Reasons for Anti-Retroviral Regimen Changes in HIV/AIDS patients of Ayder Referral Hospital ART clinic, Mekelle, Ethiopia.

LEMLEM GEBREMEDHIN[1*], AMANUEL BIRHANE[2]

[1, 2] Pharmacology and Toxicology course and research unit,
Department of pharmacy, college of health sciences, Mekelle University. P.O.Box: 1871
Email address:- Lemlemgatt2006@gmail.com/lemlemgd@yahoo.com
Phone number:- +251-911-54-41-98

Abstract

This study was performed to determine the reasons of anti-retroviral regimen changes among HIV/AIDS patients of Ayder referral hospital, ART clinic. It was conducted using a retrospective institution based cross-sectional study from April 22, 2013-May 22, 2013, by preparing pre-tested questioner and reviewing the patient's information cards. Out of 720 patients who were taking antiretroviral therapy, 157 of them have switched their regimen and all of the Patient cards who changed from the initial treatment regimen were assessed and analyzed using SPSS version 20.0.The study have showed that out of the patients who switched their regimen, majority 80 (51%) were male. The main reason for regimen change was toxicity which accounted for 119 (75.8%) followed by tuberculosis 22 (14.01%), treatment failure 15 (9.55%) and pregnancy 1 (0.64%). The major type of toxicity was anemia which accounted for 47 (39.8%) followed by peripheral neuropathy 32 (27.1%), lipatrophy 21 (17.8%), rash 11 (9.3%), Central nervous system toxicity 5 (4.2%), hepatotoxicity and renal failure taking up 1 (0.8%) each. The major toxicity causing anti-retroviral drug was Stavudine 54 (45.4%) followed by Zidovudine 47 (39.5%), Nevirapine 12 (10.1%), Efavirenz 5 (4.2%) and Tenofovir 1 (0.8%). Out of the patients who switched their regimens, 16 (10.2%) of them switched twice and 1(0.6%) thrice. The main reason for the second switch was toxicity 15 (93.75%) and treatment failure 1 (6.25%). The reason for thrice switch was toxicity (100%). Toxicity was the main reason for modification of the regimen followed by tuberculosis, treatment failure and pregnancy, respectively.

Key words: HAART, HIV/AIDS, reasons, regimen switch, Ayder referral hospital

1. Introduction

Human immune deficiency virus/acquired immune deficiency syndrome (HIV/AIDS) has first appearance in 1981 and remains a major global public health challenge; with dramatic consequences for entire communities [1]. HIV has killed more than 25 million people worldwide since the first diagnosis in 1981. In the 1980's and 1990's HIV/AIDS was the major cause of death among adults [2]. According to the joint 2011 HIV/AIDS report of World Health Organization (WHO), Joint United Nations programme on HIV/AIDS (UNAIDS), and United Nations Children's Fund (UNICEF), an estimated 34 million people were living with HIV/AIDS globally with 2.7 million new HIV infections in 2010. Of these, 68% were residing in sub-Saharan Africa [3]. Ethiopia is one of the seriously affected countries in sub-Saharan Africa with a large number of people (approximately 800,000) that are living with HIV/AIDS and 44,751 AIDS-related deaths [4].

Until 1995, treatment for HIV infection consisted mainly of single-drug and dual-drug therapy regimens that provided limited success. With the introduction of protease inhibitors (PIs), HIV viral loads and AIDS related deaths has declined dramatically. At present, combination therapy involving three classes of antiretroviral drugs—nucleoside reverse transcriptase inhibitors (NRTIs), non-NRTIs (NNRTIs), and PIs—formed the basis of potent anti-HIV regimens known as highly active antiretroviral therapy (HAART) [5]. When taken diligently, these regimens have improved patients' prognosis by delaying the emergence of resistant strains of virus, thereby slowing the progression of HIV infection to AIDS. Observational and retrospective cohort studies from many countries have confirmed striking improvements in mortality with combination Anti-Retroviral Therapy (ART); compared to earlier one- or two-drug regimens [6].This combination therapy caused gradual evolution of HIV/AIDS from a fatal disease to a chronic condition. A total of 2.5 million deaths have been averted in low- and middle-income countries since 1995 due to antiretroviral therapy being introduced. Actually in 2010 alone, 700,000 AIDS related deaths were averted due to the rapid scale-up of access to treatment [7].

Despite ARTs being of much help to the health of HIV/AIDS patients, the issues of drug induced toxicities &complexity of current HAART regimens has remained of great concern. Treatment toxicities and adherence

problems may lead to suboptimal therapy, discontinuation, and treatment failure [8]. These influences may compromise the effectiveness of HAART programmes, complicating the management and lead to toxicity, drug interactions, loss to follow-up and drug resistance amongst diverse populations such as Ethiopia [9]. As a result, treatment modification and discontinuation of therapy has become a common phenomenon and hence limitation of treatment option has turn out the major concern of the future HAART and HIV/AIDS patients. So, the aim of this study is to assess the reasons for regimen changes, from the initial treatment, in HIV/AIDS patients followed in Ayder referral hospital, ART clinic.

2. Methodology

Study area

The study was conducted in Ayder referral hospital (ARH) located in Mekelle, capital city of Tigray regional state; 783 Kilometers away from Addis Ababa, the capital city of Ethiopia. Mekelle has 1 referral hospital (ARH), 3 governmental general hospitals (Mekelle, Quiha and Adishimdhun) and 9 health centers (Mekelle, Simen, Aynalem, Kasech, Quiha, Hawelti, Adishimdhun, Felagado and Adha). ARH is a teaching hospital of Mekelle University and the only referral hospital in Tigray regional state. The hospital gives its service to Tigray, Afar and nearby Amhara regions with the total capacity of about 500 inpatient beds in four major departments and other specialty units. ARH has more than 45 specialists in various areas of medical specializations and fairly adequate numbers of other health professionals constituting the health care team. ARH has made remarkable achievements in last four years since its establishment. It is providing several health services including ART service for the community.ART service program was initiated in 2001 E.C in the hospital.

Study design and period

A retrospective institution based cross sectional study was conducted by reviewing patient information card. Study was conducted from April 22, 2013- May 22, 2013 G.C.

Study population

All HIV/AIDS patient information cardswho were taking ART in ART clinic ofAyder referral hospital.

Target population

All HIV/AIDS patient information cards who had undergone regimen switch in ART clinic ofAyder referral hospital.

Sample size

A total of 951 patients had cometo the ART clinic of Ayder referral hospital. Out of these 720 were on HAART and out of these 720 patients on HAART, 157 patients have switched from their initial regimen. So the sample includes all the 157 patient information cards who had undergone switching in ART clinic of Ayder Referral hospital.

Data collection tools, procedure and analysis

Data was collected from patient information card using an approved questionnaire which includes all the patient and clinical information's such as Medical record number, unique ART numbers, date of admission, start of ART, base line CD-4 count, WHO clinical stage, start ARV regimen, the number of drugs switched, reason for switch & duration before switch. After collecting data, it was cleared, categorized and analyzed using Statistical Package for the Social Sciences (SPSS) version 20.0 software.

Ethical consideration

Prior to data collection a formal letter was obtained from Mekelle University quality assurance office. The confidentiality of data collected was maintained by omitting the Name and address of patient and prescriber.

3. Results

In this study 157 patient information cards were assessed. From these 80 (51%) were male and 77 (49%) were female. The mean age of the patients was 37±9 (standard deviation=9) and the mean weight was 51±8 K.G (S.D=8). Majority of the patients (72%) were working (able to perform usual work in and out of the house) while 19.7% were ambulatory(able to perform activity of daily living) and 8.7% were bed ridden (not able to perform activity of daily living). Eighty three (52.3%) were transferred in after starting their ARV medications in other areas. Fifty six (35.7%) of the patients started their ARV medications based on their CD-4 counts and the rest 18 (11.5%) were both clinically and CD-4 eligible for ARV medication.

Majority of the patients, 91 (58%) had started their treatment at WHO clinical stage 3, while 50 (31.8%) had started at WHO clinical stage 4, 8 (5.1%) at stage 2 and 8 (5.1%) at stage 1. Forty two (26.8%) patients had baseline CD-4 count >200, 54(34.4%) patients had CD-4 count in range of 101-200, 31 (19.7%) had CD-4 count in the range of 51-100 and the rest 30 (19%) had CD-4 count<50 (**Fig-1**).

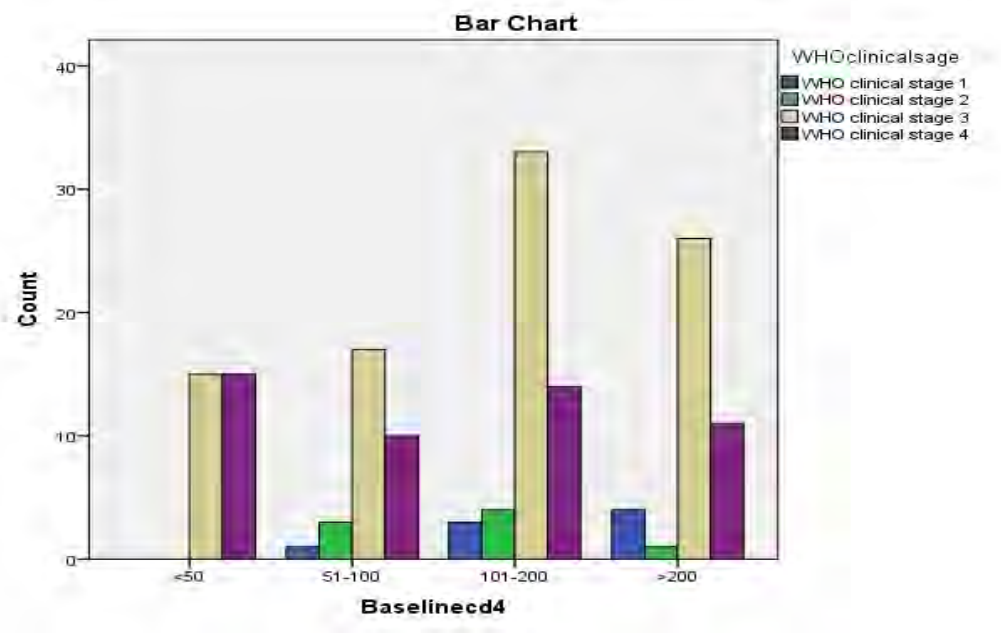

Fig-1. Initial CD-4 counts and WHO clinical stages in Ayder referral hospital, ART clinic, April-May, 2013.

One hundred thirty six (86.6%) of the patients had good adherence status i.e. < 2 doses missed, 9 (5.7%) of them had fair adherence status i.e. 3-5 doses missed and the rest 12 (7.6%) had poor adherence status i.e. > 6 doses missed from total of 30 doses (**Table-1**).

Table-1. Adherence status of patients on ART in Ayder referral hospital, ART clinic, April-May, 2013.

Adherence status	Frequency	Percent
Good (< 2 doses missed)	136	86.6
Fair (3-5 doses missed)	9	5.7
Poor (> 6 doses missed)	12	7.6
Total	157	100

Out of the 157 patients who have switched their ART regimens, 122 (77.7%) were on Co-trimoxazole prophylaxis therapy (C.P.T), 25 (15.9%) were not taking C.P.T and 10 (6.4%) have discontinued their C.P.T due to the adverse drug reaction they developed. Majority of patients 60 (38.2%) were on zidovudine (AZT) + lamivudine (3TC) +nevirapine (NVP) at the beginning of anti-retroviral treatment and the rest 52 (33.1%), 21(31.4%), 16 (10.2%), 5 (3.2%) and 3 (1.9%) were on stavudine(D4T)+ lamivudine (3TC) +nevirapine (NVP), stavudine (D4T) + lamivudine (3TC) +efavirenz (EFV), zidovudine (AZT) + lamivudine (3TC) +efavirenz (EFV), tenofovir (TDF) + lamivudine (3TC) +efavirenz (EFV)&tenofovir (TDF) + lamivudine (3TC) +nevirapine (NVP), respectively (**Table-2**).

Table-2. Initial ART regimen in Ayder referral hospital, ART clinic, April-May, 2013.

Start regimen	Frequency	Percent (%)
D4T+3TC+NVP	52	33.1
D4T+3TC+EFV	21	13.4
AZT+3TC+NVP	60	38.2
AZT+3TC+EFV	16	10.2
TDF+3TC+NVP	5	3.2
TDF+3TC+EFV	3	1.9
Total	157	100

Majority 42 (26.8%) of the patients switched their initial ART regimen after 2 years. From all those patients who took AZT/3TC/NVP, 22 patients remain in their first regimen for 4 months while 12 patients remain on their therapy for 26-52 weeks. Nineteen patients who were on D4T/3TC/NVP and 18 patients on D4T/3TC/ EFV stayed on their first regimen for more than 2 years (**Table-3**).

Table-3.Duration on initial ART regimen before Switch in Ayder referral hospital, ART clinic, April-May, 2013.

Start regimen	Start-12 weeks	12-26 weeks	26-52 weeks	52-104 weeks	>105 weeks	Total
D4T+3TC+NVP	5 (9.6%)	3 (5.8%)	13 (25.0%)	12 (23.1%)	19 (36.5%)	52 (100%)
D4T+3TC+EFV	2 (9.5%)	0 (0.0%)	3 (14.3%)	6 (28.6%)	10 (47.6%)	21 (100%)
AZT+3TC+NVP	22 (36.7%)	10 (16.7%)	12 (20%)	10 (16.7%)	6 (10%)	60 (100%)
AZT+3TC+EFV	2 (12.5%)	4 (25%)	1 (6.2%)	4 (25%)	5 (31.2%)	16 (100%)
TDF+3TC+NVP	2 (66.7%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	3 (100%)
TDF+3TC+EFV	1 (20%)	1 (20%)	0 (0.0%)	1 (20%)	2 (40%)	5 (100%)
Total	34 (21.7%)	18 (11.5%)	30 (19.1%)	33 (21.0%)	42 (26.8%)	157 (100%)

The main reason reported for modification of initial ART regimen was: toxicity119 (75.8%), tuberculosis 22 (14%), treatment failure 15 (9.6%) and pregnancy 1 (0.6%) (**Fig-2**).The majority 54 (45.38%) of the toxicity was caused by D4T containing regimens followed by AZT 47 (39.5%), NVP 12 (10.08%), EFV 5 (4.2%) and TDF 1 (0.84%) (**Fig-3**).From all the toxicities reported; anemia was the most common which accounted for 47 (39.5%) of the toxicity, followed by peripheral neuropathy 33 (27.7%), lipatrophy 21 (17.6%), rash 11 (9.2%), CNS toxicity 5 (4.2%), hepatotoxicity 1 (0.8%) and renal failure 1(0.8%).Among the toxicities, 46(38.7%) were due to AZT/3TC/NVP and the remaining 40(33.6%), 18(15.1%), 12(10.1%) and 3 (2.5%); were due to D4T/3TC/NVP, D4T/3TC/EFV, AZT/3TC/EFV& TDF+3TC+EFV, respectively (**Table-4**). From the patients who switched due to treatment failure; 5 (33.3%) were onAZT+3TC+NVP), 4 (26.7%) were on AZT+3TC+EFV, 3 (20%) were on D4T+3TC+EFV, 2 (13.3%) were on D4T+3TC+NVP& 1 (6.7%) were on TDF+3TC+EFV. Tuberculosis was the major cause of switch for NVP containing regimens; 10 (45.5%) were on D4T+3TC+NVP, 9 (40.9%) were on AZT+3TC+NVP & 3 (13.6%) were on TDF+3TC+NVP. One patient who switched due to pregnancy was on TDF+3TC+EFV (**Table-5**).

Table-4.Drugs and types of toxicities reported as reasons for initial regimen switch in Ayder referral hospital, ART clinic, April-May, 2013.

Start regimen	Lip atrophy	Rash	Anemia	Peripheral neuropathy	CNS toxicity	Hepato toxicity	Renal failure	Total
D4T+3TC+NVP	12 (30%)	3 (7.5%)	0 (0.0%)	25 (62.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	40 (100%)
D4T+3TC+EFV	9 (50%)	0 (0.0%)	0 (0.0%)	8 (44.4%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	18 (100%)
AZT+3TC+NVP	0 (0.0%)	8 (17.4%)	37 (80.4%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	0 (0.0%)	46 (100%)
AZT+3TC+EFV	0 (0.0%)	0 (0.0%)	10 (83.3%)	0 (0.0%)	2 (16.7%)	0 (0.0%)	0 (0.0%)	12 (100%)
TDF+3TC+EFV	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)	0 (0.0%)	1 (33.3%)	3 (100%)
Total	21 (17.6%)	11 (9.2%)	47 (39.5%)	33 (27.7%)	5 (4.2%)	1 (0.8%)	1 (0.8%)	119 (100%)

Table-5. Types of drugs and reasons for initial regimen switch in Ayder referral hospital, ART clinic, April-May, 2013.

Start regimen	Toxicity	Treatment failure	Due to T.B	Pregnancy	Total
D4T+3TC+NVP	40 (33.6%)	2 (13.3%)	10 (45.5%)	0 (0.0%)	52 (33.1%)
D4T+3TC+EFV	18 (15.1%)	3 (20%)	0 (0.0%)	0 (0.0%)	21 (13.4%)
AZT+3TC+NVP	46 (38.7%)	5 (33.3%)	9 (40.9%)	0 (0.0%)	60 (38.2%)
AZT+3TC+EFV	12 (10.1%)	4 (26.7%)	0 (0.0%)	0 (0.0%)	16 (10.2%)
TDF+3TC+NVP	0 (0.0%)	0 (0.0%)	3 (13.6%)	0 (0.0%)	3 (1.9%)
TDF+3TC+EFV	3 (2.5%)	1 (6.7%)	0 (0.0%)	1 (100%)	5 (3.2%)
Total	119 (100%)	15 (100%)	22 (100%)	1 (100%)	157 (100%)

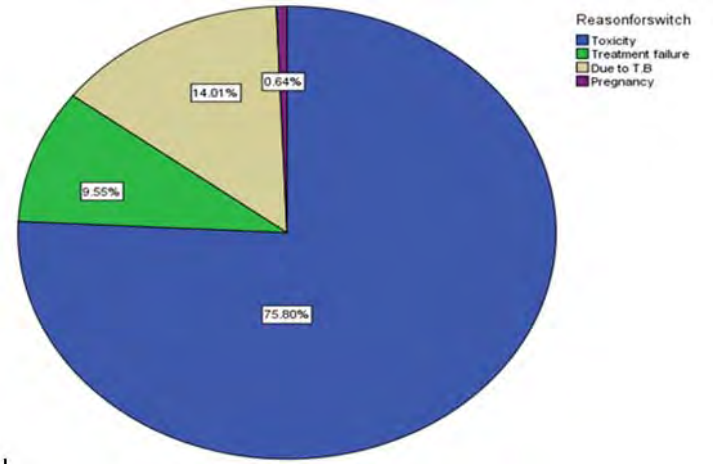

Fig-2.Reasons for modification of initial treatment regimen in Ayder referral hospital, ART clinic, April-May, 2013.

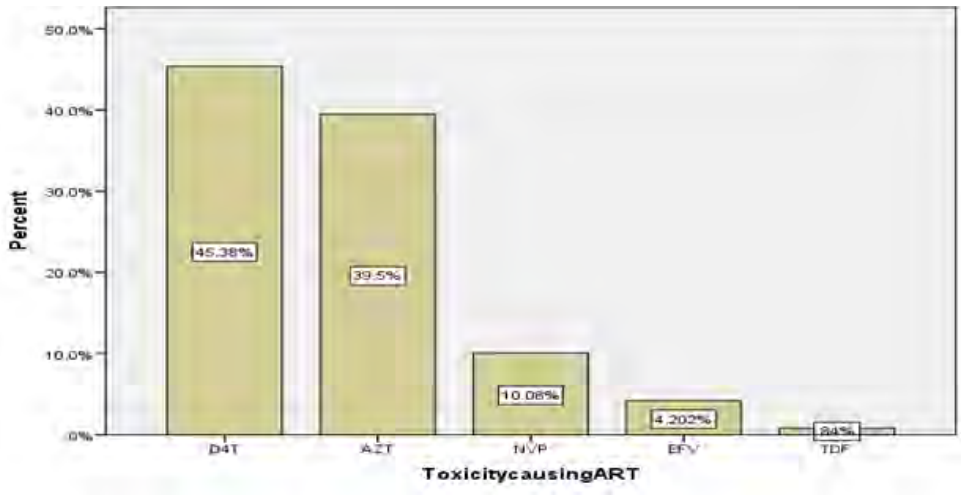

Fig-3. Toxicity causing anti-retroviral drugs in Ayder referral hospital, ART clinic, April-May, 2013.

Out of the 157 patients who switched their regimens, 16 (10.2%) of them have switched their regimens twice and out of the 16 patients switched twice, 1 (0.6%) patient has switched three times. The reason for the second switch was toxicity 15 (93.75%) and treatment failure 1(6.25%) (**Fig-4**). Of the toxicities caused; 8 (53.3%) was lipatrophy, 3 (20%) was anemia, 3(20%) was peripheral neuropathy and 1 (6.7%) was renal failure. Seventy three point three percent of the toxicity was due to D4T, followed by 20% AZT and 6.7% TDF (**Table-6**). Out of the 16 patients who switched twice, 11 (68.8%) had switched to TDF+3TC+EFV, 2 (12.5%) switched to AZT+3TC+EFV, 1(6.3%) to TDF+3TC+NVP, 1(6.3%) to TDF+3TC+LPV/r & 1(6.3%) to TDF+3TC+ABC+LPV/r. Three of the patients switched their regimen in the duration of 12-26 weeks, 7 patients switched their regimen from 26-52 weeks, 1 in 52-104 weeks and 5 of them >105 weeks. One patient has modified her initial regimen three times. She was in WHO clinical stage 4 with baseline CD-4 count of 13. She was initially on D4T+3TC+NVP and switched to D4T+3TC+EFV due to T.B then she faced D4T induced toxicity i.e. lipatrophy and was switched to TDF+3TC+EFV then developed renal failure due to TDF and was switched for the third time to ABC+3TC+EFV.

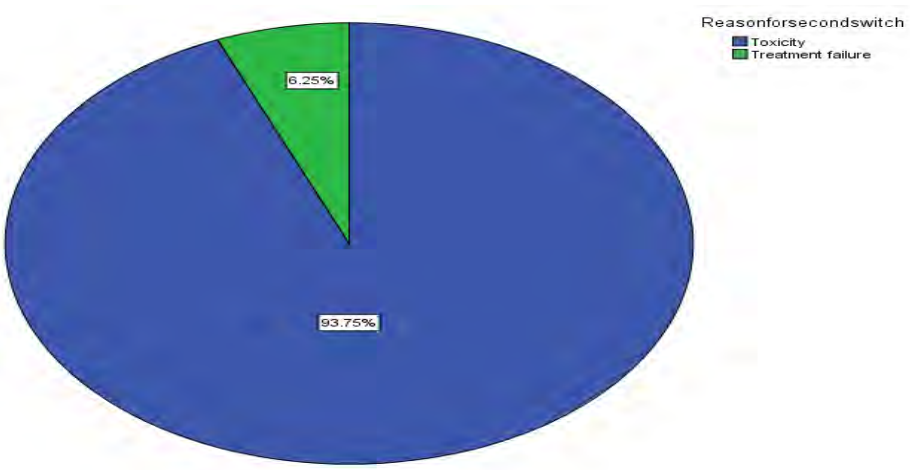

Fig-4. Reasons for second switch in Ayder referral hospital, ART clinic, April-May, 2013.

Table-6. Types of toxicities and toxicity causing ARV drugs for second switch in ayder referral hospital, ART clinic, April-May, 2013.

Drugs	Lipatrophy	Anemia	Peripheral neuropathy	Renal failure	Total
D4T	8 (72.2%)	0 (0.0%)	3 (27.3%)	0 (0.0%)	11 (100%)
AZT	0 (0.0%)	3 (100%)	0 (0.0%)	0 (0.0%)	3 (100%)
TDF	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100%)	1 (100%)
Total	8 (53.3%)	3 (20%)	3 (20%)	1 (6.7%)	15 (100%)

4. Discussion

This study showed that out of the 157 patients who switched their regimen, majority (51%) were male patients. The main reason for regimen change was toxicity (75.8%) followed by T.B (14%), treatment failure (9.6%) and pregnancy (0.6%), respectively. The major toxicity causing ARV drug was D4T (45.38%) followed by AZT (39.5%), NVP (10.08%), EFV (4.2%) and TDF (0.84%), respectively. The common types of toxicities were anemia (39.5%), peripheral neuropathy (27.7%), lipatrophy (17.6%), rash (9.2%), CNS toxicity (4.2%), hepatotoxicity (0.8%) and renal failure (0.8%). Zidovudine (AZT) containing regimens were responsible for Anemia. Stavudine (D4T) containing regimens were responsible for Peripheral neuropathy and lipatrophy. Skin rash and hepatotoxicity were due to Nevirapine (NVP) containing regimens. CNS toxicity was due to Efavirenz (EFV) containing regimens. Renal failure was due to Tenofovir (TDF) containing regimens.

The main reason for regimen change in this study was toxicity (75.8%) which was much higher than the study done in United Kingdom (35%) [10] and quite similar with three studies done in Ethiopia; Dessie [11] (66%),Nekemte [12] (65.58%) and southern Ethiopia[13] (67.65%), with significant heterogeneity in the distribution of adverse events. From all toxicities reported in this study, anemia (39.5%) was the most common

reason for modification which was same as the study done in Dessie [11], but the study in Dessie showed higher percentage (77.1%) of anemia, this showed that most (63%) patients in Dessie were started on AZT based regimen compared to this study (48.2%).When compared with the two studies in southern Ethiopia [13] and Nekemte [12], the main reason for switch was peripheral neuropathy 36.5% & 43.33%, respectively. This showed that majority of patients in southern Ethiopia (75.58%) and Nekemte (80.3%) were started with D4T based regimens. Anemia accounted for 17.4% in southern Ethiopia & 13% in Nekemte which showed that most of the patients start regimens were mostly less AZT based regimens. Majority (48.2%) in this setting, 16.7% in Nekemte and 24.42% in southern Ethiopia were started on AZT indicating high AZT related toxicity in this study, i.e. anemia, compared with the other two studies. But the study in U.K [10] showed that fat & metabolic change were the most common toxicities affecting 16% overall, this showed patients were on D4T and protease inhibitors (PI's). With respect to individual drug the commonest toxicity causing ART was D4T (45.4%) in this study, that was similar with the other three studies; southern Ethiopia [13] (32.35%), Nekemte [12] (43.3%) & U.K [10] (54%) except the one in Dessie [11] which showed less (18%) D4T related toxicities. This is one of the major reasons for the remotion of D4T from the current market due to its high toxicity that cause regimen switch. As a result of several researches [10],[12],[13] that indicate toxicity of D4T as a reason for regimen change, currently new patients with HIV/AIDS are not starting with D4T containing regimens.

Nevirapine containing regimens were responsible for T.B related switches; this is due to the drug-drug interaction that exists between Nevirapine and Rifampin. Rifampin is a strong liver enzyme (CYP 3A4) inducer and it decreases the therapeutic level of Nevirapine up to 40% and some studies [14] have also demonstrated the additive hepatotoxicity effects when the two drugs are used together so it's preferable to switch to Efavirenz based regimens which have lesser interaction with rifampin.

T.B accounted for 14% patient's treatment modification which was almost similar to the three studies in Nekemte [12] (8.66%), southern Ethiopia [13] (19.11%) & Dessie [11] (14%) conducted in Ethiopia but when compared with other countries like U.K [10] two patients switched their regimen due to T.B, this showed the high prevalence of T.B in Ethiopia compared to U.K.

Treatment failure is also another factor for treatment modification and it can be classified into three; virological failure, immunologic failure and clinical failure. Virological failure is when plasma viral load is above 10,000 copies/ml in duplicates after 6 months on ART. Immunologic failure is fall of CD-4 count to pre-therapy (or below), 50% fall from the on treatment peak value or persistent CD-4 levels below 100 cells/mm^3. And clinical failure refers to new or recurrent WHO stage 4 conditions. The practice in this study setting is that the three mentioned criteria's must be fulfilled in order to say treatment failure.

Studies done in Nekemte [12] and southern Ethiopia [13] showed lesser switches (3% & 2.65%, respectively) due to treatment failure compared to the 9.6% in this study and 8% in Dessie [11].This difference can be due to the difficulty to diagnose treatment failure in this setting. And in U.K [10] it showed 30% switch due to virological failure but as mentioned above the three criteria's must be fulfilled for treatment failure in this setting which is hard to compare it with UK's study.

Efavirenz based regimens were the main reasons for switch due to pregnancy that was because EFV based regimens were considered to be teratogenic but recent studies have shown that Efavirenz has similar safety during pregnancy like the other ART's [15]. But generally switches related to Efavirenz were not common like before.

When pregnancy related switches were compared, this study has lesser (0.6%) switches as compared to the 10.5% in southern Ethiopia [13], 11% in Dessie [11], and 6.67% in Nekemte [12] & 4.3% in U.K [10] which showed that the current study setting is implementing the new researches on EFV's safety to use during pregnancy [15].

After the modifications of the initial ART regimen, majority of the patients were on TDF (48.7%) based regimen; (TDF+3TC+EFV & TDF+3TC+NVP) which are considered to be the safest regimen to reduce regimen change. Two patients were put on quadruple ART (TDF+3TC+ABC/AZT+LPV/r) this was because the viral load couldn't be controlled with triple ART.

In this study the major problem during regimen switch was regimens were modified wrongly i.e. 11 patients on D4T based regimen D4T+3TC+NVP were switched to TDF+3TC+EFV with only D4T related toxicity; switching NVP with EFV was not rational. Same for 3 patients on AZT based regimen, AZT+3TC+NVP were switched to TDF+3TC+EFV with only AZT related toxicity which was again not rational. This could indicate that the ART health care providers were careless or they lack knowledge on how to switch. Since the numbers of ARV drugs are limited their use should be appropriate and rational requiring trained ART health care providers.

Out of the 157 patients who switched their initial regimens, 10.2% of them have switched their regimens twice and 0.6% patient has switched three times. The main reason for second time switch was toxicity (93.75%) followed by treatment failure (6.25%). The commonest type of toxicity was lipatrophy (53.3%) followed by

anemia (20%), peripheral neuropathy (20%) and renal failure (6.7%). This showed that the patients were on D4T and AZT based regimen for the second time which shouldn't have been done because the reasons for first switch was due to D4T based regimens followed by AZT based regimens.

5. Conclusion and Recommendations

The three reasons for modifications of ART regimen in Ayder Referral Hospital were toxicity (75.8%); T.B (14%) and treatment failure (9.6%).For any modification of antiretroviral drug regimen to be done, there should be a Guideline for switching based on benefit-risk ratio and the guide line should be updated based on new findings. Since, most of modifications of ARV regimen require laboratory result monitoring, there should be enough, quality and well effective laboratory equipment's and trained professionals in Ayder Referral Hospital. National level study on reasons for regimen change should be done that can help for drug suppliers and policy makers to improve and solve the problem.

6. Acknowledgment

I want to thank Mekelle University for financially supporting of this paper.

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