ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES,

SCHOOL OF PUBLIC HEALTH

VIRAL LOAD SUPPRESSION AND ASSOCIATED FACTORS AMONG HIV/AIDS PATIENTS ON ART IN ADDIS ABABA, ETHIOPIA 2021.

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A THESIS SUBMITED TO ADDIS ABABA UNIVERSITY, COLLAGE OF HEALTH SCIENCES, SCHOOL OF PUBLIC HEALTH IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS IN PUBLIC HEALTH (GENERAL)

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APPROVED BY THE EXAMINING BOARD

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Acronyms and Abbreviations

AAU: Addis Ababa University

AIDS: Acquired Immuno Deficiency Syndrome

BMI: Body Mass Index

DHS: Demographic and health survey

DTG: Deltogavire

EFV: Efaviranz

HIV: Human Immuno Deficiency virus

KP: Key Population

NVP: Neverapine

PC: Pill Count

PLHIV: People live with Human Immuno Deficiency virus

PP: Priority Population

SNNP: South Nation Nationalities and People

SSA: Sub Saharan Africa

START: Strategic timing of antiretroviral therapy

TDF: Tenofovire

UNAIDS: United Nations Program on HIV/AIDS

VAS: Visual analogy scale

VLS: Viral Load Suppression

WHO: World Health Organization

3TC: Lamivudine

Abstract

Background: HIV continues to have a major impact on public health globally with an estimated 36.9 million people living with HIV (PLHIV) including 1.8 million new infections in 2017.As 2017 national guidelines for comprehensive HIV prevention, care and treatment of Ethiopia, all people living with HIV are eligible for ART irrespective of their CD4 count and clinical stage. Little is known about the viral load suppression of clients who initiate ART irrespective of their CD4 count and clinical stage in Addis Ababa. The aim of this study is to assess the viral load suppression of rapid ART initiation of confirmed HIV positive client's and factors associated with their outcome.

Objectives: To assess the viral load suppression of rapidly initiated ART clients compared with not rapid ART initiated clients and its associated factors at public health facilities of Kirkos s/city, Addis Ababa, Ethiopia in 2021.

Methods: A retrospective cohort study was conducted among 356 HIV/AIDS positive patients selected from nine public health facilities of kirkos sub-city in Addis City from July to August /2020. The main exposure variable is Rapid ART initiation and the main outcome variable is the viral load suppression. The data were entered and cleaned using EPI data version 3.1 and analyzed with SPSS version 25. Bivariate and multivariable logistic regression analyses were employed to know the factors that affect the viral load suppression of clients who start ART by their category.

Result: This study Clients who start ART rapidly were 4.5 times more likely to have viral load suppression when compared with not rapid ART started clients with p-value 0.008[AOR 4.46 (95% CI= (1.48-13.42)].Clients who have primary education were almost 13 times [AOR = 12.88, (95% CI= 2.90-57.12)] more likely to have viral load suppression compared with clients who do not educated. Clients who have poor drug adherence were less likely to have viral load suppression with p-value of <0.001[AOR 0.00(95% CI=0.00-0.02)] compared with clients who have good drug adherence.

Conclusion: This study shows rapid ART initiation has good viral load suppression than not rapid ART initiation. To get viral load suppression clients adherence to ART is a crucial part.

1. Introduction

1.1. Background of the study

HIV continues to have a major impact on public health globally with an estimated 36.9 million people living with HIV including 1.8 million new infections in 2017.It remains one of the biggest contributors to mortality and morbidity in the world with most deaths occurring in the Sub-Saharan Africa(1).Beginning in 2013, the Coordinating Board of the Joint United Nations Program on HIV/AIDS (UNAIDS) set targets with the goal of ending the AIDS epidemic globally(2).

Global HIV Prevention Coalition selects 25 countries with the highest numbers of new HIV infections. Of these, 17 are African countries, including Ethiopia(3)(3)(3)(3)(3)(3). The situation of HIV in Ethiopia continues to be characterized with a low-intensity, mixed epidemic with significant heterogeneity across geographic areas and defined by independent self-sustaining HIV transmission streams within Key and Priority Populations and in pockets of the general population. Per the 2016 DHS estimate, the prevalence HIV in adult is estimated to be 0.9%. There is prevalence variation by region (4.8% in Gambella, 3.4% in Addis Ababa, and 0.4% in SNNP). The overall PLHIV burden has decreased significantly from time to time(4).In 2017, an estimated 613,000 people were living with HIV, of whom 62% female. Three-fourths (74%) of PLHIV are from Amhara, Oromia, and Addis Ababa(3).

To control this epidemic in collaboration with all stakeholder's and national government globally, WHO introduces different strategies to strengthen HIV/AIDS prevention and control program. Of these strategies, the 90-90-90 strategy was introduced in 2014, laying out an ambitious worldwide target of 90% of all PLHIV knowing their status, 90% of these PLHIV receiving sustained antiretroviral therapy (ART), and 90% of all PLHIV on ART achieving durable viral suppression by 2020(2). In 2017, despite freely available treatment for HIV/AIDS over the past decade, only (66.0%) of people living with HIV in the eastern and southern part of SSA were on treatment (1).

The government of Ethiopia adopted the goal to attain the three 90s targets on the development of the current HIV National Strategic Plan (3)

Over the past several years, studies have demonstrated clear benefits for treating PLHIV early in disease progression.2013 WHO treatment guidelines for starting HIV-positive people on antiretroviral therapy (ART) were CD4< = 500 cells/µl and for pregnant women to start ART regardless of their CD4 cell count. In 2015 the WHO guidelines changed to initiate ART for all HIV-positive clients irrespective of their CD4 cell count and WHO staging(1). This shown that immediate initiation of ART could contribute to epidemic control, which prompting the launch of the World Health Organization *Treat All(*"test and treat" approach) guidelines in 2015(5)**.** This is the other strategy of the World Health Organization (WHO).

Ethiopia also adopts the treat all approach on 2017 national guidelines, all people living with HIV are eligible for ART irrespective of their CD4 count and clinical stage and early enrolment in care uses as an opportunity for close clinical and laboratory monitoring, early assessment for opportunistic infection, co-morbidities and timely screening and management of OIs(6).

1.2. Statement of the problem

To reduce morbidity and mortality in all patients with HIV early initiation of ART is important. Based on clients clinical assessment rapid ART initiation should be offered to all people with a confirmed HIV result if they don't have any contraindication to start the treatment. The WHO defines rapid initiation as starting ART within seven days of confirmed HIV diagnosis(7).

Two randomized controlled trials done by Southern African, rapid ART initiated clients don't have adherence problem and they don't have adverse events. in both trials in the immediate arms high proportion of patients achieving HIV viral suppression seen (8, 9).On the other hand A study conducted in Nigeria, there is lower suppression among Test and Treat patients compared to previously diagnosed patients at 12 months(2)**.**

A study done in Mozambique, for newly diagnosed clients under the Test and Treat policy they found that already established barriers to care remain a problem; barriers for healthy clients where being healthy makes it difficult for clients to accept a positive status or

treatment initiation. By both clients and health care providers mentioned the dominant barriers to initiate ART rapidly are feeling healthy; denial of the positive HIV result; fear of ART adverse events; poor knowledge about the medication and fear of disclosure of the result for others and lack of partner involvement due to stigma and discrimination.(12)

Currently all health facilities in Addis Ababa with ART clinic has implementing test and treat strategy starting from 2017 irrespective of their client CD4 count and clinical staging and start ART rapidly for HIV positive clients. But there is complain of that this strategy can increase the number of lost cases, decrease clients adherence which might lead to poor viral load suppression.

By considering the contradiction of the result between these different findings this study was designed to assess viral load suppression of rapid ART initiated clients in comparison with not rapid ART initiated clients and associated factors. And also little is known about the viral load suppression of clients who initiate ART irrespective of their CD4 count and clinical stage in Addis Ababa. Identifying the real factors could help to resolve the problem related to high viral load.

1.3. Significance of the Study

This study was address the effectiveness (decrease viral load) of clients who start ART rapidly when compared with clients who didn't start ART rapidly. It also identifies factors associated with viral load suppression.

The study will benefit as an input for the health system which time is appropriate to start ART for HIV positive clients by comparing the two groups regarding to their outcome. It will serve as future reference for researchers on the area since little is done on the area on this topic

2. Literature Review

Over the last two decades the question of when to start antiretroviral therapy (ART) in people living with HIV (PLHIV) has been a major focus of research. Following that the results of two large randomized control trials demonstrating a clinical benefit to starting ART at any $CD4^+$ cell count and at any WHO stage, as soon as HIV diagnosis is confirmed ,all clients should start ART. Globally there has been a rapid shift in guidelines toward adopting a policy of treating all PLHIV (10)**.**

More recent attention has focused on the question of after confirmed HIV diagnosis how quickly ART should be started. In the early years to make the clients more adherent to the care multiple counselling sessions were prepared before initiation of ART and the other reason to delay to start the treatment was clients response to HIV, limited resources and until the client fulfils the illegibility criteria PLHIV underwent multiple counselling that could last several weeks or months before the start of the treatment. But in 'treat all' era, and several national guidelines in different countries have recently revised to recommend rapid ART initiation for all illegible clients(10)**.**

A Randomized controlled trials done in Southern Africa, there are two main concerns about ART initiation with CD4 counts > 500 cells/μL. The First one is the benefit to start ART with high CD4 count less than the risk of adverse events. Secondly, in asymptomatic patients adherence to care could be lower. In both START and TEMPRANO trials, rapid ART initiated clients don't have adherence problem and they don't have adverse events. in both trials in the immediate arms high proportion of patients achieving HIV viral suppression(8).

A review conducted by Mateo-Urdiales A, and et.al indicates Rapid ART increases the probability of individuals being virally suppressed (87%) after 12 months.(11) And a report from systematic review shows, four randomized controlled trials provided data on the effect of rapid ART initiation for all illegible HIV positive clients on clinical outcomes. It shows high-to-moderate quality evidence of benefit with respect to all clinical outcomes assessed, including evidence that rapid ART initiation increased viral load suppression and retention in care at 12 months compared with delayed initiation of the medication(10).

A study conducted in Nigeria shows, there was no evidence is obtained in viral load suppression between rapid ART initiated patients and previously enrolled patients at six months and lower suppression among rapid ART initiated patients compared to previously diagnosed patients at 12 months using the WHO-recommended viral threshold of 1,000copies/mL(2)**.**

A study done in Mozambique, for newly diagnosed clients under the Test and Treat policy they found that already established barriers to care remain a problem; barriers for healthy clients where being healthy makes it difficult for clients to accept a positive status or treatment initiation. By both clients and health care providers mentioned the main barriers to initiate ART rapidly are feeling healthy; denial of the positive HIV result; fear of ART adverse events; poor knowledge about the medication and fear of disclosure of the result for others and lack of partner involvement due to stigma and discrimination(12).

A study done in South Africa states that to get better viral suppression, clients adherence to the care has a great effect. Clients adherence is measured using pill counts and visual analogy scale at each scheduled visit to the clinic. In this study 98% individuals who have ≥95% adherence achieved virological suppression at 12 months compared to 91% in those with <95% adherence. Similar patterns were seen with virological suppression at six months(13).

A study conducted in Taiwan, rapid ART initiated clients had a higher rate of engagement in care and a lower rate of LTFU at 12 months after confirmed HIV diagnosis compared with patients without rapid ART initiation.(14) And a randomized Controlled Trial done in South Africa shows that, the number lost from follow up after initiation the ART was higher in clients who start ART rapidly than the standard arm(15). And other study done in primary clinic in Khayelitsha, South Africa, clients have potential risk of increased loss to follow up immediately after ART initiation, if patients are uncomfortable with starting the treatment quickly or are insufficiently prepared to start the treatment but they may low losses to care prior to ART initiation (7).

A study done on Thai youth living with HIV client's with age group of 20 to 24 years who enrolled in care were less likely to start ART within one month than client's age group of

15 to 19 years who enrolled. When we compare the timing to start ART initiation by sex, female clients had higher odds of starting ART rapidly than males. Patients with history of opportunistic infection were less likely to start ART within one month than those without history.(16)

A study done in East Shewa zone, Oromiya, Ethiopia, Baseline Mid upper arm circumference for evaluation of the patient's nutritional status don't show association with a decrease in viral load suppression. Clients Educational status, MUAC, BMI and BTB has no association with viral load result. BMI affected the survival time of patients. higher viral replication was observed in clients with BMI category <18.5 kg/m2.There is no association between obesity and client viral load result(17)

3. Conceptual Framework

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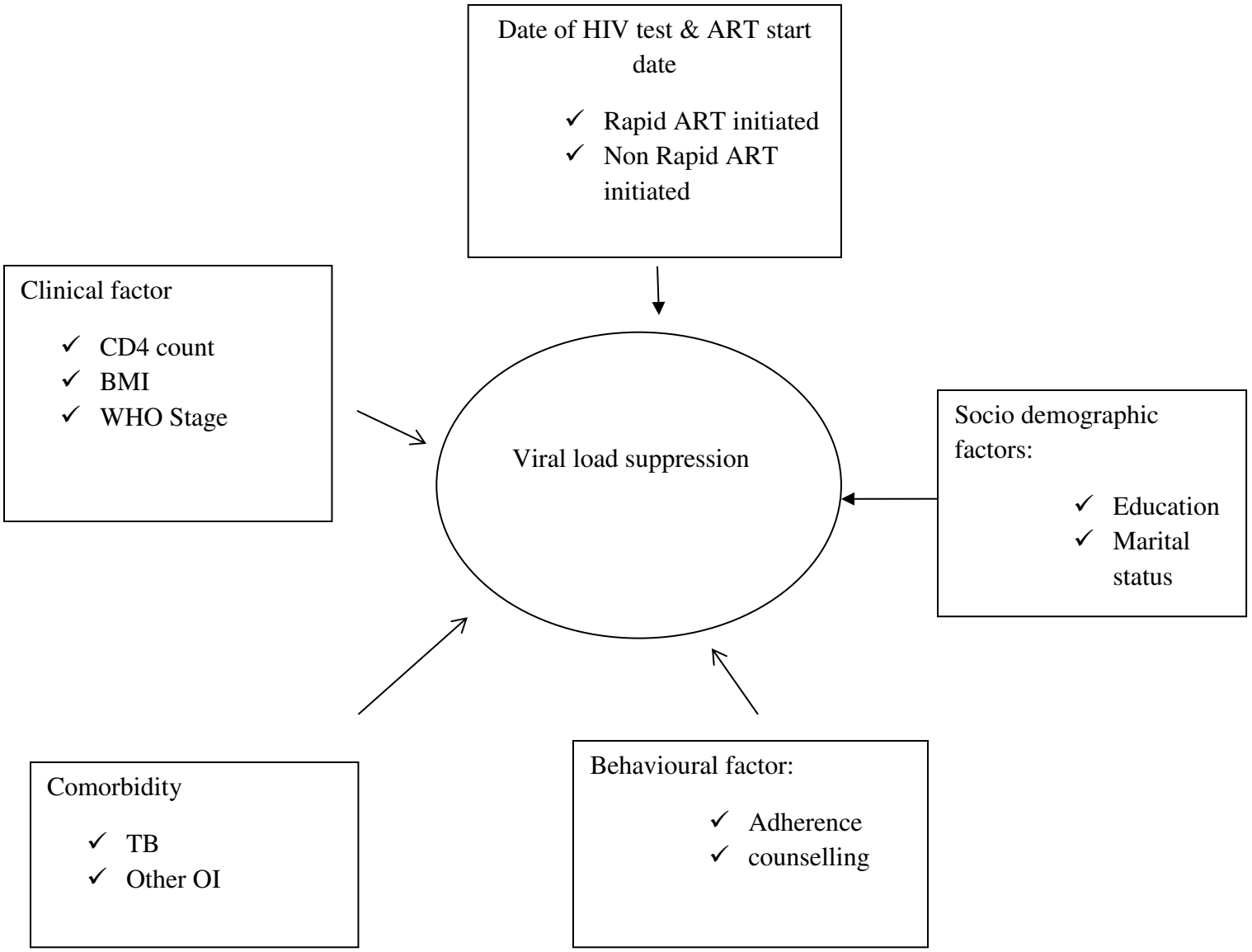

Figure 3-1 The conceptual framework for this study is constructed based on the factors that influence the viral load suppression of HIV positive clients that are indicated in the literature part and by adopting National HIV consolidated guideline.

4. Objective

4.1. General Objective

- To assess the viral load suppression among rapid ART initiated HIV positive clients compared with not start ART rapidly and its associated factors at public health facilities of Kirkos s/city, Addis Ababa, Ethiopia in 2021 G.C.

4.2. Specific Objective

- To assess viral load suppression of HIV positive clients who initiated ART rapidly.
- To assess viral load suppression of HIV positive clients who initiated ART not rapidly.
- To determine factor associated with clients viral load suppression.

5. Methods

5.1 Study Area and Period

This study was conducted at public health facilities of kirkos sub-city in Addis Ababa, Ethiopia. There were ten sub-cities under the Addis Ababa region. From sub-cities, Kirkos sub-city was selected by purposive sampling method because Kirkos sub-city is high load in HIV positive clients when compared to other sub-cities. It has also Zewditu memorial hospital under the sub-city which has more than 7000 clients under it. There are 8 public health centers, 2 public hospitals, 55 private clinics and 3 private hospitals under the sub cities. From these, all public health centers and hospitals give ART service and 3 private hospitals and 2 clinics give the service. Under the sub-city, in public health facilities there were 12,652 current on ART clients up to June/2019.Of this 727 clients start ART in one year from July 2018- June2019. One health center was excluded from the study because it was new for ART service. The study period was from July to August /2020.

Figure 5-1 Map of Addis Ababa City Administration (Source: - Addis Ababa City Administration Website Http://Www.Addisababa.Gov.Et/Es/Web/Guest/City-Map)

5.2 Study Design

A retrospective cohort study was conducted at kirkos sub city public health facilities (health centers and hospitals) from July to August /2020.

5.3 Source Population

The source population of this study was all adult clients who were on ART follow up in kirkos.

5.4 Study Population

The study populations consisted of two groups of adult clients. The first group includes newly identified HIV-positive clients from July 2018 to June 2019 who initiated ART within one week of diagnosis irrespective of clinical or immunological status (rapid ART initiated clients). The second group were HIV-positive clients from July 2018 to June 2019 enrolled in care but didn't start ART rapidly. These groups of clients were identified by their date of HIV test and ART start date. Clients who start ART on the same day after knowing their positive result or who initiate ART within one week were taken as rapidly initiated clients. But other than those clients were taken as not initiated ART rapidly. This information was obtained from ART follow up form.

5.5 Eligibility Criteria

5.5.1 Inclusion Criteria

- **For rapidly ART initiated clients**

- Newly diagnosed HIV positive clients from July 2018 to June 2019 who start ART within the same day or within one week
- Clients ≥15 years old
- Clients who have annual viral load result

- **For not rapidly ART initiated clients**

- Newly diagnosed HIV positive clients from July 2018 to June 2019 who start ART after one week.
- Clients ≥15 years old
- Clients who have annual viral load result

5.5.2 Exclusion Criteria

- Children less than 15 years
- Clients who start ART before July 2018 and after June 2019
- Pregnant mothers
- Transfer in and out clients
- Clients who don't have annual viral load result
- Clients who are lost from follow up
- Charts that don't have full information

5.6 Sample Size Determination

The sample size was calculated using the concept of logic of double population proportion. Accordingly, we assumed the proportion (p1) to be 91% and p2 was 80% and 95% confidence interval, 5% margin of error. According to results from Ethiopia population-based HIV impact assessment (18). These assumptions are indicated in the following equation designed to carrier out comparison for different groups.

$$n = \frac{\left[Z_{1-\alpha/2}\sqrt{2P(1-P)} + Z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)}\right]^2}{(P_2-P_1)^2}$$

n = Sample size

$z_{\alpha/2}$ = 1.96, which is the upper percentile of the standard normal distribution.

$\mathbf{Z_\beta}$ = 80%

$\mathbf{p_1}$=91---Percent of Exposed with Outcome (clients who start ART rapidly with <1000 viral load)

$\mathbf{p_2}$=80--- Percent of Unexposed with Outcome (clients who start ART not rapidly with <1000 viral load)

It was calculated by using open –epi version 3.

Table 5-1 Sample Size Calculation

Sample Size:X-Sectional, Cohort, & Randomized Clinical Trials

Two-sided significance level(1-alpha):	95
Power(1-beta, % chance of detecting):	80
Ratio of sample size, Unexposed/Exposed:	0.5
Percent of Unexposed with Outcome:	80
Percent of Exposed with Outcome:	91
Odds Ratio:	2.5
Risk/Prevalence Ratio:	1.1
Risk/Prevalence difference:	11

	Kelsey	**Fleiss**	**Fleiss with CC**
Sample Size - Exposed	215	229	255
Sample Size-Nonexposed	108	115	128
Total sample size:	323	344	383

The total sample size was taken the Fleiss with CC method, which is the largest and more representative.

The calculated sample size was 383, but only 356 charts fulfil the inclusion criteria which were 237 for rapid ART initiated clients and 119 for not rapid ART initiated clients. The ratio was taken for 2:1 for rapid and not rapid ART initiated clients.

5.7 Sampling Procedures

A total of 727 clients start ART in one year from July 2018- June2019.The sampling frame was all newly ART initiated clients from July 2018- June2019.Clients that fulfil the inclusion criteria 356 were included on the study for both rapid and not rapid ART initiated clients. The ratio for rapid and not rapid ART initiated clients were 2:1.This was because the number of rapid ART initiation was greater than the standard on that period because of the introduction of rapid ART initiation strategy. All public health centers and hospitals were taken to make more accurate and representative data. Private health facilities were excluded from the study because the charts of HIV positive clients were not found separately as public health facilities.

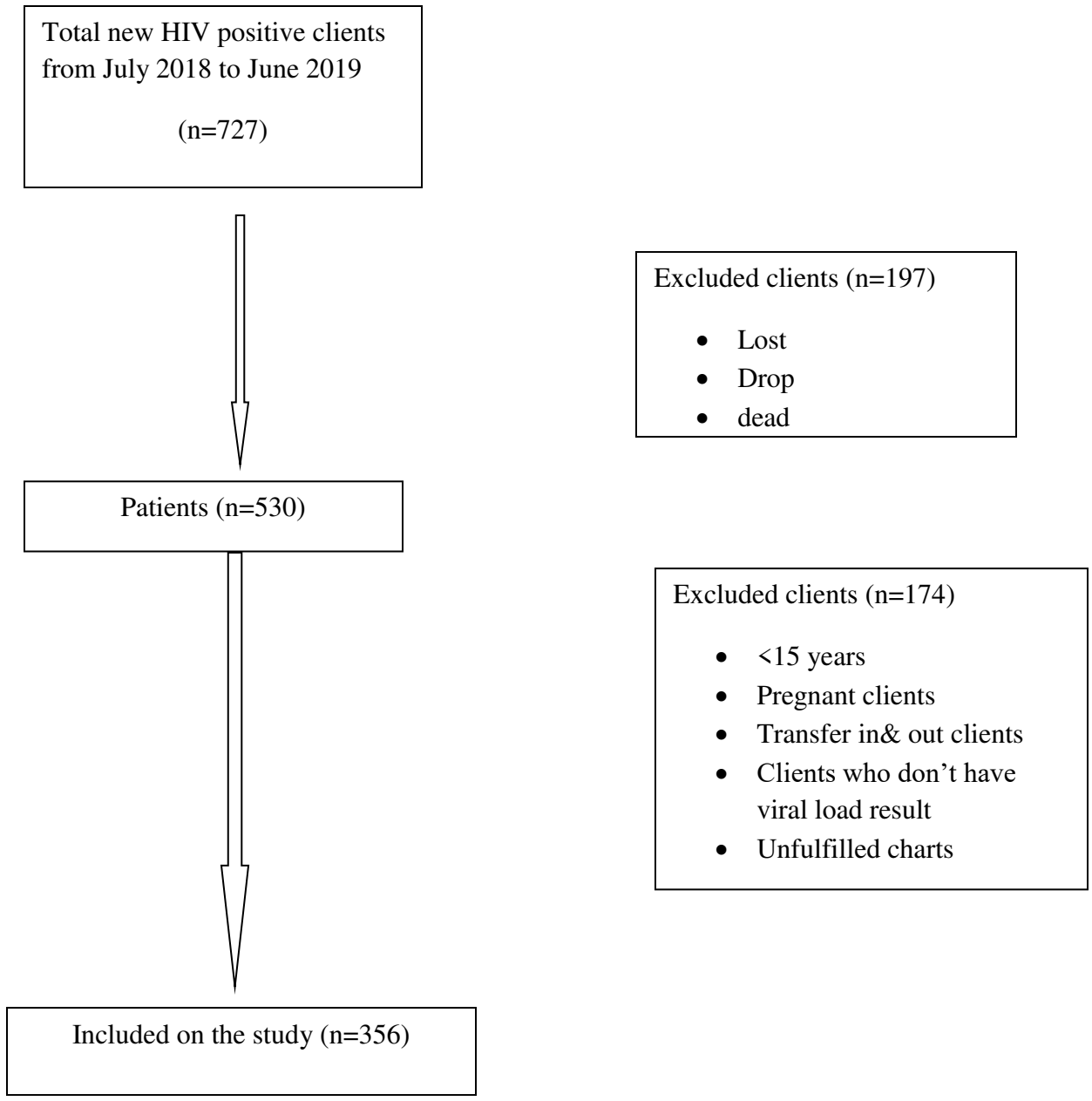

Figure 5-2 Sample Size Tree

Table 5-2 Sample Size by Health Facility

	Efoyeta HC	Meshualekia HC	Ferese Meda HC	Gotera Masale cha HC	How ot Amb a HC	Kaza nchis HC	Kirkos HC	Gandhi Hospit al	Zewditu Memorial General Hospital	Total
New HIV positive clients July 2018to June2019	18	104	35	38	33	76	67	42	314	727
Included on the study	10	54	24	22	18	40	45	33	110	356
Rapid ART initiated	7	36	16	15	12	26	30	22	73	237
Not rapid ART initiated	3	18	8	7	6	14	15	11	37	119

5.8 Study Variable

5.8.1 Exposure Variable/Independent Variables

- Socio demographic factor (Age, Sex, marital status ,educational level occupation)
- Date of HIV test and ART start date (Rapid ART initiation, Not rapid ART initiation)
- BMI
- Patient opportunistic infection
- Patient functional status
- Patient WHO stage
- CD4 cell count
- Adherence
- Disclosure status
- ARV regimen

5.8.2 Outcome Variable/Dependent Variable

- **Viral load result:** Clients who have 12 month Viral load result, the data was taken as if viral load is >1000 copies/mL as high viral load result and if its less than or equal to 1000 copies/mL taken as viral suppression.(6)

5.9 Data Collection Tools and Procedure

The data for the study was collected by 3 data collectors (ART providers) and 2 supervisors (clinical officers) after giving them on job training. It was collected by using pre-tested, structured data abstraction format which have demographic variables, clinical variables including functional status, HIV diagnosis information, ART initiation and subsequent visits, regimen information, laboratory measurements including viral load and CD4 cell count and opportunistic infections. The data abstraction format was prepared in English. The information was collected from patient medical record (demographic variables, clinical variables, HIV diagnosis information, ART initiation and subsequent visits, regimen information, laboratory measurements and opportunistic infections) information which were not obtained on medical records were checked on smart care & other related registration books (ART registration book, viral load registration book, HIV positive tracking registration book) at the sampled facilities.

5.10 Operational Definition

Rapid ART initiation-clients who start ART on the same day or within a week after knowing HIV positive result. (5)

Not Rapidly ART initiation-clients who start ART after a week after knowing their HIV positive result.

Viral suppression- refers to a viral load below the detection threshold using viral assays. Less than or equal to 1000 copies/mL.(6)

High Viral load- refers to when viral load result is greater than 1000 copies/mL.(6)

Lost to follow up-Patients who were lost to care that did not receive any clinical, laboratory or pharmacy services for 1month and more.(5)

Transfer in clients- patients who are referred from other facility and start their care in the sampled health facility. (6)

Transfer out clients- patients who are referred from the sampled health facility to other health facility.(6)

Good adherence- patients who have >95% adherence on their follow-up (number of good adherence/total follow up)*100, it is measured by the number of pills that the client took from the total pills that is prescribed (e.g. from 30 doses <2 doses missed)

Poor adherence - patients who have <95% adherence on their follow- up

5.11 Data Analysis Procedures

Collected data was cleaned for missing values, duplicates, and outliers in the data were checked and entered into the computer software using Epi-data version 3.1.Coding of different variables was also carried out before analysis by using computer software SPSS version 25. Descriptive statistical values such as; frequencies, percentage, mean and standard deviations were used primarily to summarize as well as to describe the data

A binary logistic regression model was used to identify factors associated with the annual viral load result of clients who start ART rapidly and not rapidly. Variables which are clinically important were included in bivariate analysis and entered into multivariable logistic regressions. A multivariable logistic regression model was used to identify factors associated with the annual viral load result of clients. During the analysis p-value and 95%, CI for OR was used in determining the significance of the association. The result was presented in text, table, and graphs.

5.12 Data Quality assurance

All data collectors (ART providers) and supervisors (clinical officers) was trained for two days on the objectives of the study, purposes of the study, logical order of questionnaire, data collection procedures, their roles in the evaluation, best practices for good data quality, the importance of confidentiality and supervision techniques. The data collection instrument was pre-tested and the supervisors were followed and check the way data collectors conduct and cross checkpoints. The collected data were checked daily for completeness and kept in a safe place before analysis. Each questionnaire was coded separately after data collection. Data entry was done carefully after checking each questionnaire filled by the providers. And also data cleaning was done after finalizing data entry to Epi data version 3.1 and exporting to SPSS version 25.

5.13 Ethical Consideration

Ethical clearance for the proposed research was obtained from the Research Ethical Committee (REC) of Addis Ababa University, College of health science, school of public health. Ethical clearance was also be given by Addis Ababa regional health bureau Health Research and Emergency Management Directorate. Letters of support/permission were also received from Addis Ababa Health Bureau and kirkos sub-city. Data was collected from the patient charts, registry logbook, and smart care. The information collected from this research project was kept confidential, it was stored in a file, without a name, but a code number assigned to it and was not be revealed to anyone except the investigator. While this was a document review, a waiver for informed consent was obtained from the data collection facility. The study is important to contribute necessary information for decision-makers and other concerned bodies in the study area and at the national level at large.

5.14 Dissemination of Results

The research paper will be presented to Addis Ababa University College of Health Science, Department of Public Health. An attempt will be made for the publication of the research in a reputable Journal. The hard and soft copy will be available in the library of AAU, Department of Public Health, Addis Ababa Regional health bureau, Sub City Health Office, and selected health facilities.

6. Result

A total of 356 clients charts were reviewed which were registered from July 2018- June 2019 on ART clinic giving a response rate of 93%.From those clients' charts, 237 charts were clients who start ART within a week after knowing their positive result and the rest 119 charts were clients who start ART after a week after knowing their result.

6.1 Socio demographic characteristics

From the reviewed charts for rapid ART initiated clients the number of female clients were 144(60.8%) and number of male clients were 93(39.2%). The mean age of these clients was 36.59(10.1±SD). The majority of clients 214(90.3%) were Christian in their religion. For not rapid ART initiated clients the number of female clients were 68(57.1%) and number of male clients were 51(42.9%). The mean age of these clients was 38.66 (10.6±SD). The majority of clients 103(86.6%) were Christian in their religion.

Of the total rapid ART initiated clients 32(13.5%) clients were not educated and 85(35.9%) of clients were primary educational level. Regarding the marital status 47(19.8%) of clients were single, 117(49.4%) of clients were married and the rest 73(30.8%) of clients were widowed. Of the total clients, 160(67.5%) of clients were employed and 35(14.8%) of clients were not employed. Regarding to the educational status of not rapid ART initiated clients 12(10.1%) clients were not educated and 47(39.8%) of clients were secondary educational level. Of the total clients, 29(24.4%) of clients were single, 49(41.2%) of clients were married and the rest 41(34.5%) of clients were widowed in their marital status. Of the total clients, 85(7.4%) of clients were employed and 13(10.9%) of clients were not employed.

Table 6-1 Socio-Demographic Characteristics of Clients in Kirkos Sub-City by Category, Addis Ababa, Ethiopia, 2021 (N=356)

Variables		ART start category	
		Rapid ART started (N=237)	Not Rapid ART started (N=119)
		Frequency (%)	Frequency (%)
Sex	Male	93(39.2)	51(42.9)
	Female	144(60.8)	68(57.1)
Age	15-34	93(39.2)	43(36.1)
	35-49	123(51.9)	60(50.4)
	>50	21(8.9)	16(13.4)
Religion	Christian	214(90.3)	103(86.6)
	Islam	23(9.7)	16(13.4)
Education	Not Educated	32(13.6)	12(10.1)
	Primary	85(36.2)	36(30.3)
	Secondary	79(33.6)	47(39.5)
	Tertiary	39(16.6)	24(20.2)
marital status	Single	47(19.9)	29(24.4)
	Married	117(49.4)	49(41.2)
	Widowed	73(30.8)	41(34.5)
Occupation	Employed	160(67.5)	85(71.4)
	Not employed	35(14.8)	13(10.9)
	Housewife	30(12.7)	14(11.8)
	Students	12(5.1)	7(5.9)

6.2 Clinical history

Of the total rapid ART initiated clients majority of them were working 223(94.1%) on their functional status. Regarding to WHO stage more than half 202 (85.2%) of clients were with WHO stage one and stage two. 212(89.5%) screen negative for TB and from TB screen negative clients 172(81%) started TB prophylaxis.

Among rapid ART initiated clients 50 (21.1%) had opportunistic infection. Regarding to CD4 cell count 75(31.6%) clients have less than 200cells/mm³ and 41(17.3%) clients have between 350 and 500 cells/mm³. More than half of clients 148(62.4%) took co-trimoxazole preventive therapy. Of the total clients 170(71.7%) clients took 1e (TDF/3TC/EFV) ART regimen. The majority of clients were 196(82.7%) good on their adherence.139 (58.6%) of clients disclosed their result for others.

Of the total not rapid ART initiated clients 111(93.3%) were working on their functional status. Regarding to WHO stage more than half 76 (63.9%) of clients were with WHO stage one and stage two. Of the client initiated not rapid ART, 90(75.6%) screen negative for TB and from TB screen negative clients 74 (82%) started TB prophylaxis. 34(28.6%) had opportunistic infection. Regarding to CD4 cell count 41(34.5%) clients are between 200 and 350 cells/mm³ and 14(11.8%) clients are between 350 and 500 cells/mm³. More than half of clients 66 (55.5%) took co-trimoxazole preventive therapy. Of the total clients 88(73.9%) clients took 1e (TDF/3TC/EFV) ART regimen. The majority of clients were 98(82.4%) good on their adherence. 93(78.2%) of clients disclosed their result for others.

Table 6-2 Clinical History of Clients by Category in Kirkos Sub-City by Category, Addis Ababa, Ethiopia, 2021 (N=356)

Variables		ART start category	
		Rapid ART started (N=237)	Not Rapid ART started (N=119)
		Frequency (%)	Frequency (%)
functional status	Working	223(94.1)	111(93.3)
	Ambulatory	14(5.9)	8(6.7)
WHO stage	Stage 1&2	202(85.2)	76(63.9)
	Stage 3&4	35(14.8)	43(36.1)
TB screening	Positive	25(10.5)	29(24.4)
	Negative	212(89.5)	90(75.6)
TB prophylaxis	Yes	172(72.6)	74(62.2)
	No	65(27.4)	45(37.8)
TB treatment	Yes	21(8.9)	27(22.7)
	No	216(91.1)	92(77.3)
	Total	237(100)	119(100)
OI	Yes	50(21.1)	34(28.6)
	No	187(78.9)	85(71.4)
CD4	<200	75(31.6)	36(30.3)
	201-350	70(29.5)	41(34.5)
	351-500	41(17.3)	14(11.8)
	>500	51(21.5)	28(23.5)
	Yes	148(62.4)	66(55.5)

CPT	No	89(37.6)	53(44.5)
ART drug regimen	1e(TDF/3TC/EFV)	170(71.7)	88(73.9)
	Other(DTG/3TC/EFV)& TDF/3TC/NVP	67(28.3)	31(26.1)
Adherence	Good drug adherence	196(82.7)	98(82.4)
	Poor drug adherence	41(17.3)	21(17.6)
Disclosure status	Disclosed	139(58.6)	93(78.2)
	not disclosed	98(41.4)	26(21.8)

6.3 Clinical outcome

Regarding to viral load result of rapid ART initiated clients 202(85.2%) of them have viral load suppression (≤1000copies/ml) and the rest 35 (14.8%) of clients have high viral load (>1000copies/ml) result.

Of the total not rapid ART initiated clients 95(79.8%) of them have viral load suppression (≤1000copies/ml) and the rest 24 (20.2%) of clients have high viral load (>1000copies/ml) result.

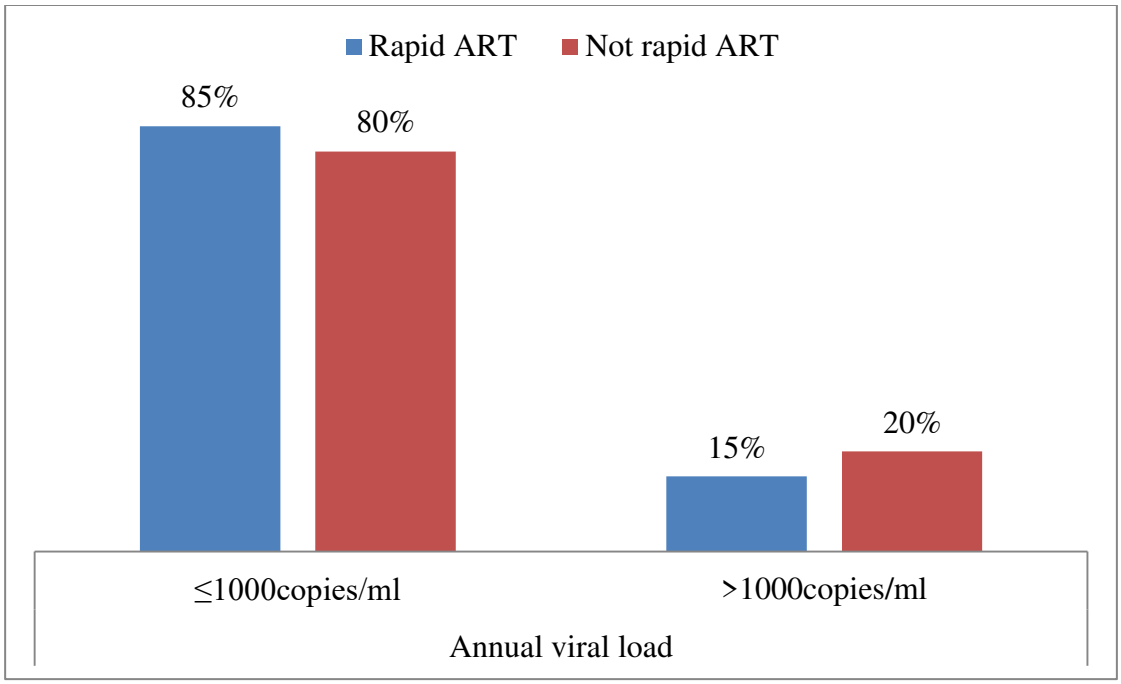

Figure 6-1 Viral Load Result by ART Start Category in Kirkos Sub-City by Category, Addis Ababa, Ethiopia, 2021 (N=356)

6.4 Factors affecting viral load suppression of ART clients

As shown in the table below, important variables that were independently associated with the clients viral load from reviewed charts such as age, sex, educational level, marital status and occupation of clients were identified. Demographic characteristics like age, sex and marital status do not show any significant association with viral load suppression. Clients educational level and occupation shows significant association with the clients' viral load suppression. Based on the analysis timing of ART initiation shows association with clients viral load.

Statistically significant association is observed between rapid and not rapid ART initiated clients. Clients who start ART rapidly were almost 4.5 times more likely to have viral load suppression when compared with not rapid ART started clients with p-value of 0.008[AOR 4.46 (95% CI= (1.48-13.42)]

Clients educational level shows statistically significant association with viral load result with p-value of 0.001 [AOR = 12.88, (95% CI= 2.90-57.12)]. Clients who have primary education have almost 13 times more likely to have viral load suppression compared with clients who do not educated.

Regarding to occupation it shows significant association with viral load result. Clients like students were less likely to have viral load suppression compared with clients who are employed with p-value of 0.01 [AOR = 0.05, (95% CI= (0.00-0.49)].

Clients WHO stage, baseline CD4, functional status, opportunistic infection, CPT uptake, ART regimen and disclosure status do not show association with clients viral load suppression.

Clients adherence shown statistically significant association with viral load suppression. Clients who have poor drug adherence were less likely to have viral load suppression with p-value of <0.001[AOR 0.00(95% CI=0.00-0.02)] compared with clients who have good drug adherence level.

Table 6-3 Bivariate and Multivariable Analysis of Factors Associated with Viral Load suppression in Kirkos Sub City, Addis Ababa, Ethiopia, 2021 (N=356)

		viral load result				
Variables		>1000 copies/ ml	≤1000 copies/ ml	COR CI (95%)	AOR CI (95%)	P-value
Type of ART initiation	Not rapid	24(20.2%)	95(79.8%)	1	1	
	Rapid	35(14.8%)	202(85.2%)	1.45(0.82-2.58)	4.46(1.48-13.42)	0.008*
Age	15-34	23(16.9%)	113(83.1%)	1	1	
	35-49	27(14.8%)	156(85.2%)			0.49

				1.17(0.64-2.15)	1.46(0.49-4.32)	
	>50	9(24.3%)	28(75.7%)	0.63(0.264-1.51)	4.93(0.68-35.74)	0.11
Sex	Male	23(16%)	112(84%)	1	1	
	Female	36(17%)	176(83%)	0.92(0.52-1.64)	1.36(0.39-4.65)	0.62
Marital status	not married	16(21.1%)	60(78.9%)	1	1	
	Married	17(10.2%)	149(89.8%)	2.33(0.10-4.92)	0.48(0.09-2.62)	0.40
	Widowed	26(22.8%)	26(77.2%)	0.90(0.44-0.82)	0.19(0.03-0.99)	0.05
Education	Not Educated	21(47.7%)	23(52.3%)	1	1	
	Primary	12(9.9%)	109(90.1%)	8.29(3.58-19.20)	12.88(2.90-57.12)	0.001*
	Secondary	21(16.7%)	105(83.3%)	4.56(2.14-9.70)	3.55(0.94-13.37)	0.06
	Tertiary	5(7.9%)	58(92.1%)	10.59(3.56-31.44)	5.39(0.87-33.09)	0.06
Occupation	Employed	37(15.1%)	208(84.9%)	1	1	
	Not employed	6(12.5%)	42(87.5%)	1.24(0.49-3.13)	0.61(0.13-2.81)	0.52
	Housewife	10(22.7%)	34(77.3%)	0.60(0.27-1.32)	0.27(0.05-1.38)	0.11
	Students	6(31.6%)	13(68.4%)	0.38(0.13-1.07)	0.05(0.00-0.49)	0.01*
Functional status	Working	54(16%)	283(84%)	1	1	
	Bed ridden	5(26.3%)	14(73.7%)	0.53(0.18-1.54)	0.35(0.04-2.57)	0.30
Stage	Stage 1&2	49(17.6%)	229(82.4%)	1	1	
	Stage 3&4	10(12.8%)	68(87.2%)	1.45(0.70-3.02)	1.23(0.29-5.15)	0.77
Baseline CD4	<200	21(18.9%)	90(81.1%)	1	1	
	200-350	18(16.2%)	93(83.8%)	1.20(0.60-2.41)	3.17(0.91-11.00)	0.06
	350-500	7(12.7%)	48(87.3%)	1.60(0.63-4.03)	4.14(0.56-30.61)	0.16
	>500	13(16.5%)	66(83.5%)	1.18(0.55-2.53)	2.49(0.38-15.98)	0.33

Opportunistic infection	Yes	9(10.7%)	75(89.3%)	1	1	
	No	50(18.4%)	222(81.6%)	0.53(0.25-1.13)	0.34(0.07-1.53)	0.16
CPT	Yes	39(18.2%)	175(81.8%)	1	1	
	No	20(14.1%)	122(85.9%)	1.35(0.75-2.44)	1.08(0.25-4.75)	0.91
ART regimen	TDF/3TC/EFV	50(19.4%)	208(80.6%)	1	1	
	Other (DTG/3TC/EFV)&TDF/3TC/NVP	9(9.2%)	89(90.8%)	2.37(1.12-5.04)	2.36(0.69-8.00)	0.16
Disclosure status	Disclosed	34(14.7%)	198(85.3%)	1	1	
	not disclosed	25(20.2%)	99(79.8%)	0.68(0.38-1.20)	1.04(0.35-3.03)	0.94
Adherence	Good	11(3.8%)	278(96.2%)	1	1	
	Poor	48(71.6%)	19(28.4%)	0.01(0.00-0.03)	0.00(0.00-0.02)	<0.001*

*p-value <0.05

7. Discussion

This study is performed to assess the annual viral load result of clients who start ART within a week and after a week after knowing their HIV positive result and its associated factors.

Regarding viral load suppression, clients who start ART rapidly are almost 4.5 times more likely to have viral load suppression when compared with not rapid ART started clients. This shows similarity with a report from systematic review which shows, rapid ART initiation increased viral suppression at 12 months with high-to-moderate quality evidence (10),and also a review done by Mateo-Urdiales A, and et.al indicates rapid ART increases the probability of individuals virally suppressed(87%) after 12 months(11). whereas a study conducted in Nigeria, there is lower suppression among rapid ART initiated patients compared to previously diagnosed patients at 12 months(2) But as present study shows clients who start ART rapidly were good viral load suppression. This might be because clients who start ART rapidly are relatively have high CD4 cell count and come with good WHO stage when compared to clients who start ART not rapidly, which leads them to have viral load suppression. This shows concordance with a study conducted in Indonesia, high CD4 count at ART initiation was associated with higher likelihood of being a good immune responder (9)

Even though rapid ART initiation has a good viral load suppression, to successfully implement it clients adherence plays a big roll. Adherence of clients should measure by pill count, which is calculated by the number of pills that the client took divided by prescribed pills. But on data collection facilities the adherence of clients is filled by the judgment of health care provider. There is association between clients adherence and viral load suppression. Clients who have good drug adherence have better viral load suppression when compared with clients who have poor drug adherence. This shows that similarity with a study done in South Africa 98% of patients achieved virological suppression with adherence ≥95%, at 12 months compared to 91% in those with <95% adherence(14). This indicates that Clients Adherence to ART has a great effect on viral suppression. To achieve the target to suppress the viral load flexible models of care are needed.

There is association between clients educational status and viral load suppression. Clients who have good educational status are better adherence than clients who do not educated, which shows when clients educational level increases, their suppression of viral load also increases. This might be because of when the level of education increases clients understand thing easily and also they may read more about their status. This will increase their level of adherence and also their viral load. But a study conducted in Ethiopia shows clients educational status do not show association with viral load suppression(17).There is also association between clients occupation and viral load suppression. Clients who are employed were better viral load suppression when compared with clients who are students. This is because of employed clients have their own income so they relatively give better care for their health than students and also they may have no a problem of transportation to go to the health facility to get the care as compared with students.

Clients age, sex, marital status, BMI, functional status, WHO stage, opportunistic infection, ART regimen and disclosure status do not show association with viral load suppression. There was also no significant association found on Educational status, MUAC BMI and BTB with viral load result on a study conducted by Jemal Hassen Ali and Tewodros Getinet Yirtaw .(17)

8. Strength and limitation

Strength

- It's a multi center study which includes health centers and hospitals.

Limitation

- Because of this is a chart review some important variable like partners HIV status, modality of testing (self-initiated or provider initiated), acceptance of the result, symptomatic presentation, sex partners, behavioural history like smoking status, alcohol consumption etc. are missed which are relevant for clients viral load suppression.
- Adherence of clients was filled by health care providers judgment, they don't use the standard way of measurement of adherence.
- Baseline viral load is not included on the study which was better to see the change of the client after initiation of the treatment. It was not included because majority of clients don't have this result.

9. Conclusion

This study shows rapid ART initiation has good viral load suppression than not rapid ART initiation. Even though rapid ART initiation has a good viral load suppression, successful implementation of this program and achieving an ultimate goal needs strict clients adherence.

10. Recommendation

- ✓ MOH
  - o Should work on large scale studies to verify on the timing of initiation of ART.
  - o Should develop strong patient tracing mechanism for lost HIV positive cases
- ✓ AARHB and sub-cities
  - o Should give continuous follow up for care giving facilities.
  - o Should avail necessary materials for virological test
- ✓ Health institutions
  - o Should strongly work on how to increase clients adherence level.
  - o Should ascertain the readiness of a clients before initiation of ART
- ✓ Institutions who are working on HIV prevention and control programs should focus on adherence care and rapid initiation of ART.
- ✓ Clients should start ART as soon as possible and they should adhere to the care

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12. Annexes

12.1 Information and waiver for informed consent

My name is Sosina Mideksa. I am MPH student at Addis Ababa University, College of Medicine and Health Science. I am conducting a study on the Annual viral load result of clients who start ART rapidly and its associated factors at public health facility of kirkos sub city.

The aim of this study is to assess the Annual viral load result of clients who start ART within a week after confirmed positive result compared to clients who don't start ART within a week and its associated factors.

Information will be collected from patient medical record, smart care & other related registration books by ART providers and supervised by program officers from sub city. The information collected from this research project will be kept strictly confidential, it will be stored in a file, without a name, but a code number assigned to it and will not be revealed to anyone except the investigator.

This questionnaire focuses on factors associated with Annual viral load result. The service providing institutions cooperation and willingness is greatly helpful in identifying the clinical outcome of clients who start ART rapidly and who don't start ART rapidly and its associated factors. There is no possible risk associated with taking this information from clients medical records.

While data is collected from patient medical records it's difficult to get informed consent from each individuals on the time of data collection. Therefore I kindly request the institution who are selected for the study to give me their permission to get the data.

I would like to inform you that after completion of the study I will inform you the results finding. If you have questions regarding this study please feel free to contact the principal investigator.

Address of principal investigator:

Sosina Mideksa

Tel: +251-911 193915

E-mail: sosinamidtulu@gmail.com

የሚጃ እና ሚጃ ለማገኘት ፈቃድ ማዘየቂያ ቅፅ

ስሜ ሶስና ሚቅሳ ነዉ፡ በአዲስ አበባ ዩኒቨርሲቲ ጤና ሳይንስ ኮሌጅ ዉስጥ የህብረተሰብ ጤና አጠባበቅ የድህረ ምረቃ ተማሪ ነኝ፡ አሁን ላይ የመመረቂያ ጥናት እየሰራዉ እገኛለዉ፡ የጥናቴ ትኩረት የኤች.አይ.ቪ ቫይረስ በደማቸዉ በተገኘባቸዉ በሳምንት ዉስጥ የፀረ የኤች.አይ.ቪ ቫይረስ መድሀኒት የሚዎስዱ ታካሚዎች እና በሳምንት ዉስጥ የሚጀምዱ ታካሚዎች ያላቸዉ ዉጤት ምን እንደሚመስል እና በተጓዳኝነት ተፅዕኖ የሚደርጉ ነገሮችን በቂርቆስ ክ/ከተማ የጤግስት ጤና ተቋማት ላይ ማጥናት ነዉ፡

የጥናቱ አላማም የኤች.አይ.ቪ ቫይረስ በደማቸዉ በተገኘባቸዉ በሳምንት ዉስጥ የፀረ የኤች.አይ.ቪ ቫይረስ መድሀኒት የሚዎስዱ ታካሚዎች እና በሳምንት ዉስጥ የሚጀምዱ ታካሚዎች ያላቸዉ ዉጤት ምን እንደሚመስል እና በተጓዳኝነት ተፅዕኖ የሚደርጉ ነገሮችን ማፃፀር ነዉ፡

ሚጃዉ የሚበሰበዉ ፀረ የኤች.አይ.ቪ ህክምና ክፍል በሚሩ ባለሙያዎች እንዲሁን ክትትል የሚረገዉ በክ/ከተማዉ ፕሮግራም አስተባባሪዎች ነዉ፡ በመሆኑም የሚሰደዉ ሚጃ የታካሚዎችን ስም ያልያዘ እና ሌሎች ሚጃዎችም በከፍተኛ ምስጢራዊነት የሚጠበቀ ይሆናል፡፡

ማስያቁ በዋናነተ ትኩረት የሚደርገዉ በታካሚዎች ላይ የሚሞከዉን ዉጤት ተፅዕኖ የሚደርጉ ነገሮች ላይ ነዉ፡ የተቋማቱ ቀናነት እና ተባባሪነት በከፍተኛ ሁኔታ መድሃኒታቸዉን ቶሎ የጀመሩትን እና ያልጀመሩትን ታካሚዎች ያላቸዉን ዉጤት እንዲሁም በተጓዳኝ ተፅዕኖ የሚደርጉትን ነገሮች ለማዬት ያስችላል፡፡

የዚህ ጥናት ሚጃ የሚበሰበዉ ከታካሚዎች ካርድ ላይ ሲሆን ሚጃዉ በሚበስጠት ወቅት ታካሚዎችን አግኝቶ ፈቃደኝነታቸዉን ማዘየቅ አስቸጋሪ ነዉ፡ ስለሆነ ም ይህ ሚጃ የሚበሰጠቸዉ ጤና ተቋማት ፈቃደኝነታቸዉን እንዲሰጡኝ በትህትና እጠይቃለዉ፡

በሜጪሻም ይህ ጥናት ሲያልቅ የተደረሰበትን ዉጤት ለሁሉም ጤና ተቋማት አደርሳለዉ፡ ጥናቱን በተመለከተ ማንኛዉም ጥያቄ ካለዎት ከታች ባለዉ አድራሻዬ ሊያገኙኝ ይችላሉ፡

:አድራሻ

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12.2Questionnaire

Tick appropriately

Clients who start ART between July/2018 to June /2019 G.C OR

Hamle/2010 to Sene 2011 E.C

Date	Rapid ART initiated	Not Rapid ART initiated

Part I: socio_ demographic characteristics

1)	Age	_____ years(in complete years)	
2)	Sex	M F	
3)	Religion:	1) Christianity_____ 2) Islam_____ 3) Others(specify)_____	
4)	What is the highest level of education? (write down the level)	1) Not Educated 2) Primary 3) Secondary 4) Tertiary 5) Other	
5)	Marital status?	1) Single ------- 2) Married------ 3) Never married ------ 4) Widowed ------ 5) Divorce ----- 6) Other ----- (specify)……..	
6)	Place of residence?	1) Addis Ababa-------- 2) Outside Addis Ababa ----------	

7)	Client's current occupation? (**tick appropriately)**	1) Student_____ 2) Housewife_____ 3) Daily laborer_____ 4) Business man _____ 5) Government employee_____ 6) Private company employee_____ 7) Driver---------- 8) Jobless---------- 9) Other (specify)_____	

Part II: Date of HIV test and start

1)	Date confirmed HIV/date of retesting done		
2)	Date of ART started	1) Same day after confirmed positive result 2) Within a week after confirmed positive result 3) After a week	

Part III: Clinical history

1)	Clients body mass index(BMI)	1) Not mal nourished 2) Moderate mal nutrition 3) Sever mal nutrition	
2)	Clients functional status	1) Working 2) Ambulatory	

		3) Bedridden	
3)	Clients WHO stage	1) Stage 1 2) Stage 2 3) Stage 3 4) Stage 4	
4)	TB screening	1) Positive 2) Negative	
5)	TB prophylaxis	1) Yes 2) No	
6)	TB treatment	1) Yes 2) No	
7)	Opportunistic infection	1) Yes 2) No	
8)	Base line CD4 cell count	1) <200 cells/µL 2) 200-350 cells/µL 3) 350-500 cells/µL 4) >500 cells/µL 5) Not done	
9)	Co Trimoxazole preventive therapy	1) Yes 2) No	
10)	Nutritional supplement	1) Yes 2) No	
11)	ARV drug regimen	1) 1e()	

		2) 1f() 3) 1j(DTG/3TC/EFV) 4) Other	
12)	Clients adherence level for ARV drug	1) Good ->95% 2) Fair-85-94% 3) Poor-<85%	
13)	Disclosure status of the client	1) Disclosed the result 2) Not disclosed the result	

Part IV: Clinical outcome

1)	Clients annual viral load result	1) ≤1000 copies/mL 2) >1000 copies/mL 3) Not done	
2)	Client current status	1) On follow up 2) Lost to follow up 3) Drop from follow up 4) Died 5) unknown	

Declaration

I the undersigned declare that this is my original work and has not been presented in this or any other University and all source of materials used for the thesis have been fully acknowledged.

Name of principal investigator: SOSINA MIDEKSA TULU

Signature:- _____

Date:- _____

Place: Addis Ababa University College of Health Science School of Public Health

Department of General master of public health

This thesis has been submitted for approval to:

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Signature:- _____

Date:- _____