

Research Article

Antiretroviral Treatment Monitoring and Factors Affecting Response to Treatment of HIV Patients in Massawa Hospital of Eritrea, Cross-Sectional Study, 2019

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Abstract

Background: Adherence to Antiretroviral therapy has been strongly correlated with HIV viral suppression, reduced rates of resistance, increased survival, and improved quality of life. The objective of this study was to evaluate antiretroviral treatment monitoring and determine the factors affecting response to treatment of HIV patients in Massawa hospital, Eritrea.

Methods: It was a cross sectional type with medical records review among HIV patients in Massawa antiretroviral therapy clinic. A checklist was used as data collection tool from patients and medical cards, from April 16 to June 23, 2019. Data was entered in CSPro 7.2 and analyzed by SPSS version 21. Results were presented in tables, chi-squared test and odds ratio. Ethical approval was obtained from Ministry of health research and ethical clearance committee of Eritrea, and written Consent was obtained from the patients.

Results: A total of 180 patients were enrolled in the study, dominated by females (74.4%) and Tigrigna ethnic group (71.7%). During starting antiretroviral treatment, 62.8% patients had CD4 level <200 cells/µl and were on clinical stages II (32.2%) and III (46.7%). The current CD4 and viral load level of most patients were above 500 cells/µl (52.8%) and undetectable (<40 copies/ml) in 75% of cases respectively. Furthermore; 98.3% of the patients were currently in clinical stage I. Patients with fair adherence had lower CD4 count (AOR=0.03, 95% CI=0.0-0.19) and viral load suppression (AOR=0.02, 95% CI=0.0-0.2). Nonsmokers were about two times and 37 times more likely to have a higher CD4 level and undetectable viral load <40 copies/ml when compared to smokers respectively.

Conclusion: Most patients' current viral load was undetectable with increased CD4 count and improved clinical stage. Male gender and poor adherence was the main factors significantly associated with poor response to Antiretroviral Therapy. Further prospective studies with larger sample size are required.

Keywords: HIV; Antiretroviral therapy; viral load; Adherence; Virulogical failure; Immunological failure

Background

Increasing access to antiretroviral therapy (ART) for people living with HIV/AIDS has been identified as a key strategy to control the HIV epidemic and avoid its cost in the future. In 2015, an estimated 15 million people living with HIV/AIDS were receiving ART, a remarkable milestone in the fight against HIV/AIDS [1]. Routine viral load testing should be conducted at 6 and 12 months after ART initiation and every 12 months thereafter [2]. Clinical and laboratory assessments should be performed at baseline for those who have entered care but are not yet eligible for antiretroviral treatment at initiation of and while on ART. In resource limited settings, World Health Organization recommends that clinical parameters to be used in conjunction with laboratory assessment. The inability to perform laboratory monitoring, notably for CD4 or viral load, should not prevent HIV patients from receiving ART [3].

The cut off for undetectable viral load differs among studies from resource limited countries; however, the proportion of patients who achieved virologic success is comparable to that in resource rich countries. For HIV-infected individuals on ART, it has been found that the CD4 cell count and viral load after six months of ART are the strongest predictors of disease progression and death [2]. Adherence to ART is an essential component of individual and programmatic treatment success. Higher levels of drug adherence are associated with improved virological, immunological and clinical outcomes. The five commonest reasons for failure to adhere were forgetfulness, Stigma, seeing someone with HIV doing well on ART, fear of discrimination and the fact that HIV has no known cure [4].

World Health Organization guidelines updated in 2013 stress that both CD4 and viral load testing should be performed only if resources permit and treatment should not be withheld if laboratory capabili-

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ties are not available [3]. Country programs should make the effort to adopt available low cost technologies in clinical care of HIV patients [5]. Failure to adherence could be due to multiple factors including late detection, stigma and discrimination, and difficulty in accessing health facilities, adverse effects of drugs, comorbidities, psychosocial factors, economic constraints, and availability of ART facilities [6].

ART in Eritrea was started in 2005 and since then it has been rendered to all patients for free of any charge. A study showed that although majority of the patients had good adherence, there were some patients who couldn't adhere because of stigma and/or adverse drug reactions. Overall, the patients had good adherence to ART treatment. Perceived stigma and discrimination and medication side effects were the main reasons for non-adherence [7].

To the knowledge of the researchers, there wasn't similar research done before in the country and specifically in Massawa hospital. So to fill this gab in monitoring treatment outcomes, management of patients and factors affecting to treatment, this study was aimed to evaluate the clinical, virological and immunological monitoring of patients to ART and the factors affecting the treatment outcomes in Massawa hospital, Eritrea.

Materials and Methods

Study design and area

It was a cross sectional with medical records review and interview of patients for some demographic characteristics, conducted in Massawa Hospital, Northern Red sea region. Massawa Hospital has different departments for outpatient and inpatient treatment of patients, as well as for communicable and non-communicable diseases treatment and follow ups. It serves for the inhabitants of Massawa subzone and other neighboring subzones as referral, for greater than 44,815 populations (source: Massawa subzone administration, 2019). Massawa city is about 102 kilometers to the North Eastern direction of Asmara in the Red sea coasts. Massawa Hospital is located in the port of Massawa and it was built during the Ethiopian colonization in 1952.

Study population and sampling

The Study population of this study was all HIV patients on follow up in Massawa hospital. Patients who lost follow up, died and had incomplete medical records were excluded from the study, as it was difficult to assess the objective of the study. The hospital has currently a total of 186 patients on ART and 180 of them were enrolled in the study and 6 patients were excluded due to incomplete medical records.

Data collection, Analysis, and Interpretation

A checklist was used to collect the socio demographic, immunological, virological and clinical parameters and to retrieve all necessary data of the patients from their clinical cards. The data was collected from April 16, to June 23, 2019. The quality of data was assured by pre testing the data collection procedure, training data collectors, and checking collected data on daily basis by principal investigators. A pilot study was conducted before starting the research in another site in a smaller sample size and the data collection procedure was tested before starting the study.

Data was coded and entered in CSPro7.2 and later transported to SPSS version 21 for analysis. Results were presented in tables, and percent to examine the patterns and the distribution of the respondents across the different demographic and clinical characteristics. Besides, chi-squared test and odds ratio were implemented to assess the association of the CD4 level and viral load with selected background characteristics of the study participants.

Four endpoints were evaluated: proportions of patients achieving viral suppression, immunological improvement of CD4 count of >350 cells/mm3, experiencing clinical response and factors affecting treatment outcomes. If viral load was not suppressed and CD4 count was not increased and/if patients were not clinically improved from the initial clinical stage after initiation of ART treatment, it was considered as poor response to ART treatment.

Ethical considerations

Ethical clearance was obtained from Ministry of Health Research and Ethical Clearance Committee of Eritrea, and permission was obtained from the zonal medical officer and medical director of Massawa Hospital. Finally, confidentiality of patient's medical cards was kept secured. Written consent was obtained from the patients to participate in the study and to give appropriate information for the interviewers before enrolment in the study.

Results

Demographic characteristics of patients

This study revealed that 71.1% of the patients were aged between 25-49 years with a mean age of 44 years, and 96.7% were inhabitants of Massawa subzone. Most of them were Christians (72.2%) and females (74.4%). Besides, 71.7% were Tigrigna in ethnic group and the composition of their educational level was illiterate (28.3%), primary (23.3%), middle (25%) and (23.3%) with secondary and college levels. About one third (33.9%) were married and 62.2% were employed in different occupations. One third (33.9%) had a monthly income between 500-1000 Eritrean Nakfa (ERN) with a mean of 613.72 ERN, and 29.4% earn monthly above 1000 ERN. Majority of patients reported that they didn't have history of smoking (87.8%) and alcohol intake (92.8%). And, about 40% of the patients had a (Body Mass Index) BMI of <18.5% (Table 1).

Variables	Frequency (N)	Percentage (%)			
Sex					
Male	46	25.6			
Female	134	74.4			
Age (years)					
15-24	3	1.7			
25-49	128	71.1			
50+	49	27.2			
Subzones	Subzones				
Massawa	174	96.7			
Foro	3	1.7			
Ghelaelo	1	0.6			
Sheeb	1	0.6			
Gindae	1	0.6			
Work status					
Employed	112	62.2			
Unemployed	68	37.8			

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Educational level		
Illiterate	51	28.3
Primary and middle	87	48.3
Secondary and above	42	23.3
Marital status	ien	ien
Married	61	33.9
Single	38	21.1
Divorced and widowed	81	45
Work type		
Civil	64	57.2
Govern- mental	45	40.2
National service	3	2.6
Ethnicity		
Tigrigna	129	71.7
Tigre	15	8.3
Afar	13	7.2
Saho	14	7.8
BMI		
<18.5	72	40
18.5-24	77	42.8
25+	31	17.2
Monthly income	(ERN)	
<500	66	36.7
500-999	61	33.9
1000+	53	29.4
Smoking		
Yes	22	12.2
No	158	87.8
Alcohol intake		
Yes	13	7.2
No	167	92.8
Total	180	100.0

ity,	(96%)	of	the	patien	its had	good	adherence	to	ART	(Table	2).	

Table 1: Demographic characteristics of patients: N=180

Immunological, virulogical and clinical monitoring of the patients

During starting antiretroviral treatment, 61.7% of the patients had a CD4 level of <200 cells/ μ l with clinical stages of II (32.2%) and III (46.7%). Meanwhile; currently 52.8% of patients' CD4 level was >500 cells/ μ l and their viral load was suppressed (<40 copies/ml) in 75% of cases. Besides; 98.3% of the patients were currently in clinical stage I. Majority of patients (57.8%) was taking TDF/FTC/3TC ART regimen. The mean duration of illness of patients was 9.4 years, and almost half of them had started ART between the years of 2010-2014, in which 80% of them took the treatment between 6-15 years duration. Major-

Variables	Frequency (N)	Percent (%)
CD4 level on star	ting ART(cells/µl)	
<200	113	62.8
200-349	40	22.2
350-499	13	7.2
500+	14	7.8
Current CD4 (cel	ls/µl)	
<200	19	10.6
200-349	21	11.7
350-499	45	25
500+	95	52.8
Current viral load	l (copies/ml)	
<20	81	45
20-39	54	30
40-999	22	12.2
1000-9,999	12	6.7
10,000- 99,999	11	6.6
100,000+	0	0.0
Clinical staging o	n starting ART	
Ι	36	20
II	58	32.2
III	84	46.7
IV	2	1.1
Current clinical s	tage	
Ι	177	98.3
II	3	1.7
Type of ART treat	tment	
TDF/ FTC/3TC	104	57.8
AZT/3TC/ NVP	51	28.3
AZT/3TC/ EFV	19	10.5
Second line	6	3.4
Other	9	5
Adherence	J	
Very good	110	61.1
good	62	34.4
Fair	7	3.9
poor	1	0.6
Year treatment st	arted	
<2010	45	25
2010-2014	100	55.6
2015+	35	19.4

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Duration of treatment (years)						
1-5	32	17.8				
6-10	72	40				
11-15	72	40				
16+	4	2.2				

 Table 2: Immunological, virulogical and clinical monitoring of the patients: N=180

Association of selected background characteristics with immunological parameters

Females were about three times more likely to have improved CD4 level when compared to males (AOR=2.8, 95% CI=1.3-6.0) and non-

smokers were 37 times more likely to have a higher CD4 level compared to smokers (AOR=1.4, 95% CI=0.5-3.8). Patients who doesn't consume alcohol had about two times better CD4 level compared to these who drink alcohol (AOR=2.4, 95% CI=0.7-7.7) and, those with BMI of greater than 25 were having about three times more likely to have better CD4 level when compared to these with BMI of <18.5 (AOR=3.4, 95% CI=0.9-12.3). Patients with fair adherence to ART were having about 97 times lower CD4 count of <350 cells/µl compared to those with very good adherence (AOR=0.03, 95% CI=0.01-0.2). The odds of patients who started ART treatment after the year of 2015 were having 59 times more likely of lower CD4 count as compared to these started treatment before 2010 (AOR=0.4, 95% CI=0.2-1.2). besides, patients who took treatment for more than 11 years had about two times more likely to have higher CD4 count >350 compared to those started treatment before 10 years. (AOR=2.3, 95% CI=0.9-5.9) (Table 3).

		Current Cl	D 4 level N (%)	D 1	0.11	
· ·	ariables	<350cells/µl	≥ 350cells/µl	P-value	Odds ratio	95%CI
C ou	Male	17(37.0)	29 (63.0)	0.005	1	
Sex	Female	23 (17.2)	111(82.8)	0.005	2.83	(1.34-5.98)
<u>Canaking</u>	Yes	6 (27.3)	16(72.7)	0.544	1	
Smoking	No	34 (21.5)	124 (78.5)	- 0.344	1.37	(0.50-3.76)
Alcohol in-	Yes	5(38.5)	8(61.5)	0.145	1	
take	No	35 (21.0)	132 (79.0)	0.145	2.36	(0.73-7.65)
	<18.5	19(26.4)	53 (73.6)		1	
BMI	18.5-24	18(23.4)	59 (76.6)	0.088	1.18	(0.56-2.47)
	25+	3 (9.7)	28 (90.3)		3.35	(0.91-12.29)
	0	13 (19.7)	53(80.3)	0.677	1	
Monthly in- come (ERN)	500-999	15(24.6)	46(75.4)		0.75	(0.32-1.74)
	1000+	12(22.6)	41(77.4)		0.84	(0.35-2.03)
Educational level	None	12 (23.5)	39(76.5)	- 0.904	1	
	Primary	9(21.4)	33(78.6)		1.13	(0.42-3.01)
	Middle	9(20.0)	36(80.0)		1.23	(0.46-3.27)
	Sec & college	10 (25.0)	32(75.0)		0.92	(0.35-2.42)
	Ι	3(8.3)	33(91.7)		1	
Clinical stag-	II	18(31.0)	40(69.0)	0.219	0.2	(0.05-0.75
ART	III	18(21.4)	66 (78.6)		0.33	(0.09-1.21)
	IV	1(50.0)	1(50.0)		0.09	(0.01-1.85)
X7 ()	<2010	8(17.8)	37(82.2)		1	
ment started	2010-2014	20(20.0)	80(80.0)	0.094	0.86	(0.35-2.14)
	2015+	12(34.3)	23(65.7)		0.41	(0.15-1.17)
	1-5	11(34.4)	21(65.6)		1	
treatment (vears)	6-10	15(20.8)	57(79.2)	0.099	1.99	(0.79-5.02)
	11+	14(18.4)	62(81.6)		2.32	(0.91-5.89)
	Very good	8(7.3)	102(92.7)		1	
Adharanaa	Good	26(41.9)	36(58.1)	<0.001	0.11	(0.05-0.26)
Aunerence	Fair	5(71.4)	2(28.6)		0.03	(0.01-0.19)
	Poor	1(100.0)	0(0.0)		1	

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Type of ART treatment	AZT+3TC+NVP	11 (22.4)	38 (77.6)		1		
	LAM+ZID+EFV	2(10.0)	18 (90.0)	0.871	1.4	(0.23-8.13)	
	Second line	2(28.6)	5(71.4)		3.6	(0.40-32.36)	
	TDF/FTC/3TC	25 (24.0)	79(76.0)		1.3	(0.23-6.92)	
Note: AZT/3TC	Note: AZT/3TC/NVP-Zidovudine (ZDV, AZT), Lamivudine (3TC), Nevirapine (NVP)						
AZT/3TO	AZT/3TC/EFV-Zidovudine (ZDV, AZT), Lamivudine (3TC), Efavirenz (EFV)						
TDF/FTC/3TC-Tenofovir (TDF), Emtricitabine (FTC), Lamivudine (3TC)							

 Table 3: Association of background of patients with immunological parameters; N=180

Association of socio demographic of patients with current virulogical parameters

The result revealed that females and nonsmokers were about two times more likely to have undetectable viral load <40 copies/ml compared to males (AOR=2.2, 95% CI=1.07-4.6) and smokers (AOR=2.4, 95% CI=0.9-5.9) respectively. Patients who didn't consume alcohol were about 1.35 times more likely to have suppressed viral load compared to those who consumed alcohol (AOR=1.4, 95% CI=0.4-4.7). Patients

with fair adherence had about 98 times more likely to have lower viral load suppression when compared to these with very good adherence (AOR=0.02, 95% CI=0.0-0.2). moreover, patients who took treatment for 6 to 10 years were about 1.2 times more likely to have undetectable viral load compared to those who took treatment for less than six years (AOR=1.17 95% CI=0.44-3.09). Besides, patients on clinical stage IV on starting ART were having about 76 times lower viral load suppression when compared to these of clinical stage I (AOR=0.24, 95% CI=0.01-4.4) (Table 4).

		Current Viral Load N (%)					
V	Variables		≥ 40copies/ ml	P-value	Odds ratio	95%CI	
Sov	Male	29(63.0)	17(37.0)	0.030	1		
Sex	Female	106 (79.1)	28(20.9)	0.030	2.22	(1.07-4.60)	
Sm alrin a	Yes	13 (59.1)	9 (40.9)	0.067	1		
Smoking	No	122 (77.2)	36 (22.8)	0.067	2.35	(0.93-5.93)	
Alcohol in-	Yes	9 (69.2)	4 (30.8)	0.610	1		
take	No	126 (75.4)	41 (24.6)	0.019	1.37	(0.40-4.67)	
	<18.5	56 (77.8)	16 (22.2)		1		
BMI catego- ries	18.5-24	58 (75.3)	19 (24.7)	0.312	0.312	0.87	(0.41-1.86)
1105	25+	21 (67.7)	10 (32.3)		0.6	(0.24-1.53)	
	0	50 (75.8)	16 (24.2)	0.791	1		
Monthly in-	500-999	46 (75.4)	15 (24.6)		0.98	(0.44-2.21)	
	1000+	39 (73.6)	14 (26.4)		0.89	(0.39-2.05)	
	None	41 (80.4)	10 (19.6)		1		
Educational	Primary	32 (76.2)	10 (23.8)	0.233	0.78	(0.29-2.10)	
level	Middle	33 (73.3)	12 (26.7)	0.233	0.67	(0.26-1.75)	
	Sec & College	29 (67.5)	13 (32.5)		0.51	(0.19-1.32)	
	Ι	29 (80.6)	7 (19.4)		1		
Clinical stag-	II	40 (69.0)	18 (31.0)	0.828	0.54	(0.20-1.45)	
ART	III	65 (77.4)	19 (22.6)	0.020	0.83	(0.31-2.18)	
	IV	1 (50.0)	1 (50.0)		0.24	(0.01-4.35)	
37	<2010	34 (75.6)	11(24.4)		1		
Year treat- ment started	2010-2014	74 (74.0)	26 (26.0)	0.897	0.92	(0.41-2.08)	
	2015+	27 (77.1)	8 (22.9)		1.09	(0.39-3.09)	

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	1-5	24 (75.0)	8 (25.0)		1	
Duration treatment (years)	6-10	56 (77.8)	16 (22.2)	0.640	1.17	(0.44-3.09)
u cauncile (years)	11+	55 (72.4)	21 (27.6)		0.87	(0.34-2.25)
Adherence -	Very good	98 (89.1)	12 (10.9)	< 0.001	1	
	Good	36 (58.1)	26 (41.9)		0.17	(0.08-0.37)
	Fair	1 (14.3)	6 (85.7)		0.02	(0.00-0.18)
	Poor	0 (0.0)	1 (100.0)			
	AZT+3TC+NVP	37(75.5)	12 (24.5)		1	
Type of ART treatment	LAM+ZID+EFV	15(75.0)	5(25.0)	0.965	1.2	(0.23-7.20)
	Second line	5(71.4)	2(28.6%)	0.905	1.2	(0.17-8.24)
	TDF/FTC/3TC	78 (75.0)	26(25.0)		1.2	(0.22-6.56)

 Table 4: Association of socio demographic with current virulogical parameters: N=180

Discussion

This study was conducted to evaluate the factors which determines the immunological, clinical and virulogical monitoring of HIV patients and to monitor the treatment outcomes in HIV patients in Massawa hospital. The age distribution of majority patients was between 25 to 49 years and these started treatments on the last five years were low, which could explain the incidence of new infection is significantly decreased. Even though most of the patients were employed that could show their improved quality of life, but majority of them had low monthly income that can have negative impact on their immunological status.

Most patients were Christians, in which Muslims conservative cultural believes might have value as a preventive measures, as they might not engaged on different risky works which could expose them to sexual intercourse. Males, smokers, alcohol consumers and those with poor adherence were having low CD4 count and high viral load level, which could need an immediate public health intervention to stop these harmful habits which impact their HIV status.

This study revealed that, gender and adherence were the main factors associated with treatment outcomes. But; level of education, marital status, body mass index, and monthly income doesn't show significant association to their treatment outcomes. Other study reported that gender, religion, finance, and education do not show significant associations with adherence to ART [8]. Besides; sociodemographic, psychosocial, health status, treatment and intervention related determinants were interlinked and contribute to optimal adherence [9].

Before starting ART, most patients were on clinical stage II and III and having lower CD4 count, which displays they were immunologically and clinically suppressed. After starting ART, most patients CD4 count had increased with undetectable viral load and improved clinical stage, a sign of immunological, clinical and virological improvement. Other study reported that, lower CD4 cell counts and higher viral loads at baseline were not associated with poorer virulogical outcome of ART [10].

This study reported that most patients were taking TDF/ FTC/3TC regimen ART treatment and had increased CD4 count and undetectable viral load of (<40 copies/ml). The positive impact of this rampant treatment modality could be due the convenient daily frequency and single dosage of the medication. In this study, as the initial viral load was not measured, patients were monitored initially by clinical and immunological parameters and showed good response to ART treatment. Another study showed that if CD4 monitoring alone was used; about half of the patients would had switched ART despite actually having undetectable HIV viral loads [3].

About half of the patient's BMI was below 18.5, but their nutritional status doesn't show significant association to their viral load and CD4 count. However; malnutrition could further suppress the immune system of the patients and can contribute in poor treatment outcomes. Majority of patients took treatment from 6 to 15 years and four patients took treatment for more than 16 years, which shows that the significance of monitored treatment and adherence to their therapy can positively influence their current outcome of longer life span of patients.

This research had several strengths. It proved that the three ART treatment monitoring parameters (clinical, immunological and virological) were effective and important in monitoring patients on ART. These parameters showed consistent association among each monitoring strategy. This also showed that ART is effectively working on these with good adherence to treatment and showed poor response on patients with bad habits as smoking and alcohol intake and on those with fair adherence to treatment.

This study was not without limitation. The initial viral load of the patients were not recorded that there was no viral load monitoring before one year in the hospital, thus only clinical and immunological monitoring were used. The sample size was small which could affect the power of the study; and also the study was conducted in one hospital, that it can't be generalize to other hospitals of the country. Patients who lost follow up and who died before years were excluded, which the research was done only on the alive patients, lacks definitive explana

tion of cause of death of the patients.

Conclusion

Before starting treatment, most patients were on advanced clinical stage with high viral load and low CD4 count. However, after initiating of ART treatment, most patients were clinically, virologically and immunologically well monitored with acceptable adherence and follow up. Gender and level of adherence showed significant association with the treatment outcome of the patients.

Further prospective studies with larger sample size are required which includes additional monitoring parameters, and the advantages and ben-

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efits between the different ART monitoring parameters should be evaluated. The impact of smoking and alcohol intake and the higher rate of Christian patients may also need further qualitative studies to explain their association. Physicians should develop the habit of monitoring their patients, educate and continuously counsel patients to increase the adherence to treatment.

Competing of interest

Authors declare that they didn't have any competing of interest to disclose

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Author's Contribution

BT, AD, ZM, FG and MA drafted the proposal and all authors participated on the final designing of the proposal. MR and FK contributed in designing the data collection tool. All authors participated on data collection and FK designed the CSPro software and all authors participated on data entry. FK analyzed the data by SPSS software and all authors participated on data analysis and writing the first draft of the manuscript. Finally BT, FK and MR finalized the final editing of the article and at last all authors revised and approved the last form of the manuscript.

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