

# Immunological and clinical progress of HIV/AIDS patients on antiretroviral therapy at a health center in Addis Ababa, Ethiopia

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## ABSTRACT

**Objective:** The objective of the following 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 Addis Ababa, Ethiopia. **Materials and Methods:** A retrospective follow-up study was carried out using the medical records of HIV/AIDS patients who initiated ART between August 2005 and 2007. A total of 83 patients were included in the study. The records were used to get a 1 year progress since ART initiation. **Results:** At ART initiation the median CD4<sup>+</sup> cell count was 127 cells/mm<sup>3</sup> and the median weight 50 kg. Out of the total patients 47% were ambulatory and 16% were bedridden in their functional status. The regimen initiated by most patients, 59 (71%), was “Stavudine/Lamivudine/Nevirapine (D4T/3TC/NVP)”. After 12 months on ART, 63 (76%) of the patients were still actively following the treatment. After the same period, 12% of them were deceased. The functional status of 69 (83.1%) of the patients on ART improved to “working” status after 6 months. At the end of the 1 year on ART all the 63 patients, who were actively following the treatment, improved to “working” status. Weight of the patients improved to 54 and 56 kg after 6 and 12 months respectively. The increase in the CD4<sup>+</sup> cell count was 92 and 118 cells/mm<sup>3</sup> after 6 and 12 months respectively. **Conclusion:** This study showed that immunological and clinical status of the patients had improved within the 1 year of therapy as evidenced by increase and improvement in the functional status, median weight and CD4<sup>+</sup> cell count.

**Key words:** Antiretroviral therapy, clinical progress, Ethiopia, human immunodeficiency virus, acquired immune deficiency syndrome, immunological progress

## INTRODUCTION

The emergence of the human immunodeficiency virus (HIV) epidemic is one of the biggest public health challenges the world has ever seen in recent history.<sup>[1]</sup> It is among the most important public health problems world-wide and according to the

report of the World Health Organization (WHO) 34.0 million people were living with HIV at the end of 2011 at a global level.<sup>[2]</sup> Of all parts of the world, Sub-Saharan Africa is the most affected constituting 69% of those living with the virus. Ethiopia, located in the Sub-Saharan Africa, is highly stricken by HIV with an estimated prevalence of 1.5% among adults.<sup>[1]</sup>

In combating HIV/acquired immune deficiency syndrome (AIDS) medications used to suppress the virus and stop the progression of the disease are combination drugs which usually are comprised by at least three different drugs known by the name antiretroviral therapy (ART).<sup>[3]</sup> The combination therapy is also called highly active antiretroviral therapy (HAART).<sup>[4]</sup>

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In 2003, nearly 20 years after the identification of HIV cases in Ethiopia, antiretroviral drugs use guideline and ART program was launched.<sup>[5]</sup> After the launch in 2003, it was expanded for the use of the population widely in the form of free ART rollout in 2005. This was done first in hospitals followed later by health centers. Following this progress and expansion in 2010/2011 the ART program reached more than 330,000 patients.<sup>[1,6,7]</sup> Together with the increase in the enrollment of patients in ART the overall outcome associated to the therapy needs to be assessed in terms of the virological, clinical and immunological progresses. The objective of this study was to assess the immunological and clinical progress of HIV/AIDS patients on ART in a health center in Addis Ababa.

## MATERIALS AND METHODS

A retrospective follow-up study was done to determine the immunological and clinical progress of HIV/AIDS patients on ART. Data was collected from the medical records of HIV/AIDS patients who initiated ART in Addis Ketema Health Center, Addis Ababa. In this study, the sample size used was the medical records of all adult HIV/AIDS patients who started ART in the health center since the launch of the program in August 2005 up to January 2007. This enabled the retrospective follow-up of the records of all these patients for at least 1 year. Hence, a total of 89 medical records of patients who initiated ART in the mentioned period were found. The inclusion criteria were; being HIV/AIDS patient, adult (18 years or older) and starting ART in the institution at least 1 year before data collection commenced. 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. Using these criteria out of the total medical records of the 89 patients who initiated ART during the period between August 2005 and January 2007, 83 were included in the study and followed-up for a 1 year progress. The data collection was carried out from January 30 to February 5, 2008.

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 nurses using a data collection format under the

supervision of the principal investigator. The data collection format was prepared to get data on patients' age and sex, adherence level, immunological and clinical status at the start of ART and the progress after 6 months and 1 year on the therapy. In carrying out this study, the 83 patients who started ART using different regimens were tracked for their change in CD4<sup>+</sup> cells count, functional status and weight change after 6 and 12 months.

A pretest was done before the actual data collection and appropriate modifications were instituted to the data collection format. This study was approved by Jimma University and the health center. Furthermore, the data collected was kept confidential and used strictly to the purpose of the study. The data collected was entered and descriptively analyzed by Statistical Packages for Social Sciences (SPSS) for Windows Version 13.0.1. Chicago: SPSS Inc. 2005 to present frequencies and percentages of different parameters.<sup>[8]</sup>

## RESULTS

### Patients' condition at ART start

A total of 83 medical records of HIV/AIDS patients who initiated ART from the start of the program in August 2005 until the end of January 2007 were used in the study. Out of these, 60 (72.3%) were females. The median age of the patients was 38 years for males and 29.5 years for females by the time of initiation of ART in the health center [Table 1].

By the time of initiation of ART, the CD4<sup>+</sup> cell count of 23 (27.7%) of the patients was between 50 and 100 cells/mm<sup>3</sup> followed by the patients having CD4<sup>+</sup> cell count between 150 and 200 cells/mm<sup>3</sup>. At the initiation of ART, the clinical stage of the patients around 41 (49.4%) were in WHO Clinical Stage III, followed by Stage II and Stage IV, respectively [Table 1].

At the start of ART the weight of most of the patients was between 40 and 60 kg. Of these, 34 (41.0%) were between 40 and 50 kg, whereas 29 (34.9%) being between 50 and 60 kg [Table 1]. At the initiation of ART the median weight of the patients was 56 kg for males and 49 kg for the females. The overall median weight of the patients was 50 kg.

Regarding functional status most of the patients, 39 (47%) were ambulatory and 28 (33.7%) were working, the remaining being bed ridden. The median CD4<sup>+</sup> cell counts of the patients at the initiation of therapy was 94 cells/mm<sup>3</sup> among males and 139.5 cells/mm<sup>3</sup> among

**Table 1: Demographic and health status of patients at the start of ART**

Patient characters	Frequency (%)
Sex	
Male	23 (27.7)
Female	60 (72.3)
Total	83 (100.0)
Age	
18-29	32 (38.6)
30-39	27 (32.5)
40-49	18 (21.7)
50+	6 (7.2)
Total	83 (100.0)
CD4 <sup>+</sup> cell count	
<50	12 (14.5)
50-99	23 (27.7)
100-149	18 (21.7)
150-199	21 (25.3)
200+	9 (10.8)
Total	83 (100.0)
Clinical stage	
I	7 (8.4)
II	19 (22.9)
III	41 (49.4)
IV	16 (19.3)
Total	83 (100.0)
Weight	
<40	8 (9.6)
40-49	29 (34.9)
50-59	34 (41.0)
60+	12 (14.5)
Total	83 (100.0)
Functional status	
Working	28 (33.7)
Ambulatory	39 (47.0)
Bedridden	16 (19.3)
Total	83 (100.0)
ART regimen	
D4T30/3TC/NVP (1a30)	59 (71.1)
D4T40/3TC/NVP (1a40)	8 (9.6)
D4T30/3TC/EFV (1b30)	11 (13.3)
D4T40/3TC/EFV (1b40)	1 (1.2)
ZDV/3TC/NVP (1c)	3 (3.6)
ZDV/3TC/EFV (1d)	1 (1.2)
Total	83 (100.0)

D4T30=Stavudine 30 mg, D4T40=Stavudine 40 mg, 3TC=Lamivudine, NVP=Nevirapine, ZDV=Zidovudine, ART=Antiretroviral therapy, EFV=Efavirenz

females with an overall median CD4<sup>+</sup> cell count of 127 cells/mm<sup>3</sup>.

Distribution of patients by regimen shows that 14 of males and 45 of the females were on stavudine 30 mg/lamivudine/nevirapine (D4T30/3TC/NVP/1a30) at the initiation of ART, accounting for 71.1% of the total patients in the study [Table 1].

### Patients' conditions after 6 and 12 months of ART initiation

Concerning follow-up status of the patients after 6 months of ART, the study showed that most of the patients, 69 (83.1%) were active on the therapy while 9 (10.8%) were deceased and 5 (6.0%) dropped the follow-up. 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. The follow-up status after 1 year on ART indicated that 63 (75.9%) of the patients were still active and the number of deceased patients became 10 (12.05%) and those who dropped the treatment increased to 10 (12.05%) respectively. After 1 year on ART, 45 (71.4%) were recorded to have had "Good" adherence level and 16 (25.4%) had "Fair" adherence level out of those who remained active on treatment.

The median weight of the patients increased to 62.5 kg for males and 50 kg for females after 6 months of therapy. The same variable became 61.5 kg for the males and 52 kg for the females after 1 year of ART. The overall median weight of the patients increased to 54 kg (improved by 8%) after 6 months and 56 kg (improved by 12%) after 1 year on ART [Figure 1].

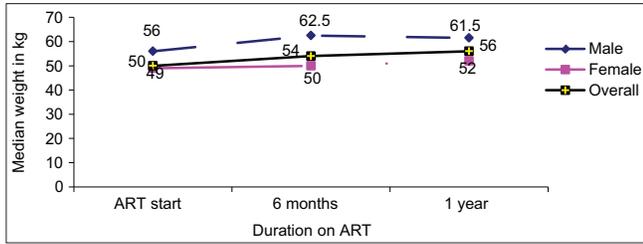
After 6 months of ART, the median CD4<sup>+</sup> cell count increased to 207.5 cells/mm<sup>3</sup> for the males and 244 cells/mm<sup>3</sup> for females. After 1 year of therapy, this count increased to 211.5 cells/mm<sup>3</sup> for males and 245 cells/mm<sup>3</sup> for females. The overall change in the CD4<sup>+</sup> cell count was 92 (72.4%) and 118 cells/mm<sup>3</sup> (92.9%) after 6 and 12 months on ART respectively [Figure 2].

The functional status of the patients improved during the follow-up as 69 (83.1%) of the patients acquired working status after 6 months of ART while the remaining being on ambulatory condition. The change in functional status after 1 year showed that all the patients active on ART were on working status [Figure 3].

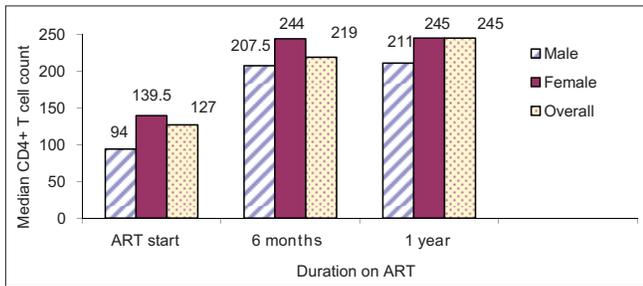
In the duration of 1 year on ART two changes in regimen and six changes in the strength of the drug stavudine had occurred. During the 1 year of ART ten patients were deceased (six males and four females).

### DISCUSSION

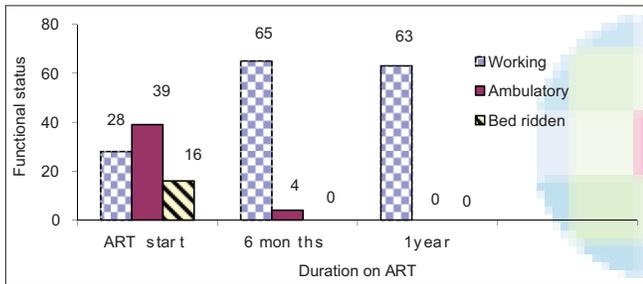
In this study, 83 HIV/AIDS patients who were on ART in the health center were involved. 69 (83%)



**Figure 1:** Change in median weight of patients during the 1 year on antiretroviral therapy



**Figure 2:** Change in median CD4<sup>+</sup> cell count of people living with human immunodeficiency virus/acquired immune deficiency syndrome on antiretroviral therapy



**Figure 3:** Functional status of people living with human immunodeficiency virus/acquired immune deficiency syndrome at antiretroviral therapy (ART) start, after 6 and 12 months of ART

patients were still active after 6 months and 63 (80%) after 1 year of ART follow-up. This number was greater as compared to that reported by a study done in western Kenya which involved 2059 HIV-positive non pregnant, where after 10 months of follow-up on HAART 70% of the patients remained active on treatment.<sup>[9]</sup> After 6 months on ART, 9 (11%) of the patients were deceased. This is greater than the indicated number of death in the study referred above where around 5.4% of the patients on follow-up were deceased.<sup>[9]</sup> 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<sup>+</sup> cell count which helped in improving the overall health conditions of patients thereby decreasing the chance of occurrence of death.

The median weight increased by 4 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.<sup>[10]</sup> This shows good response to HAART concerning weight. In this study, the median weight of patients increased further by 2 kg in the next 6 months.

The median CD4<sup>+</sup> cell count among the patients increased by 113 cells/mm<sup>3</sup> for males and by 104 cells/mm<sup>3</sup> for females respectively in the first 6 months on ART. This was lower compared to a prospective study done in South India where the CD4<sup>+</sup> cell change after 6 months of HAART was increased by mean of 140 cells/mm<sup>3</sup>.<sup>[11]</sup> The CD4<sup>+</sup> T-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<sup>+</sup> cell count change after 6 months of ART was about 175 cells/mm<sup>3</sup>.<sup>[12]</sup>

In the 1 year of ART the functional status of the patients was improved significantly. In the first 6 months, the number of working patients has changed from 28 (34%) to 65 (78%) and the ambulatory ones from 39 (47%) to 4 (5%) which shows a clear improvement in the quality of life of the patients respectively. In case of bed-ridden patients, all the 16 (19%) had improved to working or ambulatory status after the 1 year of therapy.

Concerning regimen change 2 (2.4%) of the patients changed their regimen and 6 (7.2%) changed the strength of stavudine from 30 to 40 mg during the 1 year. The latter ones changed strength of the drug due to weight improvement to 60 kg and above.

**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 clinically as witnessed by the increase in the weight, CD4<sup>+</sup> cell count and the improvement in the functional status of the patients after 6 months as well as 1 year of ART initiation.

Based on the aim 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.

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