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Research Article

Factors Associated with High Viral Load Re-Suppression among People Receiving Antiretroviral Therapy in Hawassa City Public Facilities, Sidama Regional State, Ethiopia

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Abstract

Background: Viral load monitoring is the gold standard for monitoring adherence and confirming treatment response, while treatment failure is often caused by either therapeutic failure due to ART resistance or poor adherence to treatment. Assessment for viral load suppression (< 1000copies/ ml) is one of HIV indicators therefore monitoring and reporting outcome of ART is very important for the program implementation and monitoring. Therefore, the objective of this study is to assess factors associated with high viral load re-suppression among HIV patients receiving antiretroviral therapy in Hawassa City public facilities.

Method: A retrospective cross-sectional study was conducted between September 1, 2017 and June 30, 2020, among people living with HIV (PLHIV) in three public facilities at Hawassa city, Ethiopia. Patients with a Viral Load (VL) > 1000 copies/ml received three sessions of Enhanced Adherence Counselling (EAC) one month apart, after which a repeat VL was done. The main outcome was viral re-suppression following EAC. Structured checklist was used to extract data by reviewing medical records focusing on patient related data (age, sex, and residence), monitoring response to ART (VL, CD4 count, WHO clinical staging), Co-morbidities, adherence, and duration of medication. Data was entered in EpiData version 3.1. and the analyses were done using SPSS for Windows version, 25.0.

Result: A total of 220 records of high viral load HIV seropositive were reviewed and 40% of viral re-suppression was observed. Odds of viral re-suppression observed among patients enrolled in to enhanced adherence counseling (AOR = 2.1, 95% (1.0-4.2)) and who had TB infection (AOR = 0.53, 95%CI (0.2-0.8)).

Conclusion: The study showed low viral load re-suppression prevalence among HIV high viral load patients. Enhanced Adherence Counseling (EAC) had great roll in viral re-suppression and TB infection decreases odds of HIV viral re-suppression. Enhanced Adherence Counseling (EAC) and TB infection prevention is recommended for all high viral load HIV patients.

Keywords: *HIV; antiretroviral therapy; High Viral load; Enhanced Adherence Counseling; Hawassa; Ethiopia.*

INTRODUCTION

Acquired Immune Deficiency Syndrome (HIV/AIDS) is a continuum of conditions caused by infection with the Human Immunodeficiency Virus [1]. HIV/AIDS can affect all age and sex, almost two thirds of all people living with HIV in 2018 were receiving antiretroviral therapy, and more than half had suppressed viral loads [2]. Unlike some other viruses, the human body can't get rid of HIV completely. Untreated, HIV reduces the number of CD4 cells (T cells) in the body, making the person more likely to get AIDS. It describes a set of symptoms and illnesses that happen at the final stage of HIV infection [3]. Globally, the number of people living with HIV was increased in 2018 from 37.9 million, compared to 24.9 million in 2000. This shows continued transmission of HIV despite reductions in incidence, and the benefits of expanded access to antiretroviral, which have helped to reduce the number of mortalities from HIV-related cause [4,5]. An estimated 23.3 million of the 37.9 million people living with HIV globally were on treatment [2]. Sub-Saharan Africa remains most severely affected, more than two-thirds of the people living with HIV worldwide [4,6]. Bezabih and his colleagues were reported a study in 2019, in Ethiopia about 710,000 people were living with HIV and the prevalence of HIV/AIDS in the general population is estimated to be 1.5% [7]. The epidemic in Ethiopia is heterogeneous by sex, geographic areas and population groups; the prevalence among women and men aged 15-49 is 0.9 percent; by region, it is highest in Gambella (4.8%) but lowest in SNNPR (0.4%) next to Somalia (0.1%) [8,9].

World Health Organization (WHO) recommended regular Viral Load (VL) monitoring for all People Living with HIV (PLHIV) who are on Antiretroviral Therapy (ART), as the most accurate available measure of effective treatment response [1]. A high viral load (> 1000 copies/ml) in a patient who has been on ART for at least six months can show either therapeutic failure due to antiretroviral resistance, and/or poor adherence to ART. To differentiate between these two conditions, a patient with an high VL should receive Enhanced Adherence Counseling (EAC) followed by retesting VL three to six months later [10]. After an adherence intervention, 70% people with high load have a re-suppressed viral load [1]. This high vial load management approach is used to differentiate that those clients who have unsuppressed Viral Load (VL),

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immune suppression, developing new OI or have multiple adherence barriers [11]. It explores the patients' barriers to adherence and identifies together with the patient a way forward. Three or more sessions proceed in a structured way, with the support of a session guide and registration in a patient file and register [12].

METHODS

Study Site and Study Area

The study was carried out at Hawassa city located in Sidama Regional State. It is found at 275km from Addis Ababa, a capital city of Ethiopia, in the Southern part of the country, within the rift valley depression. Hawassa city accommodates 210,676 inhabitants. It covers 50.24 square kilometers and divided into eight sub-cities [13].

Study Design and Study Population:

This was a retrospective study. The records of 220 adult and pediatric HIV patient who are on ART for at least 6 months and have HIV viral load results available at the ART clinic between September 1, 2017, and June 30, 2020, were reviewed.

Eligibility Criteria

All HIV patients on first line antiretroviral therapy at least for 6 months and have high viral load result (viral load results greater than 1000 copies/ml) archived in their chart, from September 1, 2017, to June 30, 2020 were included. Patients who had no second viral load result were excluded.

Sample Size Calculation

Sample size (n) is calculated by assuming 66.4% as anticipated proportion of viral load suppression reported from North Wollo by Gedefaw and his colleagues [14]. The power of the study is 80% with margin of error of 5%. Based on these assumptions the total samples size was estimated using a single population proportion formula. The sample size required was 342, but the study population was small, population correction was applied, and the sample size became 200, with 10% of contingency for incomplete data, 220 study subjects were included in the study.

Data Collection Instruments and Procedures

The source of data for the study was individual patient record. Data was collected by using 14 structured checklists. The check list was developed from consolidated HIV prevention care and treatment guideline [15], and reviewing related literatures to collect the required individual information from patient chart. The checklist sought information on: Patient related data (age, sex, and residence), monitoring response to ART (VL, CD4 count, WHO clinical staging), Co-morbidities, adherence, and duration of medication. Three data collectors and one supervisor who have been trained with basic ART and/or are working in ART site and experienced with HIV clinical system mentorship were involved. In addition, data collectors were trained on the checklist to get common understanding and make aware of the context of each question in the checklist.

Data Quality Management

To keep data quality supervisor and data collectors was oriented on how and what information they should collect from the targeted data sources. The prepared checklist was pretested before actual date of data collection and any correction was made based on the finding. Proper categorization and coding of the data completeness and consistency of the collected data was checked on daily during data collection by supervisor and the principal investigator. Whenever there was incompleteness and ambiguity of recording, the filled information formats were crosschecked with source data.

Data Processing and Analysis

Data was checked for completeness and consistency, coded, and enter in EpiData version 3.1. The analyses were done using SPSS for Windows version, 25.0 (IBM SPSS Statistics). Descriptive statistics such as mean and standard deviation (± SD) were used to summarize the characteristics. Finally, to explore factors associate with re-suppression of viral load among high viral load patients, we were carried out adjusted analysis for suppression of viral load. Variables significant at $P < 0.25$ level in the bivariat analysis were candidate for multivariable, which have medical and/or public health significant were include in the final multivariable analysis. Variables which was statistically significant at $P < 0.05$ was concluded as predictors of suppression of viral load.

Viral Load Estimation

Viral load was estimated in 0.2 ml plasma using a second-generation RT-PCR assay (Abbott Molecular Inc. Des Plaines, USA) with a lower detection limit of 150 copies/ml was quantified. The routine viral load determination is implemented according to the national sample referral network system at Hawassa Regional reference Laboratory.

Ethical Consideration

Ethical clearance was obtained from the ethical clearance Committee of Pharma College. Official letters were taken from Regional Health bureau; Hawassa city administration health department. Permission was obtained from the selected heath facilities. Patients' names were not retrieved from the archives. Data retrieved were anonymous and not linked to any patient.

RESULTS

Socio Demographic Characteristics of the Study Participants

In the study period, 6120 active patients on ART for over six months attended ART service providing facilities in Hawassa city. Of these, 481 individuals had high viral load (> 1000 copies per ml) result. A total of 220 participants in HIV chronic care and treatment who had a viral load above 1000 copies per ml were included in the study, of whom 134 (60.9%) were female. The overall age ranges from 7 to 62 year, Inter Quartile Rang (IQR) (27 -42 Years). Seventy-three (33.2%) patients were in the age group of 30-39 years. Most (187/220, 85%) of participants were adults. Majority (90.9%) of them were urban residence, 46.6% were married. Around 38.6% of participants had secondary educational level (Table 1).

Clinical Characteristics of the Study Participants

One hundred thirty-four (60.9%) of the study participants had suppressed immune (i.e. CD4 count below 200 cells/ µl). Most of them 127 (57.7%) had AIDS defining illness (WHO clinical stage 3 and 4). Around half of participants 115 (52.3%) had co-morbid disease (infected with TB) and most 179 (81.4%) of high viral load participants had good adherence to Antiretroviral (ARV) which means self-repot of patients or care providers showed less than 5% of doses of medication they had missed. One hundred fifty-three (69%) high viral load patients had enrollment of Enhanced Adherence Counseling (EAC) session for detailed steps of adherence counseling to determine adherence problems like cognitive, behavioral, and socio-economic barriers. Among them 127/153 (83%)

Table 1: Socio-demographic characteristics of high viral load patients, Hawassa city, Sidama Regional State, Ethiopia, (n = 220).

Variable	Frequency (n = 220)	Percent
Sex		
Male	86	39.1
Female	134	60.9
Age		
0-14	19	8.6
15-19	15	6.8
20-29	36	16.4
30-39	73	33.2
40-49	57	25.9
> = 50	20	9.1
Marital status		
Never married(Single)	54	24.5
Married	100	45.5
Separated	8	3.6
Divorced	30	13.6
Widowed	28	12.7
Educational status		
No education	27	12.3
Primary	80	36.4
Secondary	89	40.5
Tertiary	24	10.9
Residence		
Urban	200	90.9
Rural	20	9.1

Table 2: Clinical characteristics of high viral load patients, Hawassa city, Sidama Regional State Ethiopia, (n = 220).

Variable	Frequency	Percent
Baseline CD4 count (cells/ml)		
< 200	134	60.9
> 200	86	39.1
Baseline WHO clinical stage		
Stage -1&2	93	42.3
Stage-3&4	127	57.7
Co-morbid diseases		
TB infected	115	52.3
Not TB infected	105	47.7
Adherence to ART		
Good adherence to ART (> 95%)	179	81.4
Not good adherence to ART (< 95%)	41	18.6
Enhanced adherence counseling		
Enrolled	153	69.5
Not enrolled	67	30.5
Number of EAC sessions attended (n =153)		
EAC1	48	12.4
EAC2	35	4.6
EAC3	127	83
Extended EAC (n =153)		
EAC4 or more	43	28.1

of them completed the three EAC sessions and 43 (23.5%) continued extended session (four and more EAC session) (Table 2).

Socio Demographic and Clinical Conduction towards Viral Re-Suppression

From a total of 220 participants 88 (40.0%) had virally re-suppressed. From all viral suppressed participants, 54 (61.0%) were females and 89.70% were adult. Majority (80.0%) were urban inhabitants, (76.1%) were married and 40.0% had secondary educational status. Majority 59 (67.0%) had less than 200cell/ml CD4 count and had virally re-suppressed. Half of virally suppressed participants had WHO clinical stage 1 and 2, and fifty-one (57.9%) were not infected with TB. Most of 153 (69.5%) participants enrolled to enhanced adherence counseling session intervention; out of them 69 (78.4%) had viral suppression. (Table 3).

Table 3: Characteristics of viral re-suppression among high viral load patients, Hawassa city, Sidama Regional State, Ethiopia, (n =220).

Variable	Re-suppressed	
	Frequency	Percent
Sex (n = 88)		
Male	34	38.6
Female	54	61.3
Age category (n = 88)		
Pediatrics& adolescent	9	10.2
Adult(> 20years)	79	89.7
Marital status (n = 88)		
Never married	21	23.8
Married	67	76.1
Educational status (n = 88)		
No education	9	10.2
Primary	29	32.9
Secondary	36	40.9
Tertiary	14	15.9
Residence (n = 88)		
Urban	80	90.9
Rural	8	9
CD4 count (cells/ml) (n = 88)		
< 200	59	67
> 200	29	32.9
WHO clinical stage		
Stage -1&2	44	50
Stage-3&4	44	50
Co-morbid diseases		
TB infected	37	42
Not TB infected	51	57.9
Adherence to ART(n = 88)		
Good	71	80.6
Enhanced adherence counselling (n = 88)		
Enrolled	69	78.4
Not enrolled	19	21.5
EAC number of sessions attended (n = 88)		
EAC3	59	67
Extended EAC sessions		
Enrolled	16	18.1
Not enrolled	63	71.5

Factors Associated with Viral Re-Suppression

The bi-variate logistic regression analysis showed that being pediatrics and adolescents, suppressed immunity (CD4 count < 200 cells/ml), being WHO clinical stages 1 and 2, presence of TB infection, good adherence level for ART, and enrollment to enhanced adherence counseling session were associated with viral re-suppression (Table 4). In the multivariable analysis age, CD4 count, WHO clinical stages, and adherence level to ART were not significantly associated with viral re-suppression; but TB infection did (AOR = 0.43, 95%CI: 0.21-0.88). This indicates that HIV high viral load patients with TB infection decrease viral re-suppression by 57% and enrollment to Enhanced Adherence Counseling (EAC) session (AOR = 2.15, 95%CI: 1.09, 4.28) had statistically significant association with viral re-suppression. This result shows HIV high viral load patients those enrolled to EAC session two times more likely to re-suppress viral load count as compared to non-enrolled ones (Table 5).

DISCUSSION

This study had tried to assess factors that are significantly associated with HIV viral load re-suppression among HIV patients who are on Antiretroviral Therapy (ART) in Hawassa city public facilities. Accordingly, the prevalence of viral load re-suppression among HIV patients who are on ART for six month or more with first high vial load count was 88/220 (40%). This finding is low as compared to study conducted in Ghana; 69% [16]. This shows the weakness of viral load determination in the follow-up of high viral load or diagnosis of treatment failure of patients on ART. Delays in repeat viral load determination and keeping them on a failing regimen unnecessarily, result in the development and accumulation of drug-resistant strains of the virus [17]. Challenges in providing rapid and comprehensive care to patients of ART adherence, delayed repeated viral load tasting and delayed switch to second line ART. As per our study results, routinely recorded demographic, and clinical characteristics enrollment to Enhanced Adherence Counseling (EAC) session had independently significant association with viral re-suppression. In our study finding 153/220 (69.5%) high viral load patients enrolled in to enhanced adherence counseling session. This is slightly decreased from WHO recommendation, Ethiopian national guideline and study conducted in Zimbabwe where 75.7% of high viral load patient enrolled in to EAC.

All suspected virologic failure should be addressed by enhanced adherence counseling as well as repeat measurement before consideration of treatment switch to second line drug [1,11]. The enrollment of high viral load patients with such an initiative was valuable to address the gap and challenges in the monitoring and management of patients with high viral load and used as a form of differentiated care for unstable clients with high viral load. The overall viral load re-suppression after enhanced adherence counseling was 69/153 (45.1%), this shows patients with high viral load who enrolled in to Enhanced Adherence Counseling (EAC) session and received enhanced adherence support for one or more months by health care provider and adherence counselors were more likely to have suppressed viral load than those who did not enrolled into the session. The patients with high viral load got enrolled in to EAC and of those enrolled 83% of the patients attended all the three sessions. All age

Table 4: Association of factors with viral re-suppression among high viral load patients, Hawassa city, Sidama Regional State, Ethiopia, (n = 220).

Variable	Viral re-suppression status		Total	COR (95%)	AOR (95%)
	Suppressed	Non suppressed	n (%)		
Age category					
Pediatrics & adolescent	9 (10.2%)	24 (18.1%)	33 (15.0%)	0.51 (0.2-1.6)	
Adult(> 20years)	79 (89.7)	108 (81.8%)	187 (85.0%)	1 (Ref.)	
CD4count (cells/ml)					
< 200	59 (67.0%)	75 (56.8%)	134 (60.9%)	0.59 (0.3-1.0)	
> 200	29 (32.9%)	57 (43.1%)	86 (39.1%)	1 (Ref.)	
WHO clinical stages					
Stage 1&2	44 (50%)	49 (37.1%)	93 (42.2%)	1.69 (0.9-2.9)	
Stage 3&4	44 (50%)	83 (62.8%)	127 (57.7%)	1 (Ref.)	
Co-morbid diseases					
TB infected	37 (32.2%)	78 (67.8%)	115 (52.2%)	0.01 (0.2-0.8)	0.43 (0.2-0.8)*
Not TB infected	51 (48.6%)	54 (51.4%)	105 (47.7%)	1 (Ref.)	
Adherence to ART					
Good	77 (87.5%)	102 (87.5%)	88 (40.0%)	2.05 (0.9-4.3)	
Not good	11 (8.3%)	30 (22.7%)	132 (60.0%)	1 (Ref.)	
EAC					
Enrolled	69 (78.4%)	84 (63.6%)	153 (69.5%)	2.0 (1.1-3.8)	2.15 (1.0-4.28)*
Not enrolled	19 (21.5%)	48 (36.3%)	67 (30.4%)	1 (Ref.)	

on ART is necessary to identify persons with high viral load, exhaust all possible adherence barriers and provide an ongoing EAC for 3-6 months and assess for viral load suppression.

There is a threat that the remaining 17% patients with high viral loads may develop Adverse Antiretroviral Therapy (ART) outcome or of reversing the potential ART gains of reduced HIV transmission in the community [1]. Patients with high viral load who enrolled in EAC and repeated viral load tested after 3 or more months had viral 45% re-suppression rate. This re-suppression rate is lower than the study reported (66%) from Wollo zone Northeast Ethiopia [14]. This indicates that the high viral load seen in our setting is not due to poor adherence. Further studies are needed to sort this out. Both bivariate and multivariable analyses showed that enrollment to enhanced adherence counseling session is statistically significantly associated with increased odd of viral re-suppression as compared as not enrolled to EAC session. But it is different than the viral suppression rates reported in Zimbabwe which was not observed EAC as one of the factors of viral load re-suppression [18]. For this discrepancy we recommended qualitative analyses of the EAC session to assess of these sessions are appropriate for identifying and correction adherence related issues. In this study TB infection is another factor found to be associated with high viral load re-suppression. The study indicates approximately half of high viral load patients had TB infection, among them 37% got viral re-suppression in retest result, although multivariable analyses showed TB infection decreased the odds of viral re-suppression, our finding is in support the result of study conducted in Uganda [19].

The risk of active TB infection and fast progression to disease remains high in the group of HIV patients with high viral load. This could possibly be explained because HIV replication itself is associated with a distorted immune system and impaired protection against progression to disease. These mechanisms include increased cell turnover, activation, differentiation, and cytokine release [20]. HIV positive patients with high viral loads are at high risk of TB regardless of CD4 cell counts and may therefore particularly benefit from administration of Isoniazid Preventive Therapy (IPT) to reduce the risk of developing TB [21]. This point toward Minster of Health (MOH) to enhance integrated TB/HIV services which include regular TB screening and provision of TB preventive therapy for all eligible patents at all levels.

CONCLUSION AND RECOMMENDATIONS

This study investigated the determinants of high viral load re-suppression (< 1000 copies/ml) at 3 month or late second or retread viral load test result revealed that the patient with high viral load and enrolled in to Enhanced Adherence Counseling (EAC) session and TB infected were to increase and decreased odd of viral re-suppression respectively. In this study, high viral load patients enrolled in to EAC session were positively and strongly associated with viral re-suppression. This might be due to the age of the participants, most of patients (antiretroviral) ARV medication adherence were good. TB infection is also an important determinant of viral re-suppression for high viral load patients, it was negatively associated with viral re-suppression. The study highlights gaps in the viral load re-suppression and routine enrollment of EAC sessions for high viral load patients. Due to the gap, the role of EAC in achieving viral load suppression under routine programmatic conditions appears to be limited. The reason for this gap needs to be assessed in further research studies and addressed by suitable changes in policies/ practices. TB infection control and prevention were the main factor for viral re-suppression.

LIMITATIONS OF THE STUDY

The limitation of our study is that the study design and methodology involved review of records, for this reason analysis and interpretation of the data are limited to only those variables that are routinely collected from patient's records. Some of important variables like socio-demographic status of the patient, occupation, and address (distance of patients' residence to the ART center), patients' clinical condition like TB preventive therapy information, date of first & repeated viral load, and number of EAC session were incomplete.

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