Novelty Journals

ISSN 2394-9716

International Journal of Novel Research in Interdisciplinary Studies
Vol. 4, Issue 4, pp: (17-25), Month: July – August 2017, Available at: www.noveltyjournals.com

Preliminary Study on Effectiveness of Antiretroviral Therapy in Environment and Nutrition Variations: Chencha and Arba Minch Cases

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Abstract: **The Antiretroviral Therapy (ART) is well known drug used to improve the quality of life in persons living with HIV AIDS. HIV medication is very important but a variety of other factors may influence the effectiveness and adherence of ART that needs devotion from patients, provisions of health services and health care professionals, and having social and economical support from the society. The purpose of this study was to assess the effectiveness of ART in nutrition and environment as risk factor.**

Methods: A Hospital based cross sectional study was conducted from February to April, 2016 at Arba Minch and Chencha Hospitals. A total of 400 person who admitted ART drug were used in this Study. Data were collected through interviewer administered questionnaire technique and records and analyzed using descriptive statistics like frequency, percentage and average. The difference was again checked for significance at 0.5 confidence interval. The study participants were employed by using systematic random sample selection method.

Results: The average increment of CD_4 Cell after ART admission in Chencha was 155.60 while that of Arba Minch was 99.00. The difference was significant at 1% confidence interval. The co-infection of TB at the ART admitted period was also compared in the two sites. TB co-infection in Arba Minch was 24.4% while it was 13.3% in Chencha. Average increment of CD_4 in males (134.11) was significantly higher than that of females (107.95).

Conclusion: The study showed that variation existed on the effectiveness of ART in different environment of Chencha and Arba Minch town. Knowledge was poor on ART effectiveness and the relationship with nutrition. There was correlation between the number of CD_4 cell and prevalence of TB co infections. Nutrition and Environmental condition play great role in the prevalence of opportunitistic TB co infection.

Keywords: **ART, Effectiveness, HIV Patients, Nutrition, Environment, CD_4 Cell.**

1. INTRODUCTION

AIDS (Acquired Immunity Deficiency Syndrome) is extremely serious health disorder that compromises the body's defenses against diseases **[1]**. The causative virus, human immunodeficiency virus (HIV), is a type of retrovirus which infects white blood cells including T-helper cell and macrophages **[2, 3]**. There are various interventions to prevent HIV/AIDS: condom distribution, behavioral change programs, and blood supply safety are among them. Also, to reduce deaths related with HIV/AIDS, we make use of Antiretroviral Therapy (ART), which was first introduced in the United States as a combination therapy in 1996; with the goals of achieving maximal and durable reduction in plasma viral load and restoration of immunological function **[4, 5, 6]**. In worldwide, around 12.9 million PLWHA (37% of the total) had access to ART in 2013 **[2]**.

The medication of ART is a term used to describe the treatment of HIV/AIDS using antiretroviral drugs (ARVs). Now a day, there are three major classes of ARV drugs: nucleoside or nucleotide analogue reverse transcriptase inhibitors (NRTIs), protease inhibitors (PIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs) **[7, 8]** these may take once, twice, or thrice times a day, when several such drugs are taken in a combination is known as Highly Active Antiretroviral Therapy (HAART) **[9]**.

ART has been a known and the sole life saver for the HIV victims. Effective ART treatment is known to prolong the life expectancy of individuals for one to three decades and it decreases the viral load in the body **[10]**. As a result of improving the survival rates among HIV-infected persons **[11].** ART during pregnancy has been effective at significantly decreasing the likelihood of vertical transmission of HIV. In the period 2002-2012, the wide range use of ART increased life expectancy by 5.5 in worldwide, but its rate is not uniform universally **[12]**. All adherence measures were significantly associated with viral suppression. However, patients when do not take the drug correctly, the consequence on the patient start to develop new opportunistic infections that is a treatment failure and they have poor viral suppression **[13, 14, 15].**

The massive distribution of ART, however, cannot be successful without close monitoring, evaluation and correction **[16]**. This becomes imperative while considering the rural society where the environmental, social and economic perspectives completely defer from that in urban area **[17]**. This work can be exemplified as the possible research intervention, and expected to be a call for further detailed epidemiologic study.

1.2. Justification of the Study:

Several researches have been conducted on ART risk factors. Sex, age, nutrition and environmental factors are researched in relation to the epidemiology of opportunistic infections. But, neither of these researches directly addresses the grass root situations. In spite of the fact that these risk factors influence the effectiveness of the drug, and the different corners of the globe experience different situations, the same ART is distributed.

There are few studies on energy expenditure in HIV infected individuals. Energy requirements are likely to increase by 10% to maintain body weight and physical activity in asymptomatic HIV infected adult and growth in asymptomatic children (WHO, 2003). The energy requirement can be solely satisfied by nutrition. But, the food variety, availability and accessibility vary according to environmental variation. This signifies assessment of various geographic locations and nutrition variation with the health implication on HIV patients. Worth mentioning, the medication along with food and other requirements are optimized in developed countries while the beneficiaries at large are in the low economy sub-Saharan countries. This does not mean that these countries are harmed by the specified reason. But, it would have been risk free and more successful if accompanied by closer monitoring and evaluation and multi factorial researches of the therapy. The risk factors and their consequence on the effectiveness of the drug should be monitored, documented and updated.

With this regard, the ART service in rural Ethiopia is limited to the delivery of the drug and the loosen follow up. Even though the general health implication of ART in Ethiopia is promising, the basic researches on the identified risk factors should be explicitly trucked rather than the generic conclusions made about the therapy. Improved attention to diet and nutrition may enhance ART acceptability, adherence and effectiveness. Balanced diet and quality drinking water has been recommended for the long and healthy life of HIV patients. ART effectiveness is also positively related to the quality of life.

This proposed preliminary research was intended to have a momentum of characterizing the nutrition and environment as risk factors for opportunistic infection and CD_4 count in Ethiopian geographic locations as a case study of Arba Minch and Chencha, SNNP. There is about 1,447 m altitude difference between these two sites. Following the environmental difference, agricultural practices, food variety, availability, accessibility and the subsequent feeding habits/preferences/ are expected to be different. The rationale behind this work was the expectation of significant relation (in any direction) among the environment, nutrition and ART effectiveness.

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2. METHODOLOGY

2.1. Study Design and Period:

A Hospital based cross sectional study was conducted from February to April, 2016.

2.1. Description of the study area:

The study was conducted in Arba Minch and Chencha Hospital, which is found in Arba Minch town and Chencha town respectively, Gamo Gofa Zone. Arba Minch is located in SNNPR 505 km South of Addis Ababa, capital city of the country and 275 km South West away from Hawassa and the total population of Arba Minch town was estimated to be 103,355 (in 2014). The hospitals provides general health care service and higher levels of clinical care for the catchment area populations and they have been providing ART for thousands of HIV/AIDS adults and paediatric patients come from rural and urban areas. Currently, there was 1501 and 1330 adult patients started ART treatment at AMH and CH, respectively and on follow up in 2016. Arba Minch has 623.5 - 1061mm annual rain fall and temperature of 30.1˚c. It has an altitude range of 1200-1400 m above sea level. Chencha has longitudinal and latitudinal degree of 6˚15'N; 37˚34'E and an elevation of 2732 m above sea level.

2.2. Source population:

Source populations were all adult HIV positives who started ART-drug and have been on follow up in Chencha and Arba Minch Hospital.

2.3. Study population:

Study populations were all adult HIV positives outpatients systematically selected who receiving ART-drug and on follow up at the study settings.

- **Inclusion criteria**: All individual whose age greater than or equal to 18 years and who have been on treatment for more than 3 months period were interviewed. After interviewing, only ART drug users with adherence to antiretroviral therapy were selected as study participant for further analysis.
- **Exclusion criteria**: All HIV positive patients who were mental ill and missing clinical record.

2.4. Assessment of adherence:

Adherence was assessed by asking patients to recall their intake of prescribed ART doses in the previous 7 days. Self-reported ART adherence was calculated as the ratio of the doses taken during the specific time-period to the total number of ART doses prescribed for the same time-period. The results were expressed as percentages and patients were considered adherent to ART if they reported taking ≥95% of their prescribed ART in the previous 7 days before interviewing day.

2.5. Data collection procedures:

In this study, data were collected through interviewer administered questionnaire technique and records.

CD_4 count in ART admitted patients at the ART admission time was taken as base line, and CD_4 count after six month was taken to get the difference at six month interval. The data was separately taken in location (Chencha and Arba Minch), and sex (male and female). The food accessibility in both sites and their specific weather condition were taken to indicate the possible causes of probable differences. The sixth month CD_4 count was directly taken (primary data) while the base line was taken from the records (secondary data).

ART admitted individuals were directed to the laboratory physician to give blood sample. The physician use syringe and lancet (needle) to take blood sample. The sample was collected by vacuum tube and transported to CD_4 room and then EDTA was added as an anticoagulant. the bead containing reagent is pierced by coring station then 50 micro litter of blood sample was added to the bead containing reagent and placed in working station which is a dark place for the blood sample , 50 micro litter blood sample was measured using micropipette. Then the solution was mixed using shaker genteelly. The bead containing reagent have two region, CD_4 and CD_8 ,finally following the principle of CD_4 counter machine , the CD4 cells of patient were counted.

The interview questionnaire consists of the number of doses missed in last week, socio-demographic characteristics, food related (nutrition affects ART effectiveness, most accessible food, most affordable food, and Most preferable food), and current CD_4. Patient information sheets (records) involved to collect additional clinical information on CD4 cell count at enrolment and co-morbid TB were recorded.

There were four data collectors who were Diploma nurses and two supervisors were used for each hospital. The investigator offered one day training for data collectors and supervisors. Training was included explanation of the study objectives, techniques for interviewing, how to approach potential respondents and how to keep confidentiality later.

Pre-testing was done (5% of the sample size) in both Chencha and Arba Minch town health centre. After the pre-testing some improvement of the tool was done. The supervisors performed immediate supervision on a daily basis. Each and every completed questionnaire was checked for completeness.

2.6. Sample size and sampling:

A sample of 200 person was taken from those who are taking ART drug as a sample size from each hospital (Chencha and Arba Minch) so the total number of sample size for this study become 400. The study participants were employed by using systematic random sample selection method.

As to the sampling procedures, patients on follow up at ART treatment fulfilling the inclusion criteria were selected by using systematic random sampling method through appointments. There were 1501 and 1330 adult HIV/AIDS patients on HAART treatment at AMH and CH, respectively.

The individuals was selected by using the interval: J, J+k, J+2k, J+3k……J+(n-1) k

Where:

- N (total number of study population) = 1501 for AMH and 1330 for CH
- n (total number of sample size) = 200 from each Hospital
- K (interval size) = N/n ≈ 7 for AMH and ≈ for CH
- J (the first participant or starting point) = 1

The first participant was selected by using lottery method and then every 7^{th} and 6^{th} patients were taken among daily appointees depending on the order they come to the ART unit from AMH and CH, respectively.

2.7. Data analysis:

The data were analyzed using descriptive statistics like frequency, percentage and average. Average CD_4 cell increment were calculated by taking sum of the difference of CD4 in samples and dividing by the No of sample individual. Average CD_4 increment was also calculated based on location (Chencha or Arba Minch) and sex. The difference was again checked for significance at 0.5 confidence interval.

2.8. Ethical considerations:

The study obtained ethical clearance from the Institutional Review Board of College of Natural Science, Arba Minch University. Supportive letter was obtained from the Arba Minch and Chencha health office before data collection. The baseline study is on the effect of ART drug on HIV patients considering nutrition and environment as risk factors. Official permission to conduct this assessment was secured at each level. Verbal informed consent was taken from each respondent. The right to deny responding was respected. Confidentiality of all the information was assured at all levels.

3. RESULTS AND DISCUSSION

One of the main concerns of this study was to assess whether there is variation in the effectiveness of ART taking environment, nutrition and sex as risk factors using Hospital-based study in Arba Minch and Chencha town, Southern Ethiopia. Total data of 400 individuals was totally taken and analyzed 200 from each hospital. The average increment of CD_4 cell after ART admission in Chencha was 155.60 while that of Arba Minch was 99.00. The difference was significant at 1% confidence interval.

3.1 Socio-demographic Characteristics:

A total of 400 ART admitted adult, 200 from each site were participated in this study, of these, most of the respondents in Arba Minch were females 60.5%, aged 31-39 years 53%, Urban resident 78% and attained primary school 43%. In this study, most of the interviewees from Arba Minch were found to be married (52.5%) and government employee (48.5%). Most of the respondents in Chencha. One hundred and three (51.5%), 49.5%, 55.5%, 46.5%, 28.5% and 46.5% of participants of Chencha are female, 31-39 age, urban residents, married, attained primary school and employed respectively **(Table 1)**.

3.2 Nutrition Availability, Affordability and Preference Characteristics:

Table 2 shows the respondents' nutrition availability, affordability and preference characteristics of ART admitted individual at Arba Minch and Chencha Hospitals. Most of the respondents 62.5% in Arba Minch and 51.5% Chencha were replied that they don`t know whether nutrition affects ART effectiveness or not with and respectively. Almost 43.5% and 53.0% of respondents were mentioned Mango, Banana, Vegetable and Apple as the most accessible and affordable food stuff in Arba Minch respectively, whereas in the case Chencha, 38.5% of the respondents said cultivated crop like Teff, Wheat are the most accessible food item with Potato, Sweet potato and Carrots preference. Most of the participants 50.5% in Arba Minch and 62.5% in Chencha were reported Meat, Fish, Chicken, Egg and Milk are preferable food items (**Table 2**).

Table 1. Socio-demographic characteristics of ART admitted individual at Arba Minch and Chencha Hospital, Gamo Gofa Zone, Southern Ethiopia, 2016

Sites	**Arba Minch Case**		**Chencha Case**	
Variables	**Frequency**	**Percentage (%)**	**Frequency**	**Percentage (%)**
Sex				
Male	79	39.5	97	48.5
Female	121	60.5	103	51.5
Age				
20-30	23	11.5	31	15.5
31-39	106	53.0	99	49.5
40-49	60	30.0	53	26.5
≥50	11	5.5	17	8.5
Residence				
Urban	156	78.0	111	55.5
Rural	44	22.0	89	44.5
Marital status				
Single	31	15.5	43	21.5
Married	107	53.5	93	46.5
Windowed	29	14.5	24	12.0
Divorced/Separated	33	16.5	40	2.0
Education status				
No any school	32	16	43	21.5
Elementary	22	11	37	18.5
Primary	86	43	57	28.5
Secondary	19	9.5	12	6.0
Diploma and above	41	20.5	6	3.0
Occupation				
Employed	97	48.5	87	43.5
Merchant/business	88	44.0	93	46.5
Unemployed	15	7.5	20	10.0

Novelty Journals

ISSN 2394-9716

International Journal of Novel Research in Interdisciplinary Studies
Vol. 4, Issue 4, pp: (17-25), Month: July – August 2017, Available at: www.noveltyjournals.com

Table 2. Nutrition availability, affordability and preference characteristics of ART admitted individual at Arba Minch and Chencha Hospitals, Gamo Gofa Zone, Southern Ethiopia, 2016

Sites	Arba Minch Case		Chencha Case	
Variables	**Frequency**	**(%)**	**Frequency**	**(%)**
Nutrition affects ART effectiveness?				
Yes	51	25.5	52	26.0
No	28	14.0	45	22.5
I Don`t Know	121	60.5	103	51.5
The Most accessible food in Arba Minch				
Mango, Banana, vegetable and Apple	87	43.5	20	10.0
Maize and its derivatives	84	42.0	13	6.5
Fish, Meat, Chicken, Egg and Milk	15	7.5	23	11.5
Potato, Sweet potato, Carrots etc.	11	5.5	67	33.5
Cultivated crop like Teff, Wheat	3	1.5	77	38.5
The Most affordable food for you				
Mango, Banana, vegetable and Apple	106	53.0	25	12.5
Maize and its derivatives	44	22.0	4	2.0
Meat, Fish, Chicken, Egg and Milk	5	2.5	13	6.5
Potato, Sweet potato, Carrots etc.	30	15.0	89	44.5
Cultivated crop like Teff, Wheat	15	7.5	69	35.5
The Most preferable food in for you				
Mango, Banana, vegetable and Apple	51	25.5	12	6.0
Maize and its derivatives	5	2.5	3	1.5
Meat, Fish, Chicken, Egg and Milk	101	50.5	125	62.5
Potato, Sweet potato, Carrots etc.	20	10	10	5.0
Cultivated crop like Teff, Wheat	23	11.5	50	25.0

The co-infection of TB at the ART admitted period was also compared in the two sites. TB co-infection in Arba Minch was 24.4% while it was 13.3% in Chencha. As indicated in the above Table 3, TB co-infection percentage in HIV patients of Arba Minch is significantly higher than that of Chencha ($P < 0.05$). These indicate there were significant differences in opportunistic infection between the two locations. This is friendly with the CD_4 increment data, therefore, CD_4 increment is higher and expected to give higher disease resistance. However, Arba Minch is also known to be hot, and expected to harbor the bacteria and make the residents more susceptible to different kinds of opportunistic infections (**Table 3)**.

Table 3. Result of prevalence of opportunistic TB infection by site.

S. No.	Site	No of TB infected patients out of 200 ART admitted individuals	Percentage (%)
1	Arba Minch	49	24.4
2	Chencha	27	13.3
	Total	**76**	**37.7**

Table 4 shows the results of average CD_4 cell increment based on sex of ART admitted individual at Arba Minch and Chencha Hospitals. Average increment of CD_4 in males (134.11) was significantly higher than that of females (107.95). The average increment and percentage in the above table indicates that the presence of gender base on the effectiveness of ART drug (**Table 4)**.

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Table 4. Results of average CD_4 cell increment based on sex

S. No	Sex	Average increment	Percentage (%)
1	Female	107.95	44.59
2	Male	134.11	55.41
	Total	**242.06**	**100**

As indicated in Tables 5, most of Arbaminch ART admitted individual CD4 Cell count increment reside or fall between (-7)- 96) and (97-199) which is 33% and 24% respectively. However, most of the Chencha HIV/ AIDS patients who taken ART drug, increment of their CD_4 cell resides between (97-199) and (200-302) with 35.5% and 33.5% respectively (**Table 6**).

Tables 5. Frequency of Average CD_4 Cell level of Arbaminch ART admitted individual.

S. No	Ranges of CD_4 Cell Difference	Frequency	Percentage (%)
1	(-110) - (-6)	13	6.5
2	(-5) - 96	67	33.5
3	97-199	49	24.5
4	200-302	40	20
5	303-405	18	9
6	405-508	9	4.5
7	509-611	4	2
	Total	**200**	**100**

(Key: - = Negative Value indicate Decrement of CD_4 Level from the start of ART Admission)

Tables 6. Frequency of Average CD_4 Cell level of Chencha ART admitted individual.

S. No	Ranges of CD4 cell Difference	Frequency	Percentage (%)
1	(-110) - (-6)	9	4.5
2	(-5) - 96	9	4.5
3	97-199	71	35.5
4	200-302	67	33.5
5	303-405	26	13
6	405-508	9	4.5
7	509-611	9	4.5
	Total	**200**	**100**

In fact, nutrition variation was existed between Chencha & Arba Minch town. In Arba Minch most people are accessible for the following nutrition includes fruit like mango, banana, apple, vegetable, fish and soup of fish so on. In Chencha, the most commonly accessible food include, roots (like potato, sweet potato, carrots etc), teff, wheat, and apple and generally rooty and cultivated crop used in Chencha. There is well known difference in both Chencha and Arba Minch ART admitted individuals based on their CD_4 cell count according to the analysis of data. This may be the result of different nutritional system among the two sites or environmental factor difference. The questioner filled by sampled patients plus personal observation of the two sites witnessed that there is definite variation in food accessibility, affordability and preference. This study is consistent with the previous reports **[14, 15, 18]**. However, this observation can not be a base to conclude which is malnourished, only indicative for factor which cause increased or decreased effectiveness of ART in person living with HIV/AIDS.

Adequate nutrition, which is best achieved through consumption of a balanced healthy diet, is vital for health and survival for all individuals regardless of HIV status. Any immune deficiency as a result of HIV/AIDS leads to malnutrition, and malnutrition leads to immune deficiency. Malnutrition further worsens the effectiveness of ART drug and contributes to more rapid progression to AIDS by decreasing CD_4 level. Good nutrition helps in Supporting the effective action of drug treatment of opportunistic infections and ART. From researcher point of view, food insecurity is significant risk factor for effectiveness of ART among HIV-infected individuals in the in the study area. Similar finding were reported in the previous work **[19, 20]**

TB is one of the leading causes of illness and death among people living with AIDS in developing countries. The majority of people infected with the HIV virus develop TB as the first manifestation of HIV/AIDS **[21]**. Generally, inverse relationship between the increment of CD_4 cell and prevalence of opportunity infection like TB. Most of opportunistic infections were as a result of weekend immune system, which means less number of CD_4 cells level. Percentage of TB prevalence of Arbaminch town are higher than the percentage of TB prevalence in Chencha. However, but average increment of CD4 cell in Chencha HIV patient are greater than Arbaminch HIV patients. In the present study the prevalence of TB and average increment of CD_4 cell count were correlated. From this point of view environment creates suitable conditions for increment of CD4 cell and simultaneously control of TB prevalence in Chencha. In Chencha most of HIV/AIDS patients resist the TB co infection not by increment of CD_4 cell level couple with environment. Also temperature may plays great role resistance of many deaths. This all considered relative to Arba Minch. The present study is continent with the previous reports **[20, 22, 23]**

In Ethiopia, the federal ministry of health ratified policy for free distribution of ART drug to each regional hospital and health centers. So the people living with HIV/AIDS taken without any cost or free service. Each hospital and health centers may recommended to add advice on relationship of ART effectiveness and adherence beside free service of ART drug.

4. CONCLUSION

ART is an essential component of care for people living with HIV/AIDS. Nutritional intervention and other factors should be integral part of all HIV treatment program improved attention to diet and nutrition may enhance ART acceptability, adherence and effectiveness. The study showed that variation existed on the effectiveness of ART in different environment of Chencha and Arba Minch town. Knowledge was poor on ART effectiveness and the relationship with nutrition. There was correlation between the number of CD_4 cell and prevalence of TB co infections. Environmental condition play great role in the prevalence of opportunitistic TB co infection. Our findings highlight there should be need for strategies to improve food access among ART admitted individual in order to ensure ART effectiveness.

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