PROPORTION OF CD4 CELLS BEFORE AND AFTER ANTIRETROVIRAL THERAPY (ART) IN PEOPLE LIVING WITH HIV/AIDS VISITING ART CENTER IN SUKRARAJ TROPICAL AND INFECTIOUS DISEASE HOSPITAL, TEKU, KATHMANU, NEPAL

A thesis submitted in partial fulfillment of the requirements for the award of the degree of Master of Science in Zoology with special paper Parasitology

Submitted to

Central Department of Zoology

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Nepal

Submitted by

Suman Neupane

T.U. Registration No: 5-2-19-535-2006

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DECLARATION

I hereby declare that the work presented in this thesis has been done myself, and has not been submitted elsewhere for the award of any degree. All sources of information have been specifically acknowledged by reference to the authors or institutions.

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RECOMMENDATIONS

This is to recommend that the thesis entitled "PROPORTION OF CD4 CELLS BEFORE AND AFTER ANTIRETROVIRAL THERAPY (ART) IN PEOPLE LIVING WITH HIV/AIDS VISITING ART CENTER IN SUKRARAJ TROPICAL AND INFECTIOUS DISEASE HOSPITAL, TEKU, KATHMANU, NEPAL" has been carried out by Suman Neupane for the partial fulfillment of Master's Degree of Science in Zoology with special paper Parasitology. This is his original work and has been carried out under our supervision. To the best of our knowledge, this thesis work has not been submitted for any other degree in any institutions.

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LETTER OF APPROVAL

This thesis submitted by Suman Neupane entitled "PROPORTION OF CD4 CELLS BEFORE AND AFTER ANTIRETROVIRAL THERAPY (ART) IN PEOPLE LIVING WITH HIV/AIDS VISITING ART CENTER IN SUKRARAJ TROPICAL AND INFECTIOUS DISEASE HOSPITAL, TEKU, KATHMANU, NEPAL" is approved for the examination and submitted to the Tribhuvan University in partial fulfillment of the requirements for Master's Degree of Science in Zoology with special paper Parasitology.

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CERTIFICATE OF ACCEPTANCE

This thesis work submitted by Suman Neupane entitled "PROPORTION OF CD4 CELLS BEFORE AND AFTER ANTIRETROVIRAL THERAPY (ART) IN HIV PATIENTS VISITING ART CENTER IN SUKRARAJ TROPICAL AND INFECTIOUS DISEASE HOSPITAL, TEKU, KATHMANU, NEPAL" has been accepted as a partial fulfillment of Master's Degree of Science in Zoology with special paper Parasitology.

EVALUATION COMMITTEE

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LIST OF ABBREVIATIONS

Abbreviated form	Details of abbreviations
3TC	Lamivudine
AIDS	Acquired Immune Deficiency Syndrome
ART	Antiretroviral Therapy
ARV	Antiretroviral
CD4	Cluster of Differentiation
d4T	Stavudine
EFV	Efavirenz
HIV	Human Immuno Deficiency Virus
IDUs	Intravenous Drug Users
NCASC	National Center for AIDS and STD Control
NNRTIs	Non Nuclease Reverse Transcriptase Inhibitors
NRTIs	Nuclease Reverse Transcriptase Inhibitors
NVP	Nevirapine
Pis	Protease Inhibitors
PLHIV	People living with HIV/AIDS
STIDH	Sukraraj Tropical and Infectious Disease Hospital
VCTC	Voluntary Counseling and Testing Center
WHO	World Health Organization
ZDV	Zidovudine

I

INTRODUCTION

1.1.HIV AND AIDS

Human Immunodeficiency Virus (H.I.V.), probably leads to AIDS, although the timescale is variable, and depends upon numerous factors, including: treatment regimes; infections to which the person is exposed. Essentially, HIV attacks and disables a group of cells in the immune system, the CD4 cells. These are necessary for defending the person against cell mediated infections (eg. TB).

Acquired Immune Deficiency Syndrome (A.I.D.S.) , is a term used to describe the presence of specific infections that indicate end stage immune system breakdown. The onset of AIDS is manifested by the appearance of 2 major opportunistic infections: Kaposi's sarcoma, pneumocystis carina pneumonia (P.C.P.) (Hodgson 2000).

Acquired Immune Deficiency syndrome (AIDS) is a chronic illness caused by retrovirus known as Human Immunodeficiency Virus (HIV) (WHO 2009). The progressive impairment of body immune system leading to increased susceptibility to infection and tumors and such fatal condition is known as AIDS. More than sixty million people have already been infected and about 33 million people are estimated to be living with HIV/AIDS. The first case in Nepal was reported in 1988 and since than 55,626 adults and children are infected with HIV virus. People who inject drugs, men having sex with men, female sex workers are the key populations spreading the epidemic. About three fifth (58%) of the infection was among adults (15-49), whereas it was 8% among children under age of 15 years and 6% among population above 50 years (DOHS 067/068).

Nearly 55,626 adults and children are estimated to be living with HIV/AIDS in Nepal. HIV/AIDS virus induced epidemic is one of the most serious health concerns in the world because of its high fatality rate and lack of curative treatments and vaccine. With consistently exceeding the HIV prevalence of more than 5% among the most at risk population (particularly FSWs, PWIDUs, MSMs, Migrants and their spouse) year after year, the country has remained at the critical juncture of " concentrated epidemic" stage with alarming threat of HIV/AIDS being one of the number one killer in the country. The fact that the

epidemic remains extremely dynamic, growing and changing character as the virus exploits new opportunities for transmission poses constant challenges for program intervention and generating adequate information (NCASC 2007).

1.2. CD4 CELLS

T-cells (or T-lymphocytes) are white blood cells that play important roles in the immune system. There are two main types of T-cells. One type has molecules called CD4 on its surface; these 'helper' cells organize the immune system's response to bacteria, fungi and viruses. The other T-cells, which have a molecule called CD8, destroy cells that are infected and produce antiviral substances.

HIV is able to attach itself to the CD4 molecule, allowing the virus to enter and infect these cells. Even while a person with HIV feels well and has no symptoms, billions of CD4 cells are infected by HIV and are destroyed each day, and billions more CD4 cells are produced to replace them (Carter 2012).

A normal CD4 count in a healthy adult can vary but is usually between 600 and 1200 CD4 cells/mm3 (though it may be lower in some people). Most people with HIV find that their CD4 count falls over time. This often happens at a variable rate, so the count can still be quite stable for long periods.

It is recommended that HIV treatment should be started when CD4 cell count is around 350 but for the positives with WHO stage (annex 1) 3 and 4, ART should be started irrespective of CD4 cell count (annex 2). Starting treatment at this time (rather than waiting until the CD4 cell count is lower) reduces risk of HIV-related illnesses and some other serious illnesses as well. If it drops below 200 people are at increased risk from serious infections and should start HIV treatment (Carter 2012).

1.2. ANTIRETROVIRAL THERAPY (ART)

Standard antiretroviral therapy (ART) consists of the combination of at least three antiretroviral (ARV) drugs (annex 3) to maximally suppress the HIV virus and stop the progression of HIV/AIDS. Huge reductions have been seen in rates of death and suffering when use is made of a potent antiretroviral regimen, particularly in early stages of the disease. There are different preconditions and principles according to which ART is given to the HIV positives (see annex 4). Furthermore, expanded access to ART can also reduce the HIV transmission at population level, impact orphan hood and preserve families. In 2010, an estimated 34 million people were living with HIV, of whom more than 30 million were living in low- and middle-income countries (WHO 2010).

WHO and UNAIDS estimate that at least 15 million people were in need of antiretroviral therapy in 2010. As of the end of 2010, 6.6 million people had access to antiretroviral therapy in low- and middle-income countries. WHO is providing countries with ongoing guidance, tools and support in delivering and scaling up antiretroviral therapy within a public health approach. WHO now recommends starting HIV treatment when a person's CD4 count drops below 350cells/mm3 (used to be 200). All HIV-positive people with TB are now recommended to start ART regardless of their CD4 cell count. Estimates developed through epidemiological modeling suggest that HIV-related mortality can be reduced by 20% between 2010 and 2015 if these guidelines are broadly implemented. However, the number of people requiring ART will increase significantly.

In 1986, antiretroviral therapy was initially introduced in other countries with the first drug Zidovudine (ZDV). Over the next few years, other antiretroviral drugs (NRTIs, NNRTIs and Pls) were introduced. Initially, mono and dual therapies were used but the problem of resistance emerged. At present, 3 or more ARV drugs are recommended worldwide for the treatment of people with HIV infection. Since the use of combination therapy, this disease has been transformed into a chronic condition. However, the use of antiretroviral therapy is not the final answer to HIV/AIDS prevention and care programs. The delivery of effective care and antiretroviral treatment for people living with HIV/AIDS in the poorest countries is considered an urgent priority and is a complementary program to HIV transmission

prevention programs. Initially, antiretroviral therapy was very expensive and so, unaffordable in most developing countries (NCASC 2010).

1.6. SIGNIFICANCE OF THE STUDY

As the number of the people living with HIV/AIDS (PLHIV) dies in a short period of time, the study will help to know that using anti retroviral therapy helps to increase the immunity power against the disease which helps to prolong the life of PLHIV. The study will also help to generate some awareness in the people regarding the narrow concept of people towards HIV/AIDS. The study also enlightens people living with HIV/AIDS towards anti retroviral therapy (ART).

Being a student of zoology it is not an easy task to deal with the medically based treatment therapy. So this research may be a good example for those zoology students who would like to work in the field of HIV/AIDS.

1.6. LIMITATIONS OF THE STUDY

It was not an easy task to deal with the PLHIV. The major barrier was during the questionnaire survey as the positives weren't willing to answer the questions because of the confidentiality problems.

During the study period, Out of the total 78 samples taken 7 people lost the follow up, 5 people died and 19 people were transferred to other ART centers so only the relevant data of 47 active samples could be taken for the study.

1.7. OBJECTIVES OF THE STUDY

GENERAL OBJECTIVE:

To know the general health status and ART profile of positives undergoing standard antiretroviral therapy.

SPECIFIC OBJECTIVES:

- To study the socio-demographic status of PLHIV.
- To know the WHO staging of the PLHIV undergoing ART
- To study the proportion of CD4 cells before and after antiretroviral therapy (ART).
- To study the effect of regimen that has been prescribed to the H.I.V. positive undergoing ART including weight gained or lossed.

II

LITERATURE REVIEW

The total number of adults and children living with HIV/AIDS in the world is 34 million. About 2.5 million adults and children are newly affected by HIV/AIDS. 1.7 million children and adults have died due to AIDS (UNAIDS 2011).

The reported HIV cases in Nepal are 20,583. Out of these cases 13,157 are male where 7,417 are female and 9 are from third genders. The age group between 30-39 years has the highest reported cases of HIV/AIDS with 7,963 cases. Out of the total sub groups, clients of sex workers have the highest reported case of HIV/AIDS with 8,772 cases (NCASC 2012).

In 1986, antiretroviral therapy was introduced in other countries with the first line drug zidovudine (ZDV). Over the next few years, other antiviral drugs (NRTIs, NNRTIs, and PIs) were introduced. Initially mono and dual therapies were used but the problem of resistance emerged. At present 3 or more ARV drugs are recommended worldwide for the treatment of people with HIV infection (NCASC 2010).

Anti-retroviral therapy (ART) started in Nepal from February 2004 from Teku Hospital. Government is providing free of cost ART service to all those in need. There are National ART Guidelines and standard operating procedures for the clinical management of ART. Currently there are 39 ART centers in 33 districts in Nepal. CD4 count service is available at 16 sites, while 4 sites have CD4 caliber (NCASC 2012).

Among total people with advanced HIV infection who are currently receiving ART in Nepal, of which the proportion of adults is 93% and that of children is 7%. Among total people with advanced HIV infection who are currently receiving ART in Nepal of which the proportion of male is 54.6%, that of female is 44.8% and that of third gender is 0.3%. The proportion of people with advanced HIV infection who are alive and currently on ART after 12 months of treatment is 84.7% and 24 months of treatment is 78.2% (NCASC 2012).

Out of total ART needed by 27,363 only 7,142 people are currently receiving ART treatment in Nepal. Out of the total people receiving ART treatment 5,142 people are on the 1st line

regimen, 1,686 positives are substituted on the 1st line and 43 people are switched on the 2nd line (NCASC 2012).

2.1. GLOBAL CONTEXT

Mahajan et al. (2004) concluded that the median change in total lymphocyte count (TLC) among positives with a CD4 count rise of >100 cells/mm3 at 1 year of highly active antiretroviral therapy was +766 cells/mm3 while that of positives with a CD4 count rise of <100 cell/mm3 was +100 cells/mm3.

Severe et al. (2005) in a research done in Haiti in 2005, during a 14 month study in 1004 positives the result showed that in adults and adolescents, the median increase in the CD4 T-cell count from baseline to 12 months was 163 per cubic millimeter (interquartile range, 77 to 251 per cubic millimeter). In children, the median percentage of CD4 T cells rose from 13 percent at baseline to 26 percent (interquartile range, 22 to 36 percent) at 12 months.

Kumarasamy et al. (2006) showed that the median CD4 count at the time of initiating highly active antiretroviral therapy (HAART) was 108 cells/microL. The most common 1st line regimen were stavudine (d4T) + Lamivudine (3TC) + Nevirapine (NVP) (63%), Zidovudine (ZDV) + Nevirapine (NVP) (19%), Stavudine (d4T) + Lamivudine (3TC) + Efavirenz (EFV) (9%) and Zidovudine (ZDV) + Lamivudine (3TC) + Efavirenz (EFV) (4%).

Moore and Keruly (2007) Out of total 655 positives observed for a median of 46 months (range 13-72 months) the median change from baseline to most recent CD4(+) cell count was +274 cells/microL with 92% of the positives having an increase in the CD4 cell count.

Gautam et al. (2008) showed that the mean baseline CD4 cell count was 112 ± 60 cells/μL and mean baseline plasma viral load of 31 positives studied was 192,686 copies/mL. Baseline plasma viral load was higher among positives with lower baseline CD4 cell count. During follow-up, 80.8% positives showed clinical improvement, while a CD4 cell count increased by ≥50 cells/μL in 84.6% cases. Mean CD4 cell count increased from 126 ± 16.6 cells/μL at baseline to 278 ± 196.7 cells/μL.

Rajasekaran et al. (2009) showed that Among 7,934 HIV positive positives in the ART program, one year cohort of 714 adult positives who had completed two consecutive follow-up CD4 values were assessed. The baseline CD4 cell count subgroups, < 100, 100-199 and 200 and more, had 53.5%, 35.2% and 11.3% positives respectively. Those with baseline CD4< 100 had cumulative probability of survival 85%, 82%, 82% and 82% at 12, 24, 36 and 42 months respectively. Those who had baseline CD4 count between 100-199 had cumulative probability of survival 96%, 93%, 92%, and 90% at 12, 24, 36, and 42 months respectively.

Wright et al. (2011) in a research done in Australia in 2011 showed that Mean CD4 counts increased above 500 cells per microliter in all baseline CD4 strata by 12 months after the use of ART.

Sunita et al. (2011) in a research conducted in India showed that Majority of the positives taking ART have CD4 count between 50 to 250 cells/mm3 of blood and there is a significant relation between the positives taking ART and the CD4 cell count ($\chi 2 = 6.384$, $p<0.05$). The mean CD4 cell count in positives at first visit was 155.7 cells/mm^3, increased significantly to 500 cells/mm^3 after six months of ART.

Woldemedhin and Wabe (2012) in a research, a total of 340 positives were assessed. Majority of the positives (69.29%) were females. The most common 1st line regimen before the 1st switch was stavudine/lamivudine/nevirapine (D4T/3TC/NVP) 54.70% and stavudine/lamivudine/efavirenz (D4T/3TC/EFV) 20.88%.

2.2. NATIONAL CONTEXT

Tiwari et al. (2008) All together 220 blood samples collected from 110 HIV positives visiting National Public Health Laboratory (NPHL), Kathmandu, were analyzed for CD4 cell count using standard protocol. CD4 cell count before and after starting of anti-retro viral therapy showed significant association ($P<0.05$). The results of this study clearly indicated that antiretroviral therapy has been playing a role in maintenance CD4 cell counts in HIV infected positives.

Paudel et al. (2009) Among 53 positives, 42 (79.2%) were males and 11 (20.8%) were females with predominant age group 30-40 years (49.1%). 19 (35.8%) positives showed

normal activity throughout the treatment period with increase in CD4 count, 10 (19%) were recovered and transferred out, only 1(1.8%) showed decrease in CD4 count even after taking ART.

Sharma et al. (2009) out of 150 positives 100 (66.7%) were males and 50 (33.3%) were females. The age group 21-30 years was predominant followed by 31-40 years. Significant relationship could be established between the intake of ART and cardinal symptoms of HIV/AIDS. However no significant relationship could be established between the intake of ART and distribution of different opportunistic infections.

Amatya et al. (2011) studied that the mean CD4 count of the subjects was 307 while those with parasitoses were 204. A statistical difference was seen between the CD4 counts of symptomatic and asymptomatic positives.

Dhakal and Aryal (2012) concluded that the CD4 count at the start was 116.51±58.65 and CD4 count after 6 months was 222.44± 8.65, also the mean increment of weight was from 50.33± 10.95 to 54.79± 10.34 after 6 months of ART.

III

MATERIALS AND METHODS

3.1. STUDY AREA

The present study was conducted at the ART center of the Sukraraj Tropical and Infectious Disease Hospital, Teku, Kathmandu, Nepal. It is a separate department of the hospital which is funded by National Center for AIDS and STD Control (NCASC) and The Global Fund under health ministry.

Kathmandu is the capital and the largest metropolitan city of Nepal. The city is the urban core of the Kathmandu Valley in the Himalayas, which also contains two sister cities namely Patan or Lalitpur, 5 kilometres (3.1 mi) to its southeast and Bhaktapur, 14 kilometres (8.7 mi) to its east. The city stands at an elevation of approximately 1,400 metres (4,600 ft) in the bowl-shaped valley in central Nepal.

To investigate this study, permission from Sukraraj Tropical and Infectious Disease Hospital (STIDH), Teku, Kathmandu, authorities of Voluntary Counseling and Testing Center (VCTC) and ART center was obtained. The collected data was provided by ART center of STIDH so the reliability of the data is very high.

In the present study, only the data of positives who tested positive for HIV at the VCTC was included. This information was recorded when the positives visited the VCTC for the first time and the positives with low CD4 counts were sent to ART center for treatment.

3.2. STUDY DESIGN

The design of the study was cross-sectional descriptive study.

3.3. SAMPLE SIZE

A total of 78 samples were taken for the study.

3.4. DATA COLLECTION AND ANALYSIS

3.4. a. Data collection

Data were collected directly by questionnaire filling in the direct interview with the respondents. Information about all the attendees of ART center was available from the records maintained at the ART center, regarding variables such as age, gender, residence, weight, CD4 counts, ART regimens and modes of transmission. Consent of respondents was taken from Medical council and Sukraraj Tropical and Infectious Disease Hospital before the research and interview.

3.4. b. Statistical analysis of data

The data tabulated and classified was then analyzed using Microsoft excel and to calculate chi-square test and wilcoxon signed rank test statistical package SPSS 16 and R/software (R console 2.15.2) was used respectively. Two statistical tests were used;

- Chi-square test was used to show the significant relationship between two variables.
- Wilcoxon signed rank test was used to show the paired difference between initial and final values since data wasn't normal. It is an alternative to paired t-test when data aren't normally distributed.

IV

RESULTS

A cross-sectional study was carried out in 78 positives, undergoing ART in ART center, Sukraraj Tropical and Infectious Disease Hospital, Teku, Kathmandu, Nepal between February 2012 to August 2012. The present study enrolled 78 PLHIV.

4.1. Demographic profile of PLHIV who are under ART

Out of 78 respondents, 45 (57.69%) were male while 33 (42.30%) were female. Respondent's age ranged from 4-60 years. Majority of positives were in the age group of 21-40 years (78.2%) (Table 1). No significant relationship between age and gender (χ^2=4.196, P>0.05) of HIV positives taking ART was found.

Age group	**Male**		**Female**		**Total**	
	No.	%	No.	%	No.	%
0-20	2	4.4	3	9.1	5	6.4
21-40	33	73.4	28	84.8	61	78.2
41-60	10	22.2	2	6.1	12	15.4
Total	45	100	33	100	78	100

(χ^2=4.196, P>0.05)

Table 1: Distribution of PLHIV taking ART according to Age and Gender

4.2. Distribution of PLHIV by Baseline CD4 count

The ART center provides free ART to all the positives with CD4 count below 350 cells/mm^3. CD4 counts were done for each positives in the baseline and then in the regular interval of six months thereafter.

After the positives have been counseled for ART, their social and support structure were assessed. Positives were referred to do CD4 count at every six months and monitoring of the progress was done. Follow up (annex 5) was maintained as: every two weeks in the first month, monthly up to the third month after the start of ART, then once in every three months and as necessary of the positives. As shown in the Table 2, about 13 of the positives (16.7%) had CD4 count<50 cells/mm^3 of blood. 9 positives (11.5%) had CD4 count between 51 to 100 cells/mm^3, 11 positives (14.1%) had CD4 count between 101 to 150 cells/mm^3, 13 positives (16.7%) had CD4 count between 151 to 200 cells/mm^3, 8 positives (10.3%) had CD4 count between 201 to 250 cells/mm^3, 8 positives (10.3%) had CD4 count between 251 to 300 cells/mm^3 , 10 positives (12.8%) had CD4 count between 300-350 cells/mm^3 and 6 positives (7.7%) had CD4 count more than 350 cells/mm^3 .

CD4 range/cu mm blood	Male	Female	Total	%
0-50	9	4	13	16.7
51-100	4	5	9	11.5
101-150	9	2	11	14.1
151-200	7	6	13	16.7
201-250	6	2	8	10.25
251-300	2	6	8	10.25
300-350	7	3	10	12.8
350+	1	5	6	7.7
Total	45	33	78	100.0

Table 2: Distribution of PLHIV by Baseline CD4 count

Out of 78 positives taking ART 72 positives (92.31%) have CD4 cell count less than 350 cells/mm^3 of blood. Statistically no significant relation between the number of positives taking ART and the CD4 cell count was found (χ^2=40, P>0.05).

4.3. Distribution of the positives on the basis of WHO staging

Out of 78 positives, 10 positives (12.8%) were on WHO clinical stage I (annex 1), 38 positives (48.7%) were on WHO clinical stage II, 21 positives (26.9%) were on WHO clinical stage III and 8 positives (11.5%) were on WHO clinical stage IV (Table 3).

WHO staging	**number of positives**	**%**
I	10	12.8
II	38	48.7
III	21	26.9
IV	9	11.5
Total	78	100

Table 3: Distribution of PLHIV on the basis of WHO staging

4.4. Effect of ARV drugs in PLHIV who are under ART

Antiretroviral therapy was started in all 78 positives. 56 (71.8%) positives were on the first line Nevirapine (NVP) containing regimen and 22 (28.2%) positives were on the Efavirenz (EFV) containing regimen. 55 positives (70.5%) were given ART regimen containing Zidovudine (ZDV), Lamivudine (3TC), Nevirapine (NVP); 22 positives (28.2%) were given ART regimen containing Zidovudine (ZDV), Lamivudine (3TC), Efavirenz (EFV); and 1 positive (1.3%) was given ART regimen containing Stavudine (d4T), Lamivudine (3TC), Nevirapine (NVP) (Table 4).

Regimen	Frequency (number of positives)	Percentage (%)
Zidovudine+Lamivudine+Nevirapine	55	70.5
Zidovudine+Lamivudine+Efavirenz	22	28.2
Stavudine+Lamivudine+Nevirapine	1	1.3
Total	78	100.0

Table 4: ART regimen prescribed

As shown in the Figure 1, there is a significant increase in CD4 counts in both NVP and EFV group in unit increase of time (i.e. 6 months) ($p<0.05$).

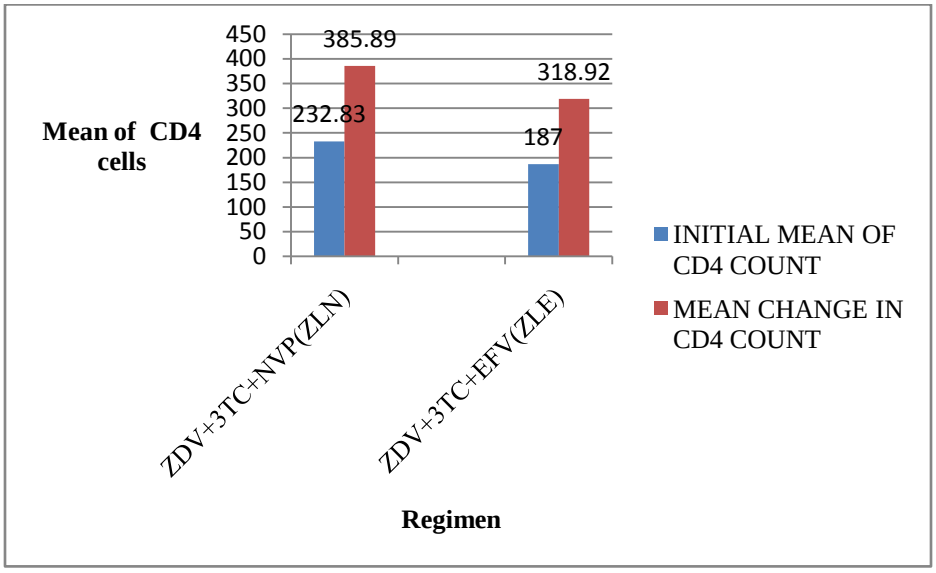


Figure 1: Initial and follow up CD4 counts

Out of the total 78 positives taken under study 47 (60.26%) were undergoing active ART. During the study period 6 positives (7.69%) lost follow up (LFU), 20 positives (25.64%) were transferred to other ART centers and 5 positives (6.41%) died.

Among 47 positives who were undergoing active ART, 43 positives (91.49%) showed normal activity throughout the study period with increase in the CD4 cells (they belong to the group with CD4 count improvement), while 4 positives (8.51%) showed decrease in CD4 count (Table 5.1 and 5.2).

Features	**Number (%)**
Active cases	47(60.26)
Lost follow up	6(7.69)
Transferred out	20(25.64)
Death	5(6.41)
Total	78(100)

Table 5.1

Features	**Number (%)**
Increase in CD4 count after start of ART	43(91.49%)
Decrease in CD4 count	4(8.51)
No change of CD4 (stable)	0(0)
Total	47(100)

Table 5.2

Table 5: Performance of the PLHIV under ART

4.5. Profile of CD4 counts in PLHIV who are under ART

Among 78 positives, all the positives had done CD4 count at the start but out of total samples to be studied 6 positives (7.69%) lost follow up (LFU), 20 positives (25.64%) were transferred to other ART centers and 5 positives (6.41%) died. So that only the brief ART profile of 47 active samples was available. Among the positives who had done CD4 count after six months of the start of the ART, significant relationship was found to be established between the ART and the increase in CD4 count ($V= 8.046$, $P<0.05$) (annex VII).

As shown in the Table 6, the mean CD4 before the start of ART is 223.21 cells/µl of blood while the mean CD4 cells after the start of ART increased to 368.79 cells/µl of blood. The minimum cell before the start of ART is 12 cells/µl of blood and the maximum cell before the start of ART is 1134 cells/µl of blood (median cells is 197 cells/µl of blood) while the minimum cell after the start of ART is 102 cells/µl of blood and the maximum cell after the start of ART is 1159 cells/µl of blood (cells/µl of blood).

CD4 count	**Frequency (no. of positives)**	**Mean CD4 (cells/µl)**	**SD**	**SEM**	**Minimum (cells/µl of blood)**	**Maximum (cells/µl of blood)**	**Median (cells/µl of blood)**
Initial	47	223.21	185.98	27.1	12	1134	197
6 months	47	368.79	227.39	33.2	102	1159	370

Table 6: Status of CD4 counts in PLHIV

4.6. Antiretroviral therapy and its effect on CD4 count and weight

In the study, out of 78 cases, antiretroviral therapy (ART) was given to all positives but only 47 active samples (6 lost follow up, 20 transferred out and 5 died) have active ART with prophylaxis for opportunistic infections. On comparison of pre and post ART data for CD4 count and initial and follow-up weight, there was a significant improvement in the two parameters (Table 7, Figure 2 and 3). In many cases quality of life had been improved after taking ART for six months on revealed by gaining CD4 cells and weight and their ability to do routine work actively.

S.N.	Variable	No. on ART	Baseline value (mean±SEM)	Follow-up value (mean±SEM)	Statistical significance (wilcoxon test)	
					V value	P value
1.	CD4 count	N=47	223.21±27.1	368.79±33.2	41	P<0.001**
2.	Weight in Kg	N=47	52.98±2.07	54.17±2.12	164	P<0.05*

*significant ** highly significant

Table 7: Change in CD4 count and Weight of the positive among those who are on ART Therapy during follow up

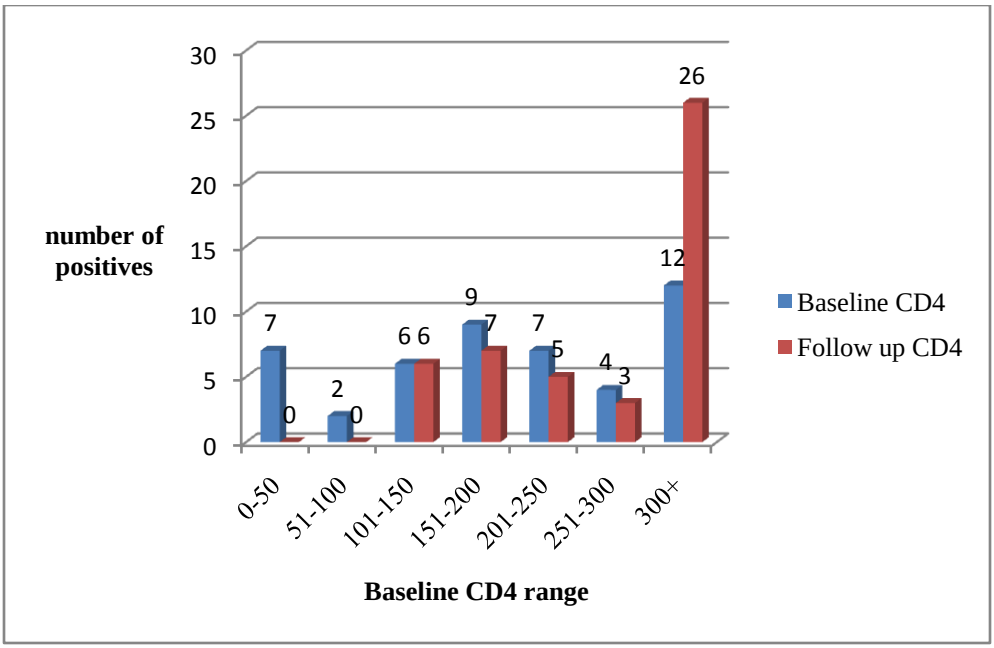
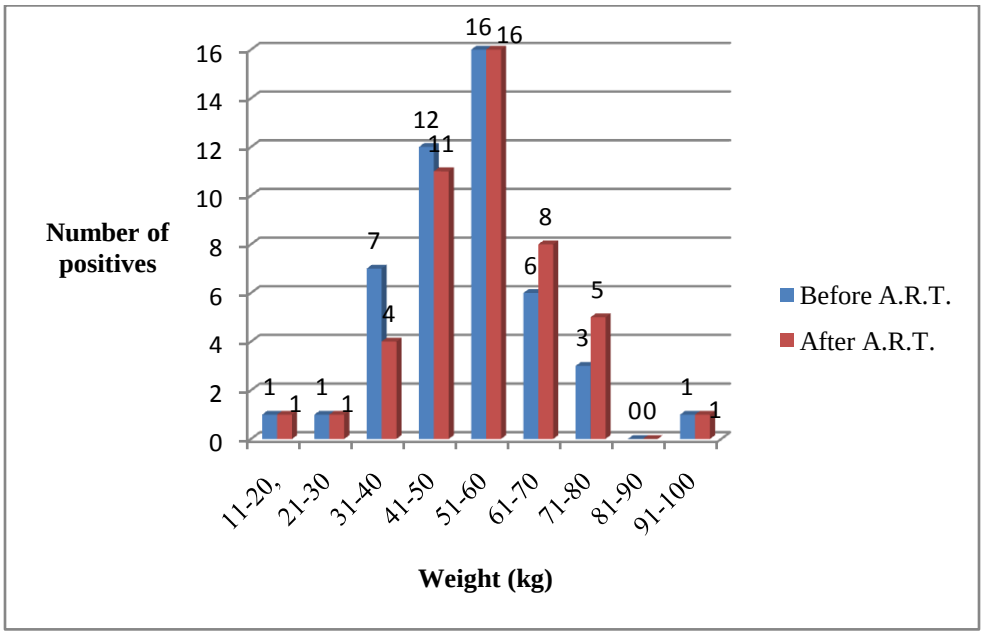


Figure 2: Distribution of PLHIV basing on Baseline and Follow up CD4 cell count



. **Figure 3**: Distribution of PLHIV basing on baseline and follow up weight in Kg.

4.7. Analysis of questionnaire survey

A questionnaire survey was conducted among the PLHIV under study. Out of 78 respondents only 45 (57.69%) were available for the questionnaire survey. The main aim of the questionnaire was to know the social status of the positives taken under the study and to know how they are being treated in the ART center.

Out of the total respondents under study, 28 (62.22%) were female while 17 (37.63%) were male. Regarding the educational status of the positives 18 (40%) were totally illiterate while 27 (60%) were educated (10 below primary level, 7 lower secondary level and 10 higher secondary level). The most common route of HIV transmission was found to be unsafe sexual practice and intravenous drug users (IDUs).

Out of the 45 respondents taken under the study 20 respondents (44.44%) answered that they have a good social status while 18 respondents (40%) answered that they are still being discriminated in their society and from their family members while 7 respondents (15.56%) expressed that they haven't told about being HIV infected in their society and family members yet with the fear that they will be discriminated from their society members.

Regarding the behavior of the people of ART center all the samples were satisfied with the way that they are being treated in the ART center. They answered that they are not being discriminated in the ART center and they are also happy with the medications prescribed from the ART center.

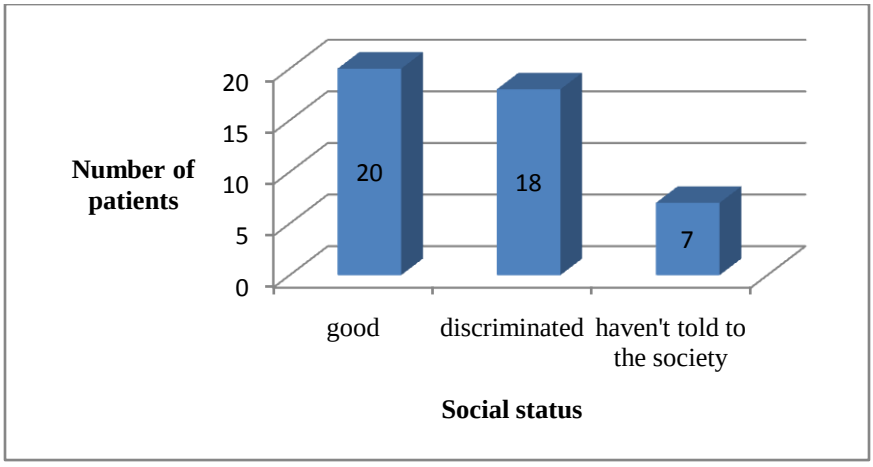


Figure 4: Social status of the PLHIV

V

DISCUSSION

As per the NSASC national guidelines, currently in Nepal, absolute CD4 cell count is being used as the basis for initiation of ART (NCASC 2012). In the present study, baseline mean CD4 cell count was 223.21±185.98 cells/µl of blood which is higher than the studies among similar positive groups from Nepal (Tiwari et al. 2008 and Dhakal and Aryal 2012). But Gautam et al. 2008 reported a much lower CD4 cell count of 112.1±60.29 cells/µl of blood which is much lower than the present study. CDCP has explained the AIDS surveillance case definition to include all HIV infected persons with CD4 + T- lymphocyte counts of less than 200 cells/µl of blood or a CD+ percentage of less than 14 (CDCP 1992). In the present study 56.41% cases with CD4 count less than 200 cells/µl was reported which is lower than the percentage (89.2%) reported by Gautam et al. 2008. In my study 57.69% were females which are lower than the percentage (69.29%) reported by Woldemedhin and Wabe (2012). The age group 21-30 years was predominant followed by 31-40 as reported by Sharma et al. (2009) which is similar to the present study. Sunita et al. (2011) reported in India

that the majority of the positives taking ART have CD4 cell count between 50-250 cells/µl which is similar to the present study. In a study from the US, it is said that the CD4 absolute count is the best predictor of an adverse event when the CD4 count is less than 200 cells/µl while CD+ percentage is a better predictor when CD4 count is above 200 cells/µl (Pirzada et al. 2006).

The antiretroviral drug Zidovudine was introduced in 1986 for the treatment of HIV/AIDS (NCASC). Over the next few years, also other antiretroviral drugs such as nucleoside reverse transcriptase (NRTIs), non-nucleoside reverse transcriptase (NNRTIs) and protease inhibitors (PIs) will be introduced. And at present, three or more ART drugs are recommended worldwide for the treatment of HIV+ (CDCP 2002).

In this study, the mean CD4 cell count in positives at first visit to the ART center was 223.21 cells/µl of blood which increased significantly to 368.79 cells/µl of blood after six months of follow up. This finding indicated that the treatment was effective. In a study conducted by Tiwari et al. (2008) the mean CD4 cell count in the positives at first visit to Nepal Public

Health Laboratory (NPHL) was 155 cells/µl of blood which increased to 297 cells/µl of blood significantly after 6 months of ART. The baseline value was quite lower than the present study and also the follow up value was lower than this study. In a study conducted by Sunita et al. (2011) in India and Wright et al. (2011) in Australia showed that mean CD4 counts increased to above 500 cells/µl which is much higher than the present study.

Paudel et al. (2009) reported that 1 out of 53 positives (1.8%) showed decrease in CD4 cell count even after taking ART but in the present study 4 out of 47 positives (8.51%) showed decrease in CD4 cell count even after taking ART. Moore and Keruly (2007) reported 92% of the positives having an increment in the CD4 cell count which is similar with the present study (91.49%).

In the present study both NVP and EFV had similar rise in CD4 cell count from baseline and at any given point of time there was no significant difference in the rate of increase of CD4 count between the two treatments ($P<0.05$) as reported by Sunita et al. (2011). The most common 1st line regimen in this study was Zidovudine/Lamuvudine/Nevirapine which is totally different than the study done by Woldemedhin and Wabe (2012) who reported the 1st line regimen to be Stavudine/Lamivudine/Nevirapine which was similar to the study done by Kumarasamy et al. (2006).

The mean baseline weight in the study was 52.98±2.07 kg which increased to 54.17±2.12 kg which is little higher than reported by Sunita et al. (2011) who showed the baseline weight 48.7±1.0 and increment to 52.8±1.1 kg after six months of follow up of ART.

People have begun using VCTC services, which reflects a change in their attitude towards HIV. The study provides us a clue to formulate an effective approach to educate people as well as health personnel who are thought of as one of the important sources of discrimination.

VI

CONCLUSION

Thus, HIV infection is in decreasing order though is one of the major infectious diseases in Nepal, and being chronic lifelong in nature, its impact is huge compared to other infectious diseases. People with high risk behavior and the spouse of the infected and affected couple need to be educated for primary and secondary preventive measures of the HIV infection. PLHIV should be educated that the timely initiation and continuous intake of antiretroviral therapy will not only prolong their survival but will also decrease the viral load and transmission of the disease. Provision of free antiretroviral treatment by the government of Nepal is a step in the right direction, and it should be extended to the entire country, as antiretroviral treatment does change the quality of life of the positives as well as his/her family and the positive is able to get back to work and restart his/her livelihood.

Hence, ART service was found to be effective enough to increase the CD4 count significantly after 6 months of therapy.

It can be concluded that ART is effective enough in slowing the progression of HIV infection to AIDS and increasing the survival rate of positives with good performance. This study reflects the real situations of ART service in resource limited setting and help to promote the ART service to other parts of the country. On the basis of this study it can be recommended that HIV should be diagnosed earlier so that ART can be started in appropriate time.

VII

RECOMMENDATIONS

- ART centers should be expanded to other districts of Nepal.
- Accessibility and availability of treatment, support and care to HIV infected people.
- Provision of medication, monitoring of usage of anti-retroviral drugs and of clinical outcomes, including drug toxicity.
- Education and training of healthcare workers.
- Educating people on Post Exposure Prophylaxis (PEP).
- Public awareness on Anti-retroviral therapy.
- A stronger emphasis should be placed on sex education.
- Facility of CD4 and ART at the community level.
- Improving public awareness and the use of safer sex practices, including condoms use, in order to interrupt the transmission of sexually transmitted diseases.
- Improving screening for sexually transmitted diseases and other infectious diseases.
- Increased support for and promotion of research into the development of drugs against AIDS, its cofactors and risk factors.
- Reducing the vulnerability of communities by improving access to health care.
- Improving literacy.
- Improving public awareness and use of safer sex practices in order to stop the transmission of HIV and sexually transmitted diseases.

VIII

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LIST OF PHOTOGRAPHS

1.RESEARCHER WITH THE IN-CHARGE OF ART CENTER MISS JUNU CHHETRI

2. FILING SYSTEM OF HIV POSITIVES AS PER THEIR ART NUMBER

3. DOCTOR OF ART CENTER (Dr. ANUP BASTOLA) CHECKING HIV POSITIVE

4. HIV POSITIVE WITH ADHERENCE COUNSELER Mr. BHOJENDRA CHAUDHARY

5. ARV DRUGS

6. ARV DRUGS

ANNEXES

ANNEX-I

WHO STAGING

The clinical staging and case definition of HIV for resource-constrained settings were developed by the WHO in 1990 and revised in 2007. Staging is based on clinical findings that guide the diagnosis, evaluation, and management of HIV/AIDS and it does not require a CD4 cell count. This staging system is used in many countries to determine eligibility for antiretroviral therapy, particularly in settings in which CD4 testing is not available. Clinical stages are categorized as 1 through 4, progressing from primary HIV infection to advanced HIV/AIDS as shown in the table below.

WHO Clinical Staging of HIV/AIDS for Adults and Adolescents
Clinical Stage 1 o Asymptomatic o Persistent generalized lymphadenopathy
Clinical Stage 2 o Unexplained moderate weight loss (<10% of presumed or measured body weight)a o Recurrent respiratory tract infections (sinusitis, tonsillitis, otitis media and pharyngitis) o Herpes zoster o Angular chelitis o Recurrent oral ulceration o Papular pruritic eruptions o Seborrhoeic dermatitis o Fungal nail infections
Clinical Stage 3b o Unexplained severe weight loss (>10% of presumed or measured body weight) o Unexplained chronic diarrhea for longer than one month o Unexplained persistent fever (above 37.5°C intermittent or constant, for longer than 1 month) o Persistent oral candidiasis o Oral hairy leukoplakia o Pulmonary tuberculosis

o Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis or bacteraemia)

o Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis

o Unexplained anaemia (<8 g/dl), neutropaenia (<0.5 × 109 per litre) and/or chronic thrombocytopaenia (<50 × 109 per litre)

Clinical Stage 4c

o HIV wasting syndrome

o Pneumocystis pneumonia

o Recurrent severe bacterial pneumonia

o Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration or visceral at any site)

o Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)

o Extrapulmonary tuberculosis

o Kaposi sarcoma

o Cytomegalovirus infection (retinitis or infection of other organs)

o Central nervous system toxoplasmosis

o HIV encephalopathy

o Extrapulmonary cryptococcosis including meningitis

o Disseminated non-tuberculous mycobacterial infection

o Progressive multifocal leukoencephalopathy

o Chronic cryptosporidiosis

o Chronic isosporiasis

o Disseminated mycosis (extrapulmonary histoplasmosis or coccidiomycosis)

o Recurrent septicaemia (including non-typhoidal *Salmonella*)

o Lymphoma (cerebral or B-cell non-Hodgkins)

(NATIONAL ART GUIDELINES 2012)

ANNEX-II

INDICATORS OF ANTIRETROVIRAL THERAPY

Recommendations for initiating antiretroviral therapy in adults and adolescents with documented HIV infection are given in the box below.

If CD4 testing available:

It is recommended to document baseline CD4 counts and to offer ART to positives with:

WHO Stage 4 disease, irrespective of CD4 cell count

WHO Stage 3 disease, irrespective of CD4 cell count

WHO Stage 1 or 2 disease with CD4 cell counts less than 350/mm3

If CD4 testing unavailable:

It is recommended to offer ART to positives with:

WHO Stage 4 disease

WHO Stage 3 disease

Note: WHO Stage 1 and 2, treatment is not recommended when CD4 testing is not available

Start ART in those with chronic active Hepatitis B irrespective of CD4 count or WHO clinical stage

(NATIONAL ART GUIDELINES 2012)

ANNEX-III

ANTIRETROVIRAL DRUGS

Categories of approved antiretroviral drugs include the following:

1. Nucleoside analog reverse transcriptase inhibitors (NsRTI)
2. Nucleotide analog reverse transcriptase inhibitors (NtRTI)
3. Non-nucleoside analog reverse transcriptase inhibitors (NNRTIs)
3. Protease inhibitors (PIs)
4. New class of drugs: Fusion inhibitors (FI), CCR5 Antagonists, Integrase strand transfer Inhibitors (INSTI)

ANNEX-IV

PRINCIPLES OF ANTIRETOVIRAL THERAPY

Goals of Antiretroviral Therapy

- Maximal and durable suppression of viral load
- Restoration and/or preservation of immunologic function
- Reduction of HIV-related morbidity and mortality
- Improvement of quality of life of HIV infected persons
- Prevention of Mother to Child Transmission (PMTCT)
- Post Exposure Prophylaxis (PEP)

Preconditions for Starting Antiretroviral Therapy

The following specific facilities and services are desirable before starting Antiretroviral Therapy:

- Availability of HIV testing and counseling (HTC) services along with follow-up counseling services.
- Medical services capable of managing common HIV-related infections including opportunistic infections (OIs) and sexually transmitted infections (STIs).
- Routine laboratory services, preferably with access to CD4 lymphocyte count and PCR facility for viral load count. Lack of viral load testing and even CD4 testing should not preclude initiation of ART.
- Access to antiretroviral drugs and other drugs to treat OIs and other associated diseases.

Evaluation of Positives before Starting Antiretroviral Therapy:

A detailed evaluation is essential prior to initiating antiretroviral therapy and should aim to:

- Assess the clinical stage of HIV infection.
- Identify past HIV-related illnesses.
- Identify current HIV-related illnesses that will require treatment.
- Identify co-existing medical conditions and treatments that may influence the choice of therapy.
- Before initiating therapy, the following evaluations should be performed:

- A history including past illnesses with emphasis on OIs and other conditions
- Psychological and psychiatric history.
- Assessment of family and social support
- Practices regarding safe sex and injecting drug use
- Physical examination

(NATIONAL ART GUIDELINES 2012)

ANNEX-V

MONITORING OF FOLLOW-UP

Follow-Up Schedule

Clinical and Adherence Monitoring Visits:

Once ART is started, follow up schedule should be as follows:

First month: two visits (every 2 weeks)

Second + Third month: every month

Fourth month onwards: one visit every three months

More frequent visits will be scheduled, if the positive develops symptoms or experiences difficulties in adhering to the medications

(NATIONAL ART GUIDELINES 2012).

ANNEX-VI

FORMAT OF QUESTIONNAIRE SURVEY

S.N. …… DATE……..…

A. Place of observation:

B. Name/positive code:

C. Sex: i. male ii. Female

D. Education: i. Primary ii. Secondary iii. Higher secondary iv. Uneducated

E. Marital status: i. Married ii. Unmarried

F. Mode of transmission:

i. Blood transfusion

ii. Unsafe sexual practice

iii. IDUS

iv. MSM

v. Placental

vi. Others

G. When did you get HIV before or after marriage?

i. Before marriage ii. After marriage

H. Are you doing CD4 test regularly?

i. Yes ii. No

I. Has the treatment regimen promoted your quality of life?

i. Yes ii. No

J. Did you find any improvement in your health after you started A.R.T.?

i. Yes ii. No

K. Are you satisfied with the services provided at ART center?

i. Yes ii. No

L. How do the people at ART center behave with you?

……

……

M. Do you have any suggestion towards ART center to make the ART center more effective?

…….

…….

N. How do your family members and society behave with you?

……..

……

O. What do you want to tell the public to reduce the stigma and discrimination towards HIV/AIDS?

……..

……

……..

Signature of the respondent

Thank you for your valuable time

ANNEX VII

CD4 counts of the positives before and after ART

S.N.	CD4 count at the start of ART(INITIAL)	CD4 count after 6 months of ART(FINAL)	Pair difference in the mean CD4(Final-initial)	Wilcoxon test
1	68	162	145.58	41($P<0.05$)
2	208	342		
3	317	157		
4	222	423		
5	334	571		
6	184	370		
7	230	197		
8	318	420		
9	26	109		
10	119	196		
11	197	274		
12	172	384		
13	41	109		
14	283	384		
15	12	127		
16	329	411		
17	217	467		
18	44	121		
19	207	528		
20	416	500		
21	116	168		
22	240	255		
23	26	272		
24	228	420		
25	154	156		
26	1134	1159		
27	148	425		
28	120	102		

29	458	422		
30	30	191		
31	158	491		
32	261	564		
33	185	247		
34	268	511		
35	115	208		
36	258	545		
37	329	483		
38	639	1143		
39	344	535		
40	22	312		
41	78	125		
42	162	206		
43	107	221		
44	153	253		
45	310	563		
46	173	489		
47	331	615		