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The reasons for regimen shift among people living with HIV/AIDS in Asella Referral Hospital

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Abstract

Highly active antiretroviral therapy (HAART) is the base for management of patients with HIV infection. On the other hand, a switch in the antiretroviral regimen could be compulsory because of various reasons. Therefore, the aim of this study was to determine the causes for initial antiretroviral regimen switch among adult HIV/ADIS patients. A retrospective cross-sectional study was conducted on patient information records of those visited the ART clinic since February 2013 to January 2015 in Asella Referral Hospital. Results: From 1468 patients' medical information reviewed, 221 of them changed their initial HAART regimens. Among these patients, 38% of them changed their first medications as a consequence of drug toxicity which was mainly triggered by AZT/3TC/NVP. The major cause for changing AZT/3TC/NVP treatment regimen associated with drug toxicity was anemia (17.85%). Other reasons stated for medication shift were co-morbidity, treatment failure, poor adherence and pregnancy. Since most of regimen modifications were in consequence of drug toxicity, these medication shifts require careful patient follow up; frequent laboratory result monitoring and selection of the right antiretroviral regimens.

Keywords: Antiretroviral therapy, HIV/ADIS, regimen change, Asella

Introduction

Globally, there were about 38.8 million people living with HIV/ADIS at the end of 2015 [1]. Sub-Saharan African countries constitute a high level of the worldwide HIV burden. Accordingly, in 2013, about 71 % of the total people living with HIV resided in sub-Saharan Africa, a region which constitutes no more than 12% of the global population [2, 3]. Similarly, the HIV/AIDS epidemic in Ethiopia continued to pose a threat to the lives of its people with an estimated of 769, 600 people living with HIV which was about 1.14% of the total population [4].

As highly active antiretroviral therapy (HAART) is the core for the treatment of HIV patients, initiation followed by extensive use of the drugs has brought a significant reduction in the occurrence of most AIDS defining conditions and mortality [5,6]. However, these advancements were not without a cost in terms of drug resistance and adverse drug reactions [7].

Once antiretroviral therapy (ART) is initiated, patients generally remain on medications indefinitely. However, a switch in the antiretroviral regimen could be compulsory because of associated clinical conditions, development of virologic failure and toxicities [8]. Moreover, different literatures reported that toxicity and/or adverse drug reactions, co-morbidity; treatment failure and drug interactions are the main reasons for the ART regimen shift or modifications [9-13].

There is no study yet conducted in the study area in particular and few data available in Ethiopia in general on reasons making for a regimen switch in HIV patients who were already on ART. Hence, this data can potentially help to draw a long term strategic plan for ART drug management. Therefore, the aim of this study was to determine the causes for HAART regimen switch among HIV/AIDS patients in Asella Referral Hospital.

Material and Methods

The study was carried out in Asella Referral Hospital, which is located at 175 km away from the capital city, Addis Ababa from January-February, 2015. The hospital provides different services: outpatient and inpatient services; Maternal and Child Health Care, and ART services. Hospital based retrospective cross sectional study was conducted by reviewing patient record cards. Patient information cards of all HIV/AIDS patients who were on HAART in the ART Clinic from February 2013 to January 2015 were the source of the population, while HIV/AIDS patients who switched their initial antiretroviral therapy were taken as the study population and included in the study. Accordingly, within the stated two years a total of 1468 patients visited the clinic; however, only 221 of them switched their initial regimen. Hence, the study included all of the 221 patient cards of those shifted their initial medications.

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A data collection instrument was developed by reviewing different relevant literatures. The tool was evaluated for its validity, reliability and consistency. Then, it was used to collect data from patient record cards. The collected data was then checked, categorized and analyzed using MS excel and SPSS version 19. Finally, the results were presented using tables and figures. Ethical approval was acquired from Health Sciences College of Jimma University. Then, the letter was presented to the administrator of Assela Referral Hospital to get permits for data collection.

Results

From 1468 patients' medical information reviewed, 221 of them changed their initial HAART regimen. More than half of the patients (57.64%) were females, and about 20.81% of them were in the age group of 26-30. Regarding CD4 count, about half of patients (52.40%) had an initial CD4 count more than 200 whereas only 10% of them had CD4 counts less than 50% (Figure1).

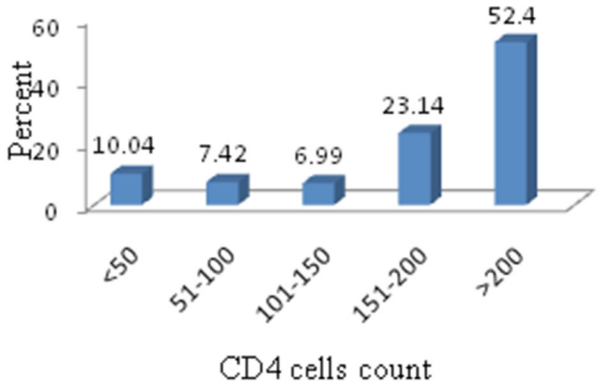

Figure 1. Patient's initial CD4 cells count /mm3 during HAART initiation

Among the patients who modified their initial regimen, 38% of them changed their first medications because of drug toxicity which were primarily due to AZT/3TC/NVP (40.5%). Other regimen switches were owing to toxicity triggered by TDF/3TC/EFV (15.5%), D4T/3TC/NVP (13.1%), D4T/3TC/EFV (11.9%), AZT/3TC/EFV (10.7%) and TDF/3TC/NVP (8.3%) regimens. Pregnancy was the other cause of the regimen change in 21 patients, of whom 33.3% of them switched AZT/3TC/NVP regimen. In addition, from patients who modified their medications due to co-morbid conditions and treatment failure, six and twelve of them were initially on AZT/3TC/NVP and D4T/3TC/NPV, respectively. Tuberculosis was the only reported co-morbid diseases triggering a shift of initial regimen among 11 patients (Table 1).

One of the main causes for regimen shift related to drug toxicity was anemia, which were due to AZT/3TC/NVP and AZT/3TC/EFV regimen among 15 (17.85%) and 4 (4.76%) patients, respectively. The other main reasons determined for the initial regimen switch were nausea due to D4T/3TC/EFV (8.33%) and AZT/3TC/NVP (8.33%); rash as a result of AZT/3TC/NVP (10.71%) D4T/3TC/NVP (4.76%); peripheral neuropathy owing to D4T/3TC/NVP (5.95%) and TDF/3TC/EFV (5.95%) (Table 2).

Greater proportion of patients (32.1%) shifted their regimen during the first three successive months because of medication toxicity and only 7.1% of patients pursued their first medications for more than 26 months (104 weeks). Similarly, most of patients with co-morbid conditions, poor adherence and pregnancy switched their regimen during the first three consecutive months (the first 12 weeks) which were accounting for 36.4%, 33.3% and 42.9%, respectively. Moreover, 37.0% of patients changed their first regimen in 27-52 weeks as a result of treatment failure (Table 3). Immunological failure was also determined as the main cause of medication shift in 57.4% patients (Figure 2).

Table 1 . Common reason for modification of initial treatment regimen

Reasons	Treatment regimen					
	D4T/3TC/NPV	D4T/3TC/EFV	AZT/3TC/NVP	AZT/3TC/EFV	TDF/3TC/NVP	TDF/3TC/EFV
Drug toxicity (n=84)	11(13.1%)	10(11.9%)	34(40.5%)	9(10.7%)	7(8.3%)	13(15.5%)
Co-morbidity (n=11)	3(27.3%)	-	6(54.5%)	-	2(18.2%)	-
Treatment failure (n=54)	12(22.2%)	9(16.7)	6(11.1%)	11(20.4%)	9(16.7%)	7(12.9%)
Poor adherence (n=51)	9(17.6%)	8(15.7%)	10(19.6%)	8(15.7%)	11(21.6%)	5(9.8%)
Pregnancy (n=21)	3(14.3%)	5(23.8%)	7(33.3%)	4(19.1%)	-	2(9.5%)

Table 2 . Toxicity reported as reason for modification of treatment regimen

Toxicity (n=84)	Treatment regimen					
	D4T/3TC/NPV	D4T/3TC/EFV	AZT/3TC/NVP	AZT/3TC/EFV	TDF/3TC/NVP	TDF/3TC/EFV
Nausea	2(2.38%)	7(8.33%)	7(8.33%)	2(2.38%)	2(2.38%)	2(2.38%)
Anemia	-	-	15(17.85%)	4(4.76%)	-	3(3.57%)
Peripheral Neuropathy	5(5.95%)	2(2.38%)	3(3.57%)	3(3.57%)	3(3.57%)	5(5.95%)
Rash	4(4.76%)	1(1.19%)	9(10.71%)	-	2(2.38%)	3(3.57%)

Table 1 . Reasons for modification of treatment regimen at different duration from initial treatment regimen

Reasons	Weeks of shifted therapy				
	Start-12	13-26	27-52	53-104	>104
Toxicity (n=84)	27(32.1%)	23(27.4%)	15(17.9%)	13(15.5%)	6(7.1%)
Co-morbidity (n=11)	4(36.3%)	3(27.3%)	2(18.2%)	1(9.1%)	1(9.1%)
Treatment failure (n=54)	5(9.3%)	10(18.5%)	20(37.0%)	12(22.2%)	7(13.0%)
Poor adherence (n=51)	17(33.3%)	11(21.6%)	13(25.5%)	6(11.8%)	4(7.8%)
Pregnancy (n=21)	9(42.9%)	5(23.8%)	4(19.0%)	2(9.5%)	1(4.8%)

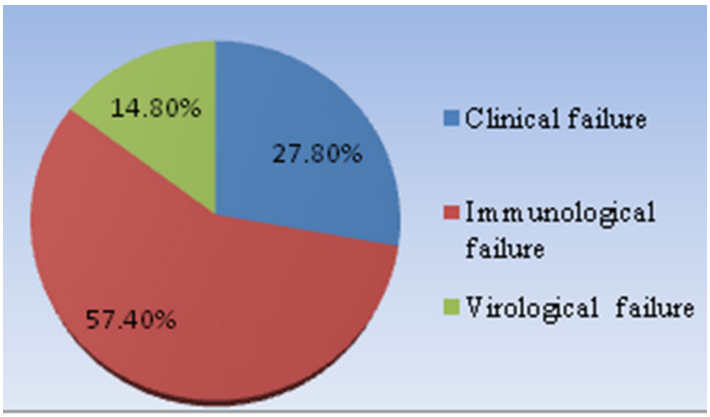

Figure 2. Treatment failure related reasons for modification of treatment regimen

Discussion

There are many reasons that lead to ineffectiveness, change of HAART combination and discontinuation of HAART regimen. The rational for treatment switch and discontinuation of the medications might belong to toxicity, treatment failure (virological, immunological and clinical failure), poor adherence, a desire to have a child and co-morbidity [7]. In this study most of the patients who switched their initial medication were because of drug related toxicity. This finding is consistent with the study done in Southern Ethiopia [8] and in Ceará, Brazil [9]. The most commonly encountered toxicity related causes for alteration of regimens were nausea, rash, anemia and peripheral neuropathy. Similar finding was reported in the retrospective study conducted among urban outpatients in New Orleans, LA., USA [11].

Both anemia and rash were reported as the main medication related toxicities triggering an initial treatment regimen shift owing to AZT/3TC/NVP which is consistent with previous research finding reported by Woldemedhin and Wabe [14]. However, it is dissimilar with another study done in Nekemete Referral Hospital [15]. Regimens such as D4T/3TC/EFV and AZT/3TC/NVP; D4T/3TC/NVP and D4T/3TC/EFV were the major causes stated for peripheral neuropathy and nausea, respectively.

Co-morbidities in patients with advanced diseases and concomitant treatments for opportunistic infections could affect antiretroviral drug tolerance and thus increase the jeopardy of toxicities [11]. This could be as a result of pill burden which is to be taken simultaneously to treat both ADIS and opportunistic infection. However, tuberculosis was the only co-morbid diseases determined in this study, which triggered the regimen modification. This is in line with the study conducted in the UK [16] and Coited'lvoire [17].

Treatment failure was also reported as the main cause for the regimen shift among a significant number of patients in the current study. Similarly, in the study conducted in Coited'lvoire [17] and Uganda [18], it was reported that treatment failure was one of the major reasons for discontinuation and modification of initial regimen.

A large proportion of patients shifted their initial medication during the first three consecutive months, whereas only a few of them continued their first regimen for more than 26 months before first switch. This finding is incomparable with the study conducted in Durame Hospital where the majority of them change their medication after 26 months [19].

Conclusion

The main cause for regimen modifications was drug toxicity. Peripheral neuropathy, nausea, anemia, and rash were the major observed manifestations of drug toxicities triggering modification of HAART. Most of drug toxicities and regimen modification were incurred from NVP-based regimen mainly AZT/3TC/NVP. Hence, careful follow up; frequent laboratory result monitoring, and selection of the right antiretroviral regimen must be done to prevent drug toxicity.

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