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Antiretroviral Therapy Regimen Change Among HIV/AIDS Patients in Nekemt Hospital: a Primary Care Hospital in Oromia Regional State, Ethiopia

Meseret Wube, Andualem Tesfaye, Segewkal Hawaze*
School of Pharmacy, College of Public Health and Medical Sciences, Jimma University, Ethiopia.

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ABSTRACT

ART brings a complex series of choices; when to initiate therapy, what regimen to use, which class of drugs to use, when to change therapy, and which alternative drugs to use. Therefore, this study aims to assess reasons for initial ART regimen change in Nekemt Hospital. A retrospective cross sectional study was done by reviewing patient information sheet recorded from January 1, 2006 to December 31, 2010. Patients who changed their regimen were included in the study to identify the reasons for change and descriptive statistics were generated using SPSS version 16. Out of 142 patients, 57.7% were females and 57.7% were inthe age group 20-34. 61.2% were WHO clinical stage III patients and 69.7% of patients had a CD_4 count below 350 cells/mm^3. The most common initial regimens were D4T/3TC/NVP (42.2%), D4T/3TC/EFV (27.5%) and AZT/3TC/EFV (12.7%). The main reasons for modification of therapy were toxicity (80.3%), pregnancy (6.3%), new TB (5.6%), stock out (4.9%) and treatment failure (2.8%). The main toxicity observed was lipoatrophy (58.8%) followed by rash (12.3%) and CNS toxicity (11.4%). Toxicity was the main reason for initial regimen modification. D4T based regimens had high incidence of lipoatrophy.

INTRODUCTION

Human Immune Virus (HIV) is responsible for a worldwide pandemic and it is the cause of Acquired Immune Deficiency Syndrome (AIDS) (UNAIDS/WHO, 2006). According to latest statistics 33.4 million individuals worldwide are living with HIV, of which 15.7 million (47%) are women and 2.1 million (6.3%) are children under 15 years. In addition there are 2.7 million new infections and 2.0 million deaths from AIDS worldwide, albeit recent improvements in access to Antiretroviral Therapy (ART) (UNAIDS/WHO, 2009).

Sub-Sahara Africa remains the region most heavily affected by HIV. 1.9 million people living in sub-Sahara Africa, become newly infected with HIV, bringing the total number of people living with HIV to 22.4 million. Moreover an estimated 1.4 million AIDS related deaths occur in sub-Sahara Africa. But the rate of new HIV infections and death has slightly declined as a result of improved access to ART (UNAIDS/WHO, 2009).

The HIV/AIDS epidemic in Ethiopia continues to pose a threat to the lives of its people. According to the single point estimate in 2007, 977,394 people are living with the virus in Ethiopia. Resulting, a prevalence rate of 2.1% (1.7% among males and 2.6% among females; 7.7% urban and 0.9% rural areas) for a total estimated population of 73 million. The number of new infections is 125,528 including 14,147 HIV positive births of which females' account 57.4% (MOH, 2008).

Since beginning of Highly Active Antiretroviral Therapy (HAART) in 1996, there have been dramatic declines in morbidity and mortality due to HIV. But these advancements were not without a cost in terms of drug resistance and side effects.

A concern about these negative effects has lead to a more conservative approach to the timing of initiation of therapy and to clinical trials of intermittent therapy in an attempt to decrease the total exposure to drugs over time. Antiretroviral management brings a complex series of choices; when to initiate therapy, what regimen to use, which drugs within each class, when to change therapy, and which alternative drugs to use (Hammer, 2002). According to the Standard Treatment Guideline of Ethiopia; the criteria for initiating ART for adults and adolescents are; 1) if CD4

* *Corresponding Author*
Segewkal Hawaze, School of Pharmacy, College of Public Health and Medical Sciences, Jimma University; P. O. Box 378, Jimma, Ethiopia. Tel: +251 911 759989

testing is available (a) WHO stage IV disease irrespective of CD4 cell count. (b) WHO stage III disease with CD4 cell counts below 350/mm^3. 2) If CD4 testing unavailable; WHO stage III and IV disease irrespective of total lymphocyte count or WHO stage II diseases with a total lymphocyte count bellow 1200/mm^3 (DACA, 2010).

Accordingly, the first line ARV regimen in Ethiopia include a triple therapy, two Nucleoside Reverse Transcriptase Inhibitors (NRTIs) and one Protease Inhibitor (PI), if this is not possible, a Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) or else a triple therapy of three NRTIs. Based on the guideline, common ART regimens in Ethiopia are; TDF/FTC/EFV, AZT/3TC/EFV, AZT/3TC/NVP, D4T/3TC/NVP or D4T/3TC/EFV (MOH, 2007; DACA, 2010).

There are many factors that lead to the ineffectiveness of Antiretrovirals (ARVs) and change in the combinations. Rationale for treatment switch may be; either pre-emptive (risk of long term toxicity, poor adherence, desire for pregnancy, a sub-optimal regimen, co-morbidity, etc.), when virological suppression is usually retained or reactive to virological rebound or (because of resistance or poor adherence) or an established acute and/or chronic toxicity (Hart *et al.*, 2007). Toxicity or Adverse Drug Reaction (ADR) starting from simple rash up to life threatening adverse effects like hepatotoxicity, mitochondrial damage and bone marrow toxicity, create adherence and compliance problems (Eichetebaum, 2002).

Except a study conducted in tertiary care Hospital in southern part of Ethiopia (Woldmedhin and Wabe, 2012), the pattern of modification of ART regimen and factors responsible for the modification are not well studied and data on modification of HAART are scarce in Ethiopia. Furthermore, no study focuses on modification of ART regimen in primary care hospitals which are fundamental in the health delivery system, serving a catchment area of 250,000 populations. Thus this study is conducted with an aim to assess reasons for ART regimen change among patients with HIV/AIDS in Nekemt Hospital.

MATERIALS AND METHODS

Study area and period

The study was conducted in Nekemt Hospital, Nekemt found 331 kms west of Addis Ababa. Nekemt is located at 9˚5'N latitudes, 36˚33'E longitudes at an altitude of 2088m. The hospital delivers outpatient and inpatient services and has five specialists (surgeon, gynecologist/obstetrician, internist, pediatrician and ophthalmologist), five general practitioners, 71 nurses, four health officers, six laboratory technicians and two lab technologists and two pharmacists and five pharmacy technicians. The study was conducted from January 20, 2011 to February 05, 2011.

Study design

A retrospective cross sectional study was done by reviewing patient cards from January 1, 2006 to December 31, 2010 to assess initial ART regimen change. A pre-tested data abstraction form was used to collect information on demographics, World Health Organization (WHO) clinical stage, CD4 count, initiation and change of regimen, duration of initial therapy, and causes for regimen change. All HIV/AIDS patients who had undergone ART regimen switching in Nekemt hospital were included in the study while patient below 15 years were excluded from the study.

Data collection and management

A pre-tested data abstraction form was used to collect demographic, clinical and ART information which was randomly tested on patient cards to identify any drawbacks and appropriate modifications were made.

Data was collected by final year pharmacy students who were trained prior to data collection and completeness of data was checked on each day of data collection by supervisors. The data was cleaned, coded and entered into SPSS version 16 (SPSS Inc, Chicago, IL, USA). Descriptive statistics were generated to meet the objective of the study.

Ethical considerations

Prior to study initiation, Ethical clearance of Jimma University Ethical Board was obtained. Official letter from Jimma University explaining the purpose of the study was submitted to the hospital administration and support of the administration was obtained prior to pursuing the study. Patient and health care provider related data was confidential and was destructed after constituting a database.

RESULTS

Demographic Characteristics

The mean age of patients was 34 years. Majority of the patients (61.3%) were in the age range of 20-34 years and 57.7% of the patients were females. 46.5% of the patients were married and 57.7 % received higher education as shown in *Table 1*.

Table.1 Demographic characteristics of HIV/AIDS patients who changed their initial ART regimen in Nekemt Hospital, January 1, 2006 to December 31, 2010.

Demographic characteristics	**N (%)**
Age group	
20-34	87(61.3)
35-49	44(31.0)
≥50	11(7.7)
Sex	**N (%)**
Female	82(57.7)
Male	60(42.3)
Marital Status	**N (%)**
Single	56(39.4)
Married	66(46.5)
Divorced	5(3.5)
Widowed	15(10.6)
Educational Status	**N (%)**
No Formal Education	4(2.8)
Primary School Education	16(11.3)
Secondary School Education	40(28.2)
Higher Institute Education	82(57.7)

Table. 2: Common reasons for modification by first treatment regimens in Nekemt hospital, January 1, 2006 to December 31, 2010.

Initial regimens	Reasons for ART regimen change				
	Toxicities	Pregnancy	New TB	Stock out	Treatment failure
D4T/3TC/NVP	53(46.5%)	-	6(75%)	1(14.3%)	-
D4T/3TC/EFV	34(29.8%)	4(44.4%)	-	-	1(25%)
AZT/3TC/EFV	14(12.3%)	1(11.1%)	1(12.5%)	1(14.3%)	1(25%)
TDF/3TC/EFV	6(5.3%)	4(44.4%)	1(12.5%)	3(42.8%)	-
AZT/3TC/NVP	4(3.5%)	-	-	1(14.3%)	1(25%)
TDF/3TC/NVP	2(1.8%)	-	-	1(14.3%)	1(25%)
AZT/3TC/LPV/r	1(0.9%)	-	-	-	-

Table. 3: Toxicity reported as reason for initial treatment regimen change per regimen in Nekemt hospital, January 1, 2006 to December 31, 2010

Toxicities	Initial Regimens						
	D4T/3TC/NVP	D4T/3TC/EFV	AZT/3TC/EFV	TDF/3TC/EFV	AZT/3TC/NVP	TDF/3TC/NVP	AZT/3TC/LPV/r
Nausea	1(33.3%)	1(33.3%)	-	-	1(33.3%)	-	-
Peripheral Neuropathy	4(50.0%)	2(25.0%)	2(25.0%)	-	-	-	-
Diarrhea	-	-	-	1(100%)	-	-	-
Lipoatrophy	40(59.7%)	27(40.3%)	-	-	-	-	-
Anemia	-	-	5(71.4%)	-	2(28.6%)	-	-
Rash	8(57.1%)	1(7.1%)	1(7.1%)	1(7.1%)	1(7.1%)	1(7.1%)	1(7.1%)
Jaundice	-	-	-	-	-	1(100%)	-
CNS toxicity	-	3(23.0%)	6(46.2%)	4(30.8%)	-	-	-

Table. 4: Weeks on initial antiretroviral treatment by treatment regimen and reason for initial regimen change in Nekemt hospital, January 1, 2006 to December 31, 2010.

Initial Regimens	Number of weeks on initial ART regimen					
	< 4	4-8	8-12	12-16	16-20	>24
D4T/3TC/NVP	-	4(28.6%)	2(66.6%)	1(50.0%)	1(20.0%)	52(52.0%)
D4T/3TC/EFV	3(16.7%)	5(35.7%)	-	-	-	31(31.0%)
AZT/3TC/EFV	6(33.3%)	-	-	-	3(60.0%)	9(9.0%)
TDF/3TC/EFV	6(33.3%)	2(14.3%)	1(33.3%)	1(50.0%)	1(20.0%)	3(3.0%)
AZT/3TC/NVP	2(11.1%)	-	-	-	-	4(4.0%)
TDF/3TC/NVP	-	3(21.4%)	-	-	-	1(1.0%)
AZT/3TC/LPV/r	1(5.6%)	-	-	-	-	-
Reasons						
Toxicities	13(72.2%)	8(57.1%)	3(100%)	-	4(80.0%)	86(86.0%)
Pregnancy	2(11.1%)	2(14.3%)	-	-	-	5(5.0%)
New TB	2(11.1%)	2(14.3%)	-	2(100%)	-	2(2.0%)
Stock out	1(5.6%)	2(14.3%)	-	-	-	4(4.0%)
Treatment failure	-	-	-	-	1(20.0%)	3(3.0%)

WHO Clinical Stage and CD_4 Count

61.2% of patients were WHO clinical stage III, while 2.8% were WHO clinical stage I as depicted in *Fig 1*. Most patients (69.7%) had CD_4 count bellow 350 cells/mm^3 and the initial CD_4 count was not recorded for 5% of the patients, illustrated in *Fig 2*. The median CD_4 cell count during initiation of antiretroviral treatment was 255 cell/mm^3.

Antiretroviral Treatment Regimens and Causes of Change

42.2% of patients were on D4T/3TC/NVP at the beginning of the antiretroviral treatment and the rest were on D4T/3TC/EFV (27.5%), AZT/3TC/EFV (12.7%), TDF/3TC/EFV (9.9%), AZT/3TC/NVP (4.2%), TDF/3TC/NVP (2.8%), and AZT/3TC/LPV/r (0.7%).

The main reasons for modification of treatment regimen were toxicity/side effects (80.3%), pregnancy (6.3%), new TB (5.6%), drug unavailability/stock out (4.9%) and treatment failure (2.8%), as shown in *Table 2*. From all toxicity reported, lipoatrophy accounted 58.8% being the most common followed by rash (12.3%) and CNS toxicities (11.4%) as depicted in *Fig 3*. Among toxicities observed 46.5% were due to D3T/3TC/NVP, and the remaining 29.8%, 12.8%, 5.3%, 3.5%, 1.8%, and 0.9% were due to D4T/3TC/EFV, AZT/3TC/EFV, TDF/3TC/EFV, AZT/3TC/NVP, TDF/3TC/NVP and AZT/3TC/LPV/r respectively.

D4T containing regimens accounted for 100% of the lipoatrophy observed, while NVP containing regimens accounted for 71.3% of the rashes reported and EFV containing regimens accounted for 100% of the CNS disturbances observed (*Table 3*).

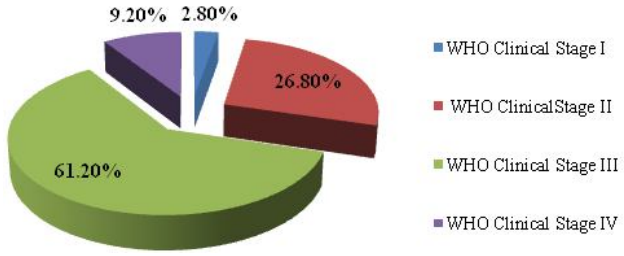

Fig. 1: Initial WHO clinical stages of HIV/AIDS patients who changed their initial regimen in Nekemt hospital, January 1, 2006 to December 31, 2010.

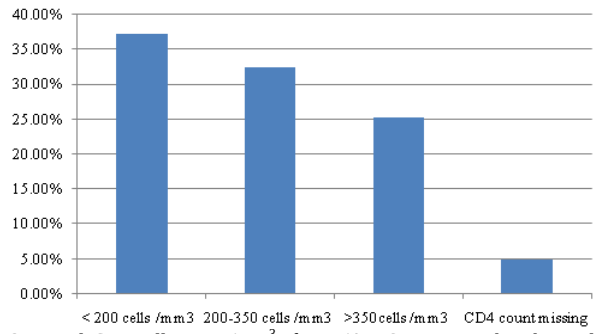

Fig. 2: Initial CD_4 cells count/mm^3 of HIV/AIDS patients who changed their initial regimen in Nekemt hospital, January 1, 2006 to December 31, 2010 .

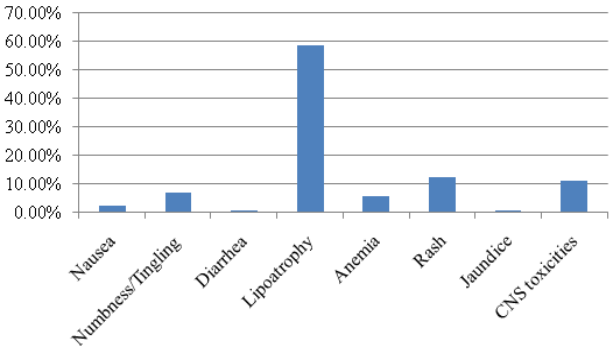

Fig. 3: Toxicities reported as a reason for initial treatment change in Nekemt hospital, January 1, 2006 to December 31, 2010.

Duration of Initial Antiretroviral Treatment before Regimen Change

In 70.4% of patients initial treatment regimen was modified after six months, while, in 12.7% and 9.9 % of patients initial regimen was modified within a month and within one to two month time respectively (Fig 4).

Of the patients who changed their initial regimen after six months 52% and 31% were on D4T/3TC/NVP and D4T/3TC/EFV respectively. Furthermore, among the initial regimen changes after six months of therapy 86% and 3% were due toxicity and treatment failure respectively.

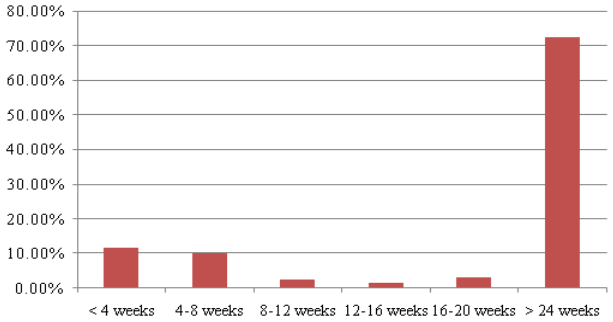

Fig. 4: Percentage of HIV/AIDS patients on initial ART regimen per duration of therapy before switching in Nekemt hospital, January 1, 2006 to December 31, 2010.

DISCUSSION

The primary goals of antiretroviral therapy are, to maintain maximum suppression of the viral load (i.e. fewer than fifty copies per micro gram) as much as possible for as long as possible; to restore and preserve immunologic function, to improve quality of life and reduce HIV related morbidity and mortality which is achieved through properly regulated antiretroviral therapy and rational treatment regimen switch (Ammassari, 2001).

69.7% of the patients in this study were on D4T based regimens, D4T/3TC/NVP (42.2%) and D4T/3TC/EFV (26.8%) while the rest were on AZT/3TC/EFV (12.7%), TDF/3TC/EFV (9.9%), AZT/3TC/NVP (4.2%), TDF/3TC/NVP (2.8%), and AZT/3TC/LPV/r (0.7%). The result of this study was not consistent with the studies done in Southern India (Kumarasamy *et al.*, 2006), Malawi (Bartlett and Shao, 2009), Cote d'Ivoire (Mess *et al.*, 2010) and southern Ethiopia (Woldmedhin and Wabe, 2012) where D4T/3TC/NVP accounts for 63%, 64.9%, 58% and 54.70% respectively. Difference in WHO clinical stage, contraindications, comorbid situations, drug-drug interaction due to comorbidities and stock status could be the possible factors that might have contributed to the variation. Toxicity/side effects was the most common cause of regimen switching in 80.3% of patients, which was higher than studies done in Canada (Park-Wyllie *et al.*, 2002), Southern India (Kumarasamy *et al.*, 2006), Uganda (Kiguba, 2007), Malawi (Bartlett and Shao, 2009) and Hospitals in southern Ethiopia (Alemu and Sebastián, 2010; Woldmedhin and Wabe, 2012). The difference in the occurrence of toxicities/side effects could be attributed to advanced HIV infection indicated by WHO clinical stage, adverse effect of concomitantly administered drugs for the treatment of opportunistic infections and genetic makeup variations. Pregnancy and comorbidity were the second and the third causes of ART regimen switching, similar to studies in Malawi (Bartlett and Shao, 2009) Cote d'Ivoire (Mess *et al.*, 2010) and southern Ethiopia (Alemu and Sebastián, 2010) but opposite to the studies in Uganda (Kiguba, 2007) and Southern India (Kumarasamy *et al.*, 2006). From all toxicities, lipoatrophy was the most common reason for modification, contrary to the studies in Southern India (Kumarasamy *et al.*, 2006) and Hospitals in southern Ethiopia (Alemu and Sebastián, 2010; Woldmedhin and Wabe, 2012). Lipoatrophy was observed in 100% of the patients on D4T based regimen which is expected as a study done in Rwanda reflected that lipoatrophy was more than three times higher in patients taking D4T. Furthermore, being female, a baseline CD4 count greater than or equal to 150 and increased duration of ART are also significantly associated with lipoatrophy accordingly (van Griensven *et al.*, 2007). Rash and CNS toxicities were second and third most causes for modification. Rash was mainly due to D4T/3TC/NVP (57.4%) regimens which coincides with a study that stipulates the mechanism of NV P induced skin rash (Popovic *et al.*, 2006). Anxiety and nightmares were seen in 46%, 38% and 23% of the patients on AZT/3TC/EFV, TDF/3TC/EFV and D4T/3TC/EFV respectively. Which may be due to EFV and studies show that EFV is associated with CNS toxicity, moreover, a CYP2B6 allelic variant is more common in African-Americans which is associated with significantly greater EFV plasma exposure (Haas *et al.*, 2004). Pregnancy was the second major reason for modifying ART drugs in this study,

44.4%, 11% and 44.4% of the patients on D4T/3TC/EFV, TDF/3TC/EFV and AZT/3TC/EFV were switched, consistent with the study in Cote d'Ivoire (Mess *et al.*, 2010). This switch was due to the recommendation of the Ethiopian guideline to avoid teratogenic effect of EFV in pregnant women during the first trimester. Contrary to the recommendation of the guideline, current studies reveal no increased risk of overall birth defects in women exposed to EFV during the first trimester of pregnancy (Ford *et al.*, 2010). 5.6% of the patients changed their regimen due to tuberculosis and it was the only comorbidity reported in this study which is consistent with the study in Cote d'Ivoire (Mess *et al.*, 2010) and hospitals in southern Ethiopia (Alemu and Sebastián, 2010; Woldmedhin and Wabe, 2012). 75%, 12.5%, 12.5% of the patients on D4T/3TC/NVP, AZT/3TC/EFV and TDF/3TC/EFV were switched. The most probable reason being over lapping drug toxicity of NVP with anti TB drugs and potential for drug interaction as TB drugs like rifampine are enzyme inducers. Contrary to studies in Southern India (Kumarasamy *et al.*, 2006) and Uganda (Kiguba, 2007) cost was not a major reason for ART regimen change because ARV drugs are provided to patients free of cost. Despite the cost free service stock out problems accounted 4.9% of the treatment regimen change which is a result of poor pharmaceutical stock management system either at the hospital or national level. Unlike the studies in Cote d'Ivoire (Mess *et al*, 2010), Asia (Zhou *et al.*, 2010) and Canada (Park-Wyllie *et al.*, 2002) treatment failure didn't account for the lion's share for regimen switch in this study. Only 2.8% of patients changed their initial regimen due to treatment failure which occurred equally in patients on AZT/3TC/EFV, AZT/3TC/NVP, D4T/3TC/EFV and TDF/3TC/NV. The result of this study was consistent with studies done in southern India (Kumarasamy *et al.*, 2006). Toxicity/side effect was the main reason for modification of initial antiretroviral drugs; while pregnancy, new TB, stock out and treatment failure were the rest reasons for initial antiretroviral regimen changes in this study. Proper clinical recording, updating ART guidelines as pharmacotherapy is dynamic and improvements in pharmaceutical procurement and stock management systems at hospital or national level are recommended.

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