

Research Article

To assess the effect of antiretroviral therapy on HIV/AIDS patients at art plus center Bhopal: a retro respective study

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ABSTRACT

Background: To assess the immunological and clinical progress of human immunodeficiency virus/acquired immune deficiency syndrome patients on antiretroviral therapy at antiretroviral therapy (ART) center Bhopal, Madhya Pradesh, India.

Methods: Retrospective medical records review was conducted to determine the immunological and clinical progress of HIV/AIDS patients. The records of patients on their clinical stage, cluster of differentiation 4 (CD4) Count, and working status were reviewed.

Results: A total number of 5295 patients were included in the study. The mean age was 33.39 Years and standard deviation 11.84 years; it ranged from 0.5 to 82years. Number of males was 3441 (64.98%), females formed 1829 (34.54%), while transgender 25 (0.47%). Out of 5295 patients 3314 (%) are eligible and initiated ART. And out of 3314 patients, 1903 patients continue to be present at their follow up visit for regular clinical and pathological checkup. The mean weight of the patients increased from 49.59kg to 52.41 after 12 months of therapy. Mean CD4 cell counts as 231cells/mm³ during the first follow up increase to 443 cells/mm³ at 2nd visit. Before ART 674 Patients were working and 373 were bedridden and after 1 year of ART 1028 were became belongs to working group and only 197 were remains bedridden. Percentage of patients in stage III became 38.94% (from 48.84%) followed by Stage II 38.36% (from 23.08%).

Conclusions: Study concluded that the patients taken ART were shown to experience improved health status in general.

Keywords: HIV, ART, CD4, HAART

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.¹ With a widespread use of antiretroviral (ARV) drugs, the once fatal disease is now a manageable chronic illness.² The drugs improve immune status,

reduce viral load, and incidence of hospitalization and mortality.^{3,4}

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. Even during the asymptomatic period, the virus is actively multiplying, infecting and killing cells of the 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 immune system's key infection fighters. The virus slowly disables or destroys these cells without causing symptoms.⁵ HIV treatment includes the use of combination antiretroviral therapy to attack the virus itself, and medications to prevent and treat the many opportunistic infections that can occur when the immune system is compromised by HIV. In light of recent research findings, WHO released a guideline in 2015 recommending starting HIV treatment earlier in the course of illness. Combination ART, first introduced in 1996, has led to dramatic reductions in morbidity and mortality, and access has increased in recent years, rising to 15.8 million people as of June 2015, achieving a goal set by world leaders in 2011 to have 15 million people on treatment by 2015. Globally, 40% of people living with HIV are receiving treatment, which includes 41% of adults and 32% of children living with HIV. Approximately 76% of all people receiving antiretroviral therapy in sub-Saharan Africa are virally suppressed, which means they are likely healthier and less likely to transmit the virus. 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. Access to ART among children has also risen significantly, although they have less access than adults.⁶ 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 significantly altered HIV disease progression by reducing the incidence of AIDS and death.⁹ Currently 15.8 million people accessing antiretroviral therapy. The treatment efficacy of HAART is mainly evaluated by the decrease in HIV viral load and the degree of reconstitution of the immune system.¹⁰ HAART is now widely available in most developed countries; the benefits of HAART have not been uniformly distributed.

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 describe updated prognostic models that estimate probabilities of immunological and clinical progression to AIDS or death and death alone up to 2 years after starting HAART, first according to CD4 counts measured at baseline, and second incorporating the successive response to treatment.

The objective of this study was to assess the immunological and clinical progress of human immunodeficiency virus/acquired immune deficiency syndrome (HIV/ AIDS) patients on antiretroviral therapy (ART) at a health center in Hamidia Hospital Gandhi Medical, Bhopal.

METHODS

After taking permission from responsible authority 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 come to the Hamidia hospital Bhopal from January 2008 to March 2016. Data was collected from the medical records of HIV/AIDS patients who initiated ART in Hamidia Hospital Gandhi Medical, Bhopal, India.

In this study, the sample size used was the medical records of all adult HIV/AIDS patients who were registered in ART center. This enabled the retrospective follow-up of the records of all these patients for at least 1-2 year. The records of patients on their clinical stage, CD4 Count, and working status and weight were reviewed at 6month and 12 month successively. In addition, data was collected regarding the age, sex, ART regime.

Total 5295 were registered during this period out of which 3314 were eligible for ART treatment, rests were advised for the regular follow up. 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. In this study, the data collection was conducted by trained paramedical workers using a data collection format under the supervision of the investigators. The exclusion criteria for the study were being on ART for <1 year, incomplete and illegible records, 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. The data collected was kept confidential and used strictly to the purpose of the study. Data which was collected was entered in MS excel and analysed by Epi-info 7.

RESULTS

A total number of 5295 patients were included in the study from ART center Gandhi medical college and Hamidia hospital Bhopal, Madhya Pradesh, India.

During this period 46 (66.7%) of the patients who were active on treatment had "Good" adherence (95%+) and 22 (31.9%) had "Fair" adherence (85-94%) level.

Distribution of patients by regimen shows that maximum patients (more than 90%) were on TLE (tenofovir/lamivudine/efavirenze) and ZLN (zidovudine/lamivudine/nevirapine) regimen at the initiation of ART.

The mean age was 33.39 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 years).

And the number of males was 3441 (64.98%), females formed 1829 (34.54%), while transgender 25 (0.47%) of the total sample (5295).

Table 1: Demographic and health status patients at the start of art.

Age group (years)	Frequency n=5295	Percentage n=5295
0-18	369	7.00
19-29	1463	25.58
30-39	1924	36.31
40-49	1017	19.23
>50	522	9.26
Total	5295	100.00
Sex	Frequency	Percentage
Male	3441	64.98
Female	1829	34.54
TG	25	0.47
Total	5295	100.00

Out of 5295 patients 3314 (%) are eligible and initiated ART, 147 (2.77%) are eligible but not initiated ART, rest patients are either opted out, Dead, transfer out or missed on their successive visit. And out of 3314 patients, 1903 patients are those who continue to be present at their follow up visit for regular clinical and pathological check up.

So the records of these 1903 patients were taken at their successive visit and analysed their clinical condition, CD4 counts and their functional statuses were noted.

Table 2: Increase in the weight of HIV patients taking art after 1 year.

Weight	Weight before ART n=1903(%)	Weight after 1 year of ART n=1903(%)
<40	192 (10.09)	109 (5.72)
40-49	674 (35.42)	485 (25.48)
50-59	766 (40.25)	929 (48.83)
60+	265 (13.92)	380 (19.97)
Total	1903 (100.0)	1903 (100)

At the start of ART the weight of most of the patients was between 40 and 60 kg. Of these, 674 (35.42%) were between 40 and 49 kg, whereas 766 (40.25%) being between 50 and 59 kg (Table 1). The overall mean weight of the patients increased from 49.59kg with SD±10.21 to 52.41 after 1 year on ART with SD±9.09. Patients with weight 40-49kg now become 485 (25.48%) and weight between 50-59 kg becomes 929 (48.83%) patients.

Follow up of these 1903 patients' shows the changes in mean CD4 cell counts as 231 cells/mm³ during the first follow up increase to 443 cells/mm³ after 12 months of

ART initiation. These increases were also shown in patients during each year.

Table 3: Variation in mean CD4 counts.

Years	1 ST follow up CD4 n=1903	2 ND follow up CD4 n=1903
2008	213	464
2009	198	457
2010	209	482
2011	224	469
2012	247	464
2013	247	414
2014	258	362
2015	252	434
Mean CD4 counts	231	443

Table 4: Functional status of art receiving HIV/AIDS patients after one year.

Functional status	Before ART n=1903	1year after ART n=1903
Working	634 (33.31%)	1028 (54.02%)
Ambulatory	901 (47.35%)	678 (35.63%)
Bedridden	368 (19.33%)	197 (10.35%)
Total	1903	1903

Regarding functional status most of the patients, 901 (47.35%) were ambulatory and 634 (33.31%) were working, the remaining being bed ridden and after 1 year of ART 1028 (54.02%) were became belongs to working group, 678 (35.63%) were ambulatory and only 197 were remains bedridden.

Table 5: Improvements in clinical stage of patients.

WHO clinical stage	Before ART initiation n=1903	1 year after ART initiation n=1903
Stage I	163(8.59)	147(7.72)
Stage II	439(23.08)	730(38.36)
Stage III	930(48.84)	741(38.94)
Stage IV	371(19.49)	285(14.97)
Total	1903(100%)	1903(100%)

At the initiation of ART, the clinical stage of the patients around 48.84% were in WHO clinical stage III, followed by stage II (23.08%) and stage IV (19.49%) respectively. Results after one year of ART percentage of patients in stage III became 38.94%, followed by stage II 38.36%. And in stage IV it became (14.97%).

DISCUSSION

In this study, 3314 HIV/AIDS patients who were on ART in the health center were involved. 1903 (57.42%) patients were still active after 6 months and after 1 year

of ART follow-up. This number was compared to that reported by a study done in Catalonia and the Balearic Islands (Spain) by Elena Ferrer et al show that in severely immune suppressed patients initiating ART, reaching CD4 ≥ 200 cells/mm³ (immunological response) and undetectable VL (virological response) during follow-up is associated with a very low rate of disease progression, regardless of BL status. In contrast, a majority of patients not reaching this virological or immunological outcome will experience disease progression. The number of death in the next 6 months was only one which is very less as compared to the first 6 months; this may be attributed to the improvements in the first 6 months in weight, functional status and CD4+ cell count which helped in improving the overall health conditions of patients thereby decreasing the chance of occurrence of death.¹¹

The median weight increased by 1 kg for patients who were on ART after 6 months which is higher than the change in a study done in the USA, which was about 0.8 kg after a follow-up duration of 5 months.¹⁰ This shows good response to HAART concerning weight. In this study, the median weight of patients increased further by 1 kg in the next 6 months.

The mean CD4+ cell count among the patients increased by 212 cells/mm³ in the 12 months on ART. This may be 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 which increase further in next 6 months.¹² The CD4+ T-cell count changed during the first 6 months of HAART was also found to be in same range as 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. And in next six month follow up CD4 counts again improved by 41 cells/mm³.¹²

In the 1 year of ART the functional status of the patients was improved significantly. During the follow up, the number of working patients has changed from 664 (35.42%) to 1028 (54.02%) and the ambulatory ones from 856 (44.98%) to 678 (35.98%) which shows a clear improvement in the quality of life of the patients respectively. In case of bed-ridden patients, all the most of the patients had improved to working or ambulatory status after the 1 year of therapy.

Our results indicate that those patients who initiates to take ART would improve in all aspects of their life, but the patients which are missed or opt out or does not follow up properly harms not only their own health but also to the community also. And those patients who reported regularly NACO will continue to monitor the characteristics and prognosis of HIV-infected patients starting HAART and update analyses at regular intervals.

CONCLUSION

This study showed that near about 60-70% of the patients found to be eligible to initiate the ART after the diagnosis

of HIV infection then 40% of them were active after 6 month and 1 year. There were improvements both immunologically and clinically as observe by the 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 assessing 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.

Limitations

In this study, information regarding the missed, and opt out patient was not available that would effects the actual outcome HIV patients and information about opportunistic infections and medications adverse reactions and cause of death of diseased patients 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.

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