ARCHIVOS LATINOAMERICANOS DE NUTRICION
Organo Oficial de la Sociedad Latinoamericana de Nutrición

Vol. 52 N° 3, 2002

Nutritional supplementation according to energy and protein requirements in malnourished HIV-infected patients

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SUMMARY. To evaluate the effects of nutritional supplements on nitrogen and energy balances, body composition and immune parameters, HIV-infected malnourished adult outpatients were prospectively studied. Forty-six patients (4 females and 42 males; 37±12 y) were supplemented with a polymeric diet (PD) or regular foods (RF) on two consecutive 45-day periods on a crossover design. Weight, skinfold thicknesses, plasma albumin (PA), CD4 and CD8 lymphocyte counts (LC), resting energy expenditure (REE) and urinary nitrogen excretion were measured at baseline, 45 and 90-day. Food intake was weekly recorded by food surveys. Thirty-five patients completed the protocol (18 in Group 1:PD → RF; 17 in Group 2:RF → PD). In both groups, weight, fat free mass (FFM), energy balance (EB) and nitrogen balance (NB) increased significantly after PD, whereas LC and PA remained unchanged in both groups. The best results in terms of weight gain were obtained in the PD group and PD plus zidovudine subgroup (n=8) during the first 45 days (weight gain/FFM gain: 4.8/2.6 kg and 6.8/3.1 kg, respectively). Nutritional supplement with PD, according to the EB and NB goals, was well tolerated and permitted to achieve a significant weight and FFM gain over a 90-day follow-up.
Key words: HIV, resting energy expenditure, weight gain, body composition, nutritional supplement.

RESUMEN. Suplementación nutricional de acuerdo al requerimiento energético y proteico medido en pacientes HIV-positivo. Para evaluar los efectos de la suplementación nutricional en los balances nitrogenado (BN) y energético (BE), composición corporal y parámetros inmunológicos, se estudió prospectivamente a adultos HIV positivos con desnutrición. 46 pacientes (4 mujeres y 42 hombres; 37±12 años), fueron suplementados con dieta polimérica (DP), o alimentos habituales (AH), en 2 períodos concecutivos de 45 días, con un diseño cruzado. Al inicio, día 45 y día 90 se midió peso, pliegues cutáneos, albuminemia (A), linfocitos CD4 y CD8 (L), gasto energético de reposo (GER), y nitrógeno ureico urinario. Se efectuó encuesta alimentaria semanalmente. 35 pacientes completaron el estudio (18 en grupo 1: DP→AH; 17 en grupo 2: AH→DP). Después de los 45 días con DP aumentó significativamente el peso, masa libre de grasa (MLG), BE y BN en ambos grupos. L y A no varió significativamente en ninguno de los grupos. Los mejores resultados en términos de ganancia de peso fueron obtenidos en el grupo 1 y en el subgrupo con DP más AZT (n=8), con una ganancia de peso/MLG de 4.8/2.6 kg y 6.8/3.1 kg, respectivamente. La suplementación con DP, de acuerdo a metas de BE y BN, fue bien tolerada y permitió una ganancia de peso y masa libre de grasa significativa en un período de 90 días.
Palabras clave: VIH, gasto energético de reposo, ganancia de peso, composición corporal, suplementación nutricional.

INTRODUCTION

Malnutrition with progressive wasting of body cell mass is a major feature of AIDS (1-4). This disease is characterised by moderate to severe metabolic stress similar to critically ill patients (5-7). This is associated to decreased oral intake secondary to anorexia (2,3,8,9), and to malabsorption (10,11). Such hypermetabolic condition has also been found in clinically stable AIDS patients (5-7,12). A weak correlation with viral load measured by plasma HIV RNA contents and with antiretroviral therapy has been found (13).

Both weight loss and a low serum albumin concentration (14) are predictive of increased risk of morbidity and decreased survival in AIDS patients. Nutritional support is hoped to improve immune system function and reduce the incidence of opportunistic infections. Also, it can improve the efficacy of drug therapies and contribute to a better patient's quality of life (15).

The aim of this study was to analyse the impact of two forms of dietary supplementation on the nutritional recovery, energy balance, and nitrogen balance in HIV+ malnourished patients over a 90-day period.

MATERIAL AND METHODS

Subjects

Forty-six HIV-infected adults outpatients (37±12 years old; 4 females and 42 males), from the AIDS wards in the "José Joaquín Aguirre" and "San Juan de Dios" Hospitals in Santiago were studied prospectively between September 1994 and August 1995. All patients had calorie-protein malnutrition according to the Body Mass Index (BMI) (low to 20 kg/m^2).

Eleven patients were in A or B category and thirty-five patients had a positive diagnosis of AIDS ("C" category) according to the guidelines issued by the Atlanta's Centre for Disease Control in 1992 (16).

The experimental design corresponded to a prospective randomised cross-over study. Patients were given two types of dietary supplements in random order, consisting of regular foods (RF) or of a polymeric diet (PD;ADN^R), over two consecutive periods of 45 days. **Group 1** (n=21): patients received a polymeric diet during the first period and then regular foods. **Group 2** (n=25): patients were supplied with RF during the first period and then with PD. Clinical characteristics of the two groups at admission to the study are presented in Table 1. Table 2 shows selected nutritional and immunological parameters of the 46 patients at baseline.

TABLE 1
Characteristics and diagnosis of the study population

	Group 1	Group 2
Number of patients	21	25
Age (y)	38.2 ± 11.5 *	37.7 ± 12.5*
Sex ratio (F:M)	2 : 19	2 : 23
AZT (yes / no)	11 / 10	12 / 9
N° of clinical illness	14	14
Candidiasis	4	4
Pneumocystis carinii		
pneumonia	3	4
Toxoplasmosis	2	2
Kaposi's sarcoma	2	1
Chronic diarrhea	1	2
Meningitis	1	0
Tuberculosis	1	0
Oral leukoplakia	0	1

* mean ± standard deviation.

AZT: zidovudine therapy.

Analyses

The following parameters were evaluated at the beginning, and on 45th and 90th days of the study: weight, height, and skinfold measurements (triceps, biceps, subscapular and suprailiac). Fat mass (FM%) was calculated by applying the sum of the skinfolds and the Durnin and Womersley tables (17). Fat free mass (FFM) was calculated by difference between body weight and fat mass.

CD4 and CD8 lymphocyte counts were obtained from peripheral blood by cytometric flow. Plasma albumin concentrations were measured by the modified Biuret method (18).

Twenty-four hours urinary ureic nitrogen (UUN) was determined by the urease method. Resting Energy Expenditure (REE) was determinated by open circuit indirect calorimetry, with Hans Rudolph™ facial mask, Douglas bag, Haloscale Wright Respirometer™ and Scholander gas microanalyses (19). Oxygen consumption (VO_2), CO_2 production (VCO_2), and REE were calculated according to Weir formula (18). Predicted energy expenditure (PEE) was obtained by the Harris and Benedict's equations (20).

Nutritional intake was recorded by 24-hour recall taken on three alternate days before the beginning of the study and during all the supplementation period. Energy and protein intakes were calculated by using the chemical composition tables of Chilean foods (21). With the data obtained, the following parameters were calculated:

- Energy Balance (EB) = Energy Intake (EI) - (REE x 1.3)
- Nitrogen Balance (NB) = Nitrogen intake* (NI) (g/d)-(UUN + 4)
- NI= protein intake / 6.25

TABLE 2
Baseline clinical characteristics of the study population

	All patients n=46	Group 1 n=21	Group 2 n=25
WEIGHT (kg)	54.2±5.7	52.7±5.5	55.4±5.6
BMI (kg/m2)	18.6±1.3	18.5±1.4	18.6±1.2
FM % (SKF)	16.9±5.5	17.6±5.7	16.4±5.4
REE (kcal/kg/d)	24.6±4.6	25.3±5.6	23.9±3.4
REE/PEE (%)	94.1±15.8	96.8±17.8	91.8±13.6
EI (kcal/kg/d)	30.4±8.8	34.2±8.8 *	27.2±7.5 *
EB (kcal/kg/d)	−1.6±9.0	1.3±9.4 *	-4.0±7.8 *
NI (g/kg/d)	0.18±0.07	0.21±0.09*	0.16±0.05*
NB (g/kg/d)	−11.6±4.7	-12.8±6.2	-10.6±2.6
Albumin (g/dl)	3.5±0.6	3.7±0.7	3.4±0.6
CD4 (x 10^6/L)	176±203	134±126	211±244
CD8 (x 10^6/L)	617±490	463±357	747±546

Mean ± standard deviation. * Significantly different between both groups ($p<0.05$). BMI= body mass index; FM= fat mass by skinfolds; REE= resting energy expenditure by indirect calorimetry; PEE= predicted resting energy expenditure by Harris and Benedict equation; EI = energy intake; EB= energy balance; NI= nitrogen intake; NB= nitrogen balance; Alb= plasma albumin.

Dietary supplementation

Dietary supplements were given in random order, consisting of regular foods (cereals, dairy products, eggs albumin; ≅ 15% of protein contribution to total energy), or of a powdered polymeric diet at 22% water dilution (ADN^R, Davis SA Laboratories, Braun Co.). Polymeric diet presents the following composition per 10 dl: 103 kcal, 3.6 g of protein (sodium and calcium caseinate; 14% of contribution to total energy), 13.0 g. of carbohydrates (maltodextrins) and 4.0 g of lipids (sunflower seed oil and coconut oil). This formula covers vitamin and micronutrient US-RDA requirements for an adult with 200 dl per day.

Energy and protein needs for supplementation were calculated as follow:

- Energy supplementation (kcal/d) = (REE x 1.5*) - EI
*30%: physical activity plus thermogenesis; 20%: anabolism.
- Protein supplementation (g/d) = ((UUN+4)+5*)- NI) x 6.25
*5 nitrogen g for to achieve a positive balance.

Clinical evaluation and antiretroviral therapy

Systemic signs and symptoms were registered for each day of the study. Also it was recorded the presence of AID´s related diseases at the entry and during the intervention periods, and as well as the prescription of antiretroviral drugs. AZT therapy (zidovudine) was present before baseline as monotherapy in almost a half of patients (Table 1) and it was maintained during all the study.

Statistical analysis

Data are presented as mean ± standard deviation. ANOVA for repeated measures was applied in order to evaluate changes on time, baseline, 45-day and 90-day of the study. The mean changes between treatment periods with polymeric or regular food supplementation, or between patients with and without AZT therapy, were compared by Student's t-test for independent samples. Jandel Sigma Stat Version 2.0 and Stats Plus Version B384 software was used for the statistical analysis.

RESULTS

Of the forty-six initial patients, eleven died between the 10^{th} and 45^{th} day of the follow-up (3 in group 1; 8 in Group 2).

These patients presented 1 to 4 AIDS-associated illnesses (21 diseases during the evolution): *pneumocytis carinii* pneumonia (4), oropharyngeal candidacies (5), toxoplasmosis (3), Kaposi's sarcoma (3), chronic diarrhoea (2), lymphoma (1), cryptococcus meningitis (1), tuberculosis (1), and encephalic herpes (1). There was no significant difference on nutritional and immune parameters between survivors and non-survivors patients, although the latter presented greater frequency of diseases.

Thirty-five patients completed the 90-day supplementation period (Table 3). A significant increase of weight, BMI, and FFM was observed in both groups, and FM% in group 2, over the 90-day period. There were no significant variations in plasma albumin, CD4 and CD8 lymphocyte counts. Average weight gain of 5.7 and 3.7 kg (3.2 and 1.7 kg of FFM) was observed over the 90-day period in Group 1 and Group 2, respectively. Taking the entire treatment periods, regardless the sequence of supplementation, the increases were 3.7±3.4 vs. 0.8±3.6 kg on weight, 2.1±2.4 vs. 0.51±2.2 kg on FFM, and 0.03±0.59 vs. –0.13±0.49 g/dl on plasma albumin levels, in PD and RF periods, respectively. Differences were significant.

TABLE 3
Anthropometrical and laboratory parameters of patients on 90 days following

	Group 1 (n=18)			Group 2 (n=17)		
	Baseline	45-Day	90-Day	Baseline	45-Day	90-Day
WEIGHT (kg)	52.7±5.5	57.5±6.3¹	58.4±9.0	56.2±5.5	57.7±6.9	59.9±8.1²
BMI (kg/m²)	18.6±1.4	20.2±1.8¹	20.5±2.7	18.8±1.1	19.3±1.4	20.0±1.9²
FM (%)	17.9±6.1	20.0±7.5	19.7±8.3	16.9±6.1	17.9±4.8	19.0±4.8²
FFM (kg)	43.2±4.3	45.8±4.2¹	46.4±5.0	46.7±5.2	47.3±5.7	48.4±6.4²
Alb (g/dl)	3.5±0.6	3.4±0.5	3.3±0.7	3.7±0.7	3.5±0.7	3.5±0.5
CD4 (x10⁶/L)	139±128	131±139	119±135	247±285	245±271	241±271
CD8 (x10⁶/L)	608±378	679±708	709±733	833±695	799±635	856±786

Mean ± standard deviation. BMI=body mass index;FM=fat mass;FFM=fat free mass;Alb=plasma albumin; [1,2,3] ANOVA significance (p<0.05): [1] from baseline after the first 45 days with polymeric diet (Group 1); [2] from 45-day measures after the second period with polymeric diet (Group 2); [3] from baseline after 90 days of supplementation (Group 1 and Group 2)

The mean of supplemented energy over the first period was 274 kcal/d of PD (13.6% of energy intake; group 1) and 538 kcal/d of RF (34.2% of EI; group 2). In this period energy intake increased by 268 and 97 kcal/d with PD and RF, respectively. On the second period the mean of supplemented energy was 388 kcal/d of PD (15.8% of EI; group 2) and 312 kcal/d of RF (15.4% of EI; group 1), and the EI increased by 875 and –26 kcal/d with PD and RF, respectively.

There were significant increases on energy balance with PD in both groups (EB: +224 kcal in group 1; +826 kcal/d in group 2), and with RF in group 1 (EB: -461 kcal/d). Nitrogen balances increased in both groups (significant on PD period in group 1 and after 90-day period in group 2) (Table 4).

TABLE 4
Metabolic and dietary parameters of patients on 90 days following

	Group 1 (n=18)			Group 2 (n=17)		
	Baseline	45-Day	90-Day	Baseline	45-Day	90-Day
REE (kcal/kg)	25.8±5.9	23.9±6.4	20.6±2.7	24.2±2.2	22.6±4.2	20.9±3.2
REE/FFM	31.3±5.9	30.1±8.1	25.8±3.3 [3]	29.2±3.2	27.6±5.3	25.8±3.7 [3]
REE/PEE (%)	98.1±18.7	95.8±28.1	82.7±13.1[3]	94.6±12.6	89.2±16.7	83.6±14.1[3]
EI (kcal/kg)	33.0±8.6	34.9±6.9	34.8±11.7	26.3±6.3	27.3±5.9	40.9±7.7 [2]
EB (kcal/kg)	-0.5±8.5	3.9±9.9[1]	7.9±11.0	-5.2±6.7	-2.1±8.2	13.8±8.5 [2]
UUN (g/d)	8.9±6.1	7.7±4.0	6.8±3.4	6.5±2.5	5.6±2.6	5.9±2.6
NI (g/kg/d)	0.19±0.07	0.22±0.06	0.23±0.06	0.15±0.04	0.19±0.05	0.25±0.07[2]
BN (g/kg/d)	-0.06±0.15	0.01±0.08[1]	0.03±0.12	-0.04±0.04	0.02±0.06	0.07±0.1[3]

Mean ± standard deviation. REE:resting energy expenditure; PEE=predicted resting energy expenditure by Harris and Benedict equation; EI=energy intake; EB=energy balance; UUN=urinary ureic nitrogen excretion;NI= nitrogen intake;NB= nitrogen balance. [1, 2, 3] ANOVA significance ($p<0.05$): [1] from baseline after the first 45 days with polymeric diet (Group 1); [2] from 45-day measures after the second period with polymeric diet (Group 2); [3] from baseline after 90 days of supplementation (Group 1 and Group 2).

Patients with normal (90%-109%), or high REE/PEE% (≥110%) at the entry of the study showed a significant reduction on mean REE/PEE% at the 45-day and 90-day evaluations (Table 5). There were no significant differences in baseline characteristics among groups according to REE/PEE%.

TABLE 5
Characteristics of subjects clustered by initial metabolic level (REE/PEE %) during 90 days of dietary supplementation

	< 90 % (n=10)	90-109 % (n=20)	≥ 110 % (n=5)
Baseline REE/PEE%	79.0±8.0	98.0±7.0	125.0±13.0
45-day REE/PEE%	79.6±14.8	96.0±22.4	104.5±30.0
90-day REE/PEE%	76.2±10.1	85.8±12.8'	86.5±17.2'
BMI (kg/m²)	18.5±1.3	18.9±0.1	17.8±1.9
FM (%)	17.1±5.5	17.8±5.2	16.5±8.0
ALB (g/dl)	3.3±0.6	3.6±0.6	3.8±0.8
CD4 (xmm³)	125±142	138±120	299±317
CD8 (xmm³)	533±270	615±554	735±462
n° illnesses *	3	5	1

REE/PEE %: resting energy expenditure as % of predicted energy expenditure (PEE) by Harris and Benedict equation. BMI: body mass index; FM: fat mass.
* infectious illnesses at entry to the study, including: *pneumocystis carinii* pneumonia, tuberculosis, encephalic herpes, meningitis.
' significantly lower than baseline and 45-day averages.

The systemic signs and symptoms (% of observation days: both groups-PD period/both groups-RF period) were: disguise (24/25%), anorexia (17/20%), dysphagia (14/20%), chewing pain (11/19%), nausea (14/16%), diarrhoea (10/11%), and vomiting (5/11%). There was no significant difference of frequency of signs and symptoms between both periods of supplementation.

Of the thirty-five patients whom completed the study, patients with AZT therapy (8 in group 1 and 8 in group 2) were compared to non-AZT patients (10 in group 1 and 9 in group 2). No significant differences were observed on nutritional and immunological baseline parameters. Although there was a greater non-significant increase on body weight in AZT (3.96±3.73 kg) than non-AZT patients (2.55±3.37 kg) during the first 45-day period, the composition of the weight gain was very similar (50.3 vs. 53.7% of FFM, respectively). On the first 45 days, only group 1 (PD) had higher weight gain (6.8±3.3 vs. 3.2±3.5 kg), energy intake (535±147 vs. 80±92 kcal/d), and energy balance (423±50 vs. 173±27 kcal/d) in AZT (+) patients compared to their AZT (-) counterparts.

DISCUSSION

Infectious complications can be the cause of mortality in AIDS patients. Nevertheless, malnutrition increases the risk of morbidity and mortality during the evolution of the illness, and it strongly predicts patient's survival regardless the immunology condition (4). In our study, there were no significant differences in nutritional status (BMI, FM%, serum albumin), immunological condition (CD4 lymphocyte counts), and REE among survivors and nonsurvivors patients. However, there were greater frequencies of infectious diseases like *pneumocystis carinii* pneumonia, tuberculosis, meningitis and encephalic herpes in nonsurvivors (7/11) compared to survivors (9/35).

Despite the well-known beneficial impact of maintaining or improving the weight, FFM, and serum albumin levels in AIDS patients, discrepancy exists about the efficacy and feasibility of nutritional supplementation. Results of hypercaloric feeding interventions indicate that the weight gained is predominantly fat mass (22). In a prospective study, Bürger et al (23) tested the effects of supplementation with a polymeric diet in 34 clinically stable HIV+ patients. These authors reported poor tolerance and a low correlation between formula intake and weight changes. Similar negative results were obtained by Hoh et al (24) on a 6-week supplementation trial with a polymeric diet (550-600 kcal/d), in thirty-nine HIV+ patients with associated wasting. Net protein and energy intake increases were not associated to increased mean FFM.

During a 6-month prospective study on fifty-five HIV-infected outpatients supplemented with a polymeric diet (606 kcal/d), Pichard et al (25) observed increased energy and nitrogen intakes, with excellent compliance and good tolerance. Also, a mean weight gain of 2 kg (50% of FFM), without change on CD4 and CD8 lymphocyte counts, viraemia or tumour necrosis factor receptors (used as inflammation parameters) were noted.

In the present study, patients achieved a mean weight gain of 4.7 kg (5.7 and 3.7 kg in group 1 and 2, respectively). 53% of weight gain corresponded to fat free mass (56% in group 1 and 46% in group 2), after 90 days of supplementation, without significant changes on CD4, CD8 and plasma albumin levels. Nonetheless, the method for evaluating body composition used in this study (skinfold thickness measurements) makes it impossible to know whether the increase of fat free mass corresponded to muscle mass or water. This nutritional recovery was obtained by increased energy and protein intakes, specially in patients with low initial food intake who were supplemented with a polymeric diet (Table 4), despite the presence of anorexia, dysgeusia, dysphagia, chewing pain, and/or diarrhoea. Observed mean energy intake increased by 1.8 and 14.6 kcal/kg/d (105 and 874 kcal/d), in group 1 and 2, respectively. Protein intake increased 0.25 g/kg/d and 0.63 g/kg/d (14.6 and 37.4 g/d) in group 1 and 2, respectively. It is suggested that these improvements were consequence of the use of a polymeric diet for supplementation (ADN^{R}). This supplement permitted to fulfil the required prescription easier than with the intake of regular foods.

Recently, Sheehan et al (26) analysed prospectively variables such as energy intake, energy expenditure, weight change, CD4 count and clinical status of 33 HIV-positive men during a 3-y period. With a linear modelling analysis they concluded that the primary determinant of energy balance was energy intake, with a minor contribution of total energy expenditure. These results magnify the importance of nutritional support in HIV-positive and AIDS patients, and the energy and protein intakes achieved in our study.

Yarchoan et al (27), observed that nucleoside analogues therapy such as AZT could explain at less partially, the body weight increase in patients with AIDS. No information about energy intake or body composition changes was available in that study. Other studies in patients treated with protease inhibitors showed significant greater weight gain than non-users of that therapy (28,29). However, weight gain was mostly fat mass in a dorsocervical and truncal distribution pattern (28,30).

In our patients (regardless the type of supplementation), there was a trend to a greater weight gain (and FFM) in AZT than non-AZT patients (although no significant), associated to increased energy and nitrogen intakes and balances. FFM was 50% and 54% of weight gain in AZT and non-AZT patients, respectively.

After the first 45 days of supplementation with a polymeric diet (group 1), AZT patients achieved greater significant weight gain than non-AZT patients (6.8 Vs 3.2 kg), this was related to greater energy intake and energy balance. Contribution of FFM to body weight gain was 41 and 46% in AZT and non-AZT patients, respectively. Polymeric diet supplementation plus AZT therapy showed to be the best combination for the nutritional recovery of our patients.

On the other hand, the resting energy expenditure in AIDS subjects showed great variability, which has not clearly been associated with the nutritional status, degree of immune impairment, presence of illnesses or weight loss history (31). In AIDS whether energy expenditure is increased or decreased depends on the balance among thermogenic factors (cytokine levels, fever, opportunistic infections), metabolic adaptation to a low energy intake and cachexia with fat free mass wasting (32). In our study, REEs at baseline evaluation in 48% of subjects were significantly different from those predicted by the Harris-Benedict equations (REE/PEE <90 or ≥ 110%). Eleven percent of patients showed increased REE (≥110%), whereas REE was decreased in 37% (<90%). These REEs were not associated to differences in nutritional status, CD4 and CD8 lymphocyte counts, frequency of infectious illnesses, or AZT therapy. At the end of study only two of thirty-five subjects presented increased REE without infectious diseases.

The reduction of resting energy expenditure during the course of treatment, both in absolute terms as well as expressed by fat free mass unit, could be explained by lower frequency of infectious diseases (9 before baseline measures, 5 during the first period, 4 during the second period).

The highly variable metabolic conditions observed during the evolution of the illness, suggests the importance of carrying out energy and nitrogen balance calculations by means of food surveys, nitrogen excretion determination, and indirect calorimetry.

CONCLUSIONS

The importance of adequate nutritional status on the survival and AIDS patient's quality of life is indisputable. Supplementation with a polymeric diet, according to energy and nitrogen requirements, should be considered for obtaining a better patient's tolerance and compliance in order to allow greater energy and protein intakes.

ACKNOWLEDGEMENTS

This study was supported by a grant from the research Project FONDECYT 1940570 (Santiago, Chile), and the collaboration from Davis Laboratories, Braun Co, Chile. The trial was part of MS Torres graduate thesis for a Master of Biological Sciences (Nutrition), Faculty of Medicine, University of Chile.

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Recibido: 13-07-2001
Aceptado: 30-01-2002