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Evaluation of the effects of the anti-retroviral drug regimen (zidovudine + lamivudine + nevirapine) on CD4 count, body weight, and Hb% of the HIV patients-a retrospective study

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Abstract

The main objective of study is to evaluate the effectiveness of triple drug therapy Zidovudine + lamivudine + nevirapine on cd 4 counts, weight and Hb% for the duration of 6 months. In this retrospective study, data was collected from the anti-retroviral therapy (ART) centre where 315 subjects infected with HIV received ZIDOVUDINE + LAMIVUDINE + NEVIRAPINE. Baseline and after 6 months of therapy; CD4 count, weight and Hb% were recorded and compared. Records with incomplete data were excluded. Statistical analysis was done using paired 't' test for body weight , Hb% and CD4 count.It was found that after 6 months of treatment, both CD4 count and body weight improved significantly(p value: 0.001). Whereas in case of haemoglobin %, even after the treatment period, no significant changes were observed in Hb % (p value: 0.227).It was concluded that ZLN regimen for treatment in HIV patient is efficacious in improving both CD4 count and body weight and not Hb%.

Keywords: ART, CD4 count, body weight, Zidovudine anemia.

Introduction

AIDS, the acquired immune-deficiency syndrome sometimes called as the "slim disease" is a fatal illness caused by a retrovirus known as the human immuno-deficiency virus(HIV) that breaks down the body's immune system leaving the victim vulnerable to a host of live threatening opportunist infections, neurological disorders, or unusual malignancies.Acquired immune deficiency syndrome (AIDS) was first recognised by the medical community as distinct clinical entity in 1981.[1]

HIV remains one of the world's most significant public health challenges, having claimed more than 25 million lives over the past 3 decades particularly in low and middle income countries[2]. There are 34 million people living with HIV worldwide in 2011[3]. There is an estimated 23.9 lakh people living with HIV AIDS in India with an adult prevalence of 0.31% in 2009[4].

As a result of recent advances in providing access to Anti Retroviral Therapy (ART), people with HIV can now enjoy long and healthy lives. By 2012, upto 10 million people had access to antiretroviral therapy worldwide [5].

Triple drug antiretroviral therapy has been shown to increase short term survival, decreased morbidity, improved the CD4 counts and decreased plasma viral loads in HIV infected patients[6,-10] making triple drug regimen the standard first line therapy[11-14].

Combination therapy consisting of 2 nucleotide analogues (reverse transcriptase inhibitors) [either Zidovudine (AZT) or Stavudine (d4T) along with Lamivudine (3TC)] and 1 non nucleoside reverse transcriptase inhibitor (NNRTI) { either Nevirapine (NVP) or Efavirenz (EFV) }are frequently used.[15-17}

Zidovudine (azidothymidine; AZT) is deoxythymidine analog that is well absorbed (63%) and reaches peak level within 1 hour of the drug administration. It also crosses the blood brain barrier and is well distributed into the cerebrospinal fluid where it is about 60-65% of the its level in the serum.It is the first antiretroviral drug to be approved and well studied. The most common side effects is myelosuppression, resulting in macrocytic anemia (1-4%) or neutropenia (2-8%)[18,19].

Lamivudine(3Tc) is a cytosine analogue with in vitro activity against HIV-1 that is synergetic with a variety of antiretroviral nucleotide analogue - including zidovudine stavudine - against both zidovudine sensitive and zidovudine resistant HIV strain. Potential side effect are headache, dizziness, insomnia, fatigue, dry mouth, and gastrointestinal discomfort, although they are typically mild and infrequent.[18]

Nevirapine is highly lipophilic and crosses blood brain barrier and placenta so has been used to prevent mother to child transmission . Serum half-life is 25-30 hours. It is metabolised by the CYP3A isoform enzymes and can induce its own metabolism. Rash occurs in up to 20% of the patient usually in first 4-6 weeks of therapy.[18,19]

Recommendations of the initiation of anti-retroviral therapy is largely based on the CD4 lymphocyte count and plasma HIV RNA levels.[20] So we took one triple therapy regimen i.e., Zidovudine + Lamivudine + Nevirapine and measured three parameters Weight, Hb% and CD4 lymphocyte count to assess the efficacy of this regimen.

Objective

To evaluate effects of the anti-retroviral drug regimen (zidovudine + lamivudine + nevirapine) on CD4 count, on body weight, and on Hb% of the patients.

Materials and Methods

Study design

In this study retrospective data was collected from antiretroviral therapy (ART) centre in Chigateri hospital, Davangere, Karnataka. The patients received Zidovudine + Lamivudine + Nevirapine and the data regarding their CD4 count, body weight and Hb% were collected from the case forms in the ART centre from the period of January 2013 to March 2013

Methodology

In this study the CD4 count, body weight and Hb% from 264 case forms were selected from 315 infected patients (patients who were on ZLN triple drug regimen for AIDS), from the period of January 2013 to March 2013. These patients were receiving Zidovudine(300mg) + Lamivudine(150mg) + Nevirapine(200mg). This drug regimen was prescribed twice a day for all 7 days in a week. Patients were asked to come for follow up after every month along with empty strips of medication for adherence. Baseline CD4 count, body weight and Hb% were recorded before the initiation of ART which was compared with CD4 counts, body weight and Hb% after 6 months of therapy. All patients

provided written informed consent. The study was carried out after the institutional ethics committee had given approval for the study.

Results

The CD4 count comparision both before and after starting treatment was done by paired 't' test which is very significant both before (mean: 2.11, standard deviation: 34.25, standard error of mean: 5.93) and after the treatment (mean: 3.57, standard deviation: 158.02, standard error of mean: 9.95)) with 95% confidence interval of -163.64006 to -127.22059 and paired Standard deviation 146.77657 and paired standard error of mean 9.24605 [**Table 1** and **Fig 1**.].

Body weight on the other hand was compared using paired 't' test which again shows the level of improvement in the patients both before(mean: 51.99, standard deviation: 12.52, standard error of mean: 0.77046) and after treatment(mean: 53.81, standard deviation: 12.23, standard error of mean: 0.75277) with 95% confidence interval of -2.58036 to -1.06522 and paired Standard deviation 6.25133 and paired standard error of mean 0.38474 [**Table 2 and Fig 2**].

Hb% was compaired using paired 't' test and was observed that the t-value was not significant and there was no significant difference in the Hb values in ZLN regimen both before (mean: 11.11, standard deviation: 1.77, standard error of mean: 0.12) and after traetment(mean: 10.93, standard deviation: 1.55, standard error of mean: 0.11) with Confidence Interval of -0.10826 to 0.45395 and paired Standard deviation 2.03121 and paired standard error of mean 0.14256 [**Table 3** and **Fig 3**.].

Discussion

Since the safety and efficacy for any drug regimen is the major concern in chronic disease like HIV AIDS, we attempted to ensure the same in the present study. Our study finding shows potent activity of zidovudine with Lamivudine and Nevirapine. The combination resulted in a more sustained increase in a CD4 counts and body weight over the 6 months period that we took to study the cases. When the haemoglobin levels were analyzed in the study subjects it was found to be non significant ;which shows that even though its non significant the numbers actually decrease post treatment with this regimen. The regimen is otherwise very well tolerated with recommendation of keeping a close watch in patients predisposed for developing anameia.

With the advent of different drug regimen the disease scenario has changed from a virtual death sentence to a chronic manageable disease. However, the success of the drug treatment is achieved at the cost of life threatening adverse drug effects, drug-drug interactions and an inconvenience of lifelong therapy.[21]

As for taking CD4 counts, body weight and hemoglobin as the parameters for the safety and efficacy of the regimen, was based similar to model designed by the EuroSIDA study group, the most recent CD4 cell count, viral load and hemoglobin level were independently related to the risk of disease progression, as was a late presentation of persons with advanced disease, before the start of HAART.[22]Several cohort studies and clinical trials have shown that the CD4 count is the strongest predictor of subsequent disease progression and survival.[23,24]Also CD4 count is critical for determining patient's disease stage and short-term and mid term risk of opportunistic infections and initation of antiretroviral therapy.[25] The use of the CD4 count as an independent and reliable marker for treatment outcome is striking from various aspects. First, CD4 counts are already the most important factor in deciding whether to initiate

antiretroviral therapy and opportunistic prophylaxis. Secondly, CD4 count is a relatively objective and simple marker to follow. Finally, the cost of CD4 counts has become more affordable, including in developing countries.[26,27]

Hemoglobin can be a predictor of morbidity and rarely mortality that is independent of CD4 counts. A decrease in hemoglobin is one of the most common presentations of HIV. The treatment with anti HIV drugs can also result in anemia.[28]Anaemia in HIV infection is associated with uniformly adverse outcomes such as opportunistic infections and neurologic deterioration and progression to AIDS[29]. Anaemia is associated with several other consequences including fatigue[30], poor quality of life[31] and increased requirement for erythropoietin therapy[32]. Several observational studies have also reported a higher mortality in HIV infected patients from low haemoglobin levels even after adjusting for CD4 cell count and viral load[33-35]. So to monitor the treatment or its adverse effects, hemoglobin becomes one of the important prognostic factors.

Bodyweight is also independent of CD4 cell count as a prognostic measure; bodyweight changes reflect the change in the rate of viral replication, and also bodyweight is affected by severe opportunistic infections or malignant disease.[36] Profound weight loss commonly occurs late in the course of HIV disease and is associated with a poor prognosis, more rapid disease progression, significant disability and increased mortality. HIV-related wasting is a starvation state characterized by protein–energy malnutrition in which mobilization of fat is accompanied by loss of somatic and visceral proteins. Loss of more than 30 percent of ideal body weight is associated with high mortality, and weight loss of as little as 5 percent of the patient's usual weight is associated with more rapid progression of disease.[37,38]

Zidovudine is the recommended initial therapy for human immunodeficiency virus (HIV) infection[39]and is generally tolerated well.[40]However, clinical studies indicate that its beneficial effects are limited in duration, partly because of the development of resistance by HIV[41,42]. Its use however, is associated with haematological toxicity particularly bone marrow aplasia leading to varying degrees of cytopenias especially anaemia in some patients. The mechanism of this anaemia is attributed to 50-70 per cent inhibition of proliferation of blood cell progenitor cells in a time-and dose-dependent fashion.[43]

This haematological toxicity is observed in most of the patients within 3-6 months and is reversible.[44]Patients who are started on AZT combination regimen for HIV/AIDS treatment, should be closely monitored during follow up for development of bone marrow toxicity.[45]The patient treated with this regimen should show an overall decrease in the Hb % levels. This may be because of zidovudine that may cause myelosuppression and in turn causes anameia or may be due to the presence of already low value of the Hb% pretreatment.[18] This may be also due to short period of 6 months taken for the follow up of the patients . Hb% is also measured to see any side effects especially anemia .

This regimen (ZLN) was similarly effective in increasing CD4 + T cell count as the other regimen used by the ART centre. The data also demonstrates that this regimen is relatively safe and equally efficacious as compared to other regimens.

In the study done by French et al. (June 2002) they compared the three antiretroviral regimen and found no serious adverse reaction in the ZLN group but in that case the no of subjects taken for the study was less which might have not shown anaemia as a side effect [17]

Agarwal et al in their retrospective study reported a high incidence of Zidovudine induced anaemia in HIV infected patients from eastern part of India. Zidovudine induced anaemia occurred within 6 months of initiation of therapy and the peripheral smear showed normocytic, normochromic anaemia in almost half of the patients and in the

remaining it showed macrocytic changes. This study reveals a very high incidence of anaemia supposedly related to zidovudine as haemoglobin levels rose after stopping zidovudine.[46]

Another retrospective south Indian study has reported a relatively lower incidence (5.4%) of anaemia due to AZT. How do we explain these different results? These differences can be attributed to different study designs, use of different methodologies including inclusion and exclusion criteria and different cut-offs used to define anaemia.[47]

Ideally, a very systematic, prospective, cohort study with application of stringent inclusion and exclusion criteria should be planned to find out the exact incidence of anaemia due to ziduvudine. Nutritional anaemia, multiple worm infestations which are rampantly prevalent in India should be carefully ruled out. Bone marrow examination should be done in those who develop haematological toxicity. one can continue with the current guidelines to use it in those patients who have haemoglobin level >8g/dl and these patients should have a detailed haematological work-up at baseline and close monitoring of haematological profile during follow up, and change to other nucleoside analogue such as tenofovir or emtricitabine in case haemoglobin level falls below 8 g/dl. AZT should not be used as the first-line drug and instead use d4T as the first drug and use AZT as a switch therapy after sometime and while on AZT patients should be carefully and closely monitored. The use of tenofovir (TDF) or emtricitabine (FTC) as the first-line drug in combination therapy should be considered if country programmes for HIV/AIDS have enough budget to afford the cost on a long-term basis.[48]

Conclusion

ZLN regimen for treatment in HIV patient is efficacious in improving both CD4 count and body weight (p value: 0.001). Now even though the combination of ZLN is very efficacious as a anti retroviral drug regimen, but should be given cautiously in patient with haematological abnormalities especially anaemia . Special attention should be paid to patient's Hb level after this drug therapy is initiated by giving the patient regular monthly tests for Hb estimation and supplementing the drug regimen with drugs that improve Hb%. First of all we should try to figure out the exact significance and predictors of zidovudine induced anaemia in HIV/AIDS patients in well planned and robust prospective studies. For now, we can continue to use zidovudine in the first line combination therapy in HIV/AIDS patients with Hb >8g/dl as a public approach since the drug is cheaper and continue doing survillence for development of haematological toxicity.

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Table 1. CD4 counts values compared by Paired t test

	Before CD4	**After CD4**
Number of values	252	252
Mean	2.1163E2	3.5706E2
Std. Deviation	94.25136	158.02733
Std. Error Mean	5.93728	9.95479
Paired Differences		
Mean	-1.45430E2	
Std. Deviation	146.77657	
Std. Error Mean	9.24605	
95% Confidence Interval of the Difference - Lower - Upper	 -163.64006 -127.22059	
T	-15.729	
Df	251	
Sig. (2-tailed) (p value)	.0001	

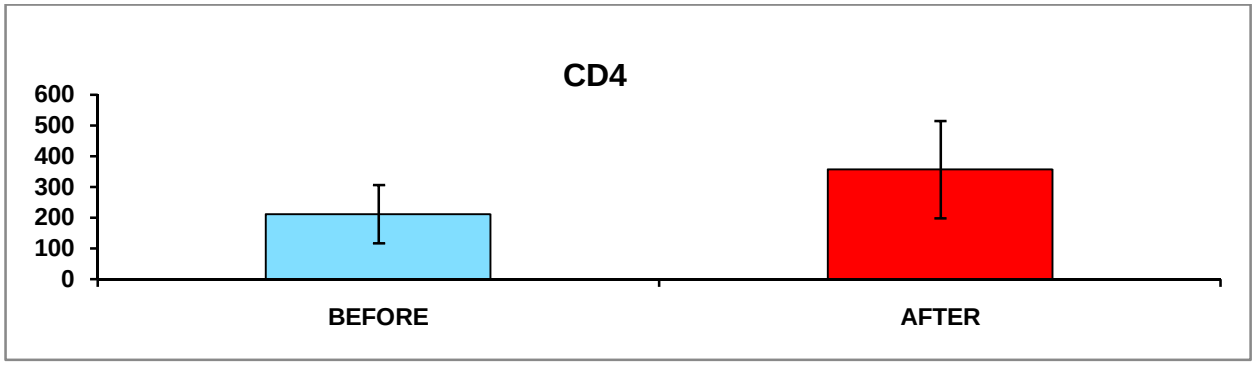

Fig 1: Graph depicting CD4 count before and after treatment

Table 2. Body weight values compaired by Paired t Test

	Weight before treatment	**Weight After treatment**
Number of values	264	264
Mean	51.9882	53.8110
Std. Deviation	12.51842	12.23113
Std. Error Mean	.77046	.75277
Paired Differences		
Mean	-1.82279E0	
Std. Deviation	6.25133	
Std. Error Mean	.38474	
95% Confidence Interval of the Difference - Lower - Upper	 -2.58036 -1.06522	
T	-4.738	
Df	263	
Sig. (2-tailed) [pvalue]	.0001	

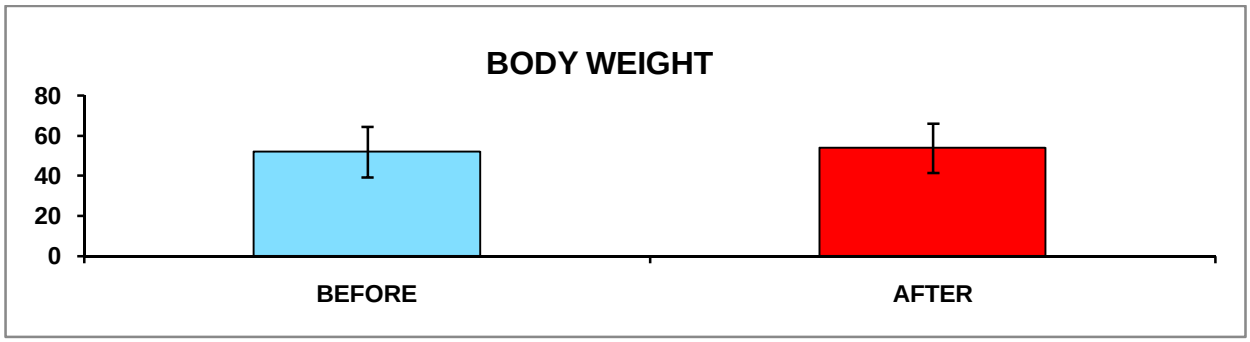

Fig 2: Graph depicting body weight before and after treatment

Table 3. Hb % Values compared by Paired t Test

	Before hb	**After hb**
Number of values	203	203
Mean	11.1052	10.9323
Std. Deviation	1.76970	1.54748
Std. Error Mean	.12421	.10861
Paired Differences		
Mean	.17285	
Std. Deviation	2.03121	
Std. Error Mean	.14256	
95% Confidence Interval of the Difference - Lower - Upper	 -.10826- .45395	
T	1.212	
Df	202	
Sig. (2-tailed) [p value]	.227	

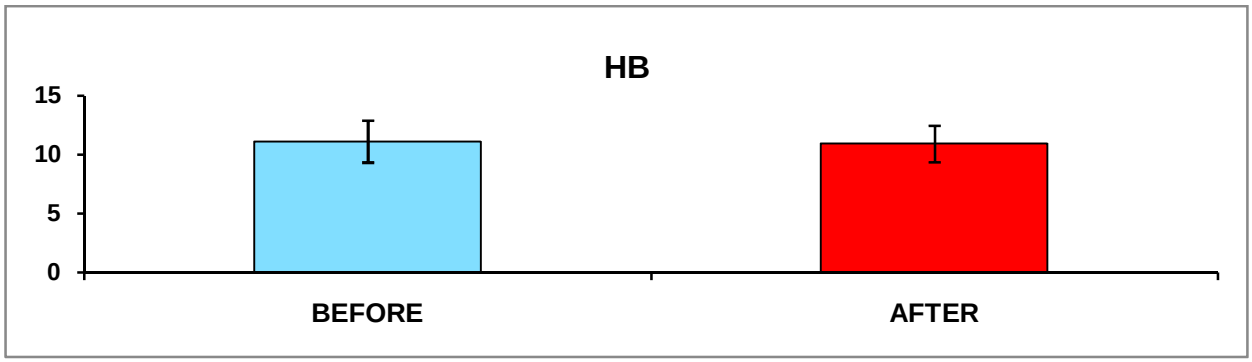

Fig 3: Graph depicting Hb% before and after treatment