

Assessment of the efficacy of dietary intervention on the CD4 counts and BMI in HIV positive Individuals receiving ART - An Open labelled, single arm, clinical study

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Abstract

Introduction: There exists a complex interaction between human immunodeficiency virus (HIV), infection and immune function, with a dominant effect of HIV infection on nutritional status. The influence of nutrition on immune function generally shows that suboptimal nutrition results in immunological deficiencies. Nutrient deficiencies cause immune suppression and increase susceptibility to infections with a resultant loss of immune cell function which allows intrusion by several different infectious agents. The result is reduction of the ability of the body to fight disease and subsequent acquisition of opportunistic infections. Nutrients that play a big role in immune function include protein, total energy, lipids, amino acids, vitamins, and minerals. Optional nutrition alters immunological function and therefore disease states. This interaction affects the body's immune status predisposing one to infections. Proteins play roles as structural components of tissues and also antibodies, cytokines, acute-phase proteins, components of the complement pathways, transcription factors and enzymes. Deficiency of protein could lead to immunologically important changes in enzyme-dependent activation, antioxidant protection, complement activation, antibody-mediated virus neutralization and intercellular communication via cytokines. Therefore the study was carried out with the aim of exploring the nutrition interventional effect of the patients suffering from HIV/AIDS at a care center in India.

Material and Methods: The present study comprised of 30 HIV positive cases (age 20 - 60 years, both male and female) who were admitted to the institution. They were provided with a standard regular nutrition guide and followed up with their CD4 count post intervention; till their discharge from the sanatorium. Patients were explained the process of the study. A written informed consent was taken from all the patients. A diet chart was prepared based on their health condition. Balanced diet rich in protein (ragi malt) and immune boosters (like wheat grass juice, citrus juice, honey, coconut milk and seasonal fruits) were provided to the patients. The patients were advised to follow the daily regimen. If any deterioration was reported, the patient was taken out of the study. The entire schedule was followed strictly for a period of minimum 3 months (to check the changes in CD4 count). Pre and post intervention changes in baseline and the CD4 count was noted. Pre and post intervention of BMI was done by using the Chi square test; to evaluate the changes in number of people in the different categories. Mean weight was compared using either the paired t-test. SPSS (22.0) (IBM Analytics, New York, U.S.A) was used for carrying out the statistical analysis.

Results: Their mean duration of stay was 94.13 ± 3.49 days at the sanatorium (range- 90-105days). The overall mean age of the participants was 37.4 ± 10.64 . There was no significant difference between the mean ages of the male and the female participants in this study. There was a significant rise in the weight from 40.34kg to 44.5 kg post intervention. When the overall BMI was compared for post intervention changes; the difference was not found to be statistically significant; even though values were slightly increased. There was a significant increase in the CD4 scores in post intervention among the study participants from 315.87 to 485.63 ($p=00000001$). There was also a mean increase in the weight of the participants post our intervention.

Conclusion: It could be concluded that healthy diet regimen has found to be beneficial, since the increased pattern of CD4 scores and weight gain was observed among the patients. Thus, it is a preliminary study; the duration should be increased up to some extent in order to study the role of nutritious food and its mechanism of action in immune suppressed patients.

Key words: HIV, Nutrition, CD4 count

Introduction

In 1948 the World Health Organization (WHO), defined health as- A complete state of physical mental and social well-being and not merely absence of disease or infirmity.¹ Human Immune Deficiency Virus (HIV) as an underlying cause compromises and alters the nutrition uptake; resulting in immense wasting of body fat, reduction in overall muscle mass, loss of appetite; thus giving rise to more vulnerable individuals who fall prey to a number of life threatening infections.^{2, 3} So this type of a compromise may also ensure that the drugs given as a part of the therapy (either Anti- retroviral therapy (ART) or Highly Active Anti-Retroviral Therapy (HAART) may not produce its desired effect. Globally a lot has been said about the association of HIV-Nutrition and Health of the person. Studies reflect that nutritional status among HIV individuals is a hall mark of the implementation program success and hence it needs to be assessed as an essential aspect.⁴⁻⁶ The prevalence of HIV/AIDS in India in 2020 has been reported to be 0.24% in males and 0.20% among the females.⁷ Even though we have a central drug distribution of ART/HAART and a very dedicated segment of health care for these cases; there is still a rise in mortality in these patients. Many of the cases are underreported and at times go unnoticed in fresh cases; due to lack of testing. Under such circumstances; building up of one's immunity to fight the opportunistic infections is the only options available. Therefore, Health doesn't mean only a physical but also a socially strong and sound state which is compromised in cases of HIV positive individuals. There exists a complex interaction between HIV, infection and immune function, with a dominant effect of HIV infection on nutritional status. The influence of nutrition on immune function generally shows that suboptimal nutrition results in immunological deficiencies. Nutrient deficiencies cause immune suppression and increase susceptibility to infections with a resultant loss of immune cell function which allows intrusion by several different infectious agents. The result is reduction of the ability of the body to fight disease and subsequent acquisition of opportunistic infections. Nutrients that play a big role in immune function include protein, total energy, lipids, amino acids, vitamins, and minerals. Optimal nutrition alters immunological function and therefore disease states. This interaction affects the body's immune status predisposing one to infections. Proteins play roles as structural components of tissues and also antibodies, cytokines, acute-phase proteins, components of the complement pathways, transcription factors and enzymes. Deficiency of protein could lead to immunologically important changes in enzyme-dependent activation, antioxidant protection, complement activation, antibody- mediated virus neutralization and intercellular communication via cytokines. Therefore, nutritional status intervention plays a pivotal role in HIV/AIDS patients. Thus, the study was carried out with the aim of exploring the nutrition interventional effect of the patients suffering from HIV/AIDS at a care center in India.

Materials and Method:

Ethical clearance was obtained from the institutional ethics committee before the start of the study. The present study comprised of 30 HIV positive cases (age 20 - 60 years, both male and female) who were admitted to the institution. They were provided with a standard regular nutrition guide and followed up with their CD4 count post intervention; till their discharge from the sanatorium. Patients were explained the process of the study. A written informed consent was taken from all the patients. A diet chart was prepared based on their health condition. Balanced diet rich in protein (ragi malt) and immune boosters (like wheat grass juice, citrus juice, honey, coconut milk and seasonal fruits) were provided to the patients. The patients were advised to follow the daily regimen. If any deterioration was reported, the patient was taken out of the study. The entire schedule was followed strictly for a period of minimum 3 months (to check the changes in CD4 count). Pre and post intervention changes in baseline and the CD4 count was noted. Pre and post intervention of BMI was done by using the Chi square test; to evaluate the changes in number of people in the different categories. Mean weight was compared using either the paired t- test. SPSS (22.0) (IBM Analytics, New York, U.S.A) was used for carrying out the statistical analysis.

Results:

There were 14 (47%) females and 16(53%) males in the study as shown in the following graph. The overall mean age of the participants was 37.4 ± 10.64 . The age range was 20 to 70 years. There was no significant difference between the mean ages of the male and the female participants in this study. There was a significant rise in the weight from 40.34kg to 44.5 kg post intervention. When the overall BMI was compared for post intervention changes; the difference was not found to be statistically significant; even though a slight rise in the values were seen. The mean duration of stay was 94.13 ± 3.49 days (range- 90-105 days). The overall mean age of the participants was 37.4 ± 10.64 . There was no significant difference between the mean ages of the male and the female participants in this study. There was a significant rise in the weight from 40.34kg to 44.5 kg post intervention. When the overall BMI was compared for post intervention changes; the difference was not found to be statistically significant; even though values were slightly increased. There was a significant increase in the CD4 scores in post intervention among the study participants from 315.87 to 485.63 ($p=0000001$). There was also a mean increase in the weight of the participants post our intervention. It could be concluded that

healthy diet regimen has found to be beneficial, since the increased pattern of CD4 scores and weight gain was observed among the patients. Thus, it is a preliminary study; the duration should be increased up to some extent in order to study the role of nutritious food and its mechanism of action in immune suppressed patients.

Discussion:

The present study comprised of 30 HIV positive cases who were provided with a standard regular nutrition guide and followed up with their CD4 count post intervention; till their discharge from the sanatorium. The diet intervention given to these people involved the complete absence of any heavy oily prepared food and more of natural food products. Sprouts, apple, wheat grass juice, coconut milk, carrots, salads, lemon honey water and seasonal fruits like water melon and musk melon was provided throughout the entire duration to the study participants (3 months). All of these are rich in vitamins; especially vitamin C and boost the supply of minerals and essential proteins. Thus they assist in the wear and tear of the body. Even though there is literature evidence related to various groups across the world with regards to malnourishment and nutritional intervention; there are no such data available on wholesome food and HIV. Hence a direct comparison of the intervention tool is not possible. We observed a significant rise in the weight from 40.34kg to 44.5 kg post intervention. When the overall BMI was compared for post intervention changes; the difference was not found to be statistically significant; even though a slight rise in the values were seen. There was also a mean increase in the weight of the participants post

our intervention. One meta-analysis published in 2015 examined the effect of micronutrient supplementation on mortality and rate of HIV disease progression. Micronutrient supplementation significantly slowed disease progression to AIDS among adults not on ART in three trials; however, only one trial was from a high-income economy, and it was conducted in the pre-HAART era. Authors also found evidence across.⁴ Seven trials in low-income settings that micronutrient supplementation may possibly reduce mortality; however, a definite assertion could not be made based on the data set. 10 Some studies have shown that HIV-associated weight loss involves greater loss of lean body mass than of fat mass, whereas other studies have shown the opposite. The former situation is likely to be associated with more-advanced HIV disease, and the latter is likely to be associated with weight loss

occurring earlier in the course of HIV infection in individuals whose health is less compromised.^{9,14} A Cochrane review from 2017 assessed micronutrient supplementation in adults for reducing mortality and HIV-related morbidity. Studies investigating the role of micronutrients in metabolic morbidity related to ART were excluded. The synthesis included 33 trials with over 10,000 participants. Ten (30%) of these trials were conducted in high-income economies (Denmark, Italy, Singapore, and USA) and included 1,706 (17%) participants receiving HAART. From the total number of included trials, authors were not able to consistently demonstrate that micronutrient supplementation had clinically important benefits, but note that this should not be interpreted as a reason to deny individuals micronutrients if a deficiency has been identified. Furthermore, authors suggest that trials with larger sample sizes are needed in order to further explore the impact of micronutrients on individuals on ART.¹¹ Another meta-analysis of six randomized controlled trials found that supplementing with multiple micronutrients reduced the mortality and morbidity of adults living with HIV, but all six included studies were conducted in low-resource settings.¹² One meta-analysis of studies found that overall REE per kilogram of fat-free mass was higher in people living with HIV by approximately 9% compared to HIV-negative individuals. Furthermore, in the subsample of people living with HIV, symptomatic individuals had a significantly higher REE per kilogram of fat-free mass compared to asymptomatic individuals, though the author suggests further studies are needed to confirm this.¹³ REE among adults with untreated asymptomatic HIV is about 10% higher compared to healthy controls, an increase which may be similar to asymptomatic adults receiving ART.¹³ Most of the studies gave similar results to the present study findings. Since the other interventions were not new and were not in a resource limited set up like that of the present study; a direct comparison could not be made. Poor nutritional status is a strong predictor of mortality. Even after controlling for CD4+ cell counts, a weight was linked to the timing of death in AIDS patients.⁸

There was a significant rise in the CD4 scores post intervention among the study participants from 315.87 to 485.63 ($p=0.0000001$). This is the first study where the CD4 count was assessed for nutrition based study. Hence more studies are required to identify the role of nutrition in immune compromised patients. A number of national and international studies have documented compromised nutritional status of PLHIV in terms of low BMI and belonging to mild to moderate category of malnutrition, but data regarding the actual intakes of nutrients and complete nutritional profile are lacking. The present study, therefore, assessed the actual intake of nutrients by PLHIV in India. Poor nutrient intake over a long period of time could contribute to further worsening of the nutritional status not only physically but in terms of biochemical derangement as well. Thus, there is a need to develop a database on actual nutrient intakes by PLHIV in India which would pave way for the development of necessary interventions to improve the nutrient intakes for better nutritional status.

Conclusion:

In conclusion; it could be concluded that healthy diet regimen has found to be beneficial, since the increased pattern of CD4 scores and weight gain was observed among the patients. Thus, it is a preliminary study; the duration should be increased up to some extent in order to study the role of nutritious food and its mechanism of action in immune suppressed patients.

Limitations of the study

1. We used convenience sampling technique to choose the study samples.
2. Associated co-morbidities with HIV/AIDS such as tuberculosis, diarrhea, cancer etc. were not taken into consideration. It is essential to consider these as confounders in the study.
3. Such studies among home based patients is also essential. Their compliance to diet regimen without any supervision should be reported.

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