

Retrospective Study of Clinico- Immunological Progress of Human Immunodeficiencyvirus/Acquired Immune Deficiency Syndrome Patients on Antiretroviral Therapy at Central India

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ABSTRACT

Introduction: Human immunodeficiency virus infection (HIV) remains a worldwide health crisis. Nearly 40 million people infected, 95% of them lives in developing countries like India, Africa etc. Aim of study is to assess immunological and clinical progress of human immunodeficiency virus/acquired immune deficiency syndrome (HIV/ AIDS) patients on antiretroviral therapy (ART).

Material and Methods: This was the retrospective study which was carried out in ART plus center at Gandhi medical college and Hamidia hospital Bhopal from March 2008 to March 2016. This enabled patient's follow-up for WHO clinical stage, weight and functional status of all these patients for minimum of one year.

Results: Total of 5295 HIV/AIDS patients were registered while 1903 patients were shown to take ART and were regularly follow up visit to the ART Center. Follow up status after 1 year on ART revealed that, 89.65% patients were still active and 71.4% had "good" adherence level. Median weight of the patients increased to 58 kg (improved by 12%). Change in CD4+ cell count was 104.5 (45.24%) and 199.75 cells/mm³ (86.47%) after 6 and 12 months on ART respectively. Functional status as working improved by 20.71%.

Conclusion Immunological and clinical improvements as reported by increase in weight, CD4+ cell count and functional status of patients after initiation of ART.

Keywords: human immunodeficiency virus, acquired immune deficiency syndrome, antiretroviral therapy, highly active antiretroviral therapy.

INTRODUCTION

Acquired immunodeficiency syndrome (AIDS) was first reported in the United States of America in 1981 and has since become a major worldwide epidemic with over 36.9 (By the end of 2014) million people infected. AIDS is caused by a retrovirus named the human immune deficiency virus (HIV)¹⁻³ By damaging or killing cells of the body's immune system, HIV progressively destroys the body's ability to fight infections and certain cancers .People diagnosed with AIDS may get life-threatening diseases and opportunistic infections (OI).⁴ Many people do not experience symptoms when first infected with HIV; however some have a flu-like illness within a month or two after exposure to the virus. The virus is actively multiplying even in the asymptomatic period and keeps destroying immune system. The virus can also hide within infected cells and lie dormant. The most obvious effect of HIV infection is a decline in the number of CD4 positive T (CD4+) cells, the main cells responsible for specific cell mediated immunity but symptoms does not begins during the initial stage.⁵ According to recent research finding WHO recommended starting the treatment of HIV in the early stage.

Combination ART has reduced morbidity and mortality, and its access has increased in recent years, achieving a goal to have 15 million people on treatment by 2015.⁶ Globally, only 40% of people with HIV are receiving treatment, out of which 41% are adults and 32% are children.⁶ Approximately 76% of all people in sub-Saharan Africa receiving ART therapy shows very suppressed viral replication and so less chance of transmitting the infection.⁶ The percentage of pregnant women receiving ART for the prevention of mother-to-child transmission of HIV increased to 73% in 2014, up from 36% in 2009. Highly active antiretroviral therapy (HAART) is currently the most effective way to treat acquired immune deficiency syndrome (AIDS). HAART can dramatically suppress the replication of human immune deficiency virus (HIV), rebuild the immune function of infected patients, and reduce the incidence of opportunistic infections.^{7,8} HAART has significant effect on HIV and reduces the incidence of AIDS and death.⁹ Currently 15.8 million people are receiving antiretroviral therapy (June 2015) The treatment efficacy of HAART is mainly evaluated by the decrease in viral load and improvement in the immune system.¹⁰ HAART is now widely available in most developed countries; As treatment with HAART, once started, is likely to be life long, it is important that models for prognosis are updated as longer follow-up time becomes available. In this paper we evaluated the effect of ART that estimate immunological and clinical progression up to minimum of 1 years after starting HAART, first according to CD4 counts measured at baseline and then on, second incorporating the successive clinical response to treatment. This study was done with the objective to evaluate the improvement in immunological and clinical scenario of Human immunodeficiency virus/acquired immune deficiency syndrome (HIV/ AIDS) patients on antiretroviral therapy (ART) at ART plus center in Gandhi Medical College and Hamidia Hospital Bhopal.

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MATERIAL AND METHODS

After taking permission from institutional ethical board a retrospective medical records review design was conducted to determine the immunological and clinical progress of HIV/AIDS patients on ART. The study population included all patients who came to the Hamidia hospital Bhopal from March 2008 to March 2016. Data was collected from the medical records of HIV/AIDS patients who were registered in ART plus center in Gandhi Medical College Bhopal, Madhya Pradesh, India. This enabled retrospective follow-up of records of all these patients for minimum of one year. Records of patients on their WHO clinical stage, weight and functional status were reviewed by the investigators at 12 month and CD4 Count at 6 month and 12 month successively. In addition, data was collected regarding the age and sex.

Total 5295 were registered during this period out of which 3314 were eligible for ART treatment (CD4 count <350 cell/mm³). Out of 3314 patients 1903 patients have attend regular follow up visit to examine their clinical and immunological status while remaining patients had opted out, transfer out, died, lost of follow up and 160 patient were registered in 2016 march so their follow up remains to begin . The medical records of HIV/AIDS patients who were under follow-up in the institution for their progress after ART initiation served as sources of data The exclusion criteria for study were being on ART for less than one year, incomplete medical records of patients, who initiated ART in another institution and transferred in and those who started in the institution and were transferred out to another institution since complete records were not available and died within one year of registration. Data collected was kept confidential and used strictly to purpose the study.

STATISTICAL ANALYSIS

Data was entered in MS excel and analyzed by Epi-info software version 7. Descriptive statistics like mean and percentages were used to interpret results.

RESULT

Patients' condition at initiation of ART

A total of 5295 medical records of HIV/AIDS patients who registered ART plus center from the start of the program in March 2008 till the end of March 2016 were used in study. The mean age was 33.40 years and standard deviation± 11.84 years, it ranged from 0.5 to 82 years, most of the patients belong to the age group between 30-39 year (36.31%) followed by 20-29 years (25.58%)and the number of males were 3441 (64.98%), females formed 1829 (34.54%), while transgender were 25 (0.47%). Out of 5295 patients3314 patients had started ART in which 1903 patients on ART are those who continue to be present at their follow up visit for regular clinical and pathological check up (for weight, WHO clinical staging, functional status and CD4 count). At the start of ART the weight of most of the patients (75.89%) was between 40 - 49 kg. Of these, 41.00% were between 40 and 49 kg, whereas 34.89% being between 50 and 60 kg. The overall median weight of the patients was 50 kg (Table-1). Regarding functional status most of the patients, 47.35% were ambulatory and 33.31% were working, the remaining being bed ridden at the start of ART (Table-1). At the initiation of ART, around 49.4% were in WHO Clinical Stage III followed by Stage II (22.86%) and Stage IV (19.28%), stage I(8.46%) respectively (Table-1). The mean CD4+ cell counts of the patients at the time of initiation of ART were 231 cells/mm³ (Table-2). Distribution of patients by regimen shows that maximum patients (more than 90%) were on TLE (tenofovir/ lamivudine/ efavirenze) and ZLN(zudovudine / lamivudine/ nevirapine) regimen at the initiation of ART.

Patients' conditions after 6 and 12 months of ART initiation

The follow up status after 1 year on ART indicated that 89.65% of the patients were still active and 71.4% were recorded to have had “Good” adherence level and 25.4% had “Fair”adherence level out of those who remained active on treatment. The overall median weight of the patients increased to 58 kg (improved by 12%) after 1 year on ART (Table-1). The change in functional status after 1 year on ART showed that 54.02% (improved by 20.71%) were on working status. The percentage of working patients has changed from 33.31% to 54.02% and 11.72% patients were improved from ambulatory to working status. which shows a clear improvement in the quality of life of the patients respectively. In case of bedridden patients 8.98% had improved to working or ambulatory status after the 1 year of antiretroviral therapy (Table-1). At the initiation of ART, the clinical stage of the patients shows, that around 72.26% of patients were in WHO Clinical Stage III and II which became

S. no.	Clinical outcome	Before art n=1903(%)	After 1 year of art n=1903(%)
A.	Weight (In kg)		
1.	<40	182(9.2%)	109(5.72%)
2.	40-49	664(34.85%)	485(25.48%)
3.	50-59	780(41.0%)	929(48.83%)
4.	60+	277(14.55%)	380(19.97%)
B.	Functional status		
1.	Working	634(33.31%)	1028(54.02%)
2.	Abulatory	901(47.35%)	678(35.63%)
3.	Bedridden	368(19.33%)	197(10.35%)
C.	WHO Clinical stage of AIDS		
1.	Stage I	161(8.46%)	142(7.45%)
2.	Stage II	435(22.86%)	725(38.11%)
3.	Stage III	940(49.4%)	756(39.73%)
4.	Stage IV	367(19.28%)	280(14.71%)

Table-1: Clinical progress (weight, who clinical staging, functional status) at 12 months of art

S No.	CD4 Count	At initial stage (Cells/mm ³)	1 ST Follow up at 6 Month (Cells/mm ³)	2 nd follow up at 12 months (Cells/mm ³)
1.	MEAN*	231	335.5	430.75
2.	Improvement in CD4	-	104.5 (45.24%)	199.75 (86.47%)

*Mean CD4 count from 2008 to 2015

Table-2: Immunological progress (mean cd4 count) at 6 months and 12 months of art

77.84% after one year of ART means improved in the number of patients by 5.58%. While 4.57% Stage IV patients were shifted to Stage III/II (Table-1). After 6 months of ART, the mean CD4+ cell count increased to 335.5 cells/mm³ and after 1 year of therapy, this count increased to 430.75 cells/mm³. The overall change in the CD4+ cell count was 104.5 and 199.75 cells/mm³ after 6 and 12 months on ART respectively (Table-2).

DISCUSSION

Gandhi medical college and Hamidia hospital Bhopal ART plus center is active in central India hence it reflects the HIV/AIDS patients in central India.

In this study, 1903 HIV/AIDS patients who were on ART in the health center were involved. 80.67% patients were active at the time of initiation of ART and 89.65% patients were still active after one year of ART follow up, improved by 8.98%. This number was greater as compared to a study occurred in west Kenya which involved 2059 HIV positive on pregnant, where after 10 months of follow upon HAART 70% of the patients remained active on treatment,¹¹ this may be attributed to the improvements in weight, functional status and CD4+ cell count after initiation of ART which helped in improving the overall health conditions of patients thereby decreasing the chance of occurrence of death. The median weight increased by 8 kg for patients who were on ART after 12 months which is higher than the study done in USA, which showed increase in about 0.8 kg after a follow up duration of 5 months.¹² This shows good response of ART concerning weight. The median CD4+ cell count among the patients increased by 104.5 cells/mm³ in the first 6 months on ART. This was lower compared to a prospective study done in South India where the CD4+ cell change after 6 months of HAART was increased by mean of 140 cells/mm³.¹³ The CD4+ cell count changed during the first 6 months of HAART was also lower than that of the change described in a retrospective study done in Yirgalem Hospital southern Ethiopia where the CD4+ cell count change after 6 months of ART was about 175 cells/mm³.¹⁴ After 1 year of ART the functional status of the patients improves significantly which shows that improvement in the quality of life of the patients.

Limitations

In this study, information regarding opportunistic infections and medications adverse reactions was not available in a complete manner among the medical records of the patients, which hindered the analysis of ART outcomes in relation to these conditions.

CONCLUSION

This study showed that more than three fourth of the patients who started the therapy were active after 1 year of ART. There were improvements both immunologically and clinical condition of patients as increase in the weight, CD4+ cell count and the improvement in the functional status of the patients after 1 year of ART initiation. Based on the objective of evaluating the immunological and clinical progress of HIV/AIDS patients, this study concluded that the patients involved in ART were shown to experience improved health status in general.

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