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Highly Active Antiretroviral Therapy Regimen Change Among HIV/AIDS Patients in Boru Meda Hospital, Amhara Regional State, Ethiopia

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Abstract

Background: *Highly active antiretroviral therapy is the cornerstone of management of patients with human immunodeficiency virus infection. Antiretroviral therapy can improve quality of life and prolong patient's survival; however they may cause a number of adverse effects; which may end with treatment failure and/or regimen changes. The aim of the study is to assess the reasons for antiretroviral regimen change among HIV/AIDS Patients in Boru meda general Hospital, ART Clinic.*

Methods: *Hospital based retrospective cross-sectional study was conducted at Boru meda general Hospital; HAART Clinic recorded from January 01, 2007 to January 30, 2018 by reviewing patients' information sheets, medical records and laboratory results. Patients who changed their highly active antiretroviral therapy regimen included in the study. A structured questionnaire was used for data collection.*

Result: *A total of 275 patients whose first line HAART drug regimen changed in BMH were reviewed. Above half (56.4%) of the patients in this study were females. The patients, 174(66.9%) were at the age groups between 30-45 years. During initial changes toxicity was the most common reason 182(66.2%)reported followed by33(12%) comorbidity, 25(9.1%) treatment failure, 17(6.2%) pregnancy and16(5.8%) adherence difficulty. Regarding to the initial regimen, 88(32%) patients were on D4T/3TC/NVP, 62(22.5%) were on D4T/3TC/EFV, 64(23.3%) were on AZT/3TC/NVP and 52(18.9%) were on AZT/3TC/EFV.*

Conclusion: *This study indicated that the main reasons for initial and second time ART regimen change were drug toxicity among the study population. Co-morbidity, treatment failure and pregnancy were the other reasons. Lipodystrophy, anemia, renal toxicity, vomiting and rash were among the most common leading toxicity causes for ART regimen change respectively.*

Keywords: Boru meda General Hospital, HA ART, Regimen Change, Toxicity, Treatment Failure.

Introduction

Background

Human Immune Virus (HIV) is responsible for a worldwide pandemic and it is the cause of Acquired Immune Deficiency Syndrome (AIDS) [1, 2]. Globally 36.9 million people were living with HIV. The number of people living with HIV continues to increase, in large part because more people globally are accessing antiretroviral therapy and as a result are living longer, healthier lives [3, 4].

In Ethiopia, antiretroviral treatment began in 2003 and free ART was launched in January 2005. Since the beginning of HAART, a linear increase has been observed in the number of people living with HIV/AIDS ever enrolled, ever started and on ART [5, 6]. The number of patients on ART reached 308,860 by the year 2014. As a result of this, there have been dramatic declines in morbidity and mortality due to HIV. Total HIV positive population was 789,960 in 2011 and it is estimated to reduce to 691,073 in 2015. Meanwhile, the new HIV infection was 24,236 in 2011 and declined to 15,073 in 2015. In addition, the annual total AIDS related deaths declined from 13,749 in 2011 to 6,827 in 2015 [7, 8].

This study will be assessed the root cause of ART regimen change, on the likelihood of patients being changed from their ART therapy due to different factors.

Objective

General Objective

To assese the HAART regimen change among HIV/AIDS patients in Boru meda general hospital, Amhara regional state, Ethiopia.

Specific Objective

- To identify the determinants of regimen highly active antiretroviral therapy Change [9-11].
- To determine the type of Regimens frequently changed
- To assess the duration of Antiretroviral Regimen Change.

Methodology

Study Area

The study was conducted in ART clinic of BMGH. It is located in Dessie town, Amhara regional state, Ethiopia, which is far 411 km, away from Addis Ababa the capital city of Ethiopia. It was established in 1947 E.C through the support of missionary organization that was primary focused on dermatology and ophthalmic services [12-15].

Study Design and Period

A hospital based cross sectional study was conducted by reviewing patient information card, medical records and laboratory results. Data was reviewed from January 1, 2007-January 30, 2018 E.C. records.

Source Population and Study Population

The source population was comprised of all adult HIV infected patients who had been on follow-up at the ART clinic of BMGH. The study population was included all HIV infected patients-initiated ART at BMGH that had experienced regimen change.

Inclusion Criteria

- Patients on follow up in the ART clinic who had undergone at least one ART regimen were change until the study period.
- Adult HIV/AIDS patients 18 years old and above
- Patients receiving ARVs solely from BMGH ART pharmacy.

Exclusion Criteria

Patients with incomplete demographic and clinical information [16].

Sample Size Determination and Sampling Technique

The sample size was calculated using the standard sample size calculation formula.

n = Z (α/2)2P (1-P)/ d2, Where: d = precision (marginal error)

Zα/2- Value of standard normal distribution (Z=1.96) with confidence interval of 95% and α is 0.05

P = the prevalence of initial ART changed in the study made at Mekelle hospital, Mekelle Ethiopia, 2014.

Sample Size for ART Regimen Change n

(Zα/2)2P(1-P)=(1.96)20.22(1-0.22)=264. (d)

2 (0.05)2

From the calculated sample size at the above, the largest one chosen is 264.Therefore, considering incomplete patient information, 5% of the sample size was added to the total sample size (264*5%) = 277.

Sampling Procedures

The recorded list of patients who had changed their regimen was used as a sampling frame. From a total of 1500 patients who changed their initial regimen 277 patients were included by simple random sampling method (by computer based).

Study Variables

Independent Variables

- Socio-demographic characteristics
- Age at initiation, Sex, Marital status, Educational status, occupation.
- Disease related variables
- Baseline WHO stage, Base line CD4, Baseline viral load, Baseline weight, comorbidity.
- ART related variable
- Types of initial regimen
- Adherence and pregnancy
- Dependent Variables
- HAART regimen change

Data Collection and Management

Data Abstraction Form

Data abstraction form (Annex I) was developed based on the objectives of the study. It contained socio-demographic, clinical information and ART information such as, CD4 count, WHO stage, initial regimen, date on which treatment was started, date of ARV drug switch, duration of initial ARV therapy before first switch, regimen switched to, and reason for changing the ART. The types of toxicity and treatment failure reasons were included. If there was ARV drug switch for the second time it was recorded in a similar manner [17-20].

Data Collector's Recruitment and Training

Four pharmacists working in the ART pharmacy was recruited and trained for one day about the methods of data collection prior to the start of actual data collection.

Data Quality Control

To ensure data quality, the data collectors was trained by the principal investigators. The data collection format was pre-tested in 5% of the sample size to check for appropriateness of the data collecting instrument. Confusions and clarity found during the process of pre-test was corrected and modifications were made accordingly. The principal investigator was made frequent

checks on the data collection process to ensure the completeness and consistency of the collected data.

Data Analysis Procedures

The data was cleaned for inconsistencies and missing values. The cleaned data was coded. Descriptive statistics were generated to meet the objective of the study. The categorical variables were described using frequency tables and figures. The continuous variables were stratified into sub groups in order to study associations using binary and multivariate logistic regression. Odds Ratios (OR) and 95% CI were used to look into the strength of association between the dependent and independent variables. Statistical significance was set at p -value <0.05.

Ethical Considerations

Official letter was written to BMH from Dessie health Science College and also permission was sought from BMH medical director to conduct the study. The confidentiality of data collected was maintained by omitting the Name and address of patient and prescriber [21, 22].

Dissemination of Results

The findings of the study will be submitted to BMH, Dandiiboru College and other interested governmental and nongovernmental organizations. Publication in scientific journal and online dissemination will be considered.

Result

Baseline Characteristics of Study Subjects

total of 275 patients whose first-line antiretroviral (ARV) drug regimens were modified at BMH were reviewed [23]. More than half of the participants (56.4%) were female. Among the patients, 174 (66.9%) fell within the 30-45 year age range. The majority of patients, 179 (65.3%), began their ARV regimens with a baseline CD4 count of ≤ 200 cells/mm³. Additionally, 69.5% of the patients were classified at WHO stage III at baseline.

Table 1: Baseline Characteristics of Study Subjects

Characteristics	Category	Number (percent)
Gender	Male	120(43.6)
	Female	155(56.4)
Baseline age category	18-29	76(27.6)
	30-45	174(66.9)
	46-65	25(9.1)
Baseline weight	<35	18(6.5)
	35-45	65(23.6)
	46-55	118(42.9)
	56-65	62(22.5)
	>65	12(4.4)
Baseline CD4	<100	85(30.9)
	100-200	94(34.4)
	201-300	61(22)
	301-400	31(11)
	>400	4(1.7)
Baseline WHO stage	I	9(3.3)
	II	49(17.8)
	III	191(69.5)
	IV	26(9.5)
Baseline Functional states	Workable	201(73)
	Ambulatory	52(19)
	Bedridden	22(8)
Baseline Hemoglobin	<7	4(1.5)
	7-10	30(10.9)
	11-13	78(28.4)
	>13	106(38.5)
	No result	57(20.7)

Initial Regimens and Reason for Regimen Change

From a total of 275 patents, during initial changes toxicity was the most common reason 182(66.2%)reported followed by33(12%) comorbidity, 25(9.1%) treatment failure, 17(6.2%) pregnancy and16(5.8%) adherence difficulty.

Regarding to the initial regimen, 88(32%) patients were on D4T/3TC/NVP, 62(22.5%) were on D4T/3TC/EFV, 64(23.3%) were on AZT/3TC/NVP and 52(18.9%) were on AZT/3TC/EFV(Table 2).

Table 2: Initial Regimens and Reason for Regimen Change

Regimen	N (%)	Toxicity(N)	Pregnancy(N)	Co-morbidity(N)	Treatment failure(N)	Adherence Problem(N)	No specified(N)
AZT/3TC/EFV	52(18.9)	30	11	2	3	4	2
AZT/3TC/NVP	64(23.3)	43	-	14	6	1	-
TDF/3TC/EFV	3(1.1)	3	-	-	-	-	-
TDF/3TC/NVP	6(2.2)	3	-	-	1	2	-
D4T/3TC/EFV	62(22.5)	44	6	-	9	3	
D4T/3TC/NVP	88(32)	59	-	17	6	6	-
Total N(%)	275(100)	182(66.2)	17(6.2)	33(12)	25(9.1)	16(5.8)	2(0.72)

Pattern of ART Regimen

Pattern of ART regimen during first ART switch, about more than half (55%) of the patients started their initial ART on d4T based regimens [Figure 1].

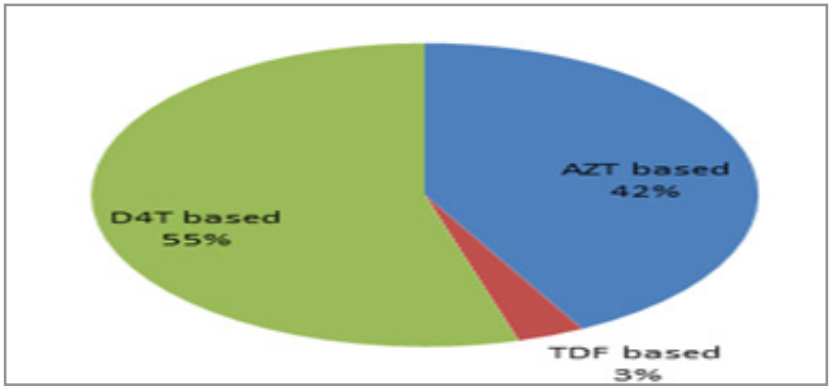

Figure 1: Initial Antiretroviral Regimen Group in Patients Included in the Study

Reason for Both First and Second Time Change

Lipodystrophy was the most prevalent cause of toxicity during both the first and second treatment changes, accounting for approximately 20.7% and 10.9%, respectively. Other significant causes of toxicity, in descending order, included renal toxicity, anemia, peripheral neuropathy, central nervous system (CNS) toxicities, rash, and hepatotoxicity. [Table 3].

The primary reason for the second treatment change was virological failure, observed in 8 patients (2.9%). In contrast, the main reason for the first treatment change was clinical failure, which affected 16 patients (5.8%).

Table 3: Reason for Both First and Second Time Change

Toxicity	1st change N(%)	2nd change N(%)	Treatment failure	1st change N(%)	2nd change N(%)
Lipoatrophy	57(20.7)	30(10.9)	Clinical failure	16(5.8)	-
renal toxicity	27(9.8)	9(3.3)	Immunological failure	6(2.2)	3(1.1)
Anemia	32(11.6)	7(2.5)	virological failure	6(2.2)	8(2.9)
peripheral neuropathy	9(3.3)	6(2.2)	Virological& Immunological	3(1.1)	6(2.2)
CNS toxicity	9(3.3)	5(1.8)	Co-morbidity	1st change N(%)	2nd change N(%)
Rash	17(6.2)	2(0.7)	TB	25(9.1)	

hepatotoxicity	7(2.5)	2(0.7)	Hepatitis	3(1.1)	
Nausea/vomiting	24(8.7)	-			

OI Drugs During Regimen Change

During the initial change of regimen, over half of the patients (61.8%) were receiving only co-trimoxazole as prophylaxis for opportunistic infections. Out of a total of 275 patients, only 2.2% were on isoniazid prophylaxis for tuberculosis, and an equal percentage (2.2%) was undergoing treatment for tuberculosis (Figure 5).

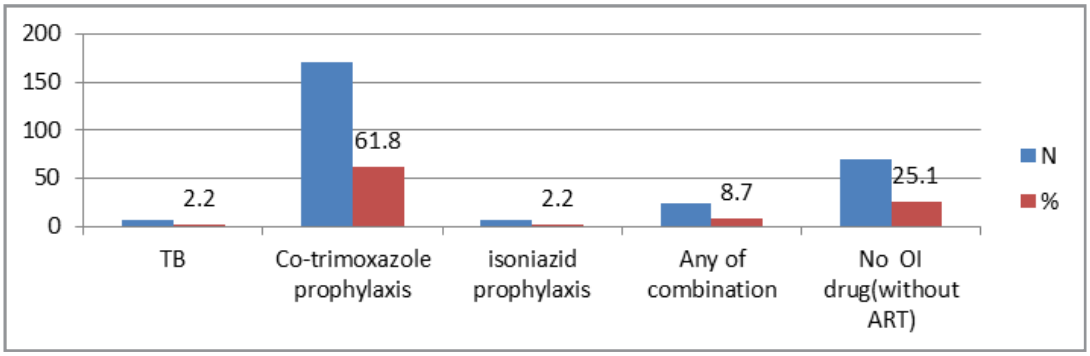

Figure 2: Initial Antiretroviral Regimen Group in Patients Included in the Study

Reasons for Second Change

Out of 93 patients were changed their regimens for second time, toxicity was the first and the highest reason for second time change, which accounts 64(68.8%) patients followed by treatment failure, co-morbidity and pregnancy

Reasons for Second Change							
	Frequency (%)	D4T based		AZT based		TDF based	
		D4T/3TC /NVP	D4T/3TC /EFV	AZT/3T C/NVP	AZT/3T C/EFV	TDF/3T C/EFV	TDF/3T C/NVP
Toxicity	64(68.8)	12	6	32	14	-	-
Pregnancy	3(3.2)	-	3	-	-	-	-
co-morbidity	9(9.7)	-	3		6	-	-
treatment failure	14(15.0)	9	-	-	5	-	-
Others	3(3.2)	-	-	3	-	-	-
Total	93(100)	21	12	35	25	-	-

Discussion

Changes to the Highly Active Antiretroviral Therapy (HAART) regimen are influenced by various factors, including both short-term and long-term toxicity, treatment failures (which encompass clinical, virological, and immunological failures, among others), issues with adherence, pregnancy, comorbidities, and the availability of new medications. Therefore, this study aims to evaluate the reasons why HIV/AIDS patients at BMGH change their HAART regimen for the first and second time.

In this study, over half (56.4%) of the patients were female, and 66.9% fell within the age group of 30 to 45 years. A significant majority (65.3%) of the patients began their HAART (Highly Active Antiretroviral Therapy) regimens with a baseline CD4 count of 200 cells/mm³ or lower. Regarding the baseline WHO clinical stage, 69.5% of patients were classified as stage III. The study was conducted at Durame Hospital, where 67.6% of the participants were female, and 53.1% were aged between 18 and 30 years [24, 25]. The initiation of HAART treatment accounted for 48.55%, while regimen modifications occurred in 49.7% of patients with a CD4 count ranging from 51 to 200 cells/mm³ and those classified as WHO clinical stage III. A study conducted in Bedele reported that the initial CD4 counts of participants were as follows: 34.5% had counts between 101-200 cells/mm³, 28.6% had counts between 51-100 cells/mm³, and 26.2% had counts above 200 cells/mm³. Additionally, research at Nekemt Hospital found that the majority of patients (57.7%) were female and that 61.3% were aged between 20 and 34 years old. In terms of clinical staging, 61.2% of patients were classified as WHO clinical stage III, while only 2.8% fell into WHO clinical stage I. Notably, 69.7% of patients had CD4 counts below 350 cells/mm³. Among the 275 patients who changed their HAART reg-

imen for a second time, 33.8% made this change in the current study. This figure is significantly higher compared to other studies, such as one conducted in Mekelle, which reported a 10.2% rate of second regimen changes, and another in Addis Ababa, where the rate was 20.8% [26].

In this study, 33.8% of the total 275 patients changed their HAART regimen for the second time. This rate is significantly higher than the findings from studies conducted in Mekelle, which reported a 10.2% rate for second regimen changes, and in Addis Ababa, where the rate was 20.8%.

This study indicates that co-morbidities such as tuberculosis and hepatitis, along with factors like pregnancy, adherence issues, and toxicity related to the initial treatment regimen, were identified as predictors for changes in treatment. Notably, toxicity emerged as the primary reason for changes, accounting for 66.2% of first changes and 68.8% of second changes. These results are consistent with research conducted in India, Nigeria, and Ethiopia. In this study, toxicity was the primary reason for switching antiretroviral (ARV) drugs, with a rate of 66.2%. This figure is significantly higher compared to studies conducted in the UK, where the rate was 35%, and in India, which reported 27%. Conversely, our findings are consistent with research from Ethiopia, where the rates of switching due to toxicity were similar: 74.1% in Addis Ababa, 75.8% in Mekelle, 65.58% in Nekemte, and 67.65% in Southern Ethiopia. Additionally, a study conducted in Southern India found that 64% of patients altered their initial ART regimen due to adverse effects, further aligning with our results. In this study, lipodystrophy emerged as the most prevalent toxicity, occurring in 20.7% of patients during their first change and 10.9% during their second change. Similarly, a significant majority of patients in southern Ethiopia reported lipodystrophy, with rates of 75.58%, while in Nekemte, were 80.3%. Additionally, studies from southern Ethiopia and Nekemte indicated lipodystrophy rates of 36.5% and 43.33%, respectively. Furthermore, a study conducted in the U.K. found that lipoatrophy comprised 18.8% of reported toxicities, with about 15% of patients being on a d4T-based regimen [27-30].

In studies conducted in Mekelle and Addis Ababa, anemia was identified as the primary reason for modifying Highly Active Antiretroviral Therapy (HAART), contributing to 39.5% and 16.7% of the reported toxicity reasons in each location, respectively. In contrast, this study found that anemia accounted for only 11.6% and 2.5% of toxicity-related reasons for the first and second therapy changes, respectively.

Conclusion

This study found that the primary reasons for switching the antiretroviral therapy (ART) regimen for both initial and subsequent treatments among the participants were drug-related side effects, particularly toxicity. Other contributing factors included co-morbidities, treatment failures, and pregnancy, while difficulties in adherence were noted as the least common reason for changes in the ART regimen. The most frequently reported toxicities leading to ART regimen changes included lipodystrophy, anemia, renal toxicity, vomiting, and rash. It was observed that the initial switch from ART was predominantly due to adverse effects from Stavudine-based regimens, whereas changes in the second regimen were often linked to Zidovudine-based regimens. Additionally, the type of initial ART regimen significantly influenced the decision to switch, and both the clinical stage and the specific ART regimen played roles in the frequency of second-round drug changes [31].

Recommendations

- There should be an increased availability and usage of HIV treatment options that are less toxic and better tolerated.
- Patients should undergo regular evaluations following any change in their treatment to monitor for potential issues related to the new regimen, assess medication tolerance, and evaluate treatment effectiveness.
- Given that most ART drug switches necessitate laboratory monitoring, routine laboratory tests should be conducted.
- Any modification to the antiretroviral therapy (ART) regimen in this context should be clearly justified [32].
- should be well recorded and documented.

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