin hypersensitivity (DHS) to skin testing was evaluated.

TABLE 5

Opportunistic Infections, Cancer, RPR Positive and Other Conditions Present Initially or During the Treatment of the Study Participants

Patient	Opportunistic Infections	Cancer	Other Conditions	Note	Dropped
1	Miliary TB				
2	S/P PCP		EBV	X	
3				X	
4					
5		Primary Liver Lymphoma	EBV	X	
6					
7			Chronic herpes		
8				X	X
9				X	
10				X	
11				X	
12	Miliary TB (Rx'd)	Kaposi's Sarcoma, 7-24-89, Cutaneous			
13	AIDS Wasting Syndrome		Anemia Secondary to AZT	X	
14					
16			Herpetic Zoster/AIDS Dementia		
16			EBV		

TABLE 5 (Continued)

Patient	Opportunistic Infections	Cancer	Other Conditions	None	Dropped
17			AZT induced Anemia	X	
18				X	
19					
20			Venereal Warts		
21	S/P PCP	Kaposi's Sarcoma, widespread, cutaneous	AZT induced Anemia		X
22					
23				X	
24	S/P PCP			X	
25					
26	S/P PCP				
27	S/P PCP		Anal Condyloma; Herpetic Proctitis; CMV		
28			ITP, S/P SPLENECTOMY Nov '85	X	
29				X	
30				X	
31				X	

TABLE 6

Sexual Practices of Study Participants

Patient	Homosexual	Heterosexual Healthcare worker	Caraboe as Dropped from Study
1	Receptive, Anal		X
2	Safe sex, Receptive, Active		X
3	Safe sex		X
4	Oral Sex		
5	Safe sex, Monogamous, Partner		X
6		Safe sex	X
7	Receptive	Orthodontist Physician	
8			X
9	Safe sex		
10	Safe sex		
11	Safe sex		
12	Safe sex, Monogamous		
13	Safe sex, Monogamous		
14	Active		
15	Receptive, Anal		X
16	Receptive, Active		X

TABLE 6 (Continued)

Patient	Homosexual	Heterosexual Healthcare worker	only also	Caraloc as Dropped) from Study
17	Safe sex, Active, Anal			
18	Safe Sex, Oral, Monogamous, + Partner			
19	Safe sex, Multiple			
20	Non-monogamous, + Partner			
21	Celibate			
22				
23	Safe sex, Monogamous, Partner			
24	Safe sex, Monogamous, + Partner (AIDS)			
25	Safe sex, Active, Anal, Oral, Multiple partners			
26	Safe sex, Anal, Oral			
27	Celibate			
28	Unsafe sex—'84; Safe sex—now Anal, Rimming, Oral—until '84			X
29	Celibate 2 1/2 yrs; always anal receptive before			
30	Safe sex, Multiple partners			
31				Safe sex

TABLE 7
Modified Walter Reed Clinical and Calculation Form Example

PATIENT ID. _____		TERRY PULSE, M.D.	
Patient ID _____		Signature _____	Date _____
		OTHER INDIVIDUAL PATIENT CLINICAL PARAMETERS	
Lymphadenopathy	<input type="checkbox"/>	Persistent Fatigue	<input type="checkbox"/>
T-4 Abs Count (less than 400) Enter actual value	<input type="checkbox"/>	Night Sweats	<input type="checkbox"/>
Delayed Skin Hypersensitivity (DHS)	M	Documented Fever	<input type="checkbox"/>
	C		
Thrush	TPP	Persistent or Episodic Diarrhea	<input type="checkbox"/>
	TR		
Opportunistic Infections	<input type="checkbox"/>	WBC	<input type="checkbox"/>
P24 Core Antigen	<input type="checkbox"/>	SED RATE	<input type="checkbox"/>
Other _____	<input type="checkbox"/>	Lesion (K.S.)# and shape	<input type="checkbox"/>
TOTAL SCORES _____			

TABLE 8
Karnofsky Quality of Life Assessment Form

	Description	Scale %
*	Normal, no complaints, no evidence of disease	... 100
	Able to carry on normal activity, minor symptoms or signs of the disease	... 90
*	Normal activity with effort, some signs or symptoms of the disease	... 80
*	Cares for self, unable to carry on normal activity or do active work	... 70
*	Requires occasional assistance, but is able to cater for most of his needs	... 60
*	Requires considerable assistance and frequent medical care	... 50
*	Disabled, requires special care and assistance	... 40
*	Severely disabled, hospitalization is indicated although death is not imminent	... 30
*	Hospitalization necessary, very sick, active supportive treatment necessary	... 20
*	Moribund, fatal processes progressing rapidly	... 10

Score * [____/____/____] %
*(any intermediate value, one item only)

The antigens used were Mumps, Candida, Trichophyton, Tuberculin Purified Protein Derivative (TPP) and a saline control. The patient with a fully functioning immune system should react to all antigens, except for TPP unless they have an active case of Tuberculosis. Thrush, or any other opportunistic infections were catalogued. Unusual persistent fatigue, night sweats, documented fever and persistent or episodic diarrhea at the time of entry into the study were noted and the location, shape and number of Kaposi's sarcoma lesions recorded. Any clinical or laboratory data furnished by a subject's personal physician were also recorded. A Karnofsky Quality of Life score was calculated initially, and at 180 days.¹⁰ (Table 8). The Karnofsky Quality of Life Assessment score is ranked by the patients them-

selves, based on their ability to function adequately at day one and day 180.

Laboratory Evaluation

Laboratory examinations performed at the initial evaluation were the Diagnostic Reflex Panel II, which included a CBC with differential, SMAC-24, thyroid studies with TSH, sedimentation rate, Rapid Plasma Reagin Test (RPR), T cell subsets by flow cytometry, and P24 core antigen assay. At each subsequent visit, laboratory examinations performed included a complete blood count with differential, platelet count, sedimentation rate, SMAC-24, a lymphocyte enumeration panel and a T4/T8 ratio. Other tests were performed as required, depending upon the clinical state.

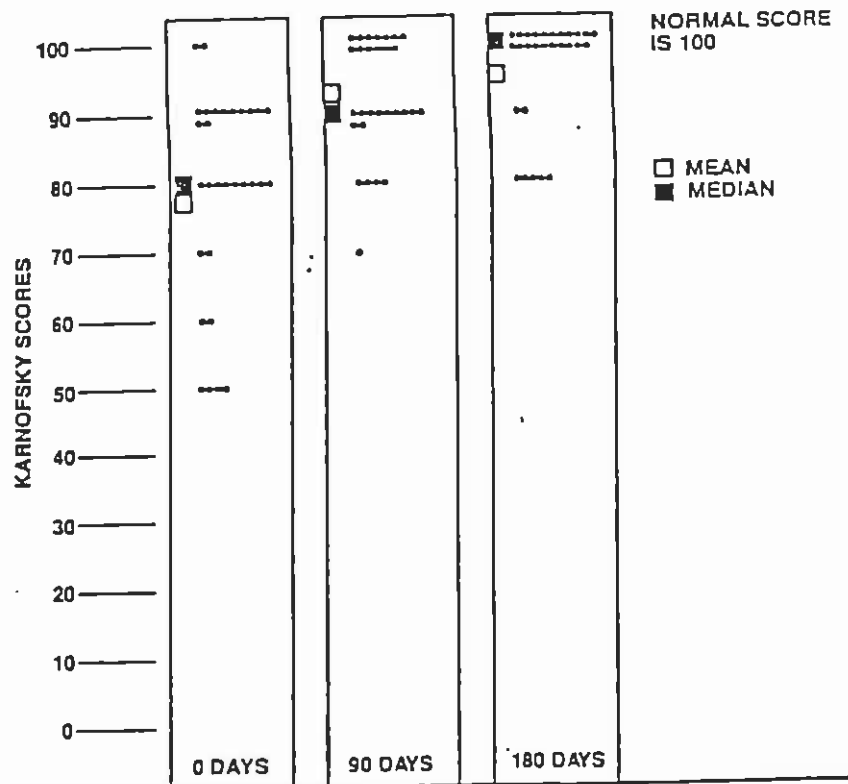
It was agreed that there might be a six to twelve month extension of the study for any individual who had derived benefit, if he so desired.

Results

Initially, 31 patients were to be studied, of whom 2 dropped from the study for non-compliance. Of the 29 remaining, 15 had an initial Walter Reed scores consistent with a diagnosis of AIDS, 12 met the criteria for ARC and 2 were HIV seropositive but asymptomatic. Modified Walter Reed scores on initial evaluation showed a median of 6.25 and a mean of 5.39; at 90 days the evaluation period showed a median drop to 1.50 and a mean drop to 2.0. The Modified Walter Reed score shows improvement when it decreases. All 29 of the patients had lower Modified Walter Reed scores at 90 days for 100% improvement as a group; at 180 days 2 remained the same and 27 improved further for 96.4% improvement. Although statistical significance was shown at 90 days ($p = 0.0001$), at 180 days the scores on the Modified Walter Reed were significantly lower than the initial scores. ($p = 0.0001$ on both the Wilcoxon Signed Rank Test and the t-test). Karnofsky Quality of Life Assessment scores were done initially with a median of 80 and mean of 78.97 and at 90 days the median was 90 and the mean was 92.41. The Karnofsky Quality of Life Assessment shows improvement when it increases. Twenty seven patients improved on the Karnofsky score at 90 days and two remained the same

FIGURE 1

Karnofsky quality of life scores at 0, 90, and 180 day testing.

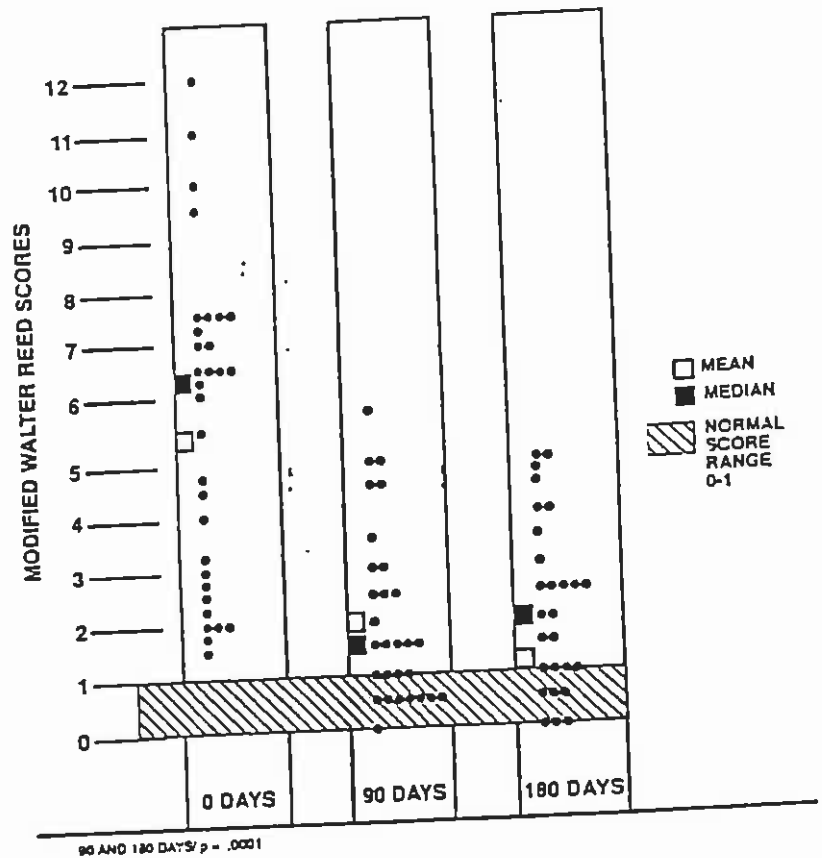


90 AND 180 DAYS/ $p = 0.001$

for 93.1% improvement; all improved at 180 days for 100% group improvement. (Figure 1) Again, although statistical significance was shown at 90 days ($p = 0.0001$), at 180 days the scores were significantly higher than the initial scores. ($p = 0.0001$ on both the Wilcoxon Signed Rank Test and the t-test). (Figures 1,2). Of greatest significance was the P24 core antigen assay in which at 90 days 3 out of 12 (25%) of those that were originally positive for the P24 core antigen had converted to nonreactive (not due to spontaneous deterioration of a failing immune system or end stage AIDS); at 180 days this figure remained the same. The P24 core antigen is a measurement of viral replication. Although not all patients present positive for P24, a

FIGURE 2

Modified Walter Reed scores at 0, 90, and 180 day testing.



reduced or negative P24 is desired. The P24 was statistically significant on the Wilcoxon Signed Rank Test at 90 days and showed a trend on the t-test at 90 days. At 90 days the P24 value indicated a statistical improvement over the initial measurement. (Figure 3).

The T4 helper lymphocytes at 90 days increased in 15, decreased in 12 and remained unchanged in two. At 180 days 9 had increased and 19 had decreased. Theoretically, the higher the T4 count the healthier the person. Because of the wide range of values in the normal range for T4 helper lymphocytes, the number of the patients with

FIGURE 3

P24 scores at 0, 90, and 180 day testing.

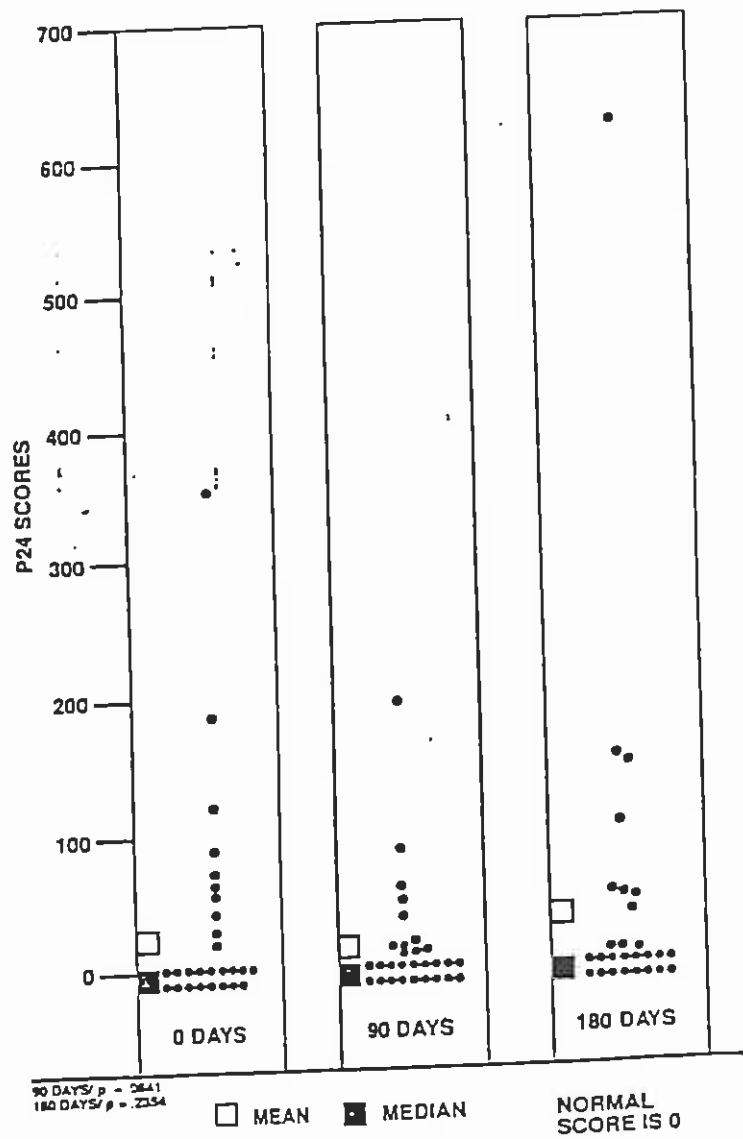
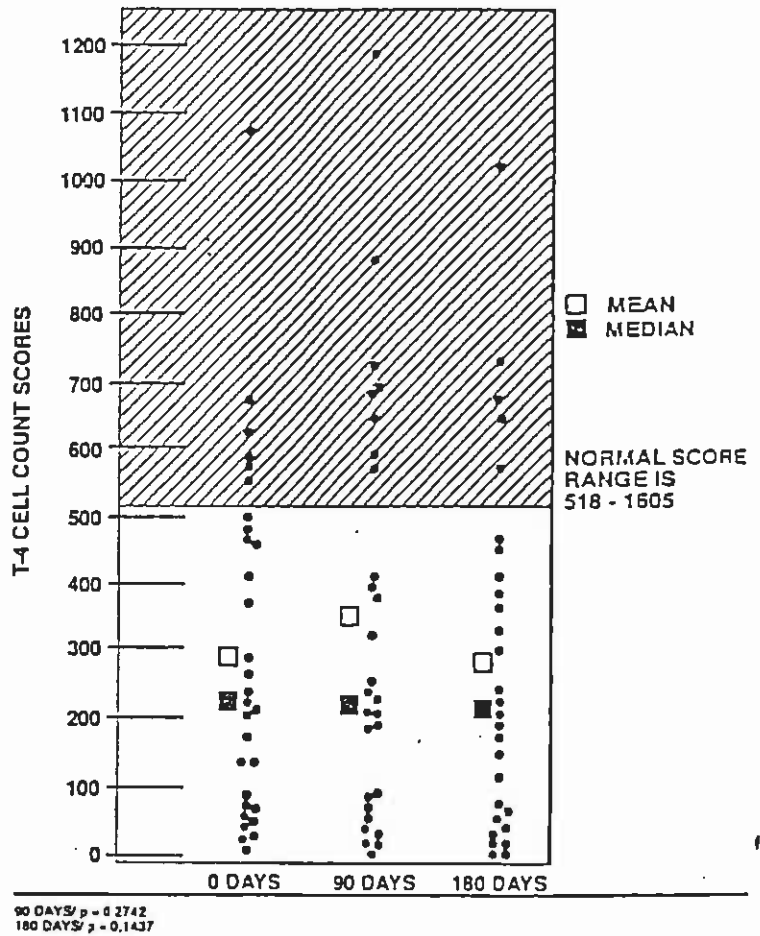


FIGURE 4

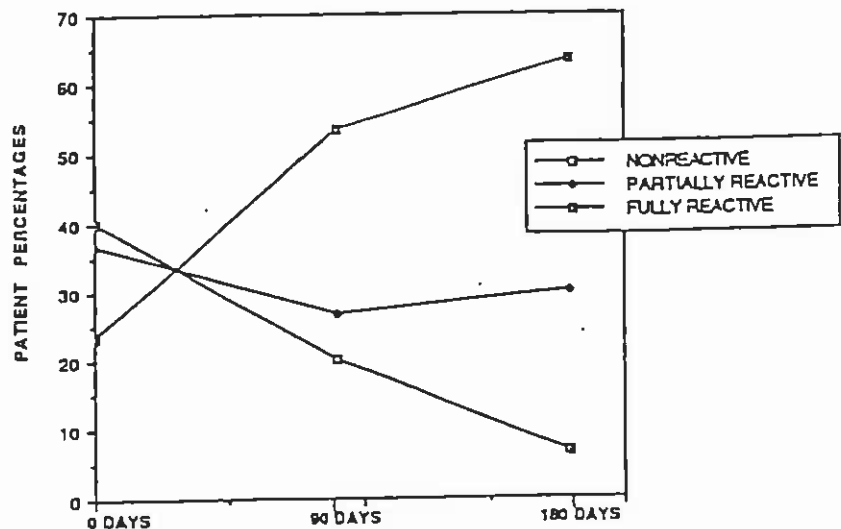
T-4 cell count at 0, 90, and 180 day testing.



increased T4 lymphocyte counts was compared to the number decreased. Statistically, No exact statistical difference occurred in the T4 counts ($T^4_{90} p = 0.2742$, $T^4_{180} p = 0.1437$) (Figure 4). Hypersensitivity skin testing to all antigens improved in 10 patients at 90 days and 19 of them had fully restored delayed hypersensitivity (63.3%) at 180 days. The desired result was fully restored delayed hypersensitivity. (Figure 5)

FIGURE 5

Delayed hypersensitivity testing results. Nonreactive: 0 days, 12(40%); 90 days, 6(20%); 180 days, 2(6.6%). Partially reactive: 0 days, 11(36.6%); 90 days, 8(26.7%); 180 days, 9(30%). Fully reactive: 0 days, 9(23.3%); 90 days, 16(53.3%); 180 days, 19(63.3%). Three hypotheses were tested and rejected at a significance level of 0.5. Ho1: There is no difference in the reactivity of patients at the initial and 90 day testing. Ho2: There is no difference in the reactivity of patients at the initial and 180 day testing. Ho3: There were no changes over time in the reactivity of patients. The difference in reactivity in the initial and 90 day testing was statistically significant (Chi Square = 5.9954, $p = .0499$). Statistically fewer patients were non-reactive and partially reactive and more patients were fully reactive than initially. The difference in reactivity in the initial and 190 day testing was statistically significant (Chi-Square = 12.8813, $p = .0016$). Significantly fewer patients were non-reactive and partially reactive and more patients were fully reactive than initially. The test results involving Ho3 looked at the initial, 90 day and 180 day results simultaneously and concluded that there was a statistically significant shift to more reactivity over time (Chi-Square = 13.6714, $p = .008$).



No adverse effects were attributable to the nutritional supplements. Most of the symptomatic patients reported that within three to five days their energy level improved, fever disappeared, night sweats stopped, cough decreased or stopped altogether, shortness of breath decreased, lymph nodes decreased in size, diarrhea stopped,

weakness improved and they began to gain weight favorably. At the end of the study there was a 7% average weight gain in all the subjects.¹⁹ There were no biochemical abnormalities noted on SMAC-24 throughout the study. Anemia induced by AZT showed improvement in all patients either previously on AZT or remaining on Retrovir throughout the study. Chest x-rays and EKG tracings remained within normal limits.

Discussion

It has been shown in previous studies that a deficiency in certain essential fatty acids might predispose to AIDS.^{20,21} It has also been noted that unsaturated free fatty acids inactivate animal enveloped viruses.²² Therefore, we set out to investigate the possible beneficial effects²⁷ of a balanced nutritional⁴ supplementation as described. Specific objectives of the study were to determine if this treatment caused remission, regression or halted the progression of this disorder as evidenced by clinical evaluation, laboratory testing, and subjective evaluation based upon questionnaire forms.

Based on this clinical pilot study, we conclude that nutritional supplementation is synergistic in lowering antigenemia and improving immune function in HIV seropositive patients at all stages. Some studies show that diets high in arginine improve T4 function and laboratory counts.²³ Many AIDS patients are actually dying of starvation. Where wasting occurred, which is common in this disease, because of decreased food intake, malabsorption or metabolic alterations, by appropriate nourishment, significant improvement occurred in all our patients, even in those patients who would conventionally require TPN, without exposure to the risks of parenteral caloric intake. Most notably, diarrhea stopped and wasting reversed in all affected patients. A majority of them showed elevated triglycerides and decreased cholesterols at the outset of the study. Over half of the patients began normalizing their HDL, and cholesterol levels increased with a concurrent drop in P24 core antigens in those who were positive initially.

Because of continued improvement in a majority of patients at 180 days and beyond the conclusion of the studies, these nutritional pilot studies would indicate that this protocol might form the foundation of nutritional treatment in AIDS patients, as synergism is clearly seen in those patients taking other medications including AZT and Pen-

tamidine. More specific and individualized studies with controls are now warranted as a large number of dietary products alter immune system function, and may be thought to possess pharmacologic nutritional effect, for example arginine, glutamine, omega 6 and omega 3 fatty acids, short-chain fatty acids, zinc, iron, and vitamins A, C, and E.² To this purpose a study should be initiated.

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