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Research Article

STUDY OF ADVERSE EFFECTS OF ANTI RETROVIRAL THERAPY IN HIV NAÏVE PATIENTS AND THEIR ASSOCIATION WITH CD4 CELL COUNT

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ABSTRACT

Background: Acquired immunodeficiency syndrome (AIDS) is a disease of the human immune system and leaves the body vulnerable to a variety of life-threatening infections and cancers. AIDS is characterized by changes in the population of CD4 T-cell lymphocytes that play a key role in the immune defense system. However adverse drug reactions (ADR) related to HAART has limited its utility and compliance.
Aim: To study the adverse effects of ART and its correlation with CD4 cell count in a resource-restricted setting in central India.
Methods: 152 HIV naive patients on ART were studied prospectively over a period of 18 months. All patients were asked to visit the clinic if they developed any symptoms or on a six monthly basis along with CD4 count done at every six month. They were screened clinically and investigated suitably for any ADRs.
Result: Out of the 152 patients, nine patients lost for follow-up and fourteen died; 129 cases were available for evaluation. ADRs were observed in 98 cases (75.4%). Only hepatic 29% and cutaneous (24%), adverse effects were seen in patients with higher CD4 Cell count whereas other adverse effects like hematological (38%), gastrointestinal (30%), neurological (24%) and metabolic (10) were more common with lower CD4 cell count.
Conclusion: To optimize adherence and prevention of adverse effects of HAART, one must look for CD4 count at start of therapy and can prevent severe ADR whenever possible and can prevent potentially serious and life threatening events.

Keywords: Highly activated anti retroviral therapy, adverse drug reaction and CD4 count, HIV infection.

INTRODUCTION

Adverse drug reactions on HAART in HIV patients are common and show wide variations. HAART effectively restores the immune system and lowers the viral load in patients with HIV/AIDS. Thus, with the widespread introduction of highly active antiretroviral therapy (HAART), the pattern and prevalence drug reactions are different and expected to change. The purpose of our study was to evaluate the HIV/AIDS patients who were on HAART for management of AIDS and to study the changing pattern of the various drug reactions in the HAART era along with changing immune status of the patient that was correlated with CD4 cell count. There are multiple ART regimens. The main factors that distinguish one ART regimen from another are simplicity, toxicity and cost. [2] Unfortunately, up to 25% of all patients discontinue treatment because of treatment failure or toxic effects ranging from low-grade intolerance, which may be self-limiting, to life threatening side effects.[3-5] Most of the side-effects can be adequately co-managed with efficient clinical monitoring at all levels of the health care system.

MATERIAL AND METHOD

This was a prospective, observational study conducted at the ART Centre, Department of Medicine, Gandhi Medical College And Hamidia Hospital, Bhopal from 1st September 2010 to 31st July 2011. In this one and half year period, all HIV-positive cases who were newly started on ART were included and were followed prospectively for the development of any ADRs. One hundred and fifty two HIV patients taking Anti tubercular treatment and other drugs with a potential for hepatic and renal toxicity or interactions with HAART drugs and noncompliant were excluded from the study.

A baseline interview was taken before initiating the therapy followed by further interrogation at 0, 6th,12th and 18th month for the development of ADRs. Information on adverse reactions and data related to health care utilization variables were collected from the medical charts as well as through self-reporting by patients. An adverse reaction to ART was defined as any undesirable effect or symptom registered in the medical charts by the treating physician, that occurred up to one and half year of the first ART prescription.

Baseline laboratory investigations such as hemoglobin (Hb), total and differential leukocyte counts, erythrocyte sedimentation rate, urine analysis, LFT, RFT, serum hepatitis B surface antigen (HBsAg) , X-ray chest , ECG were carried out in each patient to rule out any opportunistic infection or specific contraindications to any drug along with CD4 count done by flowmetry at every 6 months .Clinical examinations along with appropriate lab investigations were documented in the adverse reactions reported by the treating physician.

Allotment of HAART regimens was based on physician's judgment. Data were analyzed using the chi-square test for establishing correlation between severe ADR and different variables. A *P* value < 0.05 was considered to be statistically significant.

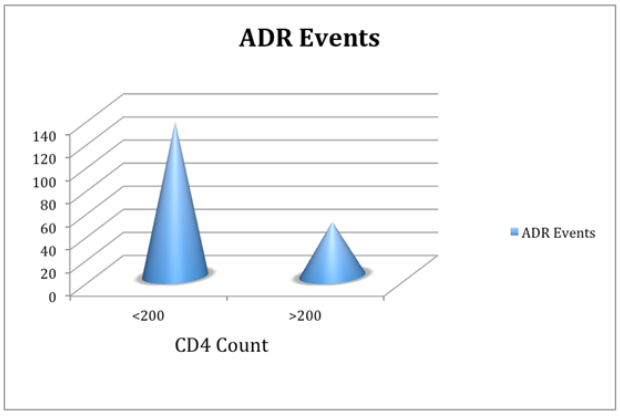
RESULT

A total of 152 Naive HIV patients were included in the study. Out of 152 patients 9 patients were not reported in subsequent visits, 14 patients died and so were excluded from study. Patients mean age was 36±9.5 yrs. with Male: female ratio is 1.98:1.

Table 1

Age	36±9.5 yrs
Sex Male	101
Female	51
CD4 count	
<200	100
>200	52
Nos of adr events	181
Mean adr per patient	1.40

Out of 129 cases on ART, 98 cases (75.6%) developed ADR. Mean ADR was 1.40+0.87 per patient. Most common ADRs were hematological (38%) followed by gastrointestinal (30%) then hepatic 29%, cutaneous (24%), neurological (24%) and metabolic in 10%. The number of ADR events were higher in patients with lower CD4 Count i.e <200.



DISCUSSION

In present study 129 patients on HAART regimen were observed over a period of 18 months. Adverse effects were seen in 75.65% of cases. Singh et al (2010) reported ADR in 86% of cases and most common ADR reported was peripheral neuropathy. In our study the most common ADR reported was anemia (27.90%), mainly with Zidovudine containing regimen. Another study by Kumarswamy et al (2002) has shown peripheral neuropathy, anemia and nail hyperpigmentation as the most common side effects.[6]

ADR to ART may depend on the baseline CD4 T- cell count at initiation of therapy. A study by Center for Disease Control and Prevention on HIV outpatients suggested that some complications were more frequent and severe when therapy is started at lower CD4 T cell counts. Thus, patients may actually experience fewer side effects over a 10-20 year period of drug exposure if they start therapy 18-24 months earlier than if they delay therapy until the CD4 T cell count decreases to less than 200 cell/ mm[3.11]

The measurement of viral loads and CD4 cell counts and the standard of care for assessing efficacy and response to HAART are not possible everywhere, particularly in resource-restricted places. Also, as eradication of the disease is currently not possible, significant problems related to compliance and long- term toxicity can be anticipated with decade-long therapies. Patient compliance can be improved with proper education and counseling regarding the disease process and inherent but innocuous side effects of HAART. More research is needed to develop low-cost investigations and algorithms for prediction of adverse effects of existing regimen, along with generation of more efficacious and less toxic drugs.

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