

Assessment of the BMI change and its contributing clinical and immunological factors among patients receiving Highly Active Anti-Retroviral Therapy (HAART) in selected public Hospitals of Addis Ababa

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**ADDIS ABABA UNIVERSITY
COLLEGE OF HEALTH SCIENCE
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Acronyms

| | |
|-------|----------------------------------------------------|
| AIDS | Acquired Immune Deficiency Syndrome |
| ART | Antiretroviral Therapy |
| ARV | Antiretroviral |
| BMI | Body Mass Index |
| BWL | Body Weight Loss |
| CPT | Cotrimoxazole Preventive Therapy |
| HAART | Highly Active Antiretroviral Therapy |
| Hgb | Hemoglobin |
| HIV | Human Immunodeficiency Virus |
| INH | Isonized |
| IPT | Isonized Preventive Therapy |
| MAM | Moderate Acute Malnutrition |
| MUAC | Mid-Upper Arm Circumference |
| MDG | Millennium Development Goal |
| OI | Opportunistic Infection |
| PLHIV | People with Human Immune Deficiency Virus |
| SAM | Sever Acute Malnutrition |
| SNNPR | Southern Nations Nationalities and Peoples' Region |
| UOG | University of Gondar |

Abstract

Introduction

Providing sufficient food and nutrition to meet people's basic needs for health, growth and development has been a long standing challenge for African countries. This challenge is further exacerbated by the emergency of HIV/AIDS. Food is often identified as the most immediate and critical need by people with HIV/ AIDS.

Objectives

The objective of the study was to assess the BMI change and its contributing factors of HIV positive adults after antiretroviral treatment.

Method

A facility based cross-sectional study was employed to study the change in BMI of HIV infected adults after ART, who were enrolled to HIV chronic care in 11 purposively selected public hospitals in Addis Ababa. A total of 399 clinical records were systematically selected from the roster of respective hospitals and assessed for their nutritional status at initiation, three and six months of ART. The nutritional status was evaluated based on body mass index (BMI). Data were entered in to a computer and analyzed using SPSS.

Result

The mean age of the study participants was 34 years. After ART, cases with body mass index (BMI) < 18.5 kg/m² dropped from 30.7% to 15.2%. With ART, decreased frequency of illness, increase CD4 count and improve functional status. In logistic regression, BMI after six months of ART was found to have significant association with baseline low CD4 count, clinical stage IV and opportunistic infection.

Conclusion

Poorer nutritional response were observed in patients who were on ART with clinical stage IV, illnesses and CD4<200 before ART. This study provided another evidence to support the WHO recommendation on initiating ART before patients clinical and immunological status deteriorates.

1. Introduction

1.1 Background

HIV has spread rapidly in the last few decades with affecting all sectors of the society. This makes it the biggest public health problem the world has ever face (1). In the year 2011, 34 million people were infected with HIV worldwide, 2.5 million were new HIV infection (2). Even though the number of people dying of AIDS-related causes fell, about 1.7 million in 2011 were died(2).

Although HIV affects all parts of the world, Sub-Saharan Africa is the region most affected by HIV. About 69% of all people infected with HIV/AIDS live in this region (2). Despite a remarkable decline in the regional rate of new infection, the region contribute 71% of new HIV infections in 2011 (2).

Ethiopia is among the 5 Sub Saharan countries labeled as having biggest epidemic with 1.5% adult HIV prevalence (3). The National HIV/AIDS Prevention and Control Council stated HIV as a national crisis; and set various mechanisms of interventions mainly focusing on prevention strategy(4). Antiretroviral drug is introduced in Ethiopia In 2003, with the goal of reducing HIV-related morbidity and mortality, improving the quality of life of people with HIV (4). Ethiopia is currently working on the accessibility of antiretroviral drugs through decentralizing HIV care and treatment services to primary health care, (4).

In 2011 EDHS report, Addis Ababa is the second region with highest HIV prevalence rate of 5.2 %(3).

Food and nutrition are the basic needs for health, growth and development but in Africa it has been a long standing challenge to provide sufficient food and nutrition, which also exacerbated by the emergency of HIV/AIDS(5). Food is one of the most important need by people with HIV/AIDS (6).HIV and nutrition are intimately linked in that HIV infection can lead to under-nutrition through Poor nutrient absorption, prevents the body from using the nutrients provided by foods, leading to energy and nutrient losses, and the deficit in energy and nutrients will further weaken the person and their immune system and speed up the progression of the disease lead to loss of appetite(7).

Anti-retroviral drug treatments improves immunity and prevent severe wasting, as well as other opportunistic infections(8). Though the drugs do not eliminate wasting, once people

with HIV begin treatment; they tend to regain weight (8). Some studies show there will be small weight loss (between 5% and 10% over six months) among people with HIV who are taking treatment(8).

Aware of the importance of food and nutrition to play in comprehensive care of people with HIV, countries and programs including Ethiopia are increasingly integrating food and nutrition services into HIV care and treatment programs. Although the Federal Democratic Republic of Ethiopia have recognized that nutrition has a significant role in the HIV disease progression and endorsing nutrition care and support in the management of HIV/AIDS is started, there is little information about the current magnitude of under-nutrition and associated factors among people infected with HIV (7).

Understanding nutritional status of HIV infected people will be important to plan substantial public health programs that could prevent under-nutrition and improve their nutritional status.

1.2 Statement of the problem

HIV/AIDS is one of serious health problems and a leading cause of under-nutrition among adults in Ethiopia (7). Introduction of anti-retroviral therapy has resulted in decrease in under-nutrition in HIV infected adults. In Ethiopia chronic HIV/AIDS care and ART therapy is on better progress with relatively good intake of adults (1). Few studies of HIV-infected adults show nutritional status has improved with ART in Adults on antiretroviral therapy. Under-nutrition in HIV positive adults is a problem due to multiple factors which include opportunistic infections, poor ART adherence, low CD4 count, functional status (7). In Addis Ababa, ART service is delivered in hospitals and health centers, but there is inadequate information on ART outcome on nutritional status and its contributing factors among HIV positive adults.

Although current health facilities have include nutritional support as part of the comprehensive care, still there is no adequate information as to whether the ART improves the nutritional status of HIV positive adults. This study is intended to contribute to fill the information gap.

1.3 Rationale of the study

HIV infection has long been recognized to have a possible negative impact on the nutritional status of people with HIV/AIDS leading to under-nutrition. ART increases the immune system which leads to decrease vulnerability to opportunistic infections and slow HIV disease progression resulting improved nutritional status. Using BMI, nutritional status of adults infected with HIV can be assessed and will be a good indicator for intervention.

ART is life-long; therefore it is important to assess nutritional status of adults on their BMI change with ART. This study used an objective to assess the change in BMI of HIV positive adults at three and six months of ART in Addis Ababa Public hospitals. Findings of this study have given a good estimate of the current situation of under-nutrition in adults on ART. Understanding the level of Nutritional status in adults will contribute to improve the comprehensive care. Data from this study is useful to health planners such as those at the Ministry of Health. This finding potentially enables Ministry of Health, design better programmes to alleviate the problem of under-nutrition in Adults and serves as resource for new research on identified gaps.

2. Literature review

2.1 HIV/AIDS among adults

HIV/AIDS continues to be a major global health priority. Although important progress has been achieved in preventing new HIV infections and in lowering the annual number of AIDS related deaths, the number of people with HIV continues to increase partly due to ART. AIDS-related illnesses remain one of the leading causes of death globally and are projected to continue as a significant global cause of premature mortality in the coming decades. Sub-Saharan Africa remains the most heavily affected region, accounting for 71% of all new HIV infections in 2008 (10).

In Ethiopia HIV infection probably began in the late 1970s or early 1980s with the first AIDS case reported in 1986(1). Even though there are still sustainable effort and decline in new HIV infection, Ethiopia still remain a country highly affected with the epidemic. HIV prevalence tends to be higher in urban settings than in rural areas(4). The prevalence of HIV in urban and rural adult is 4.2% and 0.6% respectively, with 5.2% adult prevalence in Addis Ababa(1, 4). Variations were also observed among administrative regions. HIV prevalence ranges From 0.9% in SNNPR to 6.5% in Gambella region(4).

According to the single point estimate of the 2010, an estimated of 210,306 adults are living with HIV in Addis Ababa, the prevalence rate being 9.2%. There were also an estimated 22,214 new HIV infections and 5948 annual deaths among adults in 2009 in Addis Ababa (11).

2.2 Under-Nutrition among adults infected with HIV

The effect of HIV on nutrition begins early in the course of the disease, even before an individual may be aware that he/she is infected with the virus. Asymptomatic HIV positive individuals require 10% more energy, and symptomatic HIV-positive individuals require 20-30% more energy than HIV-negative individuals of the same age, sex, and physical activity level. Low food intake combined with increased energy demands are the major factors in HIV related weight loss and wasting (7).

Under-nutrition among HIV infected individuals is a problem in many countries of the world with various economic statuses. An assessment of the nutritional status among HIV infected outpatients attending an AIDS clinic in Paris revealed that 37.9% of the patients

have some form of under-nutrition (12). Even in the era of HAART wasting is significantly affecting adults infected with HIV. This was seen from the USA study which has shown 17.6% prevalence of HIV related wasting (13).

Morbidity and mortality of HIV infected patients in the developing world remain unacceptably high, despite major advances in HIV therapy and increased international support, People with HIV infection face not just sickness, but also impaired productivity, decline income, and increasingly difficult choices among essential needs due to competitive expenses such as food versus health care(14). Further, food insecurity, under-nutrition and HIV/AIDS are overlapping and have additive effects(14). Combating HIV/AIDS and under- nutrition are the sixth and first of the eight MDG to be achieved by 2015. The complex interaction between HIV and nutrition seriously threaten the achievement of these goals(9). Weight loss and under-nutrition are common in patients with HIV infection or AIDS and are likely to accelerate disease progression, increase morbidity and reduce survival because of the impact of under-nutrition on immunity(15). Three key factors contribute to under-nutrition in HIV/AIDS patients are inadequate intake, mal-absorption, increase energy expenditure(15).

Study conducted on prevalence and pattern of HIV related malnutrition among women in sub-Saharan Africa varied widely from 0.6% in Lesotho to 16.9% in Burkina Faso. Meta analysis of all eleven countries including Ethiopia yielded an overall pooled prevalence of 10.3% with 13.2% of prevalence in Ethiopia (16,17). Currently HIV is becoming the leading cause of hospital admission in many HIV endemic areas and under-nutrition among admitted HIV positive individuals is a significant problem. Studies done on hospitalized AIDS patients in Brazil perform the nutritional evaluation within 72 hrs of hospital admission. For the majority of those enrolled, under-nutrition ($BMI < 18.5 \text{ kg/m}^2$) was found in 55 (43%) of patients and severe malnutrition ($BMI < 16 \text{ kg/m}^2$) in 19(15%)(18).

A study in university hospital, Bujumbura, Burundi has shown that 45.1% of the admitted patients are HIV sero-positive of which 47.3% had under-nutrition (19). Under- nutrition remains the most important clinical finding among patients with HIV infection. The most common (89.0%) WHO stage IV conditions among patients who started ART is wasting syndrome ($>10\%$ weight loss plus either chronic diarrhea or chronic fever) (20).

A cross-sectional study conducted in North India on Dietary adequacy of HIV infected individuals shows that Mean weight and BMI of the individuals participated in the study was 58.6 ± 11.7 (range, 34 - 94) kg and 21.5 ± 3.7 (range, 13.6 - 36.7) kg/m^2 , respectively(21). In another study which was conducted in Chennai south India on malnutrition in a population of HIV positive and HIV negative drug users, shows that the nutritional status of HIV positives were, 5.6% had Grade III malnutrition with $\text{BMI} < 16 \text{kg}/\text{m}^2$, 15.9% had Grade II malnutrition with BMI of $16 \text{kg}/\text{m}^2$ - $16.9 \text{kg}/\text{m}^2$, 30.8% had Grade I malnutrition with BMI of $17 \text{kg}/\text{m}^2$ - $18.4 \text{kg}/\text{m}^2$, 47.7% were normal with BMI of $18.5 \text{kg}/\text{m}^2$ - $24.9 \text{kg}/\text{m}^2$ (22).

PLHIV are more vulnerable to malnutrition than the general population and nutritional status is a good predictor of their mortality risk. Another study conducted on one hundred newly diagnosed HIV infected and one hundred non HIV infected Iranian individuals shows that the mean BMI in HIV positive individuals is $17.3 \text{kg}/\text{m}^2$ and 15% had severe malnutrition, 38% moderate malnutrition, 24% mild malnutrition and 23% of individuals Normal(23).

A study conducted in university of Gondar referral hospital on Adult Nutritional Status and Factors Associated with Malnutrition among PLHIV shows that the prevalence of under-nutrition ($\text{BMI} < 18.5 \text{kg}/\text{m}^2$) was 27.8% and the percent of body weight lost ($\text{BWL} > 5\%$) was 60.9%. Severe malnutrition ($\text{BWL} > 20\%$) accounted for 10.1%(24).

A study from St. Peter hospital indicated that average BMI of adult patients at start of ART was $19.3 \text{kg}/\text{m}^2$, 12.4% have severe malnutrition and 42% have BMI below 18.5 (25).

Another study on nutritional and immunological status and their associations among HIV infected adults in Addis Ababa, Ethiopia evidenced that compromised nutritional and micronutrient status begins early in the course of HIV infection and 18% of the study participants were found to be chronically energy deficient (26).

2.3 Effect of ARV drugs on nutritional status

Introduction of HAART has dramatically changed the course of HIV infection in countries that prioritized its distribution(18). Even though ART has made a significant reduction in the prevalence of wasting, largely through the reduction in viral replication, increase CD4 count and decrease opportunistic infection, still it remains a significant problem for certain HIV infected subgroups such as those diagnosed late in the course of the infection and among non adherent to the treatment(6, 15,18,). ART can reverse but does not rectify the loss of body mass that result from HIV infection (6).

Nutrition is an important component of comprehensive care for PLHIV particularly in resource limited settings where under-nutrition and food insecurity are endemic. In countries like Ethiopia where there is high prevalence of HIV disease routine nutrition screening can facilitate prompt treatment and dietary intervention which in turn can reduce the frequency and duration of opportunistic infections as well as prevent weight loss.(27)

Under-nutrition can occur at any stage of HIV disease with high occurrence in advanced stage of HIV. Among 40,778 persons with advanced HIV disease who started ART in urban Lusaka, Zambia 3624 (9%) had BMI <16 kg/m², 3097(8%) had BMI between 16.00 kg/m² -16.99 kg/m², and 6910(17%) had a BMI between 17.0 kg/m² -18.49 kg/m² (17).

Under-nutrition particularly severe acute malnutrition (SAM) is associated with poor treatment outcome which is 4 to5 times more likely to die in the first 90 days after starting ART while Patients with MAM are 2 to 3 times more likely to die in the first 90 days after starting ART(7). A low BMI at the start of ART is an independent predictor of early mortality(7, 17). In Zambia patients who started ART with a BMI <16kg/m² has two fold higher mortality when compared with those above this BMI threshold (17). In rural Malawi patients who initiated ART with a BMI<16kg/m² has a 6 fold increased risk of death at 3 month compared with those with a BMI >18.49kg/m² and those with a BMI between 16.0kg/m² and 16.9kg/m² had a > 2 fold increase risk (17). A study done on Nutritional status and mortality among HIV-infected patients receiving antiretroviral therapy in Tanzania shows that Lower BMI, MUAC, and Hgb concentrations at ART initiation were strongly associated with a higher risk of death within 3 months(28). Among patients who survived >3 months after ART initiation, those with a decrease in

weight, MUAC, or Hgb concentrations by 3 months had a higher risk of death during the first year. After 1 year, only a decrease in MUAC by 3 months after ART initiation was associated with a higher risk of death(28).

Another study conducted in Hawassa university referral hospital on the nutritional status of adults before and after ART in HIV positive adults who were on ART for 3 - 96 months shows that after ART, cases with body mass index (BMI) < 18.5 kg/m² dropped from 38% to about 20% and cases with CD4 count < 200/mm³ dropped from 73% to 9%(20). However, there were 58 and 14 cases whose BMI and CD4 count were even below the Pre-ART levels, respectively(29).

2.4 Factors associated with Under-Nutrition

As shown in figure 1 several factors are associated with under-nutrition. It is not always possible to identify one single cause as the main contributor to decline in the nutritional status or under-nutrition in PLHIV. Loss of appetite leading to reduced food intake is one of the main reasons why people lose weight with HIV infection. Leading to wasting (30). Inadequate food intake may be caused by lack of food, oral candidiasis, mouth or gastrointestinal tract ulceration, infection resulting in reduced appetite nausea vomiting and or diarrhea, antiretroviral side effect(30). Mal absorption and increasing energy intake are among the factors that lead to under-nutrition(30).

Studies have shown that Socio demographic factors also have an effect on nutritional status. Meta analysis of 11 Sub Saharan countries including Ethiopia identified that the magnitude of malnutrition among HIV patients varies by wealth status, educational attainment, occupation, and type of residence(16).

Under-nutrition is associated with different factors that may be explained partly by internal factors. The Helsinki study showed that female gender, functional impairment, difficulty of swallowing, and eating less than half of the offered food portion are significantly associated with under-nutrition (31). The Ghanaian study identified that nutritional status was significantly associated with marital status, income per month, educational level, believe in avoiding certain food types and large family size (32).

A study from Paris has identified loss of appetite, nausea, oropharyngeal pain; dysphagia, diarrhoea, prolonged fever and depressive syndrome are risk factors for under-nutrition in HIV infected patients (12).

Adherence to ART might be one factor for under-nutrition in HIV positive adults. A study conducted on the role of household food insecurity and nutritional status in anti-retroviral therapy (ART) outcomes in Chiro Ethiopia, shows that BMI categories at 6 month and 2 years are significantly associated with ART non adherence. BMI categories at 2 years period show that non-adherence is 27% among underweight, 9% among normal(33). The adjusted multivariate logistic regression shows that normal weight category at 2 years is significantly associated with ART non adherence(33). Another study on nutrition assessment of HIV-positive adults accessing care and treatment in reach out Mbuya Kampal, Uganda of 855 adults (459 females, 396 males), 150 (18%) were underweight, 76 (9%) overweight, 60(7%) obese and 569 (66.5%) had normal BMI of 18.5-24.9 (34). All the overweight and obese adults were on ART while the underweight, 65(43%) were on TB, 45(30%) on prophylaxis and 40(26%) on ART and TB(34). After three months the nutrition status improved; 56% (43%female,13%male) of the overweight and obese adult clients lost weight and attained average BMI of 24.5 from an average of 28.6 while 70.7%(15.7%female.55% male) of the underweight improved with average BMI of 20.3 from an average 17.5 in three months(34).A study from Gondar identified marital status, income, duration of treatment; eating problem and current status of the patient are significantly associated with under-nutrition (24).

A study conducted in Hawassa university referral hospital on the nutritional status of adults before and after ART in HIV positive adults who were on ART for 3 - 96 months shows that, in multiple linear regression current nutritional status was found to have significant association with baseline low CD4 count, clinical stage III/ IV, low BMI and low meal frequency(29). Multiple logistic regression also demonstrated a significant association of low BMI after ART with low CD4 count before ART(29).

2.5 Conceptual Framework

There are complex interactions between nutrition and HIV/AIDS. HIV progressively weakens the immune system and under-nutrition itself may also increase the susceptibility to infections. Those who are ill from HIV infection, from poor nutrition or both are less able to work. In many areas of the developing world, HIV infection exists with under-nutrition.

A fundamental goal in sorting out the interactions between Nutritional status and highly active anti-retro viral drugs is to determine the points of distinction among the effects of Anti-retro viral therapy on nutritional status and other contributing factors that affect BMI. Core questions addressed in the Study are depicted in Figure 1 and included the followings:

- What is the effect of ARV drug on the BMI of HIV infected adults?
- What is the impact of ARV adherence, opportunistic infections (OI), e.g. TB, diarrheal diseases etc on the change in BMI?
- Are Age, Sex, CD4 count, clinical stage, Functional status, hgb level, CPT, CPT adherence and IPT contributing factor for BMI change?

Conceptual frame work

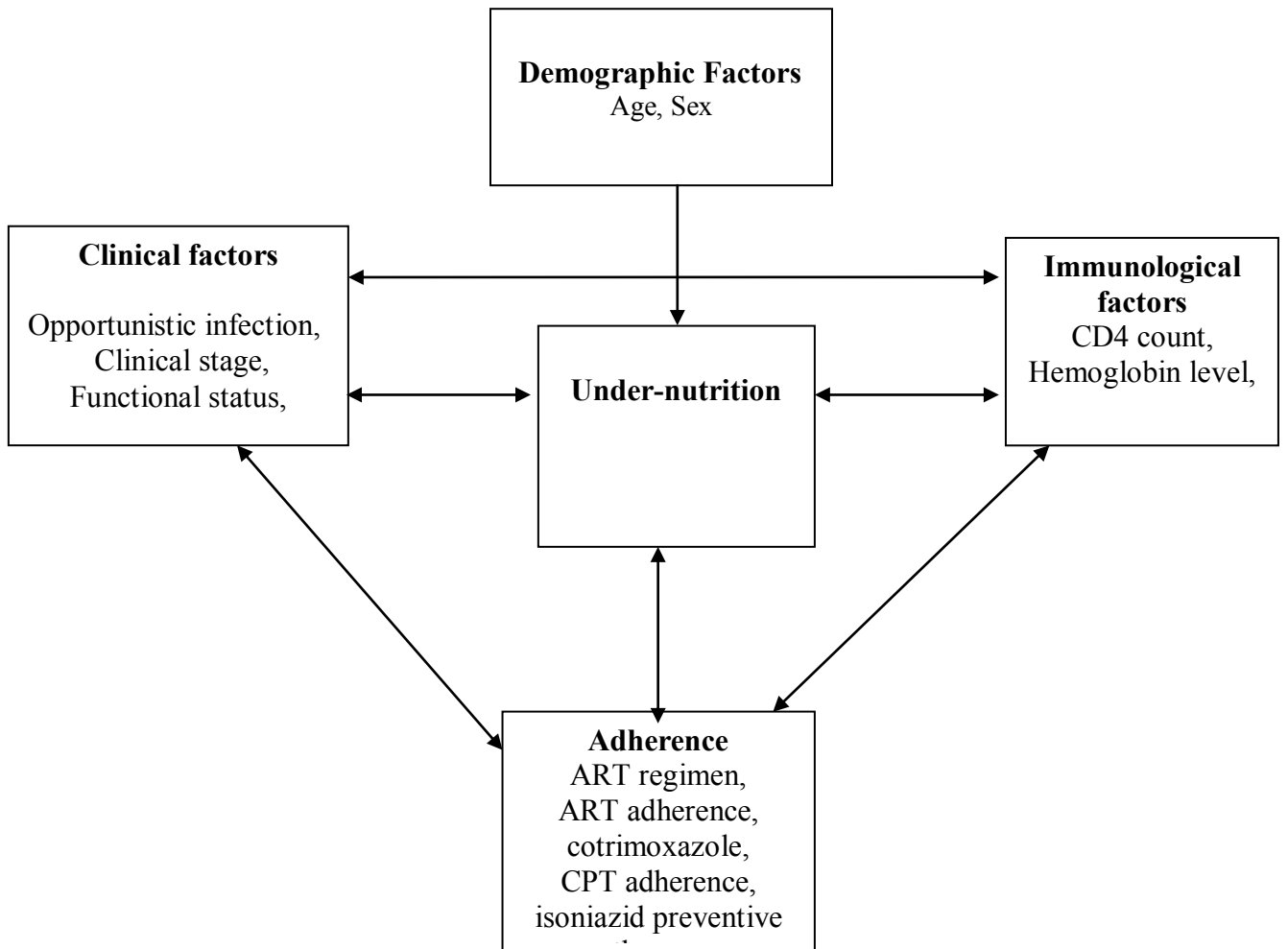


Figure 1: Factors affecting the nutritional status of patients infected with HIV

3. Objective

3.1 General Objective

To assess the BMI change and its contributing factors of HIV positive adults after antiretroviral treatment.

3.2 Specific Objective

1. To assess the BMI change of HIV positive Adults at initiation, three and six months of ART.
2. To identify factors associated with BMI change among HIV positive Adults.

4. Methodology

4.1 Study design

Facility based quantitative cross-sectional study was conducted.

4.2 Study area and Period

The study was conducted from February, 2012 to February, 2013 in Addis Ababa which is the capital city of Ethiopia with a population of 3,384,569 according to the 2007 population census with annual growth rate of 3.8%(35). Administratively the city is divided in to 10 sub-cities with 116 woredas (35). The city has 52 hospitals (11 public hospitals, 36 private hospitals, 3 uniform military hospitals and 2 NGO hospitals).Number of health centres is 61 of which 54 were public and 7 were NGO health centres. The city has also more than 700 clinics and 500 Drug vendors accountable to Addis Ababa city administration Health bureau (36). One Regional laboratory and one nursing school also fall under AARHB authority (36). As of February, 2013 there were 65 health facilities delivering ART services, and a total of 97473 cases have started ART treatment. Out of these, 46710 are in 11 public hospitals and were considered as the study sites because of high number of patients (36).

4.3 Source population

All adult HIV positive individuals who were on HAART treatment in Addis Ababa public hospitals.

4.4 Study population

All adult HIV positive individuals who took ARV drugs for at least six months in AA public hospitals

4.5 Inclusion and exclusion criteria

Inclusion criteria

A patient with the age of ≥ 18 years who are HIV positive and on ART at least for six months in Addis Ababa public hospitals.

Exclusion criteria

HIV positive women in the study age group who were pregnant or lactating.

4.6 Sample size

The sample size were determined using a single proportion formula, assuming prevalence rate of under-nutrition of 38%among adults with HIV/AIDS during initiation of ART(29).A 95% confidence level and 5% degree of precision with 10% of the original sample size was added to cater for incomplete information on the patient's card was taken. A total of 399 samples were estimated using the following formula;

$$n = \frac{(Z_{\alpha/2})^2 p(1-p)}{d^2}$$

$$n=399$$

Where n=Sample size

$$Z_{\alpha/2} = (Z \text{ value at } \alpha = 0.05) = 1.96$$

p = Proportion of occurrence of malnutrition in HIV positive = 38%

d = the margin of error (precision) = 0.05

4.7 Sampling procedure

All the 11 public hospitals in Addis Ababa were included in the study. Those who started ART six months earlier and before from the time of data collection were the sampling frame. Sample size for each hospital was calculated in proportion to the number of HIV /AIDS patients who were actively on ART before six months of data collection in each hospital. Which was Tikur-Anbesa (5545), Alert (5353), Amanuel (1147), St paulos (4876) St petros (2390), Zewditu (6883), Yekatit (4110), Rasdesta (2390), Minillik (2677), Gandi (1721), Tirunesh bejing (1053) were actively on ART. Systematic random sampling was used to select Samples (clinical record of patients on roster).Sampling interval k^{th} was determined by dividing the total patients actively on ART in each hospital by the required sample size. From the total cases in sample the first clinical record was selected by simple random sampling and every k^{th} client was selected for gathering information until the required sample was obtained.

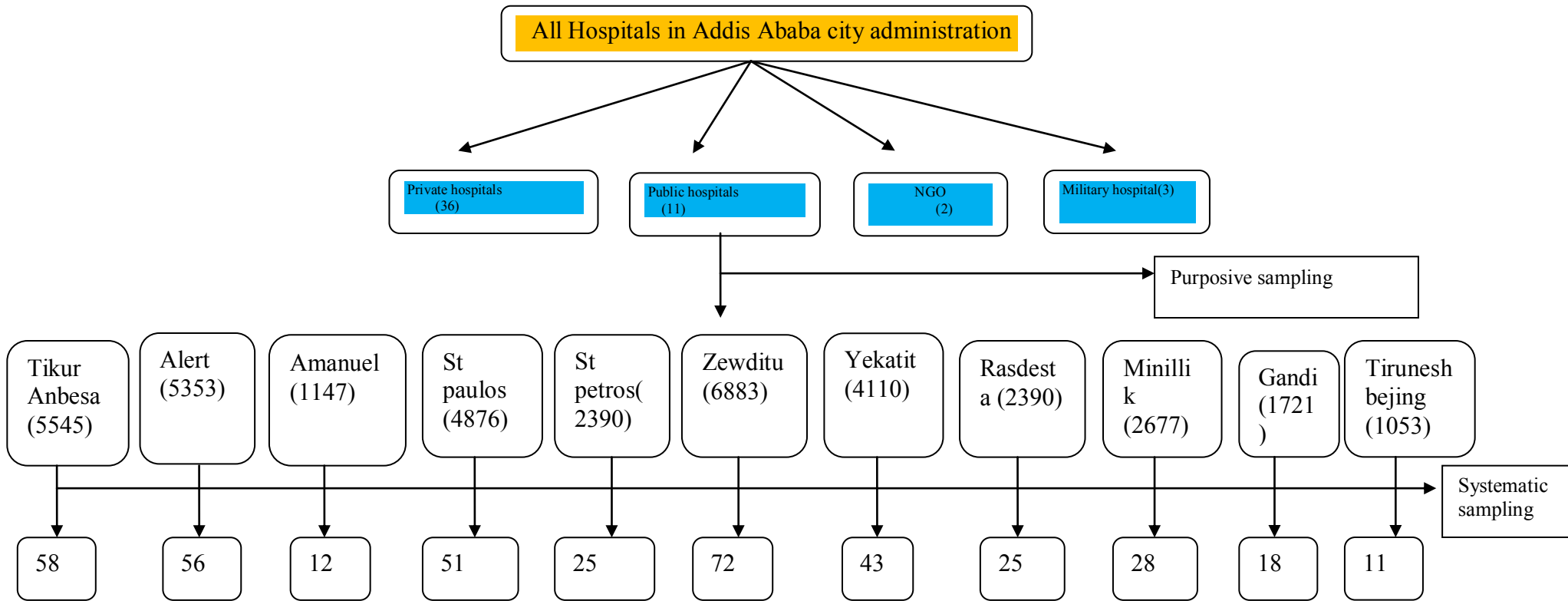


Figure 2: Sampling procedure

4.8 Data collection procedure

A structured data collection format was prepared to extract the necessary data for the study based on the patient intake and follow up form for HIV care and ART. The structured data collection format was anonymous and pretested on 5% of the sample in one health facility which was not part of the study hospital and based on the pretest findings amendments was made on the data collection format.

Three clinical nurses and one health officer who was working in the ART clinics was recruited for data collection and for supervision, respectively. One data entry personnel was employed for data entry and cleaning. The clinical nurse was doing the data collection and the health officer was doing the supervision. In order to assess the nutritional status of the study participants BMI was calculated using the study participants weight in Kg and height in m².

Variables of the study

Independent variables-age, sex, ART regimen, CD4 count, Cotrimoxazole preventive therapy, INH preventive therapy, hemoglobin, opportunistic infection, clinical stage, Adherence to ART, Adherence to Cotrimoxazole preventive therapy, functional status.

Dependent variable- BMI status

4.9 Data quality management

Training for the data collectors and supervisors on the objective of the study, sampling method, ethical issues and on the use of the data collection format to collect important information was given and pretesting of data collecting format was made to ensure the quality of data. The principal investigator and the supervisor checked and reviewed data for completeness and accuracy of the information collected.

4.10 Data Analysis

Editing and sorting of the questionnaires was done manually before data entry. The responses in the completed codebook was coded, collated and entered into a computer data entry template using Epi-Info software version 7. And analysis was done by SPSS Software version 20. Logistic regression was used to examine the relationship between the proposed dependent and independent variables.

4.11 Operational Definition

Body mass index (BMI)- BMI is the ratio of weight in kg divided by height in m².

Under-Nutrition- is inadequate amount and combination of energy or nutrients to carry out needed physiological functions with BMI <18.49kg/m².

ART Adherence

Good-If the patient missed ≤2 doses among 30 doses of ART (95% adherence)

Fair- If the patient missed 3-5 doses among 30 doses ART (85-94% adherence)

Poor- If the patient missed ≤6 doses among 30 doses ART (<85% adherence)

Cotrimoxazole adherence

Good-If the patient missed ≤2 doses among 30 doses CPT (95% adherence)

Fair- If the patient missed 3-5 doses among 30 doses CPT (85-94% adherence)

Poor- If the patient missed ≤6 doses of among doses CPT (<85% adherence)

Functional status

Working-Able to perform usual work in or out of the house, harvest, goes to school

Ambulatory-Able to perform activities of daily living

Bedridden-Not able to perform activities of daily living

Anemia

Normal-Hemoglobin ≥12 g/dl

Mild-Hemoglobin 10-11.9 g/dl

Moderate-Hemoglobin 7-9.9 g/dl

Sever-Hemoglobin <7 g/dl

5. Ethical clearance

Ethical clearance was obtained from Addis Ababa University College of Health Sciences School of Public Health Research and Ethical Committee. Official letters was written from the school of public health to Addis Ababa city Administration health bureau and federal hospitals. The name of the respondents was not included on the data collecting format to keep confidentiality.

6. Result

6.1 Sex and Age characteristics of PLHIV

Three hundred sixty two patients (90.7% response rate) of the total sample size were included in the study. The mean and median age of patients included in the study were 34 and 33 years, respectively with SD of ± 9.29 . More than 85% were below the age of 48 (figure 3). The proportion of female participants were more than male (63.5%) (Figure 4).

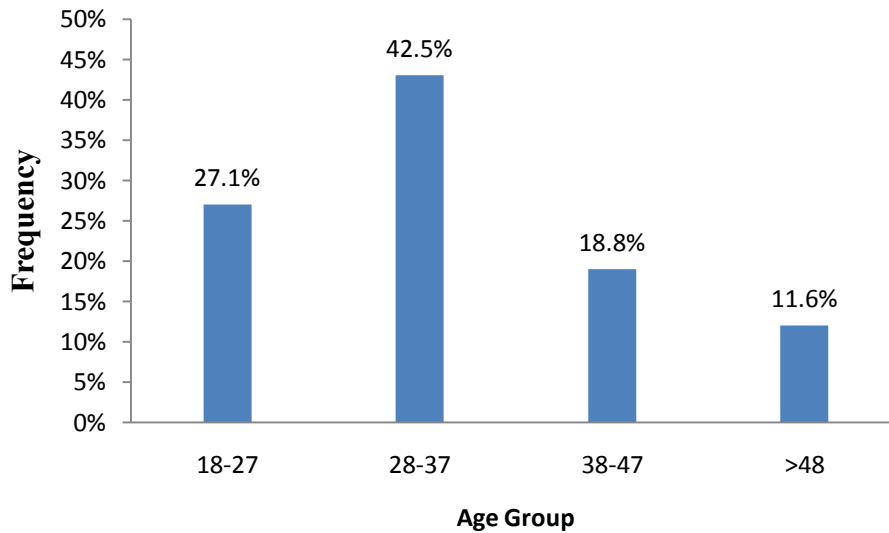


Figure 3: Age distribution of PLHIV in selected public hospitals of Addis Ababa, 2013 n=362

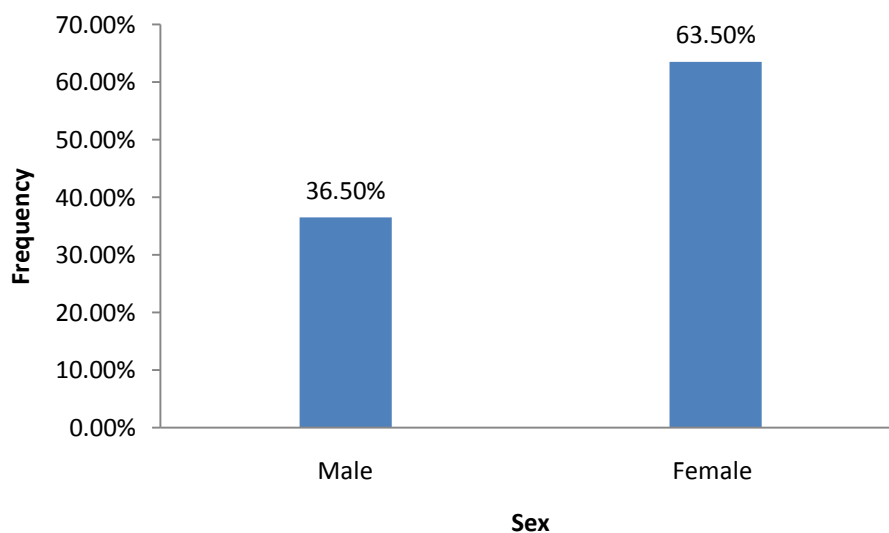


Figure 4: Sex of PLHIV in selected public hospitals of Addis Ababa, 2013 n=362

6.2 Anthropometric characteristics of PLHIV at initiation, three and six months of ART

The mean height of the study participants were 163.2cm. The mean weight at ART initiation, three and six months of ART was 55.2 kg, 56.6 kg and 57.7kg, respectively. The average weight gain per individual after six months of ART was 2.5 kg.

The mean BMI of respondents were 20.6kg/m², 21.1kg/m², 21.6 kg/m² at initiation, three and six months of ART. The average BMI change per individual was 1kg/m². The proportion of under-weight (BMI, <18.49kg/m²) patients were 30.7% at initiation of ART and 23.5% and 15.2% at three and six months of ART. (Table 1)

Table1: Anthropometric characteristics of PLHIV, at initiation, three and six months of ART at public hospital of Addis Ababa, 2013 n=362

| Variable | At initiation | Three months | Six months |
|------------|-------------------------|----------------------|------------------------|
| Height(cm) | Mean =163.2cm SD+8.3 | | |
| Weight(kg) | Mean =55.2 SD+10.5 | Mean=56.6 SD+10.7 | Mean=57.7 SD +11 |
| BMI(Kg/m2) | Mean=20.6 SD+3.55 | Mean=21.1 SD+3.6 | Mean=21.6 SD + 3.24 |
| <18.5 | 111(30.7%) | 85(23.5%) | 55(15.2%) |
| >=18.5 | 251(69.3%) | 277(76.5%) | 307(84.8%) |

BMI=Body mass index;

6.3 Immunological findings of PLHIV at initiation and six months of ART

As CD4 and hemoglobin was assessed every six month, the mean CD4 cell count at initiation and six months of ART was 222 cells/mm³ and 240 cells/mm³ respectively. 34 % of the patients had CD4 cell counts \leq 200 cells/mm³, 51.7% had between 201-350 cells/mm³ and 14.3% had $>$ 350 cells/mm³ at initiation of ART and this proportion had show a change at six months of ART which was 24%of participants had CD4 \leq 200 cells/mm³, 57.7% had CD4 between 201 cells/mm³ and 350 cells/mm³, the rest which was 18.3% of participants had CD4 $>$ 350cells/mm³.

The mean hemoglobin was 12.2g/dl at initiation of ART and 12.9g/dl at six months of ART. 56.4% and 73.2% were in normal hemoglobin range at initiation and six months of ART respectively. 29% and 19.1% of participants were in mild anemia range at initiation and six months of ART respectively. 13.3 % and 6.45% were moderately anemic at initiation and six months of ART respectively. 1.4% of the participants were severely anemic both at initiation and six months of ART (Table2).

Table 2: Immunological findings of PLHIV at initiation and six months of ART at public hospital of Addis Ababa, 2013 n=362

| Variable | At initiation | Six months |
|------------------------------------|-------------------------------|--------------------------------|
| CD4 (cells/mm³) | Mean=222 SD+102.8 | Mean=240 SD +100.7 |
| <201 | 123(34%) | 87(24%) |
| 201-350 | 187(51.7%) | 209(57.7%) |
| >350 | 52(14.3%) | 66(18.3%) |
| Hemoglobin (g/dl) | Mean =12.2 SD+2.34 | Mean=12.9 SD + 2.23 |
| Normal | 204(56.4%) | 265(73.2%) |
| Mild | 105(29%) | 69(19.1%) |
| Moderate | 48(13.3%) | 23(6.45%) |
| Sever | 5(1.4%) | 5(1.4%) |

6.3 Clinical findings of PLHIV at initiation, three and six months of ART

At initiation of ART 69.3% of study participants were in working functional status and at three and six months of ART it changed to 78.5% and 92.0% respectively. 27.3%, 19.1% and 6.6% of participants were in Ambulatory functional status at initiation, three and six months of ART respectively. 3.3%, 2.5% and 1.4% were in bedridden functional status at initiation, three and six months of ART respectively.

Regarding to clinical stage 13.5%, 21.5% and 42.8% were in WHO clinical stage one at initiation, three and six months of ART respectively and 26.8%, 31.2%, 23.5% were in WHO clinical stage two at initiation, three and six months of ART respectively. 51.7% at initiation of ART, 40.3% at three months of ART and 29% at six months of ART were in WHO clinical stage three. 8%, 7%, 4.7% were in WHO clinical stage four at initiation, three and six months of ART respectively.

23.8% of participants had opportunistic infection at initiation of ART and 18.8% and 6.9% at three and six months of ART respectively. 26.7% of participants had TB at initiation of ART and 27.9% and 32% at three and six months of ART.

Table3: Clinical findings of PLHIV, at initiation three and six months of ART at public hospital of Addis Ababa, 2013 n=362

| Variable | At initiation | Three months | Six months |
|----------------------------------------------|----------------------|---------------------|-------------------|
| Functional status | | | |
| Working | 251(69.3%) | 284(78.5%) | 333(92.0%) |
| Ambulatory | 99(27.3%) | 69(19.1%) | 24(6.6%) |
| Bedridden | 12(3.3%) | 9(2.5%) | 5(1.4%) |
| WHO stage | | | |
| Stage 1 | 49(13.5%) | 78(21.5%) | 155(42.8%) |
| Stage 2 | 97(26.8%) | 113(31.2%) | 85(23.5%) |
| Stage 3 | 187(51.7%) | 146(40.3%) | 105(29%) |
| Stage 4 | 29(8%) | 25(7.0%) | 17(4.7%) |
| Opportunistic infection | | | |
| Yes | 86(23.8%) | 68(18.8%) | 25(6.9%) |
| No | 276(76.2%) | 294(81.2%) | 337(93.1%) |
| Type of opportunistic infection(n=25) | | | |
| TB | 23(26.7%) | 19(27.9%) | 8(32%) |
| Oral candidiasis | 10(11.6%) | 5(7.4%) | 4(16%) |
| Chronic diarrhea | 7(8.2%) | 1(1.5%) | 0(0.0%) |
| Herpes zoster | 10(11.6%) | 6(8.8%) | 2(8%) |
| Pneumocystis jirovecii pneumonia(PCP) | 1(1.2%) | 0(0.0%) | 0(0.0%) |
| CNS toxoplasmosis | 1(1.2%) | 0(0.0%) | 0(0.0%) |
| Other | 34(39.5%) | 37(54.4%) | 11(44%) |

WHO=World Health Organization

6.4 Treatment Adherence at initiation, three and six months of ART

More than half of the study participants were on NVP based antiretroviral therapy through six months of ART. Which was 51.9%, 51.1% and 51.1% at initiation, three and six months of ART respectively. And more than a quarter were having the regimen D4T, 3TC, NVP (Stavudine, lamivudine and nevirapin) through six months of antiretroviral treatment. 90.6% and 93.6% had good adherence to their ART at three and six months of antiretroviral treatment respectively. 8.3% and 5.2% had fair adherence to their ART at three and six months of antiretroviral treatment respectively. 1.1% of participants had poor adherence to ART at three and six months of ART.

More than $\frac{3}{4}$ of study participants were taking cotrimoxazole preventive therapy in all months of ART with 92.8%, 94.8%, 95.7% had good adherence at initiation, three and six months of ART respectively.

10.5%, 10.8%, 10.2% of participants were having INH prophylaxis at initiation, three and six months of ART respectively.

Table4: Treatment Adherence of PLHIV, at initiation three and six months of ART at public hospital of Addis Ababa, 2013 n=362

| Variable | Initiation of ART | Three months of ART | Six months of ART |
|----------------------------------------------|-------------------|---------------------|-------------------|
| ART regimen | | | |
| D4T,3TC,NVP | 97(26.8%) | 99(27.3%) | 95(26.2%) |
| D4T,3TC,EFV | 51(14.1%) | 55(15.2%) | 53(14.6%) |
| AZT, 3TC,NVP | 75(20.7%) | 69(19.1%) | 73(20.2%) |
| AZT, 3TC,EFV | 36(9.9%) | 35(9.7%) | 35(9.7%) |
| TDF,3TC,EFV | 87(24.0%) | 87(24.0%) | 89(24.6%) |
| TDF,3TC,NVP | 16(4.4%) | 17(4.7%) | 17(4.7%) |
| ART adherence | | | |
| Good | | 328(90.6%) | 339(93.6%) |
| Fair | | 30(8.3%) | 19(5.2%) |
| poor | | 4(1.1%) | 4(1.1%) |
| Cotrimoxazole preventive therapy(CPT) | | | |
| Yes | 304(84%) | 304(84.0%) | 303(83.7%) |
| No | 58(16%) | 58(16.0%) | 59(16.3%) |
| Adherence to CPT(n=303) | | | |
| Good | 282(92.8%) | 288(94.8%) | 290(95.7%) |
| Fair | 12(3.9%) | 8(2.6%) | 8(2.6%) |
| Poor | 10(3.3%) | 8(2.6%) | 5(1.7%) |
| INH preventive therapy | | | |
| Yes | 38(10.5%) | 39(10.8%) | 37(10.2%) |
| No | 324(89.5%) | 323(89.2%) | 325(89.8%) |

D4T=Stavudine; 3TC=Lamivudine; AZT= Zidovudine; NVP=Nevirapine; EFV=Efavirenz; TDF=Tenofovir;INH= Isoniazid.

6.5 Factors associated with change in BMI

Bivariate Analysis

The Bivariate analysis revealed that the Age, Sex, opportunistic infections, WHO clinical stage, functional status of the patient and CD4 are significantly associated with under-nutrition. (Table 5)

There was statistically significant association between under-nutrition and Sex. Patients who are women's were 2.18 times more likely to be under-nourished than men [COR=2.18; 95% CI 1.06 to 3.24]. Concerning age, it has been found that older age were a risk factor for under-nutrition, Patients who are >48 age were 2.30 times more likely to be under nourished compared to those age <27 [COR=2.30; 95%CI 1.37 to 4.60]. Patients WHO clinical stage at initiation of ART was significantly associated with under-nutrition after six months of ART, in which patients in WHO clinical stage III and IV were 2.51 and 4.30 times more likely to be under-nourished compared to patients at WHO clinical stage I [COR=2.51; 95% CI=1.37 to 4.60 and COR=4.30; 95%CI 1.96 to 8.17]. CD4 >350 found to have a statistically significant association with under-nutrition. Those patients who were having CD4>350 were about 76% less likely to develop under-nutrition [COR=0.24; 95% CI 0.14-2.16](Table 5).

Those who had bedridden functional status at initiation of ART had 2.51 times more likely to develop under-nutrition after ART and was statistically significant [COR=2.51; 95% CI=1.37 to 4.60]. Those without opportunistic infection at initiation of ART have a lesser risk of developing under-nutrition after six months of ART [COR=0.21; 95% CI=0.18-5.14](table 5).

There was no significant association between hemoglobin, ART regimen, ART adherence, cotrimoxazole, CPT adherence, Isoniazid preventive therapy, type of opportunistic infection and under-nutrition.

Table 5: Factors associated with under-nutrition in PLHIV, at public hospital of Addis Ababa, 2013 n=362

| Age | <18.5 | >18.5 | COR (95% CI) |
|--------------------------------|-------------|-------------|--------------------|
| 18-27 | 11 (11.22%) | 87(88.78%) | 1 |
| 28-37 | 22(14.28%) | 132(85.72%) | 1.31 (0.47-3.68) |
| 38-47 | 12(17.65%) | 56(82.35%) | 1.50(0.56-4.15) |
| >48 | 10(23.8%) | 32(76.9%) | 2.30 (1.37-4.60)* |
| Sex | | | |
| Male | 11(8.33%) | 121(91.67%) | 1 |
| Female | 44(19.13%) | 186(80.87%) | 2.18 (1.06-3.24)* |
| CD4 | | | |
| <201 | 32(26.01) | 91(73.99%) | 1 |
| 201-350 | 19(10.16%) | 168(89.84%) | 0.32(0.25-8.02) |
| >350 | 4(7.69%) | 48(92.31%) | 0.24(0.14-2.16) ** |
| Functional status | | | |
| Working | 33(13.15%) | 218(86.85%) | 1 |
| Ambulatory | 18(18.18%) | 81(81.82%) | 1.28(0.52-3.19) |
| Bedridden | 4(33.33%) | 8(66.67%) | 2.51(1.37-4.60)** |
| WHO Stage | | | |
| Stage1 | 3(6.12%) | 46(93.88%) | 1 |
| Stage2 | 12(12.37%) | 85(87.63%) | 2.30(0.93-5.82) |
| Stage3 | 33(17.64%) | 154(82.36%) | 2.51 (1.37-4.60)** |
| Stage4 | 7(24.14%) | 22(75.86%) | 4.30(1.96-8.17)** |
| Opportunistic infection | | | |
| Yes | 29(33.7%) | 57(66.3%) | 1 |
| No | 26(9.4%) | 250(90.6%) | 0.21(0.18-5.14)** |

Multivariate Analysis

Variables with p value <0.03 on bivariate analysis were included in the model to determine the independent predictor of under-nutrition by adjusting for possible confounders. Accordingly CD4 count, clinical stage, and opportunistic infection at initiation of ART were remained significantly associated with malnutrition. (Table 6)

Independent of all other variables, CD4 at initiation was remained an important risk factor for malnutrition which was those with CD4 count >350 had 82% less likely to develop under-nutrition [AOR=0.18; 95% CI 0.11–3.56] (Table 6).

Patients with clinical stage four at initiation of ART were about five times more likely to develop under-nutrition compared to those clinical stage one [AOR=5.30; 95% CI= 2.56 to 10.78]. Opportunistic infection at initiation of ART has a significant association after adjusting. Which is those has no opportunistic infection at initiation of ART was 36%less likely to develop under-nutrition [AOR=0.64; 95% CI= 0.07-3.89](table 6).

Table 6: Factors associated with under-nutrition in PLHIV, at public hospital of Addis Ababa, 2013 n=362

| Age | <18.5 | >18.5 | AOR (95% CI) |
|--------------------------------|-------------|-------------|---------------------|
| 18-27 | 11 (11.22%) | 87(88.78%) | 1 |
| 28-37 | 22(14.28%) | 132(85.72%) | 1.18 (0.55–2.16) |
| 38-47 | 12(17.65%) | 56(82.35%) | 1.40 (0.41–4.65) |
| >48 | 10(23.8%) | 32(76.9%) | 1.70 (0.57 – 5.12) |
| Sex | | | |
| Male | 11(8.33%) | 121(91.67%) | 1 |
| Female | 44(19.13%) | 186(80.87%) | 1.30 (0.53-2.94) |
| CD4 | | | |
| <201 | 32(26.01) | 91(73.99%) | 1 |
| 201-350 | 19(10.16%) | 168(89.84%) | 0.28 (0.25-5.24) |
| >350 | 4(7.69%) | 48(92.31%) | 0.18 (0.11–3.56) ** |
| Functional status | | | |
| Working | 33(13.15%) | 218(86.85%) | 1 |
| Ambulatory | 18(18.18%) | 81(81.82%) | 1.20 (0.39 – 3.88) |
| Bedridden | 4(33.33%) | 8(66.67%) | 1.70 (0.57 – 5.12) |
| WHO Stage | | | |
| Stage1 | 3(6.12%) | 46(93.88%) | 1 |
| Stage2 | 12(12.37%) | 85(87.63%) | 1.18 (0.55–2.16) |
| Stage3 | 33(17.64%) | 154(82.36%) | 1.40 (0.41 – 4.65) |
| Stage4 | 7(24.14%) | 22(75.86%) | 5.30 (2.56–10.78)** |
| Opportunistic infection | | | |
| Yes | 29(33.7%) | 57(66.3%) | 1 |
| No | 26(9.4%) | 250(90.6%) | 0.64(0.07-3.89)** |

* p value is<0.05

** p value is <0.03

7. Discussion

Under-Nutrition and HIV/AIDS effects are interrelated and exacerbated one another in a vicious cycle. Both HIV/AIDS and under-nutrition independently cause progressive damage to the immune system and increased susceptibility to infection. Since the introduction of ART, the prevalence of under-nutrition has lowered but not yet disappeared. In this study, the prevalence of under-nutrition among clients who attended chronic care were 30.7% at initiation of ART and dropped to 23.5% and 15.2% at three month and at six months of ART, respectively.

Study done in Hawassa university hospital on the Changes in nutritional, functional and immunological status of HIV-infected adults before and after antiretroviral therapy indicated that the prevalence of under-nutrition after ART dropped from 38% to 20%(29). Which is a higher than the prevalence proportion of adult in this study at initiation of ART is 30.7% and after ART 15.2%.

Under nutrition is more common in developing countries, where patients are often not diagnosed or do not commence ART until they have advanced disease. On the other hand, in comparison to other studies, the overall prevalence of under-nutrition in this study after ART is lower than other studies from Botswana which was 30% (27). Another study conducted in Congo on Vulnerability factors for malnutrition among people living with HIV under antiretroviral treatment shows that 21% of study participants were with $BMI < 18.5 \text{ kg/m}^2$ (37). A study conducted in Singapore on The impact of malnutrition on survival and the CD4 count response in HIV-infected patients starting antiretroviral therapy results malnutrition prevalence was 43%(38).which is high compare to this study. This might be because of the secondary data that is used in this study.

A study conducted in Miami florida shows 17.6% prevalence of HIV-related wasting which is lower than this study and this could be due to the socio demographic difference of study participants or economic status difference of the two countries that resulted in undermining the prevalence (13)

This study also shows, the prevalence of under-nutrition in females is greater than males which 19.13% and 8.33% respectively after ART therapy. Meta-analysis from 11 sub-Saharan African countries indicated that the prevalence of under-nutrition in Ethiopia

among HIV-infected women was 13.2% which has a big difference from this study (16). This difference may happen because this study was conducted at the hospital level where most of the patients had advanced clinical condition.

The higher risk of developing under-nutrition in baseline low CD4 count was found in this study is agreed with other study where low CD4 exposes to opportunistic infections' and this affects the immune system and increase energy need, which in turn limits uptake of individual. The less likelihood of developing under-nutrition among respondents in the CD4 >200 implies improved CD4 count level insures low OI and less energy requirement (7). Study done in Hawassa referral hospital showed low CD4 count before ART to expose to low BMI after ART (29). Other study conducted in Paris shows CD4 count is related to body weight loss which is related to BMI (12). A study conducted in Iran resulted with individuals with severe malnutrition had a significant lower CD4 counts in comparison with individuals with normal, mild, or moderate malnutrition (23).

In this study, also shows us independent of all other variables, WHO clinical stage four has significant effect on the likelihood of malnutrition development. Malnutrition is usually encountered at the advanced phase or end of the HIV infection course. This is also shown in the study conducted in Dilla university referral hospital that clinical stage four was statistically significant association with under-nutrition (39).

This study also assessed the effect of having opportunistic infection at initiation of ART on the nutritional status of patients at six months of ART. Which shows that the high prevalence in those having opportunistic infection at initiation of ART. This finding is well supplemented by similar other studies in congo which is the presence of clinical characteristics such stomatitis, anorexia, discolored tongue, asthenia, opportunistic affections and advanced clinical HIV stage were significantly associated with lower means for BMI (37). Another study in Botswana support this study that malnutrition is associated with gastrointestinal symptoms (27). HIV induced immune impairment and heightened subsequent risk of opportunistic infection can worsen nutritional status this necessitates the importance of managing patients with opportunistic infection promptly (38). And a study done in Dilla hospital shows that the number of previous OIs has significant association with nutritional status (39).

8. Strength and Limitation of the study

Strength

- The study was conducted in hospitals which has a large number of patients

Limitation

- The study was done on a secondary data which makes the result obtained less informative than that done using a primary data.(e.g. Socio demographic data, nutritional intervention, dietary intake..);
- May not reflect the situation in other cities of Ethiopia because of difference in socio demographic, economic and other factors;
- Being a cross sectional study; it cannot show temporal relationship between the Variables studied;

9. Conclusion and Recommendations

9.1 Conclusion

The results of this study provide data on the change in nutritional status after six month of ART treatment in HIV positive adults and important associated factors. Which shows that the prevalence of under-nutrition decrease as months on ART increases.

Baseline WHO clinical stage, opportunistic infections, CD4 count were among the imperative causes of under-nutrition. It has been learnt that under-nutrition & its problems in HIV patients are complex & interwoven; no single recipe exists as solution either.

9.2 Recommendation

- Early treatment of HAART;
- Early treatment of opportunistic infection;

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Annex 1-Data collection format

Data collection format for school of public health Addis Ababa university MPH research project on assessment of the change in nutritional status of HIV positive adults after ART in 11 public hospitals.

1. Socio demographic variables

| S.No | variables | Possible answers | Remark |
|------|-----------|---------------------------------|--------|
| 101 | Age | years(in completed years) | |
| 102 | Sex | Male.....1 Female.....2 | |

2. Clinical and immunological

| s.no | Variables | Possible answers | Months on ART | | | Remark |
|------|----------------------------|-------------------------------------------------------------------------|-------------------|---------------|------------------|------------------------|
| | | | Initiation of ART | 3month of ART | Six month of ART | |
| 201 | Weight | Weight in kg | | | | |
| 202 | Height | Height in cm | | | | |
| 203 | BMI | BMI in Kg/m ² | | | | |
| 204 | Functional status | 1. Working.....1 2. Ambulatory.....2 3. Bedridden.....3 | | | | |
| 205 | Clinical stage | 1.Stage1.....1 2.Stage 2.....2 3.Stage 3.....3 4.Stage 4.....4 | | | | |
| 206 | CD4 count | | | | | |
| 207 | Hgb | | | | | |
| 208 | Cotrimoxazole | 1.yes.....1 2.No.....2 | | | | If No skip to Q no 210 |
| 209 | Adherence to cotrimoxazole | 1.Good.....1 2.Fair.....2 | | | | |

| | | | | | | |
|-----|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|--|--|
| | | 3.Poor.....3 | | | | |
| 210 | INH | 1.Yes.....1 2.No.....2 | | | | |
| 211 | ART Regimen | 1.1a1 2.1b2 3.1c3 4.1d4 5.TDF 3TC EFV5 6. TDF 3TC EFV6 | | | | |
| 212 | Adherence to ART | 1.Good.....1 2.Fair.....2 3.Poor.....3 | | | | |
| 213 | Opportunistic infection | 1.Yes.....1 2.No.....2 | | | | |
| 214 | Type of Opportunistic infection | 1. Chronic diarrhea.....1 2. CNS Toxoplasmosis2 3. Tuberculosis...3 4. Oral and/or esophageal thrush.....4 5. PCP.....5 6. Zoster.....6 7. Other.....7 | | | | |

Annex 2-Information sheet and consent form

Title of the study: Assessment of the change in nutritional status and associated factors among HIV positive adults after antiretroviral treatment in Addis Ababa 11 public hospitals.

Name of the Principal Investigator: Lucy Bayouh

Name of the organization: Addis Ababa University School of public health

Name of the Sponsor: Self-Sponsor

Information sheet and consent form prepared for participants from public hospitals in Addis Ababa, Ethiopia that studies nutritional status after ART treatment in HIV positive Adult.

Introduction:

This information sheet and consent form is prepared by the investigator whose main aim is to study the change in nutritional status and associated factors after ART in HIV positive adults in public hospitals which are found in Addis Ababa. The investigator is candidate for MSC degree in public health from Addis Ababa University School of public health.

Purpose:

The purpose of this research is to assess the change in nutritional status of patients infected with HIV after ART and to determine factors associated with it,

- To identify the change in nutritional status of HIV positive adults at initiation, three and six months of ART;
- To determine factor associated with malnutrition among HIV positive adults;

Procedure:

We invite you to take part in this study and if you are willing to participate in this research, you need to understand and sign the consent. Then, your chart will be review by the data collectors. For this study adults who are HIV positive and take ART at least for six months will be included. All the data taken from your chart and the result obtained will be kept anonymous and confidential using coding system whereby no one will have access to your data.

Risk and/or Discomfort:

By participating in this research project you may feel that it has some discomfort on breaking in your privacy. But this will not happen and comparing its potential benefits it contributes to the overall health of HIV positive adults. There is no risk in participating in this research study.

Benefits:

If you participate in this research project, you may not get direct benefit but your participation is likely to help the researcher in assessing the change in nutritional status after antiretroviral treatment and factors associated in HIV positive adults in public hospitals of Addis Ababa. Finally it will give an insight whether policy change is required or not based on the findings of the study for improving the nutritional status of HIV positive adult.

Incentives: you will not be provided any incentives to take part in this project.

Confidentiality and Anonymity:

The information that we will collect from this research project will be kept confidential. Information about you that will be collected from the study will be stored in a file, which will not have your name on it, but a code number assigned to it. Which number belongs to which name will be kept under lock and key, and it will not be revealed to anyone except the principal investigator.

Right to Refuse or Withdraw:

You have the full right to refuse from participating in this research. If you do not allow the information to be taken from your chart, you will not face any problem in your treatment. Your name and any other identifying informative will not be recorder on the questioner.

If you have any question or suggestions you can contact

Lucy Bayouh: Addis Ababa University School of public health

Tel: +251 467 45 41/ +251 920345044

E-mail: lbayouh@gmail.com

Annex 3- የመረጃ መስጫ ቅጽ እና የስምምነት መጠየቂያ፡

የጥናቱ ርዕስ

በአዲስ አበባ 11 የህዝብ ሆስፒታሎች ኤች አ ቪ በደማቸው ውስጥ ያለ አዋቂ ሰዎች የፀረ ኤች አ ቪ መድሃኒት ከጀመሩ በኋላ ያላቸው የስነ ምግብ ሁኔታና የችግሩ ተዛማጅ መንስኤዎች፡፡

አጥኝ- ለ-ሲ ባ□።

□ተቋሙ-ስም- አዲስ አበባ ዩኒቨርሲቲ የህብረተሰብ ጤና የትምህርት ክፍል

ስፖንሰርአድራሲም-በግል

መ□ቢ□

ይህ የመረጃ መስጫ ቅጽ እና የስምምነት መጠየቂያ ፎርም □ተ□□□ው፡፡ በአዲስ አበባ የህዝብ ሆስፒታሎች ኤች አ ቪ በደማቸው ውስጥ ያለ አዋቂ ሰዎች መድሃኒት ከጀመሩ በኋላ ያላቸው የስነ ምግብ ሁኔታ እና ከዚህ ጋር ተያያዥነት ያላቸውን ነገሮች ለማጥናት አላማ ባላት ተመራማሪ ነው፡፡ ተመራማሪዎቹ አዲስ አበባ ዩኒቨርሲቲ የህብረተሰብ ጤና የትምህርት ክፍል ለሁለተኛ ዲግሪ አጠቃላይ ተመራቂ ናት፡፡

የጥናቱ ዋና አላማ

የዚህ ጥናት አላማ ኤች አ ቪ በደማቸው ውስጥ ያለ አዋቂ ሰዎች መድሃኒት ከጀመሩ በኋላ ያላቸው የስነ ምግብ ሁኔታ እና ከዚህ ጋር ተያያዥነት ያላቸውን ነገሮች ለማጥናት ነው፡፡

- ኤች አ ቪ በደማቸው ውስጥ ያለ አዋቂ ሰዎች የፀረኤች አ ቪ መድሃኒት ሲጀምሩ፤ ሶስት ወር እና ስድስት ወር ከወሰዱ በኋላ ያላቸው የስነ ምግብ ሁኔታና ለ□ □
- ኤች አ ቪ በደማቸው ውስጥ ባለ አዋቂ ሰዎች የስነ ምግብ አጥረት □ር ተያያዥነት ያላቸው መንስኤዎች

የአሰራር ሂደት፡-

ፈቃደኝነት ወይንም ተጠይቆ ለመሳተፍ ፈቃደኛ ከሆኑ የስምምነት ቅጹን አንብበው ከተረዱ በኋላ መፈረም አለብዎት፡፡ ከህብረተሰብ መረጃ ሰብሳቢዎች አማኝነት ከህክምና ካረድዎት ላይ መረጃ ይሰበሰባል፡፡ ለዚህ ጥናት የሚከተቱት ኤች አ ቪ በደማቸው ውስጥ ያለ አዋቂ ሰዎች ሆነው ቢያንስ የፀረኤች አ ቪ መድሃኒት ለስድስት ወር የወሰዱ መሆን አለባቸው፡፡ ከህክምና ካረድዎ ላይ የሚገኘው መረጃም ሆነ የጥናቱ ወጤት ሚስጥራዊ ቁጥር በመጠቀም የሚመዘገብ ስለሆነ ምስጥራዊነቱ የተጠበቀ ሲሆን ማንም ሰው መረጃውን ማግኘት አይችልም፡፡

የጥናቱ ጉዳት:

በዚህ ጥናት-በመሳተፍዎ ምስጥርዎ የባከነ ያህል ሊስማዎት ይችላል። ነገር ግን ምንም አይነት ሁኔታ አይፍጠርም። የሚገኘውን ጥቅም ስናነጻጽረው ደግሞ ኤች አ ቪ በደማቸው ወስጥ ላለ አዋቂ ሰዎች ጤናቸው ላይ ከፍትኛ አስተዋፅኦ □□C□ል።በ□ህ ጥናት ላይ ለመሳተፍ ከወሰኑ የሚተወቁ ጉዳዮች የሉም።

በዚህጥናትየሚገኝጥቅም:

ይህ ጥናት በግልዎት የሚሰጥዎት ቀ□ተኛ ጥቅም ባይኖርም የርስዎ ተሳትፎ ለተምራማሪዎኤች አ ቪ በደማቸው ወስጥ ያለ አዋቂ ሰዎች መድሀኒት ከጀመሩ በኋላ ያላቸው የስነ ምግብ ሁኔታ አና ከዚህ ጋር ተያያዥነት ያላቸውን ነገሮች ለማጥናት እስከ ያደርጋል። ጥናቱ ኤች አ ቪ በደማቸው ወስጥ ያለ አዋቂዎችን የስነ ምግብ ሁኔታ ለማሻሻል ፖሊሲ ለመቀየርም ሆነ ላለመቀየር አንደ መርጃ አስተዋጽኦ □□C□ል።

ማበረተኛ:

የጥናቱ ተሳተፊ በመሆንዎት የሚሰጥዎት አንዳችም ማበረተኛ የለም

ሚስጢርስለመጠበቅ:-

ከዚህጥናት-ላ□ የሚገኘው ማንኛውም መረጃ ሚስጢር-ራዊነቱ የተጠበቀ ነው። ጥናቱ ላይ የሚሰበሰበው አርስዎን የተመለከተ መረጃ ሚስጥራዊ ቁጥር ተሰጥቶት በማህደር መልክ የሚቀመጥ ሲሆን ስምዎን አያከትትም። ከተመራማሪዎ በስተቀር ማንም መረጃውን ማገላበጥ ኤችልም።

ያለመሳተፍ መብት:

በጥናቱ ላይ □ መሳተፍ መብት አለዎት። መረጃው ከህክምና ክርድዎት ላይ አንዲዎስድባለመፈለግዎ ህክምናዎት ላይ የሚያመጣብዎት ችግር □ለም። ስምዎንም ሆነ የእርስዎን ማንነት የሚገልፅ ማንኛውም ነገር መረጽ መሰብሰቢ□□ ቅ□ ላ□ አይመዘገብም።

ናሉ።።

ማንኛውም አይነት ጥያቄ ወይም አስተያየት ካሎዎት በሚቀጥለው አደራሻ ማናገር ይችላሉ።።

ሉሲባዩህ፡ አዲስ አበባ ዩኒቨርሲቲ የህብረተሰብ ጤና የትምህርት ክፍል

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