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Assessment of Immunological Outcome Among HIV Infected Patients on First Line Highly Active Antiretroviral Therapy (HAART) in Shashamane Referal Hospital, West Arsi, Oromia Region, Ethiopia

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Abstract

Background: Antiretroviral Therapy (ART) is the cornerstone of management for RVI (Retroviral infected) patients as it restores the immune cells and thereby reducing morbidity and mortality. Understanding the biological and clinical effects of the ARTs is so crucial because a low CD4 count will advance the condition by increasing opportunistic infections.

Objectives: To assess the immunological outcome among RVI patients on HAART in Shashemane referral hospital.

Methods: Retrospective cross sectional study design was used to collect data from the records of HIV/AIDS patients on first line HAART from 2003-2008 E.C in Shashemane referral hospital.Simple random sampling technique was used. Data collection was carried out from March to April in 2017.

Results: A total of 201 RVI patients who were on ART fulfill the inclusion criteria and were included in the study. Out of them 62.2% (N=125) and 37.8% (N=76) were female and male respectively. The mean CD4 count for the regimen TDF+3TC+EFV increase from baseline 228.26 cells/mm^3 (SD=132.7) to 547 cells/mm^3 (SD=245.7). In similar manner, the mean CD4 count for the regimen ZDV+3TC+EFV increase from baseline 244.86 cells/mm^3 (SD=133.9) to 542.7 cells/mm^3 (SD=270.7).

Conclusion: The mean CD4 count for those patients who were on first line HAART increases regardless of the regimens.

Keywords: HIV; RVI patients; Immune cells; Highly active antiretroviral therapy

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Abbreviations

3TC: Lamivudine; AIDS: Acquired Immune Deficiency Syndrome; ART: Anti Retro viral therapy; CD4: Cluster Differentiation 4; CPT: Cotrimoxazole; D4T: Stavudine; EPV: Efavirenz; FMOH: Federal ministry of health; HAART: Highly Active Antiretroviral Therapy; HIV: Human Immuno Virus; INH: Isoniazid; NVP: Nevarapine; OI: Opportunistic infection; RVI: Retroviral infected patients; TDF: Tenofovirdisoproxilfumarate; TLN/E: Tenofovir/Lamivudine/Nevarapine or Efavirenz; WHO: World Health Organization; ZDV: Zidovudine; ZLN/E: Zidovudine/Lamivudine/Nevarapine or Efavirenz.

Introduction

HIV has created an enormous challenge worldwide. Globally, an estimated 35.3 (32.2-38.8) million people were living with HIV in 2012. There were 2.3 (1.9-2.7) million new HIV infections globally, showing a 33% decline in the number of new infections from 3.4 (3.1-3.7) million in 2001. At the same time the number of AIDS deaths is also declining with 1.6 (1.4-1.9) million AIDS deaths in 2012, down from 2.3 (2.1-2.6) million in 2005. The sub Saharan Africa remains the most heavily affected region, with 67% of the global burden and 90% of children living with HIV worldwide and 75% of AIDS deaths. Ethiopia is one of the seriously affected countries in sub Saharan Africa. According to HIV related estimates and projections for Ethiopia, national prevalence of HIV infection in 2014 is 1.2% (1.6% for female and 0.8% for men) among adult population. The prevalence of HIV infection in the same year was 3.3% (male 2.3%, female 4.4% female) in urban and 0.5% (male 0.3%, female 0.6%) in rural area. As of October 2013, total number of patients ever started on treatment was 499,412 out of 822,531 patients ever enrolled in the 880 health facilities (Hospital and Health center) [1].

Antiretroviral Therapy (ART) is the cornerstone of management of patients infected with Human immune deficiency virus (HIV). The treatment option for AIDS have drastically changed since 1987 when the first drug of HIV AIDS Zidovudine (ZDV) was approved by food and drug administration, even though there is no cure for it. Monotherapy has been replaced by the most effective currently in HAART which includes three drugs from one or three categories to decrease the incidence of viral resistance. As a high viral load is associated with HIV related morbidity and mortality, the goal of Antiretroviral therapy to achieve Human immune virus (HIV) viral suppression and reduce the level HIV RNA as low as level as possible, for as long as possible, restore and preserve immunological function, improve the quality of life, reduce HIV related morbidity and mortality and reduce HIV transmission to new born children [2].

The 2013 World Health Organization (WHO) recommendation for combination antiretroviral therapy (ART) for HIV is two-nucleoside reverse-transcriptase inhibitors (zidovudine (AZT)/ abacavir plus, lamivudine (3TC) or nucleotide tenofovir (TDF) plus 3TC) and a non-nucleoside reverse-transcriptase inhibitor: efavarenz (EFV) or nevarapine (NVP) [3]. Ethiopia adopted these guidelines and regimens based on TDF and ZDV are used as the first line. The current recommended preferred first line regimen for treatment of adults and adolescents naïve patients in Ethiopia consists of two NRTI with one NNRTI. Zidovudine plus Lamivudine plus nevarapine or efavarenz and Tenofovir plus lamivudine plus nevarapine or efavirenzand in selective setting, however when standard first line regimen is not possible Abacavir plus, lamivudine plus, neverapine or efavarenz (ABC/3TC/NVP OR EVF) is given as the first line regimens [4].TDF is more potent and less toxic than AZT and median decreases in plasma human immunodeficiency virus (HIV)-1 RNA levels (virus load; VL) in subjects receiving TDF and AZT monotherapy are 1.4 and 0.5 respectively [5].

Safe and efficacious ART regimens improve patient care through rapidly restoring the immune cells, promoting adherence and alleviating the hazards of mortality TDF is one of the ART drugs that come to be routinely utilized in Ethiopia since the past 2 years [6].

CD4 cell count and HIV RNA viral load in response to antiretroviral therapy (ART) are important measures of the efficacy of ART in individual patients and of the effectiveness of ART in populations of patients enrolled in HIV care and treatment programs, but viral load is limited in resource limiting setting of the countries. In addition, CD4 count at the time of ART initiation is an important determinant of the degree of immunologic and virologic response, as well as subsequent risk of morbidity and mortality. Among those patients who are able to remain on ART, robust immunologic responses can be maintained for long periods, and the risk of serious morbidity and mortality may eventually diminish to levels observed in the general population [7].

The national antiretroviral initiation criteria for both adults and adolescents states that, in places where CD4 cell count is available, WHO clinical stage IV, irrespective of CD4 cell count, WHO stage III and if CD4 cell count is less than 350 and all WHO stage IV and CD4 cell count is less than 50 are criteria for eligible patients to start ART. However, for places where CD4 cell count is not available, WHO stage IV and WHO stage III, irrespective of TLC, WHO stage II and if TLC is less than or equal to 1200 are eligible to initiate ART treatment. Large numbers of people without age and gender limitation, need to access free antiretroviral treatment and prolong survival [7,8]. But, Currently the 2013 WHO guidelines recommended ART initiation for both adults and adolescents state that, HIV infection with CD4 count ≤ 500 cells/mm^3 should be started on HAART irrespective of WHO clinical stage and WHO clinical stage 3 and 4(sever or advanced HIV clinical stage) should be started on HAART irrespective of CD4 cell count [3].

Statement of the problem

WHO continuously advocates wider access to monitoring tools, particularly CD4 testing, to guide the initiation and monitoring of ART. The most HAART-treated patients may eventually achieve an optimal CD4+ T cell count outcome an important, but poorly defined subset fail to achieve this result or do so only after many years of HAART. Those patients whose CD4+ T cell counts remain low during therapy have an increased risk of a number of complications, including those due to AIDS, as well as those not traditionally thought to be HIV related (e.g., cancer, cardiovascular disease, and liver disease). Those patients who initiate HAART with a low CD4+cells count have the highest risk of failure to achieve an optimal immunological outcome (CD4) and increase the risk of infection [9,10].

AIDS destroy the ability of immune system to defense against any infection. HIV the virus that causes AIDS induces the state of immune deficiency by attacking and destroying the CD4 cells. The main target of HIV appears to be the CD4 cells population. A progression reduction in number and function of CD4 cell population is one of the most striking and consistent immunological feature of HIV related disorders [11]. Availability of free antiretroviral drugs to HIV infected individual has provided a new lease of life to this treatment. Treatment of HIV infected patients with current available HAART drugs is successful in reducing the burden of disease, but it associated with various high side effects [12,13].

In Ethiopia most of patients were start HAART low CD4 cell counts and advanced stage, this condition may decrease the immunological recover of the patients and increases opportunistic infection. Hence it is better to understand biological and clinical effect of these HAART drugs.

Literatures that are aimed to compare the immunological outcome among RVI patients on the first line HAART regimens (TDF and ZDV based regimens) are scarce in Ethiopia and there is no study undertaken on similar title in the study area.

Significance of the study

As the study compares CD4 counts after initiation of ART at different intervals, it will provide information such as treatment response, disease progression, treatment failure and complication of disease to clinicians for improving management

of HIV infection. The study will also contributing to filling the information gap and is helpful to make some recommendations for better management and resource allocation.

Objectives

General objectives

To assess immunological outcome among RVI patients on the first line HAART in shashamane referral hospital, West Arsi, Oromia, Ethiopia

Specific objective:

• To describe the clinical characteristics of patients enrolled at SRH for HAART.

• To determine the change in mean CD4 count after the initiation of HAART.

• To identify the HAART regimen with better mean CD4 change.

• To identify contributing factors for a better immunological outcome.

Methodology

Study area and period

The study was conducted in Shashemene referral hospital ART clinic from January to April 2017. Shashemene Referral Hospital is found in Kuyera town, which is situated 238 km away from Addis Ababa to the South in West Arsi Zone, Oromia, Ethiopia. It has a latitude and longitude of 7°12'N and 38°36'E and an elevation of 1,990 meters. The hospital was established in 1952 as center for Leprosy control by SIM (Sudan Interior Mission) and gradually extended to be a referral hospital at present. It has 205 beds and provides outpatient and inpatient services for 2,596,237 million population of west Arsi Zone and neighboring zones. From the catchment population 1,287,696 are male and 1,308,541 are female. Children under one year of age are 77,887, less than five year of age are 389,436, women 15-49 years of age are 59, 7134 and number of pregnant women are estimated to be 19,535. An antiretroviral therapy (ART) service was launched in the Hospital in 2006.

Study design

A retrospective cross sectional study was conducted

Population

Source population: All HIV positive patients' data set and card present in the ART clinic of SRH

Study population: All adult ART clients data set, during 2003-2008 E.C who were started on TDF+3TC+EFV/NVP OR ZDV+3TC+NVP/EFV and has baseline and follow up CD4 count.

Inclusion and exclusion criteria

Inclusion criteria: All adult (age greater than 14) ART clients who started ART and have baseline and follow up CD4 cell count after starting first line ART.

Exclusion criteria: Clients who started ART and their information is incomplete, unreadable or their manual record is lost.

Sample size and sampling technique

Sample size was calculated from the total study population that fulfill in inclusion criteria by the following formula:

$n=Z^2 P (1-P)/D)^2$

Where:

n-Sample size

Z-Confidence interval=95% (1.96)

P=50% (0.5) to allow maximum sample size

D-Margin of errors=5% (0.05)

$n=(1.96)^2(0.5) (1-0.5)/(0.05)^2$

$n=384$

Since the total RVI patients on ART that fulfill inclusion criteria were 750

$nf=N \times n/N+n$

$nf=750 \times 384/750+384$

$=254$

Where n=initial sample size which was 384.

N=sample population taken 750 RVI patients clients.

nf=exact sample size

Sampling technique

Simple random sampling technique was used.

Variables

Dependent variables: CD4 cell count

Independent variables:

• Age,

• Sex

• ART regimen

• Marital status

• Religion

• Education status

• Prophylaxis for opportunistic effect

• WHO stage

• Opportunistic infection

• Tb treatment

Operation definitions

Adherence: Taking HIV medicines every day and exactly as prescribed

Antiretroviral (ARV) drugs: Drugs used to treat HIV

ART (antiretroviral therapy): Refers to the use of a combination

of three or more ARV drugs for treating HIV infection.

Base line CD4 count: Is the Initial CD4 count measured when a patient is ever enrolled on ART.

Follow up CD4 counts: CD4 count measured after being enrolled on ART to assess immune system reconstitution.

First line HAART: Refers to the preferred highly active antiretroviral therapy for treatment of replications.

Immunological outcome: Is the measurement of immunity system after initiation of medication.

Results

Socio-demographic characteristic

A total of 201 RVI patients who fulfill the inclusion criteria were included in the study **(Table 1)**.

The majority of the patients were females 62.2% (N=125) and the age group with many patients is 26-35 (57.2%). Though most of the patients live in urban areas (80.6%), only 27.9% and 3% completed secondary and tertiary education respectively.

Distribution of HAART regimens among RVI patients attending SRH during the period 2003 to 2008 E.C

Distribution of HAART regimens among RVI patients attending SRH is shown in **Figure 1**.

Clinical characteristic among RVI patients on the first line HAART

On initial referral to the ART clinic, most of the patients (41.8%) were on WHO stage I. Out of these, majority of them (26.86%) were started on TDF+3TC+EFV. For this regimen, though 55.2% of them adhere to taking their HAART, only 9% of them developed OIs **(Table 2)**.

Table 1: Socio-demographic characteristics of HIV/AIDS patients who were on HAART in SRH between 2003 to 2008 E.C.

Socio-demography		Number of patients	Percent
Sex	Female	125	62.2
	Male	76	37.8
Age	15-25	22	10.9
	26-35	115	57.2
	36-45	45	22.4
	>45	19	9.5
Marital status	Single	14	7
	Married	138	68.7
	Divorced	33	16.4
	Widow	16	8
Religion	Orthodox	88	43.8
	Muslim	67	33.3
	Protestant	42	20.9
	Catholic	3	1.5
Residence	Urban	162	80.6
	Rural	39	19.4
Level of education	No education	43	21.4
	Primary	96	47.8
	Secondary	56	27.9
	Tertiary	6	3
	Total	201	100

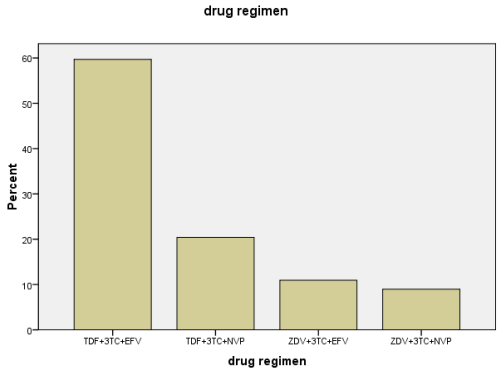

Figure 1 Frequency distribution for HAART regimens among RVI patients in SRH during the study period.

Table 2: Baseline CD4 and clinical characteristics of RVI patients who were on first line HAART in Shashemane referral hospital from 2003 to 2008 E.C.

Characteristics		Frist line HAART regimens							
		Total Freq.	Total %	Total Freq.	Total %	Total Freq.	Total %	Total Freq.	Total %
Baseline CD4 count(cells/mm³)		228.26(132.7)		195.2(102.3)		244.86(133.9)		277.2(110.9	
WHO stage	I	54	26.86	14	6.97	10	4.97	6	3
	II	16	7.96	16	7.96	1	0.5	8	4
	III	40	19.9	9	4.48	9	4.48	4	2
	IV	10	4.98	2	1	2	1	0	0
BMI	<18	33	16.4	11	5.5	9	4.5	2	1
	18-24	77	38.3	24	11.9	13	6.5	12	6
	>24	10	5	6	3	0	0	4	2
Adherence	Good	111	55.2	40	19.9	17	8.46	21	10.4
	Poor	9	4.48	1	0.5	1	0.5	1	0.5
TB Rx.	Yes	10	4.76	0	0	1	1.5	0	0
	No	110	54.7	41	20.4	19	9.5	18	8.95
Prophylaxis	Cotri.+ INH	31	15.4	7	3.5	5	2.49	2	1
	INH	6	3	0	0	3	1.49	0	0
	Cotri.	61	30.3	32	15.9	12	5.97	2	1
	Neither	22	10.9	2	1	2	1	3	1.49
OIs	Yes	18	9	7	3.48	19	9.6	15	7.46
	No	102	50.7	34	16.9	3	1.49	3	1.49

WHO stages among RVI patients

The majority of RVI patients on the first line HAART were WHO stage I (41.8%) and WHO stage III (30.8%), but some patients were WHO stage IV (7%) **(Figure 2)**.

Changes in CD4 count among different regimens

The mean CD4 count of TDF+3TC+EFV regimen increase from baseline 228.26 cells/mm³ (SD=132.7) to 547 cells/mm³ (SD=245.7) during the last follow up period after the initiation of HAART. In similar manner, the mean CD4 count for the regimen ZDV+3TC+EFVincreases from baseline 244.86 cells/mm³ (SD=133.9) to 542.7 cells/mm³ (SD=270.7) **(Table 3)**.

Change in CD4 count in relation to sex

For three of the HAART regimens except ZDV+3TC+NVP, the changes in CD4 count brought by the ARTs is higher in the female patients than males during the period 2003 to 2008 **(Table 4)**.

Adherence in relation to sex

57.2% of female patients have a good adherence to their HAART regimen as compared to males of which only 36.9% of them adhere **(Table 5)**.

WHO stages and mean CD4 change

Patients who started HAART in stage II have a mean change in CD4 count of 330 cells/mm³. However, the change in mean CD4 count of those patients who started HAART at their WHO clinical stages IV is 280 cells/mm³ **(Figure 3)**.

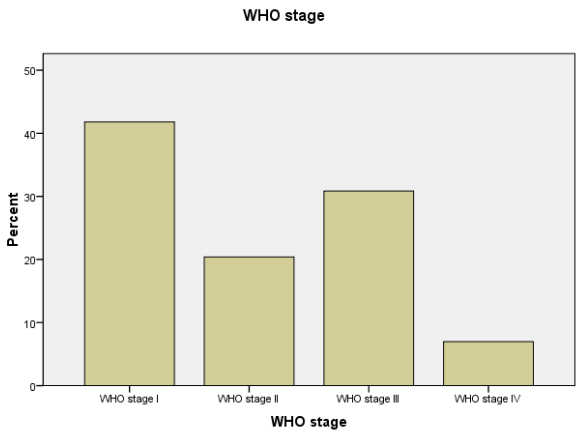

Figure 2 Frequency distribution of WHO stage among RVI patients on the first line HAART regimens in SRH from 2003 to 2008.

Table 3: The mean CD4 change among RVI patients after first line HAART in SRH from 2003 to2008 E.C.

CD4 count (cells/mm³)	HAART			
	TDF+3TC+EFV	TDF+3TC+NVP	ZDV+3TC+EFV	ZDV+3TC+NVP
Baseline mean CD4	228.26	195.2	244.86	277.2
Current mean CD4	547	502.2	542.7	527.5
Change mean CD4	318.74	307	297.84	250.3

Table 4: The net CD4 count among different regimens in relation to sex.

CD4 change(cells/mm³)	Regimen	Sex	
		Female	Male
	TDF+3TC+EFV	346.76	272.27
	TDF+3TC+NVP	339.67	272.7
	ZDV+3TC+EFV	345.71	214
	ZDV+3TC+NVP	230.42	305.15

Table 5: Frequency distribution of the relation between adherence and sex after initiation of first line HAART in SRH from 2003 to2008 E.C.

Variable		Sex of patient on HAART				Total
		Male		Female		
		Freq.	%	Freq.	%	
Adherence	Good	74	36.9	115	57.2	189
	Poor	2	0.9	10	5	12
Total		76	37.8	125	62.2	201

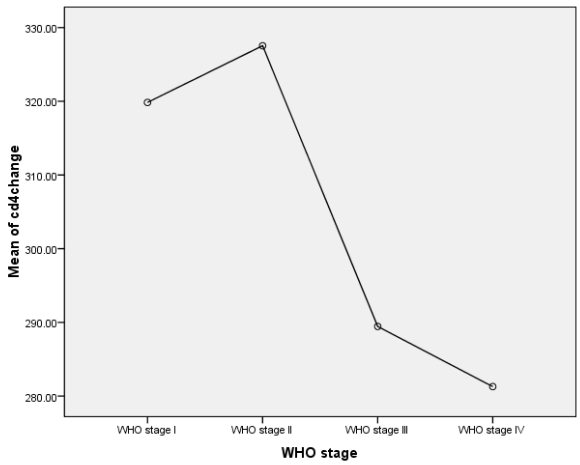

Figure 3 Baseline WHO stage and mean CD4 change among RVI patients on the first line HAART regimens.

Discussion

Most of the RVI patients who were enrolled to SRH for the initiation of HAART were on WHO clinical stage I. Though this is indicative of early diagnosis that is good for better treatment outcome, a third of these patients developed OIs during their course of treatment. Great proportion of them started the regimen TDF+3TC+EFV as a first line HAART as implicated in current WHO and Ethiopia Standard Treatment Guideline recommendations.

The immunological treatment outcome study after the initiation of HAART on the HIV infected patients enrolled for ART treatment at SRH showed varying successes among the different regimens in immunological recovery at the last follow up period. The mean CD4 count gained over different periods of time showed that patients taking the regimen TDF+3TC+EFV were superior over patients taking the other regimens. However, the regimen that showed a least increase in mean CD4 count was found to be ZDV+3TC+NVP.This study was in agreement with the study done in south Africa, that also shows an increase in mean CD4 cell count for the group taking TLE/N than ZLE/N [14]. Similarly, a retrospective hospital based cohort study conducted at Jimma University Specialized Hospital showed an increase in mean CD4 count in patients treated with TDF/EFV/3TC than the mean CD4 change of other regimens [15].

Contrary to the result of this study, the comparative study conducted in Nigeria showed that the regimen TDF/3TC/NVP is much more inferior (with a mean CD4 change of 208 cells/mm³) to AZT/3TC/NVP(221.1 cells/mm3) at 12 months of therapy [16-

18]. As this study lacks adherence data, the differences in mean CD4 changes observed between these studies might be due to poor adherence of patients in the group taking TDF/3TC/NVP.

In this study, increase in mean CD4 change is observed for three of the regimens in female patients than males. This is mainly because of the poor adherence of male patients to their medications. The other factor that seemed to affect the change in mean CD4 count is the WHO clinical stage of patients at the start of HAART. Those who started HAART in their earlier WHO stages (stage I and II) have a good change in mean CD4 count over the period of treatment.

Conclusion

Generally, RVI patients being treated in SRH with HAART have a better immunological outcome regardless of the regimen chosen as a first line. However, patients with the regimen TDF+3TC+EFV have a higher change in mean CD4 count as compared to the other regimens. A good change in mean CD4 count is also observed in patients who started HAART at their earlier WHO clinical stages.

Participation was completely voluntary and participants were informed that, they had the right to refuse or participate in the study after purpose, duration, benefit and possible risks of participation was presented for each participant. Data anonymity and confidentiality was kept throughout the study. Moreover, both written and verbal informed consent was obtained prior to collect data. The collected data were used only for the intended purpose of the study.

Ethical Considerations

Before the actual data collection process was started, an official permission letter was obtained from Ambo University, department of pharmacy research and community services office and brought to the administrative bodies of the SRH, to get permission for the study. The process of data collection was started after the willingness of SRH.

Limitations of the Study

There were some limitations that tried to hinder our research process. One is the lack of finance. Also this study generally included only governmental single health institution particularly SRH. There are others health institutions at which patients attend for their treatment follow up like public health institutions and private clinics and hospitals did not included in this study. Hence, we may not be able to generalize its result up on all on HV/AIDS patients.

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