ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF PUBLIC HEALTH

ASSESSMENT OF FACTORS FOR HIV VIROLOGIC TREATMENT FAILURE AMONG ADULT PATIENTS ON FIRST-LINE ART AT PUBLIC HOSPITALS IN ADDIS ABABA, ETHIOPIA.

by: Tizita Terefe

A THESIS SUBMITTED TO THE SCHOOL OF PUBLIC HEALTH, COLLEGE OF HEALTH SCIENCES OF ADDIS ABABA UNIVERSITY, IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER'S IN PUBLIC HEALTH

October 2022 G.C.

Addis Ababa, Ethiopia.

ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF PUBLIC HEALTH

Assessment of factors for HIV virologic treatment failure among adult patients on first-line ART at public hospitals in Addis Ababa, Ethiopia 2022.

by: Tizita Terefe

Advisors: Dr. Mesfin Addise (MD, MPH)

Mr. Werissaw Haileselassie (BSc., MPH)

APPROVAL SHEET

ADDS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCES SCHOOL OF PUBLIC HEALTH

Assessment of risk factors for HIV virologic treatment failure among adult patients on first-line ART at public hospitals in Addis Ababa, Ethiopia.

by:Tizita Terefe

Approved by:

1. _____ _____ _____

   (Chairman, Dean SPH) Signature Date

2. _____ _____ _____

   (Advisor) Signature Date

3. _____ _____ _____

   (Advisor) Signature Date

4. _____ _____ _____

   (Internal examiner) Signature Date

5. _____ _____ _____

   (External examiner) Signature Date

AKNOWLEDGEMENT

I would like to express my gratitude to my advisor`s Dr. Mesfin Addisie and Mr. Werissaw Haileselassie for their full support throughout the study. I also would like to thank Addis Ababa city administration Health Bureau (AACAHB) Monitoring and Evaluation staffs for their support. Finally, I am thankful to study Hospitals ART staffs for their support and participation in the study.

ACRONYMS

AACAHB	Addis Ababa City Administration Health Bureau
AAU	Addis Ababa University
AAU-CHS	Addis Ababa University Collage of Health Science
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral therapy
BMI	Body Mass Index
CPT	Cotrimoxazole Preventive Therapy
DTG	Dolutegravir
EAC	Enhanced Adherence Counselling
EDHS	Ethiopian Demographic and Health Survey
EFV	Efavirenz
HIV	Human Immune Virus
NNRTI	Non-Nucleoside Reverse Transcriptase Inhibitors
NVP	Nevirapine
PMTCT	Prevention of Maternal to Child HIV Transmission
RVLM	Routine Viral Load Monitoring
SPSS	Statistical Package for Social Sciences
UNAIDS	United Nations Program on HIV/AIDS
WHO	World Health Organization

Table of Contents

List of Tables

List of Figures

ABSTRACT

Background

Currently treatment for HIV is sought to improve quality of life in HIV infected people by decreasing opportunistic infections, reducing disease progression to AIDS, and preventable deaths. Thus, knowing factors for virologic treatment failure is of a key importance in the treatment of HIV.

Objective

To assess factors for HIV virologic treatment failure among adult patients on first-line ART at public hospitals in Addis Ababa, Ethiopia 2022.

Methods

A case-control study using quantitative method was conducted at randomly selected public Hospitals in Addis Ababa. A total of 284 medical records of patients on first line ART were randomly selected with a case to control ratio of 1:2; 95 cases with HIV virologic treatment failure and 189 controls with no virologic treatment failure. Data on socio-demographic clinical and adherence related variables were collected using data extraction questionnaire. Variables with p value <0.2 on bivariable logistic regression were entered to multivariable analysis. Backward likelihood logistic regression analysis was performed using SPSS (Statistical Package for Social science) -version 25 to identify independent factors for virologic treatment failure. P-value less than or equal to .05 was considered statistically significant.

Results

A total of 284 medical records were reviewed. Patients on first line ART in age group 18-24 had four times higher [AOR 4.526, 95%CI (1.253,16.351)] and those in the age group 25-34 had two times higher [AOR 2.836, 95% CI (1.103,7.295)] odds in cases than controls. Patients taking ART for a longer duration [AOR 2.349 CI (1.301, 4.242)] and discontinued ART [AOR 2.283CI (1.025-5.084)] were found to have two times higher odds in cases. Patients with ART adherence of fair status [AOR3.193CI (1.602-6.363)], poor status [AOR3.101CI (1.214-7.923)] and tuberculosis coinfection [AOR 3.193, 95% CI (1.328,7.678)] were having three times higher odds among cases than controls. Being female [AOR .323 95%CI (.174-.600)] was found inversely associated with virologic treatment failure.

Conclusion

This study showed the age group 18-34, adherence to ART medication of fair and poor status, discontinuing ART treatment for >1 month duration and taking ART for a duration longer than 5 years and TB coinfection within the past year were independent factors directly associated with virologic treatment failure while being female was found to be inversely associated.

1 INTRODUCTION

1.1 Background

Human immune deficiency virus (HIV) remains a major global public health issue accounting for morbidity and mortality among HIV infected peoples(1). According to WHO(world health organization) report in 2021 there were around 38.4 million people living with HIV and around 650,000 deaths in that year were due to HIV related illnesses; where more than two third of the infected people 20.6 million are in African countries(2).In Ethiopia, the prevalence of HIV is estimated to be 0.9% nationally and seven times higher in urban 2.9% areas compared to rural 0.4% according to Ethiopian HIV prevention road map2018-2020. Among regions Addis Ababa has the highest HIV prevalence of 3.4% next to Gambella 4.8%(3) .

Globally the three 90`s plan of treatment for all was launched in 2014 by United Nations Program on HIV/AIDS (UNAIDS) to be achieved by 2020; progressively to end the AIDS epidemic by 2030. The plan was 90% of HIV infected will be diagnosed, 90% of those diagnosed will start ART and 90% of those on ART will be virally suppressed by the end of 2020(4). Ethiopia is one of the countries who adopted the plan incorporated in 2018 national HIV/AIDS treatment guideline. One of the added futures being monitoring the viral load suppression; where a detectable viral load result of ≥1000 copies/ml is considered as virally unsuppressed(1). In relation to the third 90 plan from over all Ethiopians only 72% of those who live with HIV had viral suppression in 2020(2). According to 2018 Ethiopian treatment guideline Patients on ART with detectable viral load result ≥1000 copies/ml three to six months apart despite good adherence are virologically treatment failed(1). The recent 2022 Ethiopian treatment guideline directs to include patients with viral load of ≥50 copies/ml in the first test and the cutoff to define virologic treatment failure in the consecutive test being ≥1000 copies/ml(5).

Patients with HIV infection are started with First-line ART regimens which are less toxic, more effective, and more convenient than second- and third-line ART regimens. However patients are shifted to second and consecutively to third line regimens when first line treatment is virologically failed(1).

Patients with virologic treatment failure develop immunologic and clinical failure where opportunistic infections occur leading to increased incidence of preventable death(6). These infections and diseases take longer duration to recover due to existing lower immunity caused by double burden of a high viral load concentration and opportunistic infections. This will induce increased psychological and economic bearing in the lives of patients and their families.

Occurrence of virologic treatment failure will create openings for development of drug resistant virus to ART drugs and also transmission of drug resistant viruses(7). Probability of transmitting HIV infection is higher among virologically unsuppressed and treatment failed patients even being treated with ART(1). This will induce difficulty in the management of HIV prevention and control.

1.2 Statement of the problem

Appropriate ART usage reduces viral load concentration in the patients' blood to undetectable level within three to six months of starting a regimen which in the long run reduces morbidity and mortality in patients infected with HIV(1). Currently in Ethiopia, patients on ART are assessed routinely by viral load testing after six months of being on ART regimen and annually for virologic suppression(5).

Despite treatment with ART, HIV infected patients are experiencing virologic treatment failure. In Ethiopia a country wide study involving 63 health facilities by Getaneh Y et al reported 11% prevalence of virologic treatment failure in 2017(8). A meta-analysis by Endalemaw et al. reported a virologic treatment failure prevalence of 5.6% nationally in 2020(9). The incidence of virologic treatment failure was found to be 5.3% in 2020 at St. Paulos hospital millennium medical college in Addis Ababa, Ethiopia(10).

Virally treatment failed patients are at higher risk of contracting opportunistic infections and prolonged time of morbidity(6) and mortality(11). Those patients ART regimens will not work anymore with development of resistant viruses(7) needing to change to the next line regimens which are more complex(1).

In Ethiopia, there were studies identifying factors associated with virologic treatment failure such as suboptimal adherence to ART(12) , having opportunistic infections(10) and ART discontinuation(13).

In developing country like Ethiopia where resources are limited prevention is the first intervention modality(14); early identification of risk factors for development of virologic treatment failure is of crucial importance in the treatment goal of patients on ART.

However, there are few studies done concerning virologic treatment failure among adult patients on first line ART in Addis Ababa. Therefore, the aim of this study is to assess the risk factors for virologic treatment failure among adult patients on first line ART in public hospitals of Addis Ababa.

1.3 Justification of the study

The findings of this study will assist in the treatment of patients on ART in the study hospitals by early identification and prevention of factors for developing virologic treatment failure to decrease the opportunistic infections and death of patients occurring due to virologic treatment failure. Early assessment and preventive intervention of factors associated with virologic treatment failure reduces the shifting of patients ART regimen which will increase quality of the patient`s life. Furthermore, it will decrease the forward transmission of HIV from virally treatment failed patients to decreasing the spread of new HIV infections in the locality thereby supporting to achieve the global plan of ending the HIV epidemics by 2030.

This study will provide recent knowledge for health professionals on factors associated with virologic treatment failure in taking preventive intervention. It will also serve as a research document for other studies and support in planning HIV prevention and control related activities.

2 LITERATURE REVIEW

Globally only 66% (53-79%) of patients living with HIV were virally suppressed as of 2021 UNAIDS report which means 44% were at risk of virologic treatment failure(2). Treatment failure of patients on ART occurs in successive orders of viral, immunologic, and clinical. WHO recommends routine viral load monitoring of patients on ART to detect early virological treatment failure; which is the gold standard for diagnosing ART treatment failure(15).

There are different literatures identifying factors related with virologic treatment failure in patients on first line ART. The factors are classified and presented below as sociodemographic, clinical and adherence related factors.

2.1 Sociodemographic factors

There are studies showing gender as a factor related to virologic treatment failure. A study from Tanzania indicated that 73.5% of those patients on first-line ART who have virologic treatment failure were male patients(16).A study from Southwest Ethiopia shows a 63% prevalence of virologic treatment failure in males compared to females(17). In a study of Ethiopia, West Gojjam Zone female patients on ART had a 60 % lower risk of developing virologic treatment failure compared to males(18).This is also shown in A study of North Wollo zone that 54% of females on ART have lower risk of having virologic treatment failure(19). In another study from Southwest Ethiopia 52% of females were not having virologic treatment failure compared to males(17).

Patients on first line ART in the age group of 15-24 were 80.5 % at risk of having virologic treatment failure than older patients> 45years in a study done in Addama, Ethiopia(20). On the other hand 55% of patients on ART in the age group ≥35 were having virologic treatment failure compared to the younger patients in Waghimra(21).

A study from India showed 16.5% of those patients on first line ART with a single marital status had virologic treatment failure compared to married ones(22). While another study done in South Wollo reported a 25% prevalence of virologic treatment failure among divorced patients(23).

Concerning educational status of patients in first line ART; 67.4% of those with primary and above educational status were not having virologic treatment failure compared to those who cannot read and write in a study done in North Wollo zone(19).

2.2 Clinical factors

Currently ART is given for patients infected with HIV lifelong and are followed clinically for their treatment outcomes. One of the laboratory tests done to follow patients' immunological status is a cd4 count. In a study from India at 12 months of being on ART 16.2% of patients with a cd4 count of <100 cells/mm³ were having virologic treatment failure compared to above ones(22). Similarly at the start of ART 52.2% of patients with baseline CD4 <100 cells/mm³ were at risk of developing virologic treatment failure at Mettu karl specialized hospital compared to above ones(13). Among patients on ART in Nekemt hospital 47.7% of who had a baseline CD4 count of <100 cells/mm³ were having virologic treatment failure(24). In South Wollo those having a baseline cd4 count <100 cells/mm³ were having virologic treatment failure compared to above ones. Another study done in Abuja, Nigeria reported patients on first-line ART with a baseline cd4 count of <200 cells/mm³ were associated with having virologic treatment failure(25).

A 66.6% prevalence of virologic treatment failure was found in patients having a current cd4 count of less than 250 compared to above ones in North shoa(12). While a current cd4 count as low as ≤200 cells/mm³ is 40.3% associated with having virologic treatment failure in a study done in Woldia Dessie(26). Majority of patients 66.4% on ART with a cd4 >350 cells/mm³ were at lower risk of developing virologic treatment failure than those who had a cd4 count of <200 cells/mm³ in West Gojjam zone(18). (23). In Waghimra 43 %of patients with cd4 counts below 200 cells/mm³ were having treatment failure compare to above ones(21). Among patients on ART with a recent cd4 count of <350 cells/mm³ 51.4% were having virologic treatment failure using a viral load cutoff point as low as 100 copies/ml(27). Furthermore patients with a cd4 count of greater than or equal to 500 cells/mm³ were 55% at lower risk of virologic treatment failure in a study of North Wollo(19).

Patients on ART are classified for their disease stage based on their cd4 count and also opportunistic infections diagnosed. A study from Mettu Karl specialized hospital reported 46.9% of patients with baseline WHO stage 3&4 at initiation of ART had virologic treatment failure compared to those with WHO stage 1&2(13). Patients on ART who were coinfected with tuberculosis had 67.7% risk of developing virologic treatment failure than those who did not in Dare selam, Tanzania(16). Virologic treatment failure was prevalent in 40.7% tuberculosis coinfected patients in Mettu karl specialized hospital(13) In northern Ethiopia, Kombolcha 70.4 % of patients on first line ART who had opportunistic infection had virologic treatment failure(28).In another study of West Gojjam zone

64.9% of patients who had no recurrent opportunistic infections were not at risk of developing virologic treatment failure(18). Patients who were diagnosed with opportunistic infections were found to be 82.1 % at higher risk of developing virologic treatment failure in St. Paulos hospital(10).

Patients nutritional status is one of the assessments performed for patients on ART. Majority 55.7% of those having baseline body mass index underweight were having virologic treatment failure in Mettu Karl specialized hospital(13). In another study virologic treatment failure was more prevalent in 24% of patients with a current BMI of 16-18.5 kg/cm² compared to those having > 18.5 kg/cm² Woldia Dessie(26).

Among patients who were newly taking ART 19% were associated with having virologic treatment failure than ART experienced ones in south wollo zone(23). This is also shown in central Ethiopia, Adamma where patients with a duration on ART of less than two years had 87.3 % risk of having virologic treatment failure(20). Furthermore being on ART treatment for 6 months to less than two years is shown to have highest risk of 92.5% for virologic treatment failure than being above two years in a study of Dareselam Tanzania(16). On the other hand 89% of patients on ART with a duration on ART of greater than or equal to five years were having virologic treatment failure in Waghimra zone(21).

ART drugs, mainly NNRTI type was shown to have an effect in ART treatment outcomes. A study from Uganda reported patients on ART dolutegravir(DTG) based first line regimen had 55% lower risk than efavirenz(EFV) based regimen(25).Similarly 64% patients who were started on nevirapine(NVP) base ART regimen were having virologic treatment failure compared to efavirenz (EFV) based regimens in SouthWest Ethiopia(17). Those patients on ART whose ART regimen was changed have73.8% risk of having virologic treatment failure in Adamma(20). Among patients in Waghimra Zone 52% patients who had drug toxicities to ART were having virologic treatment failure(21).

2.3 Adherence related factors

Medication adherence is a known factor contributing to affect treatment progress. A south African cohort study involving prescribed ART pill count to assess adherence reported a 10.7% incidence of virologic treatment failure despite adherence of ≥95%(29). Patients having below 95% adherence to ART medication were reported having virologic treatment failure in an Indian study(22). Poor ART

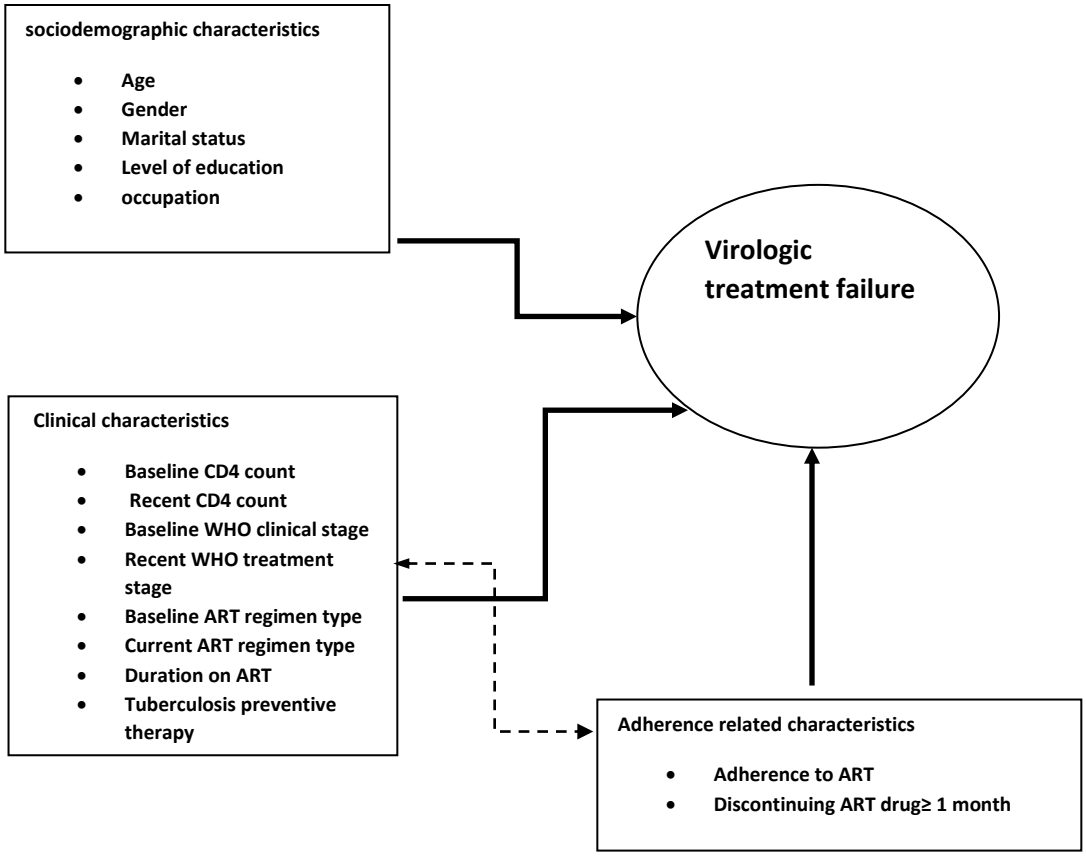
adherence is shown to have worse treatment outcomes in different studies. Majority 51% of patients with poor ART adherence in Mettu Karl specialized Hospital were having virologic treatment failure(13). Those patients having poor adherence were 42.2% having virologic treatment failure than those with good adherence in Woldia Dessie(26). In another study treatment failure was prevalent in 50.9% of those who have poor ART drug adherence in North Shoa(12). In a study from Kombolcha, showed 55% of patients on ART with poor ART adherence had virologic treatment failure(28). Patients on ART in South Wollo zone 41.5 % of with poor adherence were linked with having virologic treatment failure(23).Patients in Addama hospital with poor adherence to ART were 72.3% at risk of developing virologic treatment failure than those with good adherence(20).Majority 56.9% of who had poor ART adherence in Nekemt hospital were found to have virologic treatment failure(24).Similarly 53% of of patients with poor ART adherence were having virologic treatment failure in Waghimra Zone(21). Patients in St. Paulos hospital with poor adherence to ART medication were 80.9 % at risk of developing virologic treatment failure(20). Additionally, a study from North Wollo reported patients with a fair and poor adherence status to ART had risk of 90.3% and 65% having virologic treatment failure respectively(19).

Patients are not only non-adherent to their ART medication but also discontinue; 13.2%of patients who discontinued ART were having virologic treatment failure in Mettu Karl specialized hospital(13). Patients who miss their ART clinic appointments are at higher risk of running out of ART pills and discontinuing, where 76% of which were having virologic treatment failure in Nigeria(30).

There are other factors reported to have association with developing virologic treatment failure. Those patients who have reported living alone were related with virologic treatment failure in an Indian study(22). Patients taking cotrimoxazole preventive therapy (CPT) were 87% less likely to be at risk of having virologic treatment failure in St. Paulos hospital(10). A study from Nekemt reported 55.8% patients not participating in a support group had virologic treatment failure(24). Majority 56.% of patients having Poor health related quality of life have virologic treatment failure in North shoa(12). Patients who disclosed their HIV status had 96.2% lower risk of developing virologic treatment failure at St. Paulos hospital(10).

2.4 Conceptual framework

This conceptual framework is developed from the literature review. Factors associated with virologic treatment failure are categorized as sociodemographic, clinical and adherence related characteristics.



KEY

a. **Unbroken line: Major risk factors**
b. **Broken line: link between risk factors**

Figure 1 Conceptual framework developed from the literature review for a study on assessment of risk factors for HIV virologic treatment failure among adult patients on first-line ART, 2022.

3 OBJECTIVES

3.1 General objective

To assess risk factors for HIV virologic treatment failure among adult patients on first-line ART at public hospitals in Addis Ababa, Ethiopia 2022.

3.2 Specific objectives

To identify socio demographic factors for HIV virologic treatment failure among adult patients on first-line ART at public hospitals in Addis Ababa

To identify clinical factors for HIV virologic treatment failure among adult patients on first-line ART at public hospitals in Addis Ababa

To identify adherence related factors for HIV virologic treatment failure among adult patients on first-line ART at public hospitals in Addis Ababa

4 METHODOLOGY

4.1 Study area and period

Addis Ababa is the capital city of Ethiopia which is located almost at the center of the country. In 2021 it had an estimated population size of over 5 million. According to the Ethiopian Federal HIV/AIDS Prevention and Control Office (FHAPCO) epidemic estimate in 2021 there were 133,720 estimated people living with HIV/AIDS in Addis Ababa(3). ART service is being provided at 11 (5 federal and 6 regional) public hospitals, 3 uniformed hospitals, 74 public health centers and 30 private health facilities. In these health facilities there were 101,647 people currently on ART as of December 2020 according to Addis Ababa city administration Health Bureau (AACAHB) report. Of those 99,592 were adults where 37,262 were males and 62,330 were females. Three hospitals were selected randomly among the eleven public hospitals namely Yekatit 12, St. Peter and Tirunesh Beijing hospitals. Those hospitals are located at Arada, Shiromeda and Akaki Kality subcities of Addis Ababa respectively. There were 3014 patients on ART at Yekatit 12, 2261 patients at St. Peter and 900 patients at Tirunesh Beijing hospital as of December 2020 AACAHB report. The study was conducted from February 2022 to April 2022 G.C.

4.2 Study design

Institution based case-control study design was used by reviewing medical records of patients on ART.

4.3 Source population

All adult patients who are on first-line ART at public hospitals of Addis Ababa.

4.4 Study population

Adult patients who are on first-line ART from January 1, 2018 to December 31, 2020 G.C. at selected public hospitals; of which who had virologic treatment failure and had no virologic treatment failure were cases and controls respectively.

4.5 Inclusion criteria

Cases

ART patient's age ≥ 15 years old

Being on first-line ART for ≥ 6 months

Patients who had a virologic treatment failure during the study period

Controls

ART patient's age ≥ 15 years old

Being on first-line ART for ≥ 6 months

Patients who had no virologic treatment failure during the study period

4.6 Exclusion criteria

Both for cases and controls

Patients whose ART starting date data not available.

Patients in prevention of maternal to child transmission of HIV(PMTCT)

4.7 Sample size calculation

Sample size was calculated with two populations proportion formula using proportion of exposure in control(P_2)=.19, exposure in cases(P_1)=.36, odds ratio(OR)=2.4 from previous study(26), and 95 % confidence interval l($Z_{\alpha/2}$) and 80% power.

$$n_1 = \frac{[Z\alpha_{/2}\sqrt{(1+1/r)\,P\,(1-P)} + Z_{\beta}\sqrt{P_1\,(1-P_1) + P_2\,(1-P_2)/r}]^2}{(P_1 - P_2)^2}$$

P_1=proportion in cases

P_2=proportion in controls

Z_{β}= 0.84

P=average proportion= $P_1 + r\,P_2 / 1+r$

n_1:n_2=1:2

$r = n_2 / n_1 = 2$

n_1=sample size in cases

$n_{2=}$ sample size in control

Table 1 Sample size calculation for a study on assessment factors for HIV virologic treatment failure among adult patients on first-line ART at public hospitals in Addis Ababa, 2022.

Exposure variable	Proportion of exposure in controls (%)	Proportion of exposure in cases (%)	Sample size of controls (no.)	Sample size of cases (no.)	Total sample size (no.)
Current CD4 count<200 (cells/mm3)(25)	19.5	36.8	171	86	257

Finally adding 10% to account for incomplete data a final sample size of n_1=95 cases and n_2=189 controls with a total of 284 sample size for the study was reached.

4.8 Sampling procedure and sampling technique

Eligible medical records of patients with virologic treatment failure during the study period identified from list of ART patients on first line ART in respective hospitals were the respective sampling frame for cases. Similarly eligible medical records of patients with no virologic treatment failure during the study period identified from patients on first line ART list in respective hospitals were sampling frame for controls. The total sample size of cases and controls was proportionally allocated to each hospital respective sampling frames.

Then both cases and controls were selected randomly from each hospital sampling frames which finally added up to a total sample size of 95 cases and 189 controls.

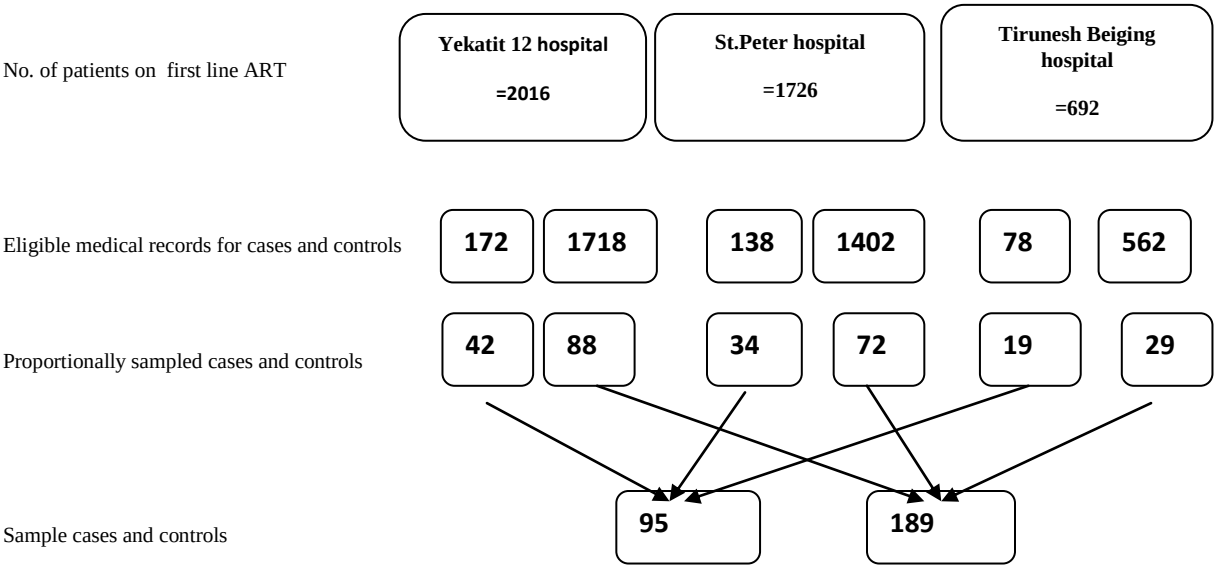


Figure 2 Sampling procedure for a study on assessment of factors for HIV virologic treatment failure among adult patients on first-line ART at public hospitals of Addis Ababa, 2022.

4.9 Data collection procedure

Data was collected from patient`s medical record using a data extraction questionnaire prepared for this specific study. Data extraction questionnaire was adapted from National ART guideline 2018 and the literature. Data was collected by three ART data clerks in respective hospitals trained for a day on how to collect data using the data collection questionnaire. Data collection questionnaire was pre-tested on 5% of samples by data collectors before actual data collection.

4.10 Study variables

Dependent variable:

Virologic treatment failure status

Independent variables are:

Socio-Demographic characteristics = age, gender, marital status, educational status, and occupation of patients on ART.

Clinical characteristics = recent functional status, baseline WHO clinical stage, recent WHO clinical stage, TB co-infection, baseline CD4 count, recent CD4 count, BMI, duration on ART, baseline ART regimen type, current ART regimen type and tuberculosis preventive therapy (TPT)status of patients on ART.

Adherence related characteristics = recent adherence to ART status and history of discontinuation of ART among patients on first line ART.

4.11 Operational definitions

The following definitions were adopted from the National ART Guideline of Ethiopia 2018.

Virologic treatment failure = having two viral load results of ≥ 1000 copies/ml measured consecutively three to six months apart

Recent CD4 count = CD4 count result of the patient within the past 6 months

Baseline WHO stage = WHO clinical staging of the patient when starting ART

Recent WHO stage = The last WHO treatment staging of the patient within the past 6 months

Current ART regimen=recent first line ART regimen taken by the patient according to national regimen code

Baseline ART regimen= first line ART regimen taken by the patient when starting ART according to national regimen code

Recent functional status of patient = functional status in the last visit W-working, A-ambulatory and B-bedridden.

Having active tuberculosis or treatment = diagnosed with active tuberculosis or started treatment for tuberculosis in the past 6 months

ART adherence status of the patient in the past month = good, fair, and poor status if the patient took ≥95%, ≥85% and below 85% of prescribed monthly ART, respectively in the last visit

Discontinuation of ART = discontinued taking ART for more than 30 days in the past three months

4.12 Data analysis procedure

The collected data is edited, cleaned, and entered to Epi info 7 then exported to SPSS version 25 for analysis. The data was recoded and prepared for analysis. Descriptive statistics of independent variables are presented with frequencies and proportions. Bi-variable logistic regression analysis was performed to select variables associated with virologic treatment failure. All variables with p-values less than or equal to 0.2 in bivariable analysis were entered to multivariable backward likelihood logistic regression analysis. The strength of the association was presented by OR with 95% confidence interval and independent risk factors with p-values less than or equal to 0.05 were considered as statistically significant.

4.13 Data quality control

Data collectors were trained how to maintain legibility, how to check completeness and consistency of each data extraction questionnaire. Data collection was supervised day to day by the principal investigator, on site data quality were checked for completeness and consistency. All corrections were made and pertinent findings found during the data collection were recorded on site separately.

4.14 Ethical consideration

Ethical approval obtained from Ethical review board of Addis Ababa University Collage of Health Science (AAU-CHS) and ethical approval to conduct the study obtained from Addis Ababa public health research and emergency management directorate. Permission letter to conduct the study was be obtained from AACAHB and head of each hospital.

All data collected during the data collection were de-identified, coded and are locked in a safe place and are not accessible to third party other than the data collectors and investigator. The data will not be used for purposes other than this study.

4.15 Dissemination of results

After completing this thesis and defending its will be submitted to AAU CHS-School of Public Health, study findings will be presented to Addis Ababa public health research and emergency management directorate and respective hospitals. The main findings of the study will be published in peer reviewed journals.

5 RESULTS

5.1 Socio demographic characteristics

Among a total of reviewed 284 sample medical records 33.4% (95) were cases and 66.6% (189) were controls. The minimum age of participants was 18 and the maximum being 62 with a mean age of 40 years. Majority of the controls 51.3% (97) and 30.5% (29) of the cases were females. Nearly half of the cases 49.5% (47) and almost half of the controls 47.1% (89) were married. One third 33.7% (32) of cases and 29.1% (55) of controls had primary educational status. When we see occupational status of the participants, majority 61% (58) of the cases and 59% (112) controls were employed.

table 2 socio-demographic characteristics of adult patients on first-line ART in selected public hospitals of Addis Ababa, 2022.

Variables	**Cases N=95(%)**	**Controls N=189(%)**	**Total N=284(%)**	**X^2 test**	**P-value**
Gender				11.078	.001
female	29(30.5)	97(51.3)	126(44.4)		
male	66(69.5)	92(48.7)	158(55.6)		
Age group				18.072	.001
15-24	12(12.6)	8(4.2)	20(7)		
25-34	34(35.8)	40(21.2)	74(26.1)		
35-44	27(28.4)	63(33.3)	90(31.7)		
45-54	12(12.6)	47(24.9)	59(20.8)		
≥55	10(10.5)	31(16.4)	41(14.4)		
Marital status				.320	.956
married	47(49.5)	89(47.1)	136(47.9)		
divorced	19(20)	36(19)	55(19.4)		
widowed	14(14.7)	31(16.4)	45(15.8)		
single	15(15.8)	33(17.5)	48(16.9)		
Educational status				1.713	.634
Unable to read and	23(24.2)	39(20.6)	62(21.8)		

write					
primary	32(33.7)	55(29.1)	87(30.6)		
secondary	25(26.3)	58(30.7)	83(29.2)		
higher	15(15.8)	37(19.6)	52(18.3)		
Employment status				.155	.925
Self-employed	28(29.5)	60(31.7)	88(31)		
Employed	58(61.1)	112(59.3)	170(59.9)		
Housewife	5(5.3)	8(4.2)	13(4.6)		
Student	4(4.2)	9(4.8)	13(4.6)		

5.2 Clinical characteristics

Among all participants the minimum months on ART was 7 and maximum 143 months with a mean of 60 months. Majority of the cases 72.6% (69) and controls 69.8% (132) had a baseline CD4 count of ≤350 cells/mm³. Concerning ART treatment regimen at baseline almost half of the cases 49.5% (47) and controls 49.2% (93) had EFV based regimens, however 65.3% (62) of cases and 66.7% (126) of controls are on a DTG based current regimen.

Controls had 11% (21) recent tuberculosis treatment while cases have two times 22% (21) more than in controls. The majority 84.5% (240) of cases and controls had last functional status of working during the study period the rest being ambulatory.

Table 3 Clinical and adherence related characteristics of adult patients on first-line ART in selected public hospitals of Addis Ababa, 2022.

Variables	Cases N=95(%)	Controls N=189(%)	Total N=284(%)	X^2 test	P-value
Baseline CD4 count(cells/mm³)				.238	.626
CD4≤350	69(72.6)	132(69.8)	201(70.8)		
CD4>350	26(27.4)	57(30.2)	83(29.21)		
Baseline WHO clinical stage				.197	.978
stage1	27(28.4)	56(29.6)	83(29.2)		
stage2	27(28.4)	56(29.6)	83(29.2)		
stage3	20(21.1)	36(19)	56(19.7)		
stage4	21(22.1)	41(21.7)	62(21.8)		
Baseline ART regimen				.002	.999
NVP based	27(28.4)	54(28.6)	81(28.5)		
EFV based	47(49.5)	93(49.2)	140(49.3)		
DTG based	21(22.1)	42(22.2)	63(22.2)		
TPT				.214	.644
no	25(26.3)	45(23.8)	70(24.6)		
yes	70(73.7)	144(76.2)	214(75.4)		
Current BMI(kg/m²)				1.731	.421
<18.4	15(15.8)	22(11.6)	37(13)		
18.5-23.9	46(48.4)	86(45.5)	132(46.5)		
≥24	34(35.8)	81(42.9)	115(40.5)		
Current functional status				1.98	.656
ambulatory	16(16.8)	28(14.8)	44(15.5)		
working	79(83.2)	161(85.2)	240(84.5)		
Tuberculosis treatment				6.064	.014
yes	21(22.1)	21(11.1)	42(14.8)		
no	74(77.9)	168(88.9)	242(85.2)		
Recent CD4 count(cells/mm³)				3.801	.051
CD4≤350	44(46.3)	65(34.4)	109(38.4)		
CD4>350	51(53.7)	124(65.6)	175(61.6)		

Recent WHO treatment stage				.549	.908
stage1	55(57.9)	116(61.4)	171(60.2)		
stage2	19(20)	32(16.9)	51(18)		
stage3	12(12.6)	25(13.2)	37(13)		
stage4	9(9.5)	16(8.5)	25(8.8)		
Current ART regimen				.363	.834
NVP based	9(9.5)	14(7.4)	23(8.1)		
EFV based	24(25.3)	49(25.9)	73(25.7)		
DTG based	62(65.3)	126(66.7)	188(66.2)		
Months on ART				9.979	.002
≤ 60 months	39(41.1)	115(60.8)	154(54.2)		
>60 months	56(58.9)	74(39.2)	130(45.8)		
Current adherence to ART					
Good	47(49.5)	146(77.2)	193(68)	22.780	.000
Fair	34(35.8)	28(14.8)	62(21.8)		
Poor	14(14.7)	15(7.9)	29(10.2)		
Discontinuation of ART ≥ 1 month					
Yes	24(25.3)	16(8.5)	40(14.1)	14.742	.000
No	71(74.7)	173(91.5)	244(85.9)		

5.3 Adherence related characteristics

Cases who have a fair 35.79% (34) and poor 14.74% (28) adherence status were almost two times of controls fair 14.81% (14) and poor 7.94% (15) adherence status respectively. One fourth 25.26% (24) of cases discontinued ART while only 8.47% (16) in controls.

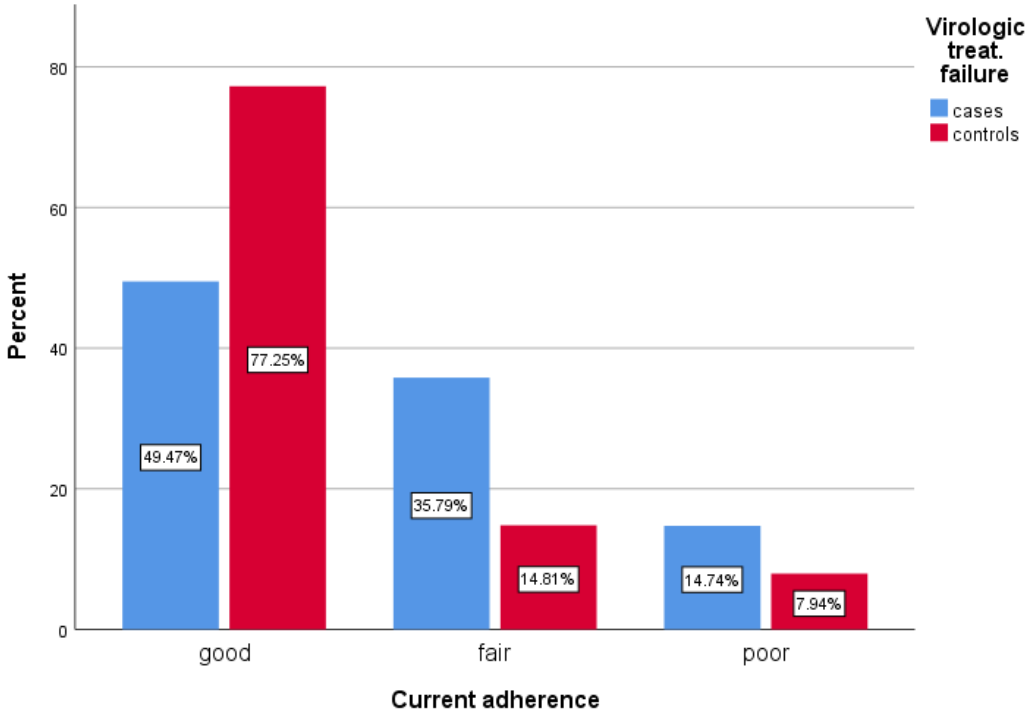


Figure 3 Percentage of current Adherence by virologic treatment failure among patients on first-line ART in selected public hospitals of Addis Ababa, 2022.

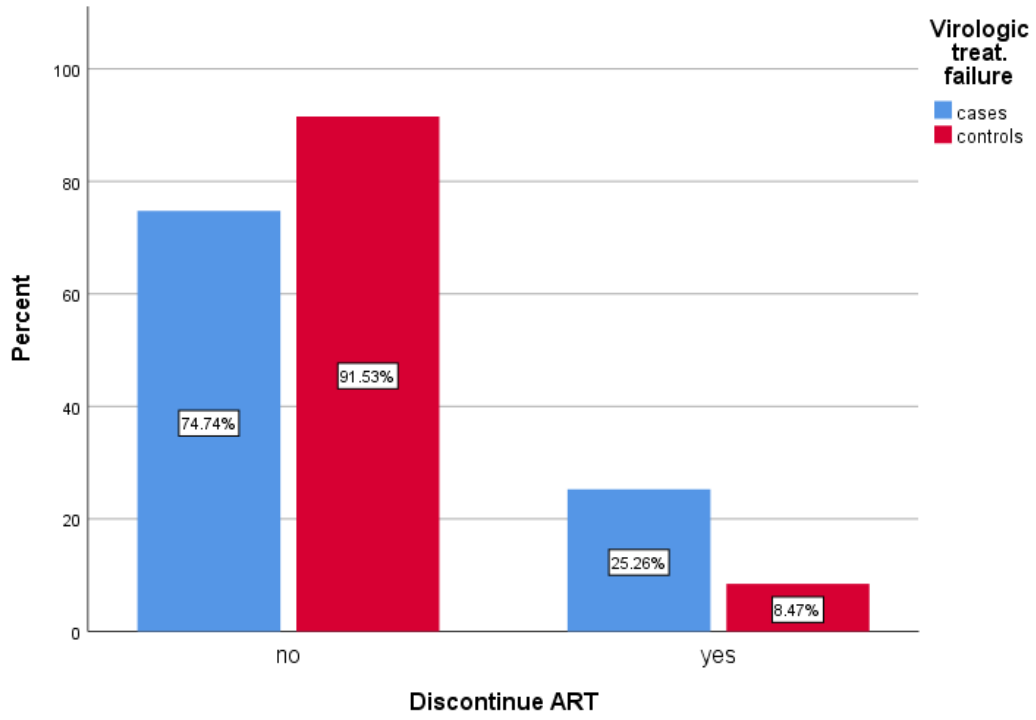


Figure 4 Percentage of ART discontinuation by virologic treatment failure among patients on first-line ART in selected public hospitals of Addis Ababa, 2022.

5.4 Factors for virologic treatment failure

All variables were entered for bivariable logistic regression. The odds of being in the age group 18-24 [COR 7.020 CI (1.383,35.636)] and 25-34 [COR 3.570 CI (1.238,10.289)], female gender [COR .308 CI (.146,.652)], patients who have taken TPT COR .347 CI (.147,.823), recent tuberculosis treatment COR 3.917 CI (1.596,10.790), current BMI of 18.5 kg/cm² [COR 3.236 CI (1.074,9.748)], recent WHO treatment stage 3 [COR .035 CI (.128,.926)], ≥60 months on ART [COR 3.061 CI (1.571,5.965)], current adherence status of fair [COR 3.885 CI (1.890,8.858)], and poor status [COR 3.726 CI (1.313,12.055)], and recent discontinuation of ART [COR 4.482 CI (1.791,11.216)] were higher in cases than controls. On multivariable stepwise backward likelihood logistic regression analysis significant variables independently associated with virologic treatment failure at p value ≤ 0.05 in the final model are age group18-24 [AOR 4.526 CI(1.253,16.351)], age group 25-34 [AOR 2.836 CI(1.103,7.295)], female gender [AOR .323 CI(.174,.600)], ≥ 60 months on ART [AOR 2.349 CI(1.301,4.242)], recent tuberculosis treatment [AOR 3.193 CI(1.328,7.678)], current adherence of poor status [AOR 3.016 CI(1.134,8.017)], current adherence of fair status [AOR 3.854 CI(1.940,7.657)], and ART discontinuation for a month or more [AOR 2.435 CI(1.086,5.459)].

Table 4 Bi-variable and multivariable logistic regression analysis of factors for virologic treatment failure among adult patients on first-line ART in selected public hospitals of Addis Ababa, 2022.

Variables	Virologic treatment failure		Bi-variate analysis			Multivariate analysis		
	yes	no	COR	95%CI	P-value	AOR	95%CI	P-value
Age group								
18-24	12	8	7.020	(1.383,35.636)	.019	4.526	(1.253,16.351)	**.021***
25-34	34	40	3.570	(1.238,10.289)	.018	2.836	(1.103,7.295)	**.031***
35-44	27	63	2.693	(.906,8.007)	.075	1.896	(.740,4.859)	.183
45-54	12	47	.704	(.239,2.630)	.792	.993	(.335,2.942)	.990
≥55	10	31	1			1		
Gender								
female	29	97	.308	(.146,.652)	.002	.323	(.174,.600)	**.000***
male	66	92	1			1		
TPT								
no	25	45	.347	(.147,.823)	.016	.467	(.216,1.010)	**.053**
yes	70	144	1					
Current BMI (kg/cm²)								
<18.5	15	22	3.236	(1.074,9.748)	.037			
18.5-23.9	46	86	1.103	(.548,2.218)	.784			
≥24	34	81	1					

Recent WHO treatment stage								
stage1	55	116	1					
stage2	19	32	1.419	(.577,3.490)	.446			
stage3	12	25	.035	(.128,.926)	.035			
stage4	9	16	1.000	(.290,3.451)	1.000			
Tuberculosis treatment								
yes	21	21	3.917	(1.596,10.790)	.004	3.193	(1.328,7.678)	**.010***
no	74	168	1					
Months on ART								
≤ 60 months	39	115	1					
>60 months	56	74	3.061	(1.571,5.965)	.001	2.349	(1.301,4.242)	**.005***
Current adherence status								
good	47	146	1					
fair	34	28	3.885	(1.890,8.858)	.000	3.854	(1.940,7.657)	**.000***
poor	14	15	3.726	(1.313,12.055)	.015	3.016	(1.134,8.017)	**.027***
ART discontinue>1 month								
yes	24	16	4.482	(1.791,11.216)	.001	3.433	(1.523,7.740)	**.003***
no	71	173	1					

6 DISCUSSION

This study shows that patients on first line ART at younger age than 35 are at higher risk of developing virologic treatment failure than becoming virally suppressed. This is supported in a study

of Central Ethiopia, Addama(20). However, this is not similar to what is reported in Waghimra Zone that older age is associated with virologic treatment failure(21).This might arise from a difference in sampling and analysis used. The odds of being virologically treatment failed at age 15-35 can be explained with patients younger age tend to have more psychological problems arising from HIV stigma leading to self-isolation and depression that they face difficulties with following their treatment appropriately than older ones(31).

The other demographic characteristics gender is also a significant factor for virologic treatment failure. The finding in this study shows that majority of females had lower risk having treatment failure than males. Supporting this females were less likely to develop virologic treatment failure compared to males in Ethiopia, West Gojjam Zone(18), southwest shoa(17) and North Wollo(19). This is also in line with finding in a study from dareselam, Tanzania(16).Females were shown to have better health seeking behavior and ART treatment adherence than males(29) which brings favorable ART treatment outcomes. Males have been shown to be less adherent to ART(32). males are more prone to drinking alcohol and are less likely to attend treatment appointments than females(33)(19). Males were shown to test for HIV infection lately that they are diagnosed with late stage of HIV with less immunity and higher viral load that makes them at higher probability of becoming treatment failed(34).

Patients on ART with recent active tuberculosis infection have higher risk of becoming virologically treatment failed in this study. This is in line with finding in Mettu(13) and Dare Selam, Tanzania(16).Tis can be explained by HIV/TB coinfection increases the risk of HIV virus replication by innate signaling of immunity cells(35). Tuberculosis infection depletes CD4 counts which puts double burden in HIV infected patients and unfavorable outcomes of virological un-suppression and treatment failure(36).

Those patients who took ART for a longer duration of greater than 60 months had higher odds of virologic treatment failure. This is also shown in a study of Waghimra(21). This can be explained by as patients experience longer duration on ART adherence to medication decreases, drug mutations and resistances develop and patients develop virologic treatment failure(1). On the contrary, findings from studies in North wollo(19) and Dareselam, Tanzania(16) show, ART treatment duration less than 2 years as a predictor and risk factor for virologic treatment failure respectively. The effect of duration on ART on virologic treatment failure needs further investigation using longitudinal studies.

This study shows having adherence to ART medication of fair status and of poor status have three times the odds of virologic treatment failure. ART reduces viral replication when taken at scheduled dose for lifelong unlikely patients who are non-adherent to their prescribed ART medication for a longer period having higher viral load than those who adhere. This is strongly supported by several studies in Ethiopia with findings of poor adherence as risk for developing virologic treatment failure in Addis Ababa(10), Woldiya and Dessie (26), Kombolcha(28), North Shoa (12), Nekemt(24) , Mettu(13), Waghimra(21), SouthWest Ethiopia(17) and a nationwide study(8). One reason for non-adherence is depression and mood disorder emanating from being HIV positive(37). ART patients who non-adhere to ART also have higher probability of higher ART resistance(38) and do tend to incur death(11). This might also be associated with inability to take medications as prescribed due to non-disclosure of HIV and fear of stigma which could all bring non adherence to ART medication reduces the efficacy of the treatment(33).

The other finding shows recent discontinuation of ART medication for duration of a month or more a significant factor having two times the odds in virologic treatment failure. This is shown in a study from a study of Nekemt(24) and Mettu(13).

7 STRENGTH AND LIMITATIONS

7.1 Strength

- ART data clerks in each Hospital were used as data collectors to ensure data quality.

- The study helped in exploring and comparing variables in both patients with longer and shorter treatment duration which is otherwise difficult to obtain data on.
- Use of secondary data avoids participant recall bias.

7.2 Limitation

- Other Social and behavioral variables cannot be assessed due to use of secondary data only.
- Selection bias may occur due to incomplete data on patients being transferred out or dropped, who would otherwise be eligible.
- The reliability of study may decrease due to use of secondary data.

8 CONCLUSION

In this study, the independent risk factors positively associated with virologic treatment failure among first line ART patients in selected public hospitals of Addis Ababa were being in age group 15-34,having recent tuberculosis coinfection, being for a longer duration on ART of greater than or equal to 5 years andhaving recent adherence of poor and fair status to ART. Being female is found indirectly associated with virologic treatment failure.

9 RECOMMENDATION

Health professionals:

younger patients on ART and of male gender should be given due attention in their treatment follow up and assessed for additional contributing factors.

Follow up of patients on tuberculosis/ART treatment to maintain virologic suppression is mandatory.

Patients approaching longer duration on ART of around 5 years need to be assessed for viral suppression, treatment resistance and counseled on continuous treatment adherence.

Adherence to ART medication and discontinuation of ART are important factor that must be discussed with patients as shown in this study. A focused assessment, follow up counseling and early management on conditions contributing to non-adherence to ART medication among patients on ART is important to reduce risk of acquiring virological treatment failure.

Researchers:

Considering time dependent and multi factorial nature of virologic treatment failure there is a need of further investigation using a longitudinal study.

Policy makers:

There is a need to provide specific intervention plans for early assessment of risk factors and preventive intervention for patients on ART.

10 REFFERENCES

1. FMOH Ethiopia. National Consolidated Guidelines for Comprehensive Hiv Prevention , Care and treatment. Fmoh [Internet]. 2018;1–238. Available from: file:///C:/Users/Tere/Desktop/University of South Africa (17-2017)/Documents on Cervical Cancer/July 22,2017/All Litratures/National Comprehensive HIV Care Guideline 2018.pdf
2. UNAIDS data 2021. 2021;
3. Federal HIV/AIDS Prevention and Control Office. HIV Prevention in Ethiopia: National Road Map. 2018;(November 2018):1–43.

4. UNAIDS. To help end the AIDS epidemic. United Nations [Internet]. 2014;40. Available from: http://www.unaids.org/sites/default/files/media_asset/90-90-90_en.pdf

5. POCKET_GUIDE_FOR_NATIONAL_GUIDELINES_FOR_COMPREHENSIVE_HIV_PREVENTION.pdf.

6. Assemie MA, Alene M, Ketema DB, Mulatu S. Treatment failure and associated factors among first line patients on highly active antiretroviral therapy in Ethiopia: a systematic review and meta-analysis. Glob Heal Res Policy. 2019;4(1):1–10.

7. Mulu A, Maier M, Liebert UG. Low incidence of HIV-1C acquired drug resistance 10 years after roll-out of antiretroviral therapy in Ethiopia: A prospective cohort study. PLoS One. 2015;10(10):1–12.

8. Getaneh AY, Egziabhier AG, Zealiyas K, Tilahun R. Treatment Failure among People living with HIV taking Antiretroviral Therapy in Ethiopia. 2019;576.

9. Endalamaw A, Mekonnen M, Geremew D, Yehualashet FA, Tesera H, Habtewold TD. HIV/AIDS treatment failure and associated factors in Ethiopia: Meta-analysis. BMC Public Health. 2020;20(1):1–12.

10. Andarge DE, Ewnetu H, Id H, Menna T. Incidence , survival time and associated factors of virological failure among adult HIV / AIDS patients on first line antiretroviral therapy in St . Paul ' s Hospital Millennium Medical College — A retrospective cohort study. 2022;1–12. Available from: http://dx.doi.org/10.1371/journal.pone.0275204

11. Ayalew MB. Mortality and Its Predictors among HIV Infected Patients Taking Antiretroviral Treatment in Ethiopia : 2017;2017(in 2005).

12. Derseh BT, Shewayerga B, Mekuria AD, Basha EA. Virological treatment failure among adult HIV/ AIDS patients from selected hospitals of North Shoa Zone, Amhara region, Ethiopia. Infect Drug Resist. 2020;13:4417–25.

13. Id SZ, Tesema T, Reshad M, Abebe E. Determinants of first-line antiretroviral treatment failure among adult patients on treatment in Mettu Karl Specialized Hospital , South West Ethiopia ; a case control study. 2021;183:1–13. Available from:

http://dx.doi.org/10.1371/journal.pone.0258930

14. FMOH. Ethiopian Health Sector Transformation Plan.2015/16 - 2019/20. Fed Democr Repub Ethiop Minist Heal. 2015;20(May):50.

15. Treatmentcare HI V. HIV TREATMENT AND CARE WHAT ' S NEW IN TREATMENT MONITORING : VIRAL LOAD AND CD4 TESTING. 2017;(July).

16. Samizi FG, Panga OD, Malugu SS, Gitige CG, Mmbaga EJ. Rate and predictors of HIV virological failure among adults on first-line antiretroviral treatment in Dar Es Salaam , Tanzania.

17. Mulisa D, Nursing H. First-line virologic-based ART treatment failure and associated factors among adult HIV Positives in Southwest Shoa , Central. 2022;21:1–10.

18. Atnafu GT. Incidence and Predictors of Viral Load Suppression After Enhanced Adherence Counseling Among HIV-Positive Adults in West Gojjam Zone , Amhara. 2022;(December 2021).

19. Diress G, Dagne S, Alemnew B, Adane S, Addisu A. Viral Load Suppression after Enhanced Adherence Counseling and Its Predictors among High Viral Load HIV Seropositive People in North Wollo Zone Public Hospitals, Northeast Ethiopia, 2019: Retrospective Cohort Study. AIDS Res Treat. 2020;2020.

20. Endebu T, Deksisa A, Moges T, Kisi T, Ensermu T. Incidence of Virological Failure and Associated Factors among Adult HIV-Positive Patients on First Line Antiretroviral Therapy Regimen , Central Ethiopia. 2018;4(2):44–51.

21. Emagnu A, Abay Z, Bulti AB, Animut Y. Determinants of Virologic Failure among Adult HIV Patients on First-Line Antiretroviral Therapy at Waghimra Zone , Northern Ethiopia : A Case-Control Study. 2020;2020.

22. Karade SK, Ghate M V., Chaturbhuj DN, Kadam DB, Shankar S, Gaikwad N, et al. Cross-sectional study of virological failure and multinucleoside reverse transcriptase inhibitor resistance at 12 months of antiretroviral therapy in Western India. Med (United States). 2016;95(37).

23. Care P. Prevalence and Predictors of Virological Failure Among Adults Living with HIV in South Wollo Zone , Northeast Ethiopia : A Retrospective Cohort Study. 2020;393–402.

24. Desalegn M, Seyoum D, Tola EK, Gayesa RT. Determinants of first-line antiretroviral treatment failure among adult HIV patients at Nekemte Specialized Hospital , Western Ethiopia : Unmatched case-control study. 2021;

25. Ndembi N, Ibrahim FM, Tola M, Jumare J, Aliyu A, Alabi P, et al. Predictors of first‐line antiretroviral therapy failure among adults and adolescents living with HIV / AIDS in a large prevention and treatment program in Nigeria. AIDS Res Ther [Internet]. 2020;1–11. Available from: https://doi.org/10.1186/s12981-020-00317-9

26. Ahmed M, Merga H, Jarso H. Predictors of virological treatment failure among adult HIV patients on first-line antiretroviral therapy in Woldia and Dessie hospitals , Northeast Ethiopia : a case-control study. 2019;1–7.

27. Jobanputra K, Parker LA, Azih C, Okello V, Maphalala G, Kershberger B, et al. Factors associated with virological failure and suppression after enhanced adherence counselling, in children, adolescents and adults on antiretroviral therapy for HIV in Swaziland. PLoS One. 2015;10(2):1–12.

28. Bisetegn G, Arefaynie M, Mohammed A, Fentaw Z, Muche A, Dewau R, et al. Predictors of virological failure after adherence-enhancement counseling among first-line adults living with HIV/AIDS in Kombolcha town, northeast Ethiopia. HIV/AIDS - Res Palliat Care. 2021;13:91–7.

29. Moosa A, Gengiah TN, Lewis L, Naidoo K. Long-term adherence to antiretroviral therapy in a South African adult patient cohort : a retrospective study. 2019;1–12.

30. Article O. Prevalence and Risk Factors of First Line Antiretroviral Therapy Failure Amongst Adult HIV Patients at a Nigerian Teaching Hospital : A 10 Year Retrospective. 2020;(6):13–7.

31. Abebe H, Shumet S, Nassir Z, Agidew M, Abebaw D. Prevalence of Depressive Symptoms and Associated Factors among HIV-Positive Youth Attending ART Follow-Up in Addis Ababa , Ethiopia. 2019;2019.

32. Semvua SK, Orrell C, Mmbaga BT, Semvua H, Bartlett JA, Boulle AA. Predictors of non-

adherence to antiretroviral therapy among HIV infected patients in northern Tanzania. 2017;1–17.

33. Desta AA, Woldearegay TW, Futwi N, Gebrehiwot GT, Gebru GG, Berhe AA, et al. HIV virological non-suppression and factors associated with non-suppression among adolescents and adults on antiretroviral therapy in northern Ethiopia : a retrospective study. 2020;1–10.

34. Haile D, Takele A, Gashaw K, Demelash H, Nigatu D. Predictors of Treatment Failure among Adult Antiretroviral Treatment (ART) Clients in Bale Zone Hospitals , South Eastern Ethiopia. 2016;1–14.

35. Letang E, Ellis J, Naidoo K, Casas EC, Sánchez P, Hassan-moosa R, et al. Article in press. 2020;(xx).

36. Sisay C, Bekele A, Sisay A, Mekonen H, Terfa K, Melese D, et al. Incidence and Predictors of Anti-Retroviral Treatment (ART) Failure among Adults Receiving HIV Care at Zewditu Memorial Hospital, Addis Ababa, Ethiopia. J AIDS Clin Res. 2017;8(12).

37. Rabkin JG. HIV and Depression : 2008 Review and Update. 2008;

38. Yuan D, Liu M, Jia P, Li Y, Huang Y, Ye L, et al. Prevalence and determinants of virological failure , genetic diversity and drug resistance among people living with HIV in a minority area in China : a population- based study. 2020;1–10.

11 APPENDIX

information sheet and consent form

Information sheet and consent form

Title of the proposal

Assessment of risk factors for HIV virologic treatment failure among adult patients on first line ART at public hospitals in Addis Ababa, Ethiopia.

Duration of research project

December to March 2021.

Principal investigator

Mrs. Tizita Terefe

Introduction

The information sheet and informed consent form are used to explain the duty of the head of study hospitals to get their permission to conduct this study in the hospitals. The research team includes the principal investigator, data collectors and two advisors.

Purpose of the proposal

To assess risk factors for HIV virologic treatment failure among adult patients on first-line ART at public hospitals in Addis Ababa.

Benefits

Knowing magnitude and factors associated with virologic treatment failure will help to identify those patients at higher risk of developing failure earlier. Appropriate measures on patients at risk will be taken during their follow-up to try and avoid development of virologic treatment failure.

Risk

Since the study will be reviewing patients charts for information there will only be minimal risk to patient`s.

Confidentiality

Information will be reviewed by data clerks in the hospital to protect subjects' confidentiality and there will also be no negative consequences on patient`s treatment. Patient`s name or any other identifying information will not be recorded on the questionnaire. All information taken from the chart will only be revealed to principal investigator, kept in a safe place and it will only be used for the study purpose.

Person to contact

This research project will be reviewed and approved by the ethical committee of Addis Ababa University College of Health Sciences School of Public Health. If you have any question, you can contact the principal investigator and you can ask at any time you want.

Name- Tizita Terefe

Tel.no-0962399361/0938552525

የ ጥናቱ ሚጃ እና የ ስምማ ት ቅፅ

የ ጥናቱ ርእስ

በአዲስ አበባ ከተማ ወስጥ የ ሚ ኙ የ መንግስት ሆስፒታሎች ወስጥ የ መጀመሪያ ደረጃ የ ፀረ ኤች አይ ቪ ኤድስ ህክምና መድሀኒ ት በ ሚወስዱ አዋቂ ታካሚዎች ላይ የ ሚከሰት ቫይረሳዊ የ ህክምና አለመሳካት መንስኤ የ ሆኑ ምክንያቶች ላይ የ ሚደረግ ግምገማ ፡

ጥናቱ የ ሚወስደውጊዜ

ከታህሳስ እስከ መጋቢት 2014 ዓ.ም.

የ ጥናቱ ዋና አጥኚ

ወ/ሮ ትዝታ ተረፈ

መግለጫ

የ ጥናቱ መጀ እና የ ጥናቱ የ ስምምነ ት ማጠየ ቂያ የ ተዘ ጋጀውጥናቱ የ ሚከሄድባቸውሆስፒታሎች ጥናቱን ለማከሄድ ፍቃዳቸወን እንዲሰጡነ ው፡ ፡ ጥናቱን የ ሚያ ካሂዱ አባላት ዋና አጥኚዋ ሁለት የ ጥናቱ አማካሪዎች እና የ ጥናቱ መጀ ሰብባቢዎች ና ቸው፡ ፡

የ ጥናቱ ዓላማ

በአዲስ አበባ ከተማወስጥ የ ሚ ኙ የ መንግስት ሆስፒታሎች ወስጥ የ መጀመሪያ ደረጃ የ ፀረ ኤች አይ ቪ ኤድስ ህክምና መድሀኒት በሚወስዱ ታካሚዎች ላይ የ ሚከሰት ቫይረሳዊ የ ህክምና አለመሳካት መንስኤ የ ሆኑ ምክንያቶችን ለመ ምረ ምር ፡ ፡

የ ጥናቱ ጥቅሞች

የ መጀመሪያ ደረጃ የ ፀረ ኤች አይ ቪ ኤድስ ህክምና መድሀኒት በሚወስዱ አዋቂ ታካሚዎች ላይ የ ሚከሰት ቫይረሳዊ የ ህክምና አለመሳካት ጋር የ ተዛመዱ ምክንያቶች አስቀድሞ ማወቅ፤ ቫይረሳዊ የ ህክምና ወድቀትን የ መያዝ ከፍተኛ ተጋላጭነ ት ያላቸወን ታካሚዎች የ ህክምና ውአለመሳካት ሳይከሰት ለመላየ ት ይረዳል፡ ፡ የ ቫይሮሎጂካል ህክምና ወድቀት የ መከሰት ጠጋላጭነ ት ላይ ላሉ ታካሚዎች ወድቀቱ እንዳይከሰት አስፈላጊወን ህክምና ለመከጠት ይረዳል፡ ፡

በጥናቱ ሊከሰቱ የ ሚቻሉ አደጋዎች

ጥናቱ መጀዎችን ከታካሚዎች የ ህክምና ሰነ ድ ስለሚበስብ ለታካሚዎች አነ ስተኛ አደጋ ብቻ ይኖረዋል፡ ፡

ሚስጥራዊነ ትን መጠበቅ

የ ታካሚዎችን ሚስጥራዊነ ት ለመጠበቅ በሆስፒታሉ ወስት ባሉ የ ሚጀ ፀሀፊዎች(Data Clercks) መጀውይሰበሰባል በመሆኑም በታካሚውህክምና ላይ ምንምአይነ ት አሉታዊ ተፅ ኖ አይኖረወም፡ ፡ የ ታካሚዎች ስም ወይም ማንኛወም የ ታካሚዎችን ማንነ ት የ ሚለዩ መጀዎች በመጀ መነ ብሰቢያ መጠይቁ ላይ አይመዘገቡም፡ ፡

ከታካሚውሰነ ድ የ ተወሰደውመጀ ሁሉ ለዋና አጥኚውብቻ ይገለፃል፤ በአስተማማን ቦታ ይቀመጥና ለጥናቱ አላማብቻ ጥቅምላይ ይወላል፡ ፡

ይህ የ ምርምር ፕሮጀክት በአዲስ አበባ ዩኒቨርስቲ ጠፍ ስይንስ ኮሌጅ በማህሚሰብ ጠፍ አጠባበቅ ትምህርት ቤት ስነ ምግባር ኮሜቴ ተገ ምግሞ ይፀ ድቃል፡ ፡

ስለ ጥናቱ መጀ ለመጠየ ቅ

በጥናቱ ላይ ማንኛወም ጥያቄ ካለኖት የ ጥናቱን ዋና አጥኚ በማንኛወም ሰዓት መጠየ ቅ ይችላሉ፡ ፡

የ ጥናቱ ዋና አጥኚ- ወ/ሮ ትዝታ ተረፈ

ስልክ ቁጥር-0962399361/0938552525

Data collection questionnaire

Questionnaire for a study to assess risk factors for HIV virologic treatment failure among adult patients on first line ART at public hospitals in Addis Ababa.		
Questionnaire code _____ Data collection date __/__/____(E.C.)		
	Section 1. Socio-Demographic characteristics	
101.	Age of the patient (in completed years)	_____
102.	Gender of the patient	☐ M ☐ F
103.	Marital status of the patient	☐ Single ☐ Married ☐ Divorced ☐ widowed
104.	Employment status	☐ self employed ☐employed

		☐ housewife ☐ student
105.	Educational status of the patient	☐ can not read and write ☐ Primary education ☐ Secondary education ☐ Higher education
	Section 3. Clinical characteristics	
201.	Recent Body mass index (wt./ht²) (Body mass index in the last visit of the patient during study period)	_____
202.	Baseline CD4 count of the patient when started ART(cells/mm^3)	_____
203.	Recent CD4 count of the patient in the past 6 months of study period(cells/mm^3)	_____
204.	WHO clinical stage of the patient when started ART(baseline)	☐ Stage 1 ☐ Stage 2 ☐ Stage 3 ☐ Stage 4
205.	WHO treatment stage in the last visit of the patient during study period(current)	☐ T Stage 1 ☐ T Stage 2 ☐ T Stage 3 ☐ T Stage 4
207.	ART regimen taken by the patient during study period (using regimen code)	☐1h ☐ 1e ☐ 1f ☐ 1g ☐ 1c ☐ 1j ☐ 1d
208.	ART regimen taken by the patient when patient first starts ART (using regimen code)	☐1h ☐ 1e ☐ 1f ☐ 1g ☐ 1c ☐ 1j ☐ 1d
209.	Took TPT	☐ YES ☐ NO

210.	History of tuberculosis treatment in the last six months during study period	☐ YES ☐ NO ☐ NA
211.	last functional status of the patient during the study period(in competed months)	☐ Working ☐ Ambulatory ☐ Bedridden
212.	Months on ART	_____
	Section 4. Adherence related characteristics	
301.	Last Adherence status of the patient during the study period	☐ GOOD ☐ FAIR ☐ POOR
302.	Discontinuation of ART ≥30 days in the past 3 months by the patient during the study period	☐ YES ☐ NO ☐ NA