"CLINICAL PROFILE OF HIV/AIDS PATIENTS SEEKING ANTI-RETROVIRAL THERAPY AT DISTRICT HOSPITAL- A LONGITUDINAL STUDY"

By

Dr. SHILPA .K

REG. NO.BD0109003

Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

DOCTOR OF MEDICINE

IN

COMMUNITY MEDICINE

Under the Guidance of
Dr. S. M. KATTI. M.D.
Professor

DEPARTMENT OF COMMUNITY MEDICINE,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELGAUM, KARNATAKA

MAY - 2012

KLE UNIVERSITY, BELGAUM, KARNATAKA

Declaration by the Candidate

I hereby declare that this dissertation entitled **"CLINICAL PROFILE OF HIV/AIDS PATIENTS SEEKING ANTI-RETROVIRAL THERAPY AT DISTRICT HOSPITAL- A LONGITUDINAL STUDY"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. S. M. KATTI.**$_{\text{M.D.,}}$ Professor, Department of Community Medicine, Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum-590010.

Date:

Place: Belgaum **(Dr. SHILPA. K.)**

KLE UNIVERSITY, BELGAUM, KARNATAKA

Certificate by the Guide

This is to certify that the dissertation entitled **"CLINICAL PROFILE OF HIV/AIDS PATIENTS SEEKING ANTI-RETROVIRAL THERAPY AT DISTRICT HOSPITAL- A LONGITUDINAL STUDY"** is a bonafide research work done by **Dr. SHILPA. K.** under my guidance and direct supervision in partial fulfillment of the requirement for the degree of **M. D. (COMMUNITY MEDICINE).**

Date:

Place: Belgaum

Dr. S. M. KATTI. M.D.
Professor,
Department of Community Medicine,
J. N. Medical College,
Nehru Nagar, Belgaum – 509 010

KLE UNIVERSITY, BELGAUM, KARNATAKA

Certificate by the Co- Guide

This is to certify that the dissertation entitled **"CLINICAL PROFILE OF HIV/AIDS PATIENTS SEEKING ANTI-RETROVIRAL THERAPY AT DISTRICT HOSPITAL- A LONGITUDINAL STUDY"** is a bonafide research work done by **Dr. SHILPA. K.** in partial fulfillment of the requirement for the degree of **M.D. (COMMUNITY MEDICINE),** examination to be held in May 2012.

Date:

Place: **Belgaum.**

Dr. SHANMUKH T. KALSAD **M.D.**
Professor & Head,
Department of Medicine,
BIMS, Belgaum-590010

KLE UNIVERSITY, BELGAUM, KARNATAKA

Endorsement by the HOD, Principal/Head of the Institution

This is to certify that the dissertation entitled **"CLINICAL PROFILE OF HIV/AIDS PATIENTS SEEKING ANTI-RETROVIRAL THERAPY AT DISTRICT HOSPITAL- A LONGITUDINAL STUDY"** is a bonafide research work done by **Dr. SHILPA. K.** under the guidance of **Dr. S. M. KATTI. M.D.,** Professor, Department of Community Medicine, Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum-590010.

Dr. VIJAYA A. NAIK M.D.,D.P.H.
Professor and Head,
Department of Community Medicine,
J. N. Medical College,
Nehru Nagar, Belgaum – 590 010

Date:
Place: Belgaum

Dr. V. D. PATIL M.D.,D.C.H.
Principal,
J. N. Medical College,
Nehru Nagar,
Belgaum – 590 010

Date:
Place: Belgaum

KLE UNIVERSITY, BELGAUM, KARNATAKA

Copyright

Declaration by the Candidate

I hereby declare that the KLE University, Belgaum, Karnataka shall have the rights to preserve, use and disseminate this dissertation in print or electronic format for academic / research purpose.

Date :

Place : Belgaum

(Dr. SHILPA. K.)

ACKNOWLEDGEMENT

At outset, I wish to thank my almighty GOD for his guidance and blessings in every step of my life.

I am indebted to my guide **Dr. S. M. KATTI** M.D. Professor, Department of Community Medicine, Jawaharlal Nehru Medical College, Belgaum for his able and expert guidance, inspiration, encouragement, constant help and some critical and valuable suggestions during the preparation of this dissertation.

I express sincere gratitude to **Dr. (Mrs.) VIJAYA A. NAIK** MD, DPH Professor and Head, Department of Community Medicine, Jawaharlal Nehru Medical College, Belgaum for her enduring encouragement and support.

I am thankful to **Dr. V. D. PATIL** MD, DCH Principal, Jawaharlal Nehru Medical College, Belgaum for having given me an opportunity to undertake the present study.

I express my sincere gratitude to **Dr. A. S. Wantamutte** MD (BHU) former Professor and Head, Department of Community Medicine, Jawaharlal Nehru Medical College, Belgaum for his invaluable suggestions and kind help rendered throughout the course of my study.

I extend my humble thanks to **Dr. M. S. Shivaswamy** MD Associate Professor, Department of Community Medicine, Jawaharlal Nehru Medical College, Belgaum for his constant inspiration and constructive criticism.

I heartily extend my sincere thanks to **Shri M. D. Mallapur** M.Sc. Lecturer in Statistics, an exemplary teacher for his valuable help in getting statistical analysis done.

My sincere thanks to **Dr. H. N. Sangolli, Dr. Padmaja R. Walvekar, Dr. Shobha S. Karikatti, Dr. C. S. Metgud** and **Dr. Sanjay Kambar, Dr. Girija S. Ashtagi, Dr. Deepti M. Kadeangadi, Dr. Asha Bellad** and **Dr. Yogesh Kumar S., Mr. V. B. Patil** and **Mrs. Shirin. A. Hukkeri** for their help and support throughout the study.

I truly thank **Dr. Sulakshana, Dr. Rajesh,Dr.Amar, Dr.Neeta, Dr. Umesh, Dr. Namrata & Dr.Chandrika** and all other Fellow Postgraduates,seniors and Colleagues for their moral support and friendly suggestions.

I express my deep sense of gratitude and love to my family **Dr.K.Mallikarjuna Gowd**, **Smt. Ratna Mallikarjuna Gowd**, my sister **Miss. Swapna.K ,** my brother **Mr.Shivkumar. Gowd K, my grandparents, all my relatives** whose cherished blessings and countless sacrifices are behind whatever success I have achieved in my life and **who have always inspired, supported and encouraged to realize my dreams.**

I express my heartfelt thanks to my fiancée **Dr.Amit** for loving support, constant co-operation and help which has contributed for the accomplishment of my study. I truly acknowledge my in laws **Mr.Rajshekar. P. Ugargol** and **Mrs. Nirmala.R.Ugargol** for their constant inspiration rendered all along.

My special thanks to **Dr.Amar & Dr. Kumar. L, for helping me out in data collection and compilation and also for their moral support and care all throughout.**

I heartly thank my friends Dr Renu, Dr. Nivedita, Dr. Spurti, Dr. Smita, Dr.Anu, Dr.Shailaja, Dr. Roopa, Dr.Jayashree and all other friends for valuable support and constant encouragement.

I wish to express my special thanks to **Mr. Mahesh Janganuri** and **Mr. K. S. Magdum,** Clerks for their affectionate concern and support throughout my study period. I am very thankful to **Mr. Nagappa, Mr Khadbadi** and **Mr. K. B. Chougala,** attenders for their co-operation and help in the study period.

I also thank **Miss. Veena** & **Mr. Deepak** of **Sai DTP & Xerox Centre,** designing, printing and binding of my dissertation.

Most important of all I thank all the **Study participants** included in the study, without whom this would not have been possible.

Last but not the least, this acknowledgement is incomplete if I fail in my duty to thank Karnataka State AIDS Prevention Society for permitting me and to share the data and thanks to Medical Officer ART centre **Dr. Shankar** and other **Staff Mr. Anwar, Mrs. Swapna, Dr. Spurti, Mr. Kiran Bagoji, Mrs. Vinoda Mr. Anil, Mr. Sanju, Mrs. Santoshi and other staff members of ART centres, District hospital Belgaum and also ART staff of Chikkodi and Gokak** for their humble support throughout the study.

Date:

Place: Belgaum

Dr. SHILPA. K

LIST OF ABBREVIATIONS USED

AIDS	-	Acquired Immuno Deficiency Syndrome
ART	-	Anti Retroviral Therapy
CD4	-	Cluster Differentiation
CMV	-	Cyto Megalo Virus
CNS	-	Central Nervous System
Efv	-	Efavirenz
HbsAg	-	Hepatitis B surface Antigen
HIV	-	Human Immunodeficiency Virus
IPD	-	In Patient Department
Lmv	-	Lamivudine
NACO	-	National AIDS Control Organization
NGO	-	Non Governmental Organization
Nvp	-	Nevirapine
OIs	-	Opportunistic Infections
OPD	-	Out Patient Department
PPTCT	-	Prevention of Parent To Child Transmission
RNTCP	-	Revised National Tuberculosis Control Program
RTI	-	Reproductive Tract Infections
STI	-	Sexually Transmitted Infections
Stv	-	Stavudine
TB	-	Tuberculosis
VCTC	-	Voluntary Counseling and Testing Centre
VDRL	-	Veneral Disease Research Laboratory
WHO	-	World Health Organization
Zdv	-	Zidovudine

ABSTRACT

Introduction:

Human immunodeficiency virus (HIV) is a lentivirus that causes acquired immunodeficiency syndrome (AIDS), a condition in humans in which the immune system begins to fail, leading to life-threatening opportunistic infections. HIV infection in humans is now pandemic. From 1981 to 2006, AIDS has killed more than 25 million people all over the world.

Aims and objectives:

1) To study the clinical profile of HIV/AIDS patients seeking anti-retroviral therapy with respect to:
   a) CD4 count
   b) Opportunistic infections.
   c) Adherence

Materials and Method:

This present study was done between Jan 2010 and Feb 2011 among HIV/AIDS patients seeking ART at District hospital Belgaum. A total of 372 participants who were seeking ART, during January & February 2010 were included in the study and were followed up for one year. Predesigned and pretested questionnaire was used for data collection. Follow-up visits were done according to the NACO guidelines. Secondary data was collected from various records of ART centre. Statistical analysis was done by using percentages, chi square test and Paired t test.

Results:

In this present study majority 51.1% of the participants were females with 93.3% cases, Hindus in religion and 52.7% were unskilled workers. Illiterates were 43.8% with 66.4% participants in socio economic status class V. Majority 51.6% of them were rural residents and 48.9% of the participants stayed in nuclear family. In 93.5% participants' heterosexual mode of transmission was seen. Majority i.e 79.3% were referred from VCTC.More than half 66.2% participants had multiple symptoms at ART initiation. More than half 50.5% had one or more opportunistic infections. Majority 58.6% of cases were in WHO clinical stage II and 91.3% cases had working functional status. For initiation of ART, 54.3% patients had both clinical symptoms & CD4 <250 cells as their eligibility criteria and majority 82.8% of patients were not using condoms.In 62.1% cases Zidovudine, Lamivudine & Nevirapine drug combination was started as initial regimen.

Majority i.e 56.4%, 48.9% and 45.9%cases were seen in stage II at 1^{st} 6th and 12^{th} month respectively. There is mean increase in CD4 count from baseline to 6^{th} month and from baseline to 12^{th} month and 14.2% of patients had one or more opportunistic infections after initiation of ART. Majority of the study participants i.e 81.2%, 71.7% and 69.1% were working functional status at 1^{st}, 6^{th} and 12^{th} month respectively. Maximum patients i.e 74.2% adhered to ART after 1^{st} month and later proportion decreased at 12^{th} month to 63.9%. Anemia was the most common side effect reported in 37.9% patients , 3.5% cases stopped ART voluntarily and 17.2% deaths were reported . Majority i.e 70.4% of male cases & 82.6% of female cases had CD4 count ≥200 and 73.0% males & 90.3% female cases had CD4 count ≥200 at 6th &12^{th} month respectively. CD4 cell count improvement ≥200 was far better in age group <30 years compared to other age groups. Good prognosis was seen in non

alcoholics & non smokers at 12th month compared to alcoholics and smokers. At 6th month >95% adherence was observed in case of 83.0% males, 91.6% females compared to figures of 80-95% & <80% adherence.

Conclusion:

In this present study CD4 cell count improvement with ART was better in patients with good adherence. CD4 count improvement was good from baseline to 6th month and from baseline to 12th month. Opportunistic infections were seen before and also after starting ART which are the main cause of morbidity and mortality. Decreased adherence to ART drugs was observed probably because of long duration of treatment and other reasons.

Keywords: ART; Clinical profile of HIV/AIDS Patients; CD4 count; Adherence; Opportunistic infection.

CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF MAP & PHOTOGRAPHS

INTRODUCTION

AIDS –Acquired immunodeficiency syndrome is a potentially lethal multisystem disorder caused by retrovirus, the Human immunodeficiency virus (HIV), a condition in humans in which the immune system begins to fail, leading to life-threatening opportunistic infections. HIV infection in humans is now pandemic. From 1981 to 2006, AIDS has killed more than 25 million people all over the world.[1]

Latest global estimates show that 33.1 million people are living with HIV/AIDS and 2.5 million people are newly infected with HIV in 2007. In India the estimated HIV/AIDS patients is 2.5 million (2 million-3.1 million).[2] About 30,000 children are born with HIV in India every year. [3] In India adult (aged 15-49 years) HIV prevalence is 0.3%. About 25 million people have died already. [4]

The primary clinical problems associated with HIV infection are the opportunistic infections and neoplasms that occur as a result of progressively severe immunodeficiency that develop during the course of the disease. The clinical profile of HIV disease in India includes a wide range of conditions like tuberculosis, cryptococcal meningitis, pruritic eruptions, cytomegalovirus retinitis etc. Infection with HIV results in selective loss of the Cluster of differentiation (CD) 4 positive T lymphocytes count and their function resulting in the progressive damage to immune system of the human host.[5]

Opportunistic infections are important causes of morbidity and mortality in patients with HIV/AIDS. When the $CD4^+$ count falls below 200cells/mm^3, the infection is associated with a wide variety of opportunistic infections. These

opportunistic infections are different in different geographical areas. In India, Tuberculosis is the major opportunistic infection, followed by Candida albicans.[2]

The Government of India launched the free Anti-Retroviral Therapy (ART) programme on 1st April 2004, starting with eight tertiary level government hospitals in the six high–prevalence states of Andhra Pradesh, Karnataka, Maharashtra, Tamil Nadu, Manipur and Nagaland, as well as National Capital Territory of Delhi. The ART centers are being scaled up in a phased manner and it is planned that free ART will be provided to 1,00,000 patients by the end of 2007 and 3,00,000 patients by 2011 in 250 centers across the country.[6]

Introduction of antiviral drugs and measures aimed at treating or preventing the development of opportunistic infections associated with HIV/AIDS, led to an increased life expectancy. The disease is continuing to spread in developing countries, and the poor cannot afford to spend on these drugs.[7]

Over the past decade, there has been tremendous increase in our understanding of molecular biology and the viral structure and pathogenesis of the disease, which has lead to the development of a number of antiretroviral drugs and treatment protocols. Although ART does not cure the HIV infection, decrease in the viral load and the improvement in immunological status brought about by the use of these drugs have resulted in a marked decrease in the mortality and morbidity associated with the disease. [6]

Without treatment, about 9 out of every 10 persons with HIV will progress to AIDS after 10–15 years. Often, many progress to AIDS much sooner. Treatment with anti-retrovirals increases the life expectancy of people infected with HIV. Even after HIV has progressed to diagnosable AIDS, the average survival time with

antiretroviral therapy (ART) (as of 2005) is estimated to be more than 5 years. Without antiretroviral therapy, death normally occurs within a year.[8]

The most common cause of ART failure is poor adherence. Adherence should be assessed and routinely reinforced by everyone in the clinical team (clinician, nurses, pharmacists, peer educators, NGO workers, etc) at each of the patient's visits to the clinic. Studies indicate that 90-95% of the doses should be adhered to for minimal suppression.[6]

There are no published data on survival rates of patients being treated in the free national ART programme that is being scaled up using a public health approach. With 8,88,000 patients cumulatively enrolled in HIV care and 2,88,000 patients currently receiving ART at public sector health facilities by November 2009, India's free national ART programme is the largest in Asia.[9]

This follow up study is being conducted with the intent to study the clinical profile of the HIV /AIDS patients before and after ART, at District hospital Belgaum. After starting ART in HIV/AIDS patients there may be changes in CD4 count, patient may develop side effects and may develop opportunistic infections. So far, such type of study is not carried out in this area. So, this study will help to assess the overall prognosis of these patients as follow up and monitoring is essential in patients initiated on ART to track clinical progress and monitor wellbeing.

OBJECTIVES OF THE STUDY

1) To study the clinical profile of HIV/AIDS patients seeking anti-retroviral therapy with respect to:

   a) CD4 count.

   b) Opportunistic infections.

   c) Adherence.

REVIEW OF LITERATURE

History: [10, 11]

Thirty years ago, the acquired immunodeficiency syndrome (AIDS) was unknown to medical science. Now, it is one of the leading causes of death among young adults and has a profound impact on the health of the people worldwide.

There have been many historical events in the evolution of AIDS and its treatment.

- 1981: AIDS was first reported in United States.
- 1982: The term AIDS (Acquired immune deficiency syndrome) was used for the first and the center for the disease control (CDC) defined AIDS.
- 1984: The causal agent of the AIDS was identified in France (Lymphadenopathy associated virus) and in United States (Human lymphotrophic virus type III) finally called Human immunodeficiency virus. Eminent HIV scientist Dr Robert Gallo (United States) is considered to be the one who discovered HIV.
- 1985: The serologic testing for HIV (Food and Drug Administration-FDA approved) became effective.
- 1986: HIV infection was first identified in India in Madras (now called Chennai).
- 1987: Zidovudine became the first anti HIV drug to be approved by FDA.
- 1993: CDC revises its definition of AIDS.
- 1995: The first Protease inhibitor was introduced and the combination of nucleoside along with Protease inhibitor generally known as Highly Active Anti Retroviral Therapy (HAART) came into wide use.

These therapies have created a revolution in the treatment of HIV disease.

EPIDEMIOLOGY.

Global HIV/AIDS estimates: End of the year 2008.

The latest statistics of global HIV/AIDS were published by United Nations Programme on HIV/AIDS (UNAIDS) in November 2009, and refer to the end of the year 2008.

Statistics of global HIV/AIDS at end of 2008.	Estimate in millions.
Total number of people living with HIV/AIDS	33.4
Women	15.7
Children	2.1
People newly infected	2.7
AIDS death	2.0

More than 25 million people have died of AIDS since 1981.[4]

India HIV and AIDS Statistics

The spread of HIV in India has been uneven. HIV epidemics are more severe in the southern half of the country and the far north east.

The highest HIV prevalence rates are found in Andhra Pradesh, Maharashtra, Tamil Nadu, and Karnataka in the south, and Manipur and Nagaland in North east.

People living with HIV/AIDS at the end of 2007: 2.31 million. The estimated adult prevalence in the country is 0.34% and it is greater among males (0.44%) than among females (0.23%).[12]

Due to lack of efficient reporting system these figures significantly under represent the actual number of people living with AIDS. Many AIDS deaths go

unreported in India, due to the stigmata and discrimination. In many situations, the cause of death is attributed to an opportunistic infection with Tuberculosis, without HIV having been diagnosed.

Perhaps 85% of HIV transmission in India is through sexual contact. Injection drug use is an important factor in the North East Myanmar, in North West near Afghanistan and Pakistan and in major cities. India still has many paid blood donors, and hence contaminated blood and blood products account for about 2% of HIV infection.[13]

ETIOLOGY: [14]

The Human immunodeficiency virus belongs to the family of retroviruses and subfamily of lentiviruses. The retrovirus has a unique manner of replication. An enzyme, reverse transcriptase (RT) carried by the virus reverses the usual flow of genetic information by causing the ribose nucleic acid (RNA) genetic information of the virus to be transcribed into DNA.

MORPHOLOGY

Electron microscopy shows that the HIV virions comprise icosahedral cores, containing the RNA genome, the RT enzyme and gag proteins, surrounded by an envelope. The complete sequence of HIV-1 contains a 9.2 kb genome. Long terminal repeats (LTRs) flank the genes for gag, pol and env and on either side of env gene additional frame for coding 6 protiens of which 5 are involved for regulation. These involve the products of following genes; *tat* (transcription gene), *rev* (regulator of virus gene), *nef* (negative factor gene), *vif* (viral infectivity factor gene), *vpu* and *vpx*. Viral protein R (VPR) imparts a rapid growth advantage to HIV-1.

Structural antigens:

Core antigens: The inner cone-shaped component of the nucleocapsid consists of a shell of the gag cleavage product p24. Its presence is a marker for viral replication.

Envelope antigens: In the envelope of the virion this protein is present as a 2 cleaved products, a transmembrane glycoprotein, gp41, and an external glycoprotein, gp120. These have the functions of attachment of the virus to the target cell (gp120) and fusion of virus envelope and cell membrane (gp41)

RT antigen: The reverse transcriptase enzyme is necessary for reverse transcription.

VIRUS CELL INTERACTION:

For the cell to be susceptible to the infection, 2 conditions have to be fulfilled. First, the envelope of the virus has to react with the cell surface and cell must be capable of supporting viral replication.

The initial function of the virus envelop is to bind to CD4 as receptor by use of recombinant HIV envelope gp 120. A second human receptor component mediated by gp41 is required for viral entry, and this second function of the viral envelope produces fusion between the adjacent membranes seen as the typical cytopathic effect of syncytium formation.

As the retrovirus is able to integrate into the host DNA, the hallmark of the infection by HIV is persistence and as a consequence of this, a person once infected will there after remain at risk of virus related disease and will remain infectious.

PATHOGENESIS OF HIV INFECTION:

Shortly after the infection and before any immune response to the virus is detectable, free virus and viral antigens circulate in the blood. As antibody titers increase, the amounts of free virus decrease, indicating a degree of immunological suppression of virus replication. Viruses are sequestrated in the lymph nodes after early viremic burst, but over time viral replication is continual and persistent. In healthy HIV seropositive individual, quantitative viral RNA analysis, estimate that 10^7 - 10^9 virions are produced each day and calculations based on CD4 T cell loss predict that 2 X 10^9 CD4 T cells are destroyed per day. Most patients maintain a reduced level of viral replication in the first few years of infection, but as the damage to immune system becomes more marked, viral replication increases.

In the disease process, the naive CD4 T cells (CD 45 Ra) are lost during disease progression at a higher rate than CD 45 Ro memory cells. Therefore an infected individuals immune response is first lost to specific recall antigens and then to allogenic antigens and finally to mitogen stimulation.

The mechanism of CD4+T cell loss has been speculated to be either due to direct effect of the virus followed by apoptosis or indirect mechanisms, such as gp120-CD4 antibody cross linking, viral protein – induced cellular dysregulation.

Finally, it should be mentioned that, as a prerequisite for HIV replication, cellular activation and proliferation are important factors and this is thought to be induced by antigens via specific T cell receptor or cytokines.

TRANSMISSION: [15, 16]

HIV infection spreads by three routes of transmission;

1. Sexual contact with an infected person (homosexual or heterosexual)
2. Blood and blood products
3. By infected mother to infant(intra partum, perinatally or via breast milk)

SEXUAL TRANSMISSION:

Worldwide, the most common mode of infection is heterosexual transmission. HIV appears to be concentrated in seminal fluid and also in vaginal fluid, particularly in situations as in genital inflammatory conditions. It is found that male to female transmission is more efficient than female to male transmission and presence of sexually transmitted disease has been strongly associated with HIV transmission.

India's AIDS case surveillance system attributes 86% of HIV infections to sexual risks.

TRANSMISSION BY BLOOD AND BLOOD PRODUCTS:

HIV can be transmitted to individuals who receive HIV-tainted blood transfusions, blood products, or transplanted tissue as well as to Injection drug users (IDUs) who are exposed to HIV while sharing injection paraphernalia. Parental transmission can occur during IV puncture, S.C or I.M injections. It is estimated that 90-100% of individuals who were exposed to HIV-contaminated products became infected. Current technology cannot detect HIV RNA for the first 1-2 weeks following infection due to low levels of viremia. Thus despite best efforts of science, one cannot completely eliminate the risk of transfusion-related transmission of HIV since.

India's AIDS case surveillance system attributes 2.4% to injection drug use, 2.0% to blood transfusions, of HIV infections.

OCCUPATIONAL TRANSMISSION OF HIV:

Health care workers and laboratory workers are potentially at risk of HIV infection while working with HIV containing materials with percutaneous injuries or contact of mucous membrane or non intact skin with blood, tissue or potentially infectious fluid. HIV transmission following skin puncture with sharp object contaminated with blood from a person with documented HIV infection is 0.3% and after a mucous membrane exposure it is 0.09%. Factors that might be associated with mucocutaneous transmission of HIV include exposure to a large amount of blood, prolonged contact, and a potential portal of entry and antiretroviral drugs as post exposure prophylaxis decreases the risk of infection. Therefore it is very important to use universal precaution when caring for all patients.

MATERNAL-INFANT FETAL / INFANT TRANSMISSION:

HIV infection is transmitted from infected mother to her fetus during pregnancy, during delivery, or by breast feeding. Relative proportions of transmission are 23-30% before birth, 50-65% during birth and 12-20% via breast feeding. Breast feeding in early months is an important modality of transmission of HIV infection in developing countries and factors that increase the likely hood of transmission include detectable levels of HIV in breast milk, presence of mastitis, low maternal CD4+T cell counts, and maternal vitamin A deficiency.

India's AIDS case surveillance system attributes 3.6% to perinatal transmission.

REVISED CDC CLASSIFICATION SYSTEM FOR HIV: [18]

The revised CDC classification system for HIV-infected adolescents and adults (greater than or equal to 13 years) categorizes persons on the basis of clinical conditions associated with HIV infection and CD4+ T- lymphocyte counts.

The three CD4+ T-lymphocyte categories are defined as follows:

- Category 1: greater than or equal to 500 cells/μl.
- Category 2: 200-499 cells/ul.
- Category 3: less than 200 cells/ul.

EXPANSION OF THE CDC SURVEILLANCE CASE DEFINITION FOR AIDS: [17]

AIDS surveillance case definition includes all HIV-infected persons with CD4+ T- lymphocyte counts of less than 200 cells/ul or a CD4+ percentage of less than 14. In addition to retaining the 23 clinical conditions in the previous AIDS surveillance definition, the expanded definition includes pulmonary tuberculosis (TB), recurrent pneumonia, and invasive cervical cancer.

REVISED WHO CLINICAL STAGING OF HIV/AIDS FOR ADULTS AND ADOLESCENTS: [18]

Primary HIV infection

Asymptomatic

Acute retroviral syndrome

Clinical stage 1

Asymptomatic

Persistent generalized lymphadenopathy (PGL)

Clinical stage 2

Moderate unexplained weight loss (<10% of presumed or measured body weight)

Recurrent respiratory tract infections)

Herpes zoster

Angular cheilitis

Recurrent oral ulcerations

Papular pruritic eruptions

Seborrhoeic dermatitis

Fungal nail infections of fingers

Clinical stage 3

Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations

Severe weight loss (>10% of presumed or measured body weight)

Unexplained chronic diarrhoea for longer than one month

Unexplained persistent fever (intermittent or constant for longer than one month)

Oral candidiasis

Oral hairy leukoplakia

Pulmonary tuberculosis (TB) diagnosed in last two years

Severe presumed bacterial infections (e.g. pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)

Acute necrotizing ulcerative stomatitis, gingivitis or periodontitis

Conditions where confirmatory diagnostic testing is necessary

a. Unexplained anaemia (< 8 g/dl), and or neutropenia (<500/mm3) and or thrombocytopenia (<50 000/ mm3) for more than one month

b. All clinical events or conditions referred to are described in the Annexes in WHO

Clinical stage 4

Conditions where a presumptive diagnosis can be made on the basis of clinical signs or simple investigations

HIV wasting syndrome

Pneumocystis pneumonia

Recurrent severe or radiological bacterial pneumonia

Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month's duration)

Oesophageal candidiasis

Extrapulmonary TB

Kaposi's sarcoma

Central nervous system (CNS) toxoplasmosis

HIV encephalopathy

Conditions where confirmatory diagnostic testing is necessary:

Extrapulmonary cryptococcosis including meningitis

Disseminated non-tuberculous mycobacteria infection

Progressive multifocal leukoencephalopathy (PML)

Candida of trachea, bronchi or lungs

Cryptosporidiosis

Isosporiasis

Visceral herpes simplex infection

Cytomegalovirus (CMV) infection (retinitis or of an organ other than liver, spleen or lymph nodes)

Any disseminated mycosis (e.g. histoplasmosis, coccidiomycosis, penicilliosis)

Recurrent non-typhoidal salmonella septicaemia

Lymphoma (cerebral or B cell non-Hodgkin)

Invasive cervical carcinoma

Visceral leishmaniasis

DIAGNOSIS AND LABORATORY MONITORING OF HIV INFECTION: [19,20]

The diagnosis of HIV-1 infection is based on the detection of specific antibodies (ELISA, Western blot) and antigens. Serological tests are generally used for screening and provide results in as little time as 20 min. Rapid tests are important tools for surveillance, screening, and diagnosis, and can be readily be done on plasma, serum, whole blood, or saliva by health care providers. The two limitations of the

serological tests are detection of infection when antibodies are absent, and in infants younger than 18 months who might bear maternal antibodies. In these instances direct viral detection is the only option (eg, quantification of viral RNA or p24 antigen).

For staging purpose and to monitor therapeutic success of HAART, measurement of CD4+T cells and plasma viral load is required. The viral load determines the rate of destruction of the immune system; the number of CD4+T cells reveals the degree of immunodeficiency. Flow cytometry analysis is the standard method for CD4+T cells quantification.

CLINICAL MANIFESTATIONS OF HIV DISEASES: [15]

The clinical course of human immunodeficiency virus (HIV) disease and pattern of opportunistic infections varies from patient to patient and from country to country. The clinical consequences of HIV infection encompass a spectrum ranging from an acute syndrome associated with primary infection to a prolonged asymptomatic state to advanced disease.

THE ACUTE HIV SYNDROME

It is estimated that 50–70% of individuals with HIV infection experience an acute clinical syndrome ~3–6 weeks after primary infection; they occur along with a burst of plasma viremia. The symptoms of the acute HIV syndrome include fever, skin rash, pharyngitis, and myalgia which persist for one to several weeks and gradually subside as an immune response to HIV develops. Opportunistic infections during this stage of infection reflect the immunodeficiency resulting from dysfunction and reduced numbers of CD4+ T cells. Lymphadenopathy occurs in ~70% of individuals with primary HIV infection. Most patients recover spontaneously from this syndrome.

THE ASYMPTOMATIC STAGE—CLINICAL LATENCY

In most patients, primary infection with or without the acute syndrome is followed by a prolonged period of clinical latency; the median time for untreated patients is ~10 years. HIV disease with active virus replication is ongoing and progressive during this asymptomatic period. The rate of disease progression is directly correlated with HIV RNA levels. Long-term non-progressors show little if any decline in CD4+ T cell counts over extended periods of time and have extremely low levels of HIV RNA (<50 copies per milliliter). During this period of HIV infection, the average rate of CD4+ T cell decline is ~50/μl per year.

SYMPTOMATIC DISEASE

Symptoms of HIV disease can appear at any time during the course of HIV infection. When the CD4+ T cell count falls to <200/μl, the resulting state of immunodeficiency is severe enough to place the patient at high risk for opportunistic infection and neoplasms. The causative agents of the opportunistic infections are *P.* jiroveci, atypical mycobacteria, CMV, and other common bacterial and mycobacterial pathogens. Fewer than 50% of deaths among AIDS patients are as a direct result of an AIDS-defining illness, and the average CD4+ T cell count of an HIV-infected patient at the time of death is 300 cells/μl. Similarly, following the widespread use of combination ARV therapy and implementation of guidelines for the prevention of opportunistic infections, the incidence of secondary infections has decreased dramatically. Overall, the clinical spectrum of HIV disease is constantly changing as patients live longer with HAART treatment.

In a study done between 1997 and 2001, 3015 patients were included in the study in France in which 2614(86.7%) patients were < 50 years and 401(13.3%) were

aged 50 or older at HAART initiation. Among patients with baseline HIV RNA above 5 log copies/ml, CD4 mean increase during the first 6 months on HAART was +42.9 3 106 cells/l per month in patients under 50 years and +36.9 3 106 cells/l per month in patients over 50 years (P < 0.0001); subsequently, the respective monthly changes were +17.9 and +15.6 3 106 cells/l per month (P< 0.0001).[21]

In a cohort study done on 6918 patients between 1996 to 2005 in Chennai, India revealed mean age was 32.6 years(SD 8.1years). 66% of patients were male and initial mean CD4 count was 318 cells/µl(SD 291cells/µl) at the time of presentation. The incidence of opportunistic infections in the absence of ART was derived using incidence density analysis, stratified by CD4 cell count. Patients receiving neither ART nor co-trimoxazol prophylaxis starting with mean CD4 count of 318 cells/µl had a projected life expectancy of 34.5 months and a discounted life time cost of US dollar 530. Co-trimoxazol prophylaxis alone increased discounted life expectancy by 0.4 months for an additional discounted cost of US dollar 50. With one line of ART available, cotrimoxazole prophylaxis in combination with stavudine/ lamivudine/ nevirapine, starting at CD4 <200 cells/ml, increased discounted life expectancy to 62.4 months(70.8 months undiscounted) at a total discounted lifetime cost of US$1540. Starting ART earlier, at CD4<250 cells/ml, increased discounted life expectancy by an additional 1.3 months.[22]

Another cohort study was done on 6833 HIV infected dults who started ART between 6th August 2000 and 30th April 2006 in South Africa. It says for the entire cohort total mean monthly costs were dollar 370. For the entire cohort (6833 participants), total mean monthly costs were $370 (SD, $664). Hospitalization costs accounted for 41% of total costs; non-ART medications, 14%; investigations, 10%;

consultations, 21%; ART medications, 9%; and other, 4% . Patients with a lower CD4 cell count at entry had higher median monthly health care costs than those with a higher count Median total cost increased with greater adherence but, paradoxically, mean total cost decreased. Median cost was $177 (IQR, $106 to $331) in the lowest versus $211 (IQR, $153 to $315) in the highest adherence quartile. Mean total monthly cost was $375.6 (SD, $598) in the lowest adherence quartile versus $313 (SD, $657) in the highest adherence quartile. Of note, costs for hospitalization increased from 29% to 51% of total costs as ART adherence decreased.[23]

A prospective, observational, multi centre, nationwide study was done on 69 recruited hospitals in Spain during Jan 1998 to Dec 1999. It comprised of 2620 patients. The data collected included socio demographic information, clinical parameters, treatment, and adherence, development of significant side effects, CD4 cell counts and viral load. Adherence was estimated at month 3, 6 and 12. Men were significantly older than the women, had lower CD4 cell counts. At baseline, CD4 cell counts were higher in women than in men: 14.5% higher in drug-naive women and 19.9% higher in drug-experienced women. CD4 cell counts increased throughout the follow-up period, although the highest increments were observed within the initial 3 months of therapy, particularly in drug-naive patients. No significant differences between genders in adherence. Regarding age, patients younger than 35 years had higher CD4 cell counts than older patients in men (280 versus 247 cells/µl; $P<0.001$) and in women (321 versus 275 cells/µl; $P=0.06$).[24]

In a descriptive analysis of routinely collected service delivery data on HIV infected patients enrolled at 28 HIV care and treatment clinics between 2003-2009 in Mozambique on 1,54,188 patients revealed 1,44,024 adults. Among them 65.4%

were women and were significantly younger than men. 48% of adult patient reported being married and 31.2% being single and this information was missing for 14.1% patients, with a proportion reported being single significantly higher among women. Half of them had primary education and 17.5% of women and 25.7% of men had 8 or more years of education. WHO stage or CD4 cell count, showed women were with less advanced disease stage than men, with a lower proportion with WHO stage 3 or 4(31.3% vs. 39.4%, p-value<0.001), CD4 count<200 cells/µl (20.0% vs. 25.9%, p-value<0.001) or TB treatment (2.8% vs. 5.5%, p-value<0.001). Among those who initiated ART the median estimated 12 month mortality rate across sites was 13.1% and 13.5% for adults and children respectively.[25]

A prospective cohort study was conducted in 9 rural district hospitals of the centre region of Cameroon, during May 2006 – April 2008. Among 401 patients median age was 36 years (30 to 44). One-fifth reported being married and half had education level higher than secondary school. The median CD4 cell count was 193 and one-quarter of patients were at clinical stage 4. Adherence to ART during follow up revealed that 101 patients were considered adherent throughout the entire follow-up, 7% were non adherent at each visit. The proportion of ART adherent patients decreased from 73% at month 1 to 61% at 24th month. patients who reported willingness to start ART before initiation, those who were satisfied with information provided by their physicians, and those who implemented reminder methods for ART intake were more likely to be adherent to ART.[26]

In an observational cohort study done between 1999 and 2006 on 7776 adolescents vs. adults in Southern Africa, there were 154 adolescent and 7622 adults. Study revealed that there was significantly smaller proportion of adolescent's

achieved 100% adherence at each time point (adolescents: 20.7% at 6 months, 14.3% at 12 months, and 6.6% at 24 months; adults: 40.5%, 27.9%, and 20.6% at each time point, respectively; P , 0.01). Patients achieving 100% 12-month adherence were significantly more likely to exhibit virologic suppression at 12 months, regardless of age.[27]

According to 2 years outcome analysis done on 287 adults started on ART in Khayelitsha, South Africa during May 2001 to 31 Dec 2002 showed the median follow-up time of 14.9 months for those surviving after starting ART. More women (70%) accessed treatment. Of 38 deaths, 36 attributed to HIV and occurred before 12 months of follow-up(71% before 3 months). 155 began treatment with CD4 count less than 50 cells/µl. In review of cause of death, 20 deaths were classified as being due to very advanced disease at the time of starting ART, with continued deterioration on treatment. Other clinical outcomes showed the median weight gain at 6 months on treatment was 5.0 kg and 9.0 kg at 12 months. The CD4 lymphocyte count increased rapidly compared to the pre-treatment level in the first 6 months on treatment, increasing by a median of 134 cellsµ/l, in subsequent intervals was lower than this, by 24 months on ART the median increase in CD4 lymphocyte count compared to baseline was 288 cells/µl , with a median absolute CD4 lymphocyte count at this duration on treatment of 323 cells/µl. Most changes occurred soon after treatment was started (median 42 days).[28]

Based on loss to follow-up data analysis on 23,430 adults receiving services in 2 HIV care networks in the cities of Beira and Chimoio in Mozambique during 1 year study period between 2004-2005, there were 7005(29.9%) HIV+ve. Only 3956(56.5%) of them enrolled at ART clinic with in ≤30 days after testing. CD4

testing was obtained in 77.1% ≤30 days of enrollment. In 1506 eligible for ART, 471(31.3%) started ART ≤90 days after CD4 testing and after ≥180 days of follow u on ART in 382 patients, 317(83%) had pharmacy based adherence rates ≥ 90%.[29]

A cross sectional 2 site hospital based study was undertaken to study the factors associated with non adherence to ART in 2005. 200 from Lok Nayak Prakash hospital, New Delhi and 100 patients from All India Medical Institute of Medical Sciences New Delhi were included with mean age of 33.3 and 36.8 years respectively. The pooled adherence for both sites was 75%. Adherence at AIIMS was 47%, whereas it was 90% at LNJP, which was statistically significant($p<0.001$). Multivariate analysis showed that non adherence was associated with not having been told about the importance of ART, having to pay out-of-pocket for ART and reported continued risk behavior post ART.[30]

A longitudinal analysis of a cohort of HIV infected adults on ART in Tanzania who were enrolled from November 2004 to June 2008 revealed that, in 13,597 adult patients, men were significantly more immunocompromised at enrollment in terms of stage 4 disease($p<0.001$) and mean CD4 cell count ($p<0.001$) than women. In multivariate analysis, men had a significantly higher risk of overall mortality, immunologic non response defined as CD4 cell count<100 cells/µl after at least 6 months of initiating ART and last to follow up than that in women. Associations did not change significantly when restricting analysis to the period of good adherence for all patients.[31]

In 1 year follow-up study on 83 Chinese pediatric ART patients on their baseline characteristics, clinical outcomes, immunologic outcomes and virologic outcomes from July 2005 to Aug 2006 showed 51 were ART new at enrollment and

32 were ART experienced. After 12 months median weight increased by 0.3 weight for age z-score, median CD4 count increased from 116 to 340 cells/mm^3 ($p<0.0001$) D4 count increased, despite little change in median viral load.[32]

In a multi centre, randomized, adherence intervention clinical trial done in United States from Nov 1999 to Jan 2002 on 928 participants followed a median of 30 months showed the median baseline CD4 count was 155 cells/mm^3. The medication manager participants had significantly better CD4 cell count ($p=0.01$) and adherence ($p<0.001$) outcomes. While a little reminder arm participants had worse virological outcomes. The study demonstrated that inter-personal structured adherence support was associated with improved long term medication adherence and virologic and immunologic HIV outcomes.[33]

In a retrospective analysis of an observational clinical cohort of 906 patients enrolled during Feb 1989 and Jan 2006 and had ART initiation dates between Dec 1995 and Feb 2006 at Johns Hopkins University School of Medicine tells there is no difference in immunologic response by age group for mean change in CD4 cell count or time to CD4 cell count increase by 50 cells/µl. After ART initiation younger patients had a higher incidence of at least 1 new opportunistic infection ($p<0.01$) than older patients. There were no differences by age in rate of diagnosis of the other opportunistic infections. The most commonly diagnosed opportunistic infection after ART initiation in both older and younger patients were Candidiasis, Herpes encephalitis and PCP.New OIs after ART initiation was shorter in younger patients than in older patients diagnosed with OIs at 39.7 months. Older patients had shorter survival time than did younger patients($p=0.02$) and also had higher overall mortality than did younger patients($p=0.04$).[34]

A multicohort study was done during Jan 2006 and Sept 2008 in 8 HIV in Sub-Saharan Africa. Total of 30,134 patients contributed 25,916 person-years of follow-up. The incidence of tuberculosis was 10.5 per 100 person years during the pre-ART and 5.4 during the ART period. For all types of tuberculosis, incidence was similar in the pre-ART period and initial 3 months of ART but declined over time receiving ART. Throughout follow-up,

Rates of pulmonary tuberculosis remained 2-fold to 3-fold higher than extra pulmonary tuberculosis rates. Smear-negative pulmonary tuberculosis was higher than smear-positive incidence and varied greatly across sites during the pre-ART period. Incidence was lower in rural sites, women, patients without prior history of tuberculosis, body mass index ≥18.5 kg/m2, and ≥200 nadir CD4 cells per micro liter. Recurrence rate was 1.7 per 100 person-years (95% confidence interval: 1.0 to 2.8).[35]

Another observational cohort study was done for 4 years in Johannesburg, South Africa on incidence, risk factors and prevention strategies in TB patients receiving ART during April 2004 and March 2007. 501 TB cases occurred among 7536 individuals, corresponding to a 10% risk in first 4 years of ART and an overall incidence rate of 4.2 cases per hundred person years. The highest incidence rate was observed in first 3 months of ART among people with CD4 count below 50 cells/mm^3. Low baseline CD4 count, anemia, and low BMI were the strongest risk factors for early incident TB. Low updated CD4 count, low updated BMI, anemia and high viral load on ART were strong risk factors for late incident TB.[36]

Based on a mixed effect model to estimate CD4 decline and incidence of OI done between 1984 and 2000 in Cape Town South Africa in two public sector clinics which included 974 patients with 2 or more CD4 cell count revealed that on follow-

up, mean initial CD4 count for patients included was 307.3 cells/µl and on enrollment 42.1% had WHO stage 1 and 15% had stage 4 HIV disease. 306 deaths and 398 loss to follow-up occurred. Higher proportion of men were lost to follow-up compared with women ($p<0.0001$), and those lost to follow-up were slightly younger (31 years) than those not lost to follow-up (34.5 years) ($p<0.0001$). Incidence rates were significantly higher($p<0.0001$) at lower CD4 cell counts for all OIs, with the highest rates in the stratum of 50 cells/µl or less .TB and oral candidiasis occurred commonly with CD4 cells more than 200 and were the only OIs to occur in cell counts more than 500 cells/µl.[37]

A randomized study was done between Jan 2002 and Jan 2006 in United States patients were randomized to continuous vs. CD4 cell count guided episodic ART at 1:1 ratio. The follow-up results on 1225 patients showed mean follow-up time was 29 months, 88% were followed for more than 1 year and 61% for more than 2 years. Median CD4 count was 575 cells/mm^3. Through follow-up, whenever quality of life (QOL) outcomes differed, the results were inferior among patients in the episodic therapy group compared with continuous group. HIV disease progression was more common in episodic therapy arm and was preceded by marked declines in QOL, but excluding participants with disease progression had minimal effect on QOL comparisons.[38]

A cross sectional study was done in Mumbai, India on cost of HIV/AIDS treatment on 152 lower middle class patients. Patients were given ART from 6 months to 5 years. 90% lived at home and commuted to the clinic by bus or train. 37% were sexually active but only 55% used condoms. In assessing adherence, income, education, knowledge of their drugs, transportation, side effects, cost of treatment,

distance from clinic and personal clinic satisfaction were analyzed, 75% reported cost of Art to be the single greatest obstacle to adherence.[39]

In another cross sectional study done from July to Sept 2007 at tertiary care hospital, Chennai, south India on QOL in HIV/AIDS patients was evaluated. QOL scores were significantly lower among persons with lower CD4 counts ($p<0.001$). Women had lower QOL scores than men despite having less advanced disease. Patients with better education had significantly higher psychological domain scores. A supportive family kept environmental scores better ($p<0.001$).[40]

In a 1 year follow-up study conducted at Christian Medical College Vellore in South India between March 2004 and May 2006, 230 consecutive ART new patients were followed up .Majority (70.4%) were in advanced stage and 78% had CD4 counts below 200 cells/µl. The cumulative incidence of treatment change was 39.6%. Drug toxicity was the reason for treatment change among 27%. Reasons for initial regimen change were deaths, drug toxicity, non adherence and treatment failure.[41]

A retrospective study was conducted on 120 children in South Africa during Aug 2004 and April 2005. At baseline, 58% of children were normal weight, 18% moderately underweight and 23% severely underweight. After 2 years of ART weight-for-age z-scores increased in all children. Mean CD4 cell percentages also increased significantly while viral loads decreased significantly with no difference among the groups at the end of 2 years of therapy.[42]

In a 2 year treatment outcome retrospective cohort analysis between Oct 2004 and Jan 2005 at 3 selected Government ART centers (Hyderabad, Mumbai and Chennai) on 972 patients showed median CD4 count was 119 cells/cmm at treatment initiation, 44% had baseline CD4 count less than 100 cells. 71% were alive after 2

years of treatment. The median increase in CD4 count was 142 cells/cmm at 6 months and 184 cells/cmm at 12 months after treatment. Over 2 years 124 patients died, majority of deaths occurred within 1st six months. Patients with baseline CD4 count were significantly more likely to die. 35% missed picking up their monthly drugs at least once and 16% were lost to follow-up.[9]

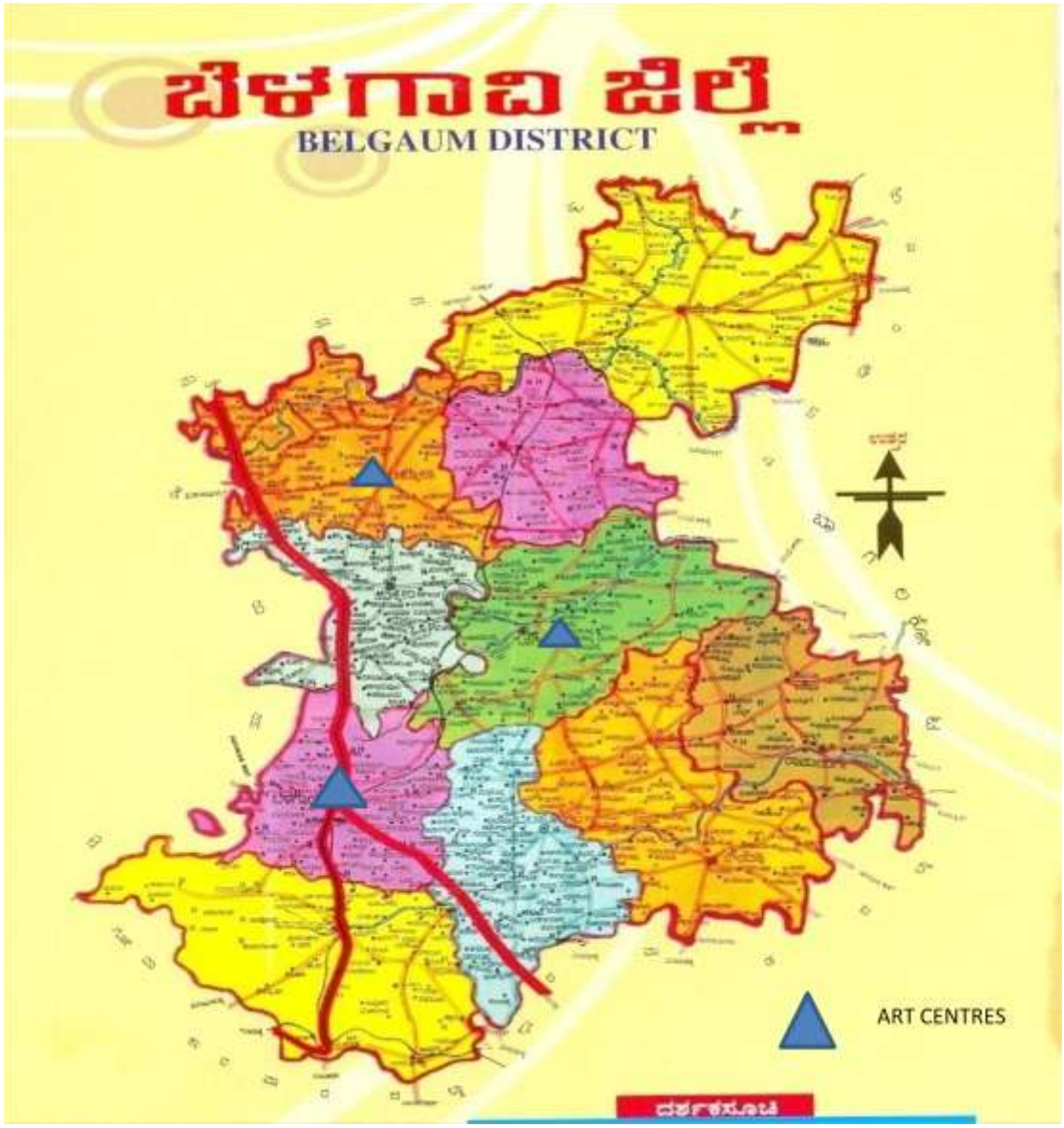
In a follow-up study outcome of ART in Northern India was assessed between May 2005 and Oct 2006. 631 out of 1325 patients enrolled were eligible for the study. Median follow-up period was 21 months. 139 had lost to follow-up. 77 died and 71 had been transferred to other ART centers. The CD4 count at 6 months was greater than the baseline value in 421 patients. Survival analysis showed 90% of the patients were alive at 6 months, 87% at 12 months and 84% at the end of 36 months. The overall mortality rate was 8.5/100 patients per year and post 90 day mortality rate was 5.8/100 patient years.[43]

Another study was done in Manipur on 161 HIV patients between March 2007 and September 2007 to study the effect of ART on CD4 count and spectrum of Opportunistic infections in HIV/AIDS patients.81 patients were followed up who were on ART every 6 months. Among them 82.7% showed an increase in CD4 count while 17.3% showed decrease. In 51 symptomatics not on ART , 28 patients developed various OIs. Remaining 29 patients who were in control group, not on ART also showed decrease in CD4 count.[2]

MATERIALS AND METHODS

Study area

The present study titled '**CLINICAL PROFILE OF HIV/AIDS PATIENTS SEEKING ANTI-RETROVIRAL THERAPY AT DISTRICT HOSPITAL- A LONGITUDINAL STUDY'** was conducted in ART centres of Belgaum district, Karnataka.



Study design and period

It was a longitudinal study, conducted over a period of 14 months from January 2010 to February 2011.

Source of data

The study was conducted on HIV/AIDS patients starting ART at District hospital Belgaum.

Sample size

All patients seeking ART at District hospital in the month of January and February 2010, who meet the inclusion criteria, are enrolled and followed up for 1year every month. Totally 372 patients were enrolled.

Sampling procedure (method)

Purposive sampling (Non probability method) or convenient sampling.

Ethical Clearance

The present study was approved by JNMC Institutional Ethics Committee on Human subjects' Research. (Ref: JNMC IEC Letter no MDC/DOME dated 14.10.2009)

Method of collection of data:

Instruments used for the data collection:

After obtaining the written informed consent, patients were enrolled in the study. A pre-designed & pre-tested proforma was used to collect information on socio-demographic variables of HIV/AIDS patients; self reported symptoms and treatment seeking behaviour of study subjects were recorded for restoring health.

Physical examination of subjects was done by the investigator at the health centre. For the required laboratory investigations, patients were referred to the laboratories and reports were collected.

Follow-up visits were done according to the NACO guidelines. i.e. First visit was done after patient registration for ART. 1st follow up was done at the end of 15days of start of treatment and further follow ups every month once. Any defaulters were contacted and followed up to know the reason for their drop out.

Secondary data was collected from various records of ART centres, i.e. Pre ART Registers, Laboratory Registers, Treatment cards and the OPD registers etc.

Initially from Januvary 2010 to April 2010 data was collected from ART centre District Hospital , Belgaum. From May 2010 and June 2010 onwards, two more ART centres were recognised at Gokak and Chikkodi respectively and the patients who were transferred from Belgaum ART centres to these two centres were also followed up.

Selection criteria

Inclusion Criteria:

1. Patients diagnosed as HIV/AIDS, who are eligible for ART.

Exclusion Criteria:

1. Patients who are already on ART.
2. Patients not willing for $CD4^+$ T cells count.

Statistical Analysis

The data was tabulated and master chart was prepared.

- Analysis was done using rates, ratios and percentage to summarize socio-demographic and clinical profile of HIV/AIDS patients.
- For comparing CD4 count before and after ART paired 't' test was used.

Definition of study variables:

***Age*:** Age was recorded to the nearest completed year.

Religion: Religion was classified and recorded as "Hindu", "Muslim", "Christian" or "Others" accordingly.

***Occupation*:** Individuals were classified into 7 groups, depends upon their occupation.[44]

Semi profession: This group consists of occupations which involve post high school or college education. They may also involve lower grade professional training. But the jobs of these people are essentially of a routine nature. The individuals belonging to this group are high school teachers, commission agents, junior engineers etc.

Clerical, Shop owners, Farm owners etc: This group consists of persons with some training in arithmetic and also in reading and writing. Here the work is essentially of a repetitive type. They have some general education and some training. They also know how to keep account and look after routine management. The persons belonging to this group are clerk, typist, accountant, primary school teacher, shop keeper, farm owners, salesman, insurance agents etc.

Skilled worker: They have got a long training in a rather complicated work. This group consists of masons, carpenter, mechanic, radio serviceman, car drivers, telephone operators etc.

Semi skilled workers: In this category, the person needs some training to do their routine jobs efficiently. The individuals belonging to this group are laboratory attenders, library attenders etc.

Unskilled worker: This group consists of all the persons who are doing work which involves neither education nor training such as watchman, peon, coolie, domestic servant, etc.

Unemployed: Persons who are unemployed irrespective of their general and professional education or training are grouped into this category.

Education[45]: Educational qualifications were grouped as:

Illiterate – A person who could not read and write with understanding in any language

Primary school education – A person who had studied upto 7^{th} standard.

High school education – A person who had studied from 8^{th} to 10^{th} standard.

Collegiate – A person who had read upto pre-university / diploma/TCH/ below degree class / ITI.

Graduate -A person who had a bachelor's degree in any field.

Type of family[46]

Nuclear family: Married couples, along with their dependent children living in the same house.

Joint family: Many married couples and their children who are living in the same household. All males are blood relatives and all females of the family are related by either marriage or blood relation.

Three generation family: Married couple with married children and their kids (three generations) related to each other by direct descent and living together.

Broken family: One where, the couple have separated, or where death has occurred for one or both the spouses.

Socioeconomic status[45]***:*** Information of total monthly income of the family in Rupees was obtained as well as the family size. Per capita monthly income in rupees was calculated, and then the family was classified using modified B. G. Prasad's classification.[42]

Modified B. G. Prasad's Classification

Socioeconomic class	Prasad's classification (1961) per capita income in Rs./ month[45]	Modified Prasad's classification in the study period (2010) Per capita income in Rs/month[47]
I	100 & above	3900 & above
II	50 – 99	1950 & 3899
III	30 –49	1170 & 1949
IV	15 – 29	585 & 1169
V	below 15	below 585

Average Consumer Price Index for Jan & Feb 2010 = 789.23 [43]

Modification was done with the aid of Multiplication Factor (M.F), which was obtained as below:

$$\text{M. F.} = \frac{\text{Average Consumer Price Index for study period}}{100} \quad \text{X } 4.93$$

$$\text{M. F.} \quad \frac{789.23}{100} = \text{X } 4.93$$

$$= 38.9 \approx 39$$

Smoking[48]**:** For the assessment of history of smoking, the period of recall was considered for the past one year.

Smokers: Subjects those who had smoked in the past or smoking at present were considered as "smokers".

Present smokers: The persons who had smoked ≥100 cigarettes/beedis and is currently smokes everyday or someday.

Past smokers: The persons who had smoked ≥100 cigarettes / beedis in his life time and not smoking since last one year.

Non Smokers: The person who had never smoked tobacco, or smoked <100 cigarettes/beedis in his life time.

Alcohol consumption[48]: For the assessment of alcohol consumption, period of recall was considered for the past one year.

Alcoholics: A person who has been taking alcohol at least 30 ml per day for at least six months preceding the survey.

Present Alcoholic: The person who consumed alcohol for the last one year.

Past Alcoholic: The person who consumed alcohol earlier but left consuming for the last one year.

Non Alcoholics: Subjects who had never consumed alcohol were considered and kept in the category of "Non Alcoholics".

Case definitions[16]:

i) HIV+ve

A person is said to be HIV+ve when all 3serological tests Coombs, Tridot and Triline are positive.

ii) AIDS

A HIV infected person who is positive for serological tests like Coombs, Tridot and Triline with major and minor signs as per WHO guidelines.

Clinical staging[16]**:**

Was done according to WHO clinical staging.

CD4 count[49]**:**

According to revised guidelines (April 2009), ART initiation was done.

WHO Clinical Stage	CD4 count(cells/mm^3)
I.	Treat if CD4 count<250(if between 251- 300, repeat CD4 count after 4 weeks)
II.	
III.	Treat if CD4 Count < 350
IV.	Treat irrespective of CD4 count

Specific Situations:

1. HIV and Tuberculosis(Start Efavirenz based regimen)

    a. Pulmonary TB and HIV- Start ART within 2 weeks of initiation of ATT for all patients with CD4 < 350 cells / mm^3 (For patients with CD4 >350, defer ART).

    b. Extra pulmonary TB and HIV- Start ART within 2 weeks of initiation of ATT in all patients irrespective of CD4 count. (Special attention to monitor hepatotoxicity.)

2. HIV and Pregnancy (avoid Efavirenz in first trimester)

    a. WHO stage 1 and 2 start CD4 < 250 cells/mm^3. (If between 251-300, repeat CD4 after 4 weeks)

    b. WHO stage3 start CD4 < 350 cells/mm^3(with strict monitor of adverse effects of Nevirapine.)

    c. WHO stage 4, start ART irrespective of CD4 count.

Functional Status[50]:

W- Working: Able to perform usual work in or out of the house, harvest, go to school or, for children, normal activities or playing.

A- Ambulatory: Able to perform activities of daily living but not able to work/ go to school/ play.

B – Bed ridden: Not able to perform activities of daily living.

Adherence[50]**:** Adherence was checked by asking the patient if he or she has missed any doses.

>95% = <3 doses missed in a period of 30 days.

80-95% = 3-12 doses missed in a period of 30 days.

<80% = >12 doses missed in a period of 30 days.

Transferred out (TO)[50]**:** Refers to when a patient who has been receiving ART at one facility transfers out of that facility.

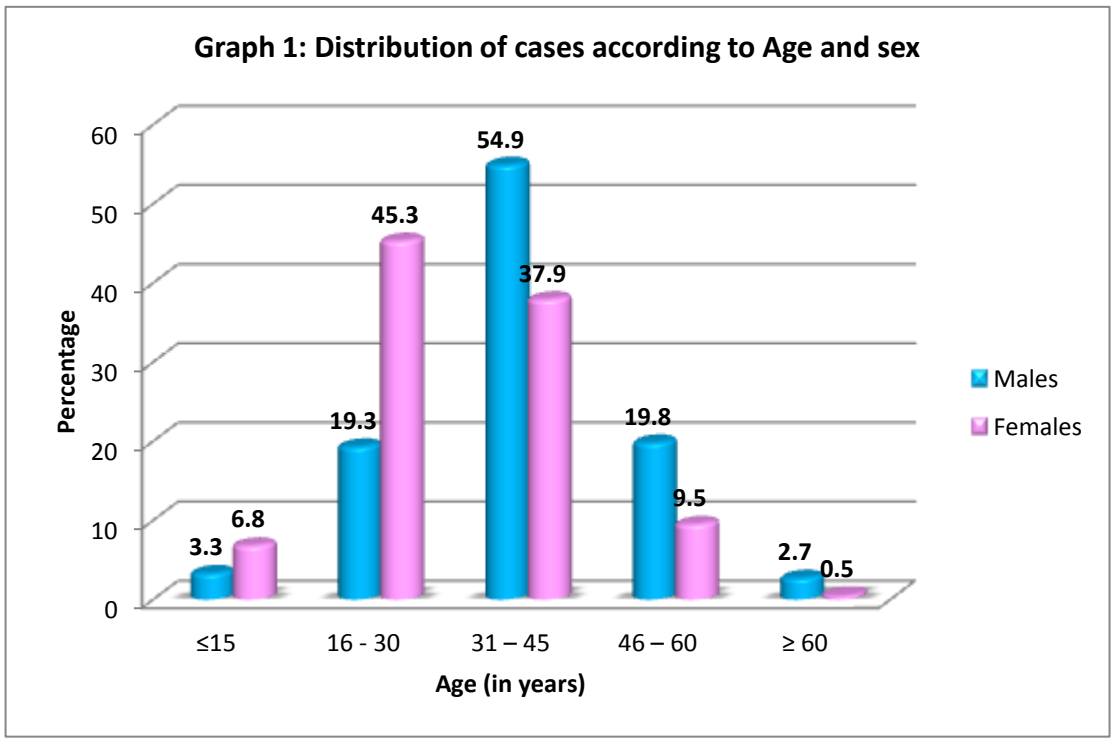
RESULTS

1. SOCIODEMOGRAPHIC PROFILE

Table – 1: Distribution of cases according to Age and sex

(n = 372)

Age (years)	Males		Females		Total		
	Numbers	%	Numbers	%	Numbers	%	
≤15	6	3.3	13	6.8	19	5.2	$\chi_3^2 = 36.54$, P=0.000
16 - 30	35	19.3	86	45.3	121	32.5	
31 – 45	100	54.9	72	37.9	172	46.2	
46 – 60	36	19.8	18	9.5	54	14.5	
≥ 60	5	2.7	1	0.5	6	1.6	
Total	182	100.0	190	100.0	372	100.0	



In the present study the mean age of the patients was 35.1years with standard deviation (SD) 11.40 years. The age of the patient ranged between 2 years to 71 years. The mean age was 38.3±11.0 years in males and 31.9±10.9 years in females. There were 182 (48.9%) males and 190 (51.1%) females. There was gender disparity in distribution of patients in different age groups .Males were more in age group 31-49 years while females were more in age group 16-30years.

Table – 2: Distribution of the study participants according to their occupation.

(n = 372)

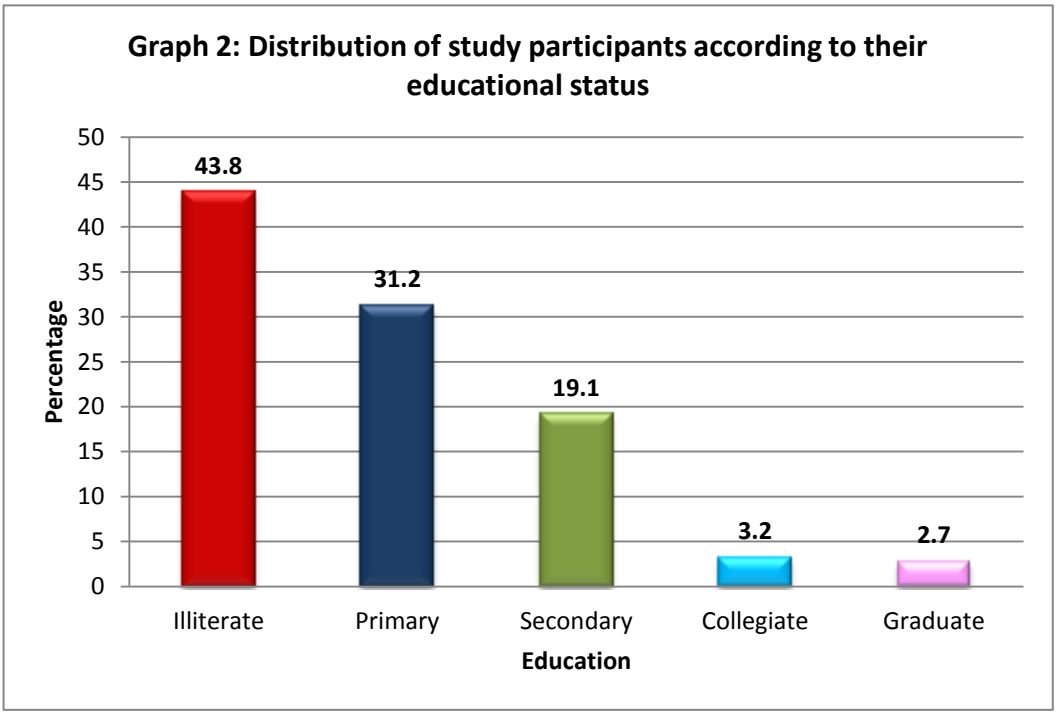
Occupation	No. of cases	Percentage
Unemployed	132	35.5
Unskilled	196	52.7
Semiskilled	22	5.9
Skilled	5	1.3
Business	16	4.3
Semi Professional	1	0.3
Professional	0	0
Total	372	100.0

In this study majority of the patients that is 196 (52.7%) were unskilled workers followed by 132(35.5%) unemployed, 22(5.9%) semiskilled, 16(4.3%) were involved in clerical work, shop owners and farm owners, 5(1.3%) were skilled workers and only one patient was semi professional.

Table -3: Distribution of study participants according to their educational status.

(n = 372)

Education	No. of cases	Percentage
Illiterate	163	43.8
Primary	116	31.2
Secondary	71	19.1
Collegiate	12	3.2
Graduate	10	2.7
Total	372	100.0



In the present study, among 372 participants 163(43.8%) were illiterates, 116(31.2%) had studied upto primary school, 71(19.1%) upto high school, 12(3.2%) had gone to college & 10(2.7%) were graduates & none were post graduates.

Religion: Majority of the study participants were Hindus i.e 347 (93.3%), 20 (5.4%) were Muslims and only one (1.3%) was Christian.

Table – 4: Distribution of study participants according to type of family.

(n = 372)

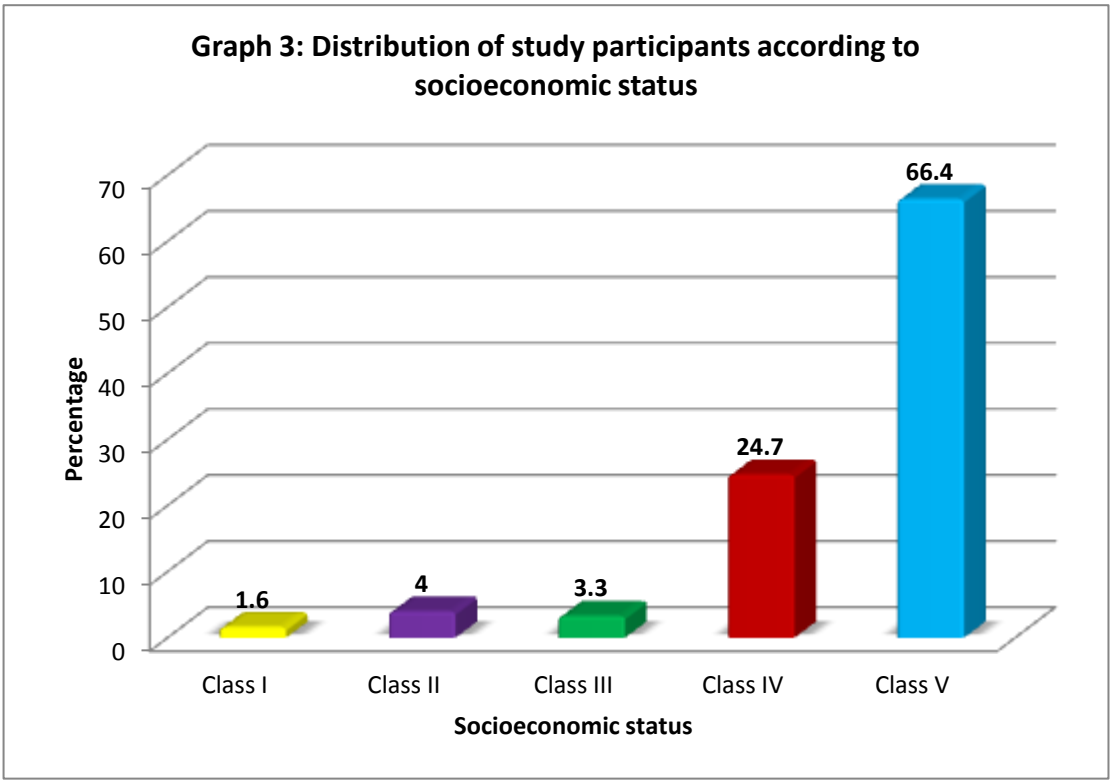
Family	No. of cases	Percentage
Nuclear	182	48.9
Joint	72	19.3
Third generation	7	1.9
Broken	111	29.9
Total	372	100.0

In this study, 182(48.9%) of the study participants belonged to nuclear family, 72(19.3%) to joint family, and 7(1.9%) to third generation family and111 (29.9%) belonged to broken family

Table – 5: Distribution of study participants according to socioeconomic status.

(n = 372)Graph

Socioeconomic status	No. of cases	Percentage
Class I	6	1.6
Class II	15	4.0
Class III	12	3.3
Class IV	92	24.7
Class V	247	66.4
Total	372	100.0

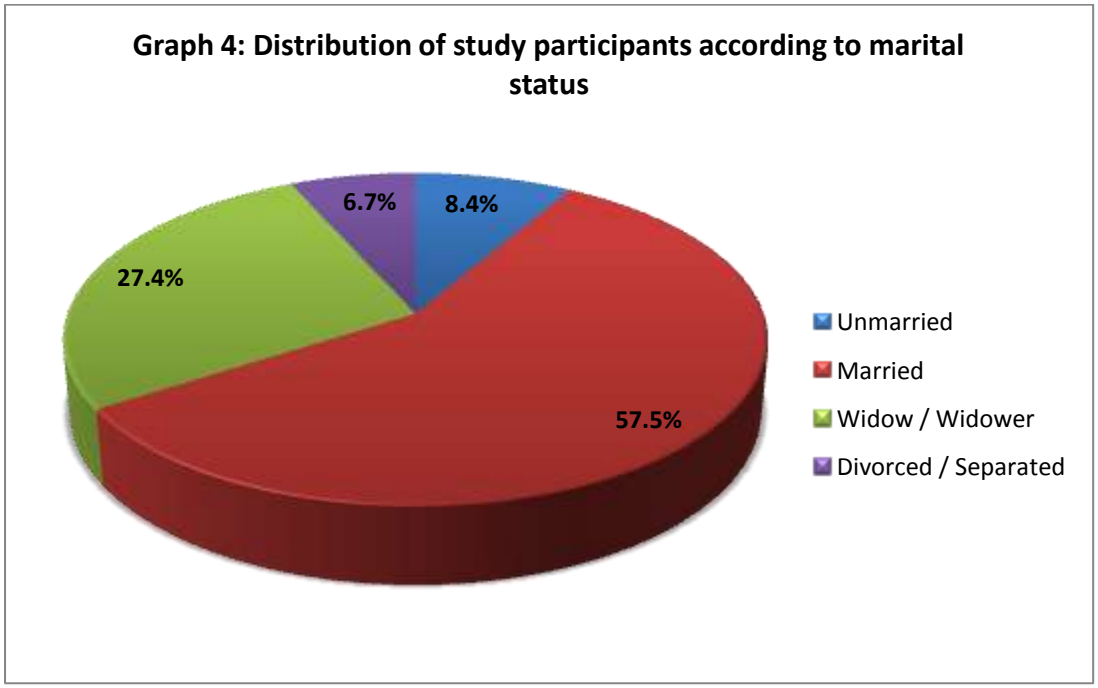


Majority of cases i.e 247(66.4%) belonged to Class V, 92(24.7%) belonged to Class IV, followed by 12(3.3%) to Class III, 15(4.0%) to class II and only 6(1.6 %) belonged to socio-economic class I.

Table – 6: Distribution of study participants according to marital status.

(n = 372)

Marital status	No. of cases	Percentage
Unmarried	31	8.4
Married	214	57.5
Widow / Widower	102	27.4
Divorced / Separated	25	6.7
Total	372	100.0



In this study maximum study participants 214(57.5%) were married, 31 (8.4%) were unmarried, 102 (27.4%) were widows / widowers and 25(6.7%) were divorced/separated.

Table – 7: Distribution of study participants according to their residence.

(n = 372)

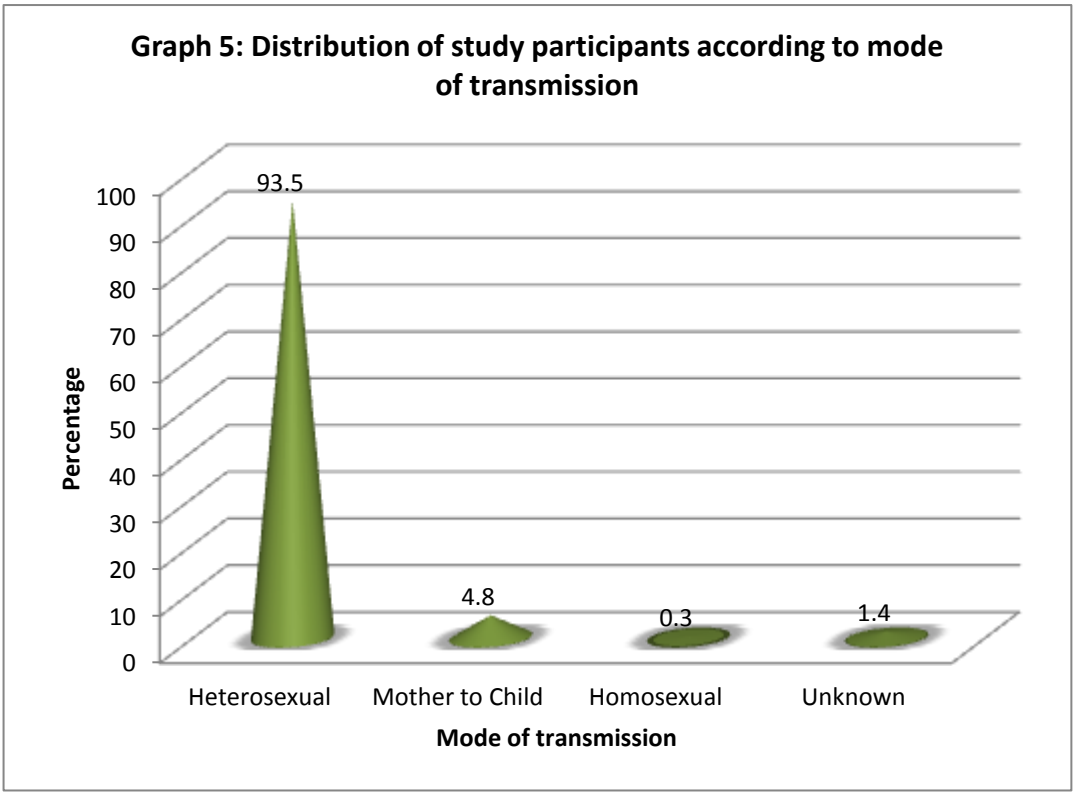
Residence	No. of cases	Percentage
Urban	180	48.4
Rural	192	51.6
Total	372	100.0

In this present study nearly half i.e192 (51.6%) patients were from rural area and180 (48.4%) were urban residents.

Table – 8: Distribution of study participants according to mode of transmission.

(n = 372)

Mode of transmission	No. of cases	Percentage
Heterosexual	348	93.5
Mother to Child	18	4.8
Homosexual	1	0.3
Unknown	5	1.4
Total	372	100.0



Of the total 372 patients majority i.e.348 (93.5 %) patients had acquired HIV infection by heterosexual route, 18(4.8%) had acquired infection perinatally and in one patient the mode of acquiring infection was by homosexual route and 5(1.4%) patients denied any of the above routes of transmission of infection.

Table – 9: Distribution of study participants according to their referral.

(n = 372)

Referred from	No. of cases	Percentage
VCTC	295	79.3
RNTCP	55	14.8
OPD / IPD	11	3.0
PPTCT	8	2.2
NGO	3	0.7
Total	372	100.0

In this study, 295(79.3%) patients were referred from VCTC center, 55(14.8%) from RNTCP, 11(3.0%) from OPD/IPD,8(2.2%) from PPTCT and 3(0.7%) patients were referred from NGO's.

Table – 10: Distribution of study participants according to the symptoms at the time of initiation of ART

(n = 372)

Symptoms	No. of cases	Percentage
No Symptoms	42	11.3
Fever/chill	27	7.3
Weight loss	19	5.1
Cough	7	1.9
Skin rash	5	1.3
Diarrhoea	5	1.3
Myalgia/Joint pain	5	1.3
Nausea/Vomiting	3	0.8
Depression	1	0.3
Others	12	3.2
Multiple symptoms	246	66.2
Total	372	100.0

In the present study,42(11.3%) patients were asymptomatic,27(7.3%)had fever/chills,19(5.1%) complained of weight loss,7(1.9%) had cough, 5(1.3%) each presented with skin rash, diarrhea and myalgia / joint pain,3(0.8%) patients had nausea/ vomiting, 1(0.3%) suffered from confusion/ depression, 12(3.2%) presented with other symptoms which included throat irritation, pain abdomen, hair loss etc and 246(66.2%) had multiple symptoms.

Table – 11: Distribution of cases according to WHO clinical stage at the time of initiation of ART.

(n = 372)

WHO clinical stage	No. of cases	Percentage
Stage I	15	4.0
Stage II	218	58.6
Stage III	120	32.3
Stage IV	19	5.1
Total	372	100.0

In the present study 15(4.0%) patients belonged to WHO clinical stage I, 218(58.6%) were in stage II, 120(32.3%) patients in stage III and19 (5.1%) patients belonged to WHO clinical stage IV.

Table – 12: Distribution of cases according to functional status at the time of initiation of ART.

(n = 372)

Fundamental status	No. of cases	Percentage
Working	340	91.3
Ambulatory	24	6.5
Bedridden	8	2.2
Total	372	100.0

In this study, functional status of340 (91.3%) patients was working, 24(6.5%) were ambulatory and8 (2.2%) patients were bed ridden at the time of initiation of ART.

Table – 13: Distribution of cases according to ART eligibility.

(n = 372)

ART eligibility	No. of cases	Percentage
Clinical symptoms & CD4<250 cells	202	54.3
CD_4 cell count <250	148	39.8
Symptomatic	22	5.9
Total	372	100.0

In this study, 202(54.3%) patients had both clinical symptoms & CD4 <250 cells as their eligibility criteria to start ART, while148 (39.8%) patients had CD4 cell count<250 & 22(5.9%) patients were symptomatic to initiate ART.

Table – 14: Distribution of cases according to condom use.

(n = 372)

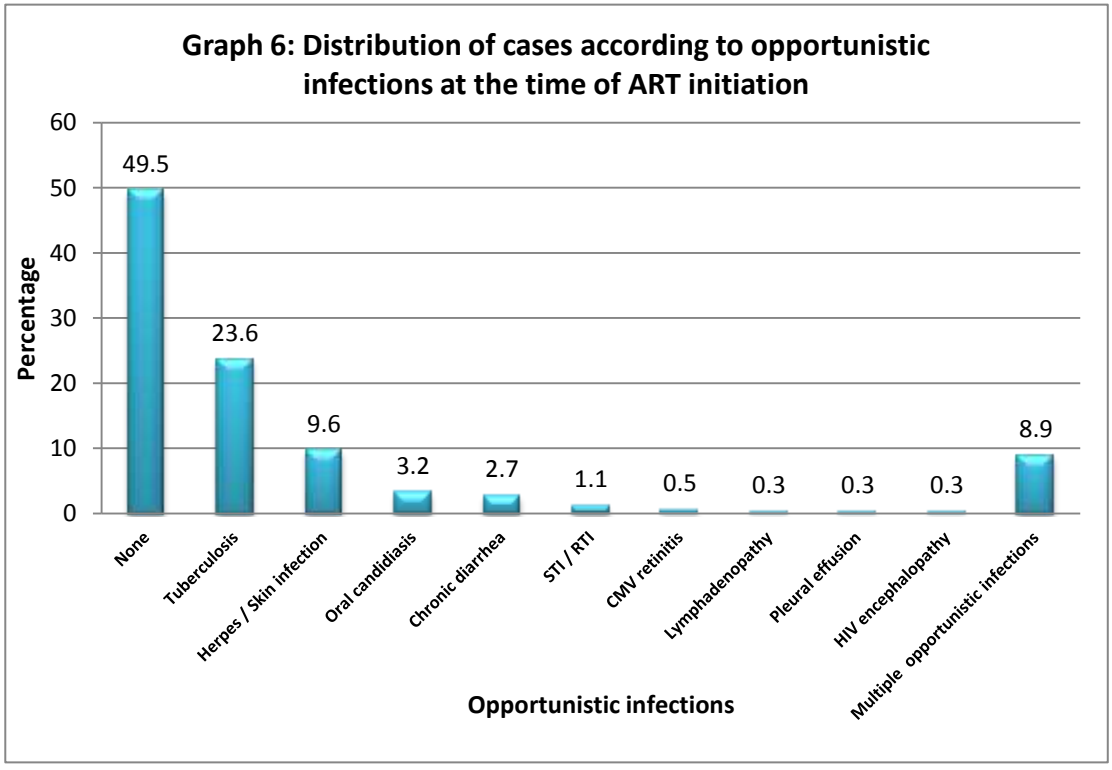
Condom use	No. of cases	Percentage
No	308	82.8
Yes	44	11.8
Not applicable	20	5.4
Total	372	100.0

In this study, 308(82.8%) of patients were not using condoms, 44(11.8%) used condoms and20(5.4%)patients were not applicable in which aged < 15 years patients were included before the start of ART.

Table – 15: Distribution of cases according to opportunistic infections at the time of ART initiation.

(n = 372)

Opportunistic infections	No. of cases	Percentage
None	184	49.5
Tuberculosis	88	23.6
Herpes / Skin infection	36	9.6
Oral candidiasis	12	3.2
Chronic diarrhea	10	2.7
STI / RTI	4	1.1
CMV retinitis	2	0.5
Lymphadenopathy	1	0.3
Pleural effusion	1	0.3
HIV encephalopathy	1	0.3
Multiple opportunistic infections	33	8.9
Total	372	100.0



In this study, nearly half,184 (49.5%) patients had no opportunistic infections when presented. While,88(23.6%)had TB which included both pulmonary and extra-pulmonary,36(9.6%)patients had herpes / skin infections,12(3.2%) had oral candidiasis,10(2.7%) had chronic diarrhea,4(1.1%) had STI/RTI infections, 2(0.5%)had ophthalmic infections,1(0.3 %)each had lymphadenopathy, respiratory infections & CNS encephalopathy and33(8.9%) patients presented with more than one opportunistic infections.

Table-15(a): Distribution of cases who had multiple opportunistic infections. (n=33).

Sl no	Multiple opportunistic infections
1.	TB + unexplained weight loss + fever.
2.	Unexplained anemia + diarrhea +Hepatitis B infection.
3.	Unexplained anemia + STI.
4.	Diarrhoea + weight loss.
5.	Diarrhoea + fever + oral ulcer.
6.	TB + weight loss.
7.	Candidiasis + weight loss + fever.
8.	TB + Herpes zoster.
9.	STD +Herpes zoster + weight loss + fever.
10.	HIV encephalitis + weight loss + fever.
11.	Diarrhoea + fever.
12.	Unexplained anemia + weight loss.
13.	TB + recurrent oral ulcer.
14.	Diarrhoea + weight loss + fever.
15.	Candidiasis + weight loss.
16.	TB + Diarrhoea.
17.	Fever + weight loss.
18.	Fever + recurrent oral ulcer.
19.	TB + recurrent ulcer+ weight loss.
20.	TB +fever + Hepatitis B infection.
21.	Fever + weight loss.
22.	TB+ lymphadenopathy.
23.	Fever + oral ulcer.
24.	Weight loss + fever + oral ulcer.
25.	Fever + diarrhoea.
26.	Diarrhoea + skin eruption.
27.	Weight loss + oral ulcer.
28.	Diarrhoea + STI
29.	STI + Candidiasis + weight loss + pneumonia.
30.	Herpes zoster + diarrhea.
31.	TB + STI.
32.	Pruritic skin eruption + fever.
33.	Weight loss + papular pruritic eruptions.

Table – 16: Distribution of cases based on HbsAg and VDRL reactivity.

(n = 372)

Investigation	VDRL		HbsAg	
	No. of cases	Percentage	No. of cases	Percentage
Non reactive	369	99.2	363	97.6
Reactive	3	0.8	9	2.4
Total	372	100.0	372	100.0

In this study, majority i.e.369 (99.2%) of patients were non reactive to VDRL, while 3(0.8%) were reactive. In 363(97.6%) patients were non reactive to HbsAg and 9(2.4%) were reactive.

Table – 17: Distribution of cases according to treatment initiated.

(n = 372)

Treatment	No. of cases	Percentage
Zdv + Lmv + Nvp	231	62.1
Zdv + Lmv + Efv	94	25.3
Stv + Lmv + Nvp	28	7.5
Stv + Lmv + Efv	19	5.1
Total	372	100.0

In this study,231(62.1%) were started with Zidovudine, Lamivudine & Nevirapine combination drugs, which is the preferred first line regimen, while 94(25.3%)cases were started with Zidovudine, Lamivudine & Efavirenz drugs, which is given in case of intolerance to the latter or if patient is on anti-TB drugs. In 28(7.5%) patients Stavudine, Lamivudine & Nevirapine drugs and in 5.1% patients Stavudine, Lamivudine& Efavirenz drugs were initiated. Stavudine based regimen was given to anemic patients, according to NACO guidelines.

Table – 18: Distribution of cases according to Co-trimoxazole prophylaxsis.

(n = 372)

Ctx – Prophylaxis	No. of cases	Percentage
Yes	339	91.1
No	33	8.9
Total	372	100.0

In this study, 339(91.1%) patients were given Co-trimoxazole prophylaxsis to prevent opportunistic infections & for 33 (8.9%) patients it was not given.

2. FOLLOW UP RESULTS:

Follow up of the patients was done every month after initiation of ART but for analysis purpose 1st, 6th and 12th month data was analysed.

Table – 19: Distribution of cases according to WHO stage at different study period after start of ART.

(n=372)

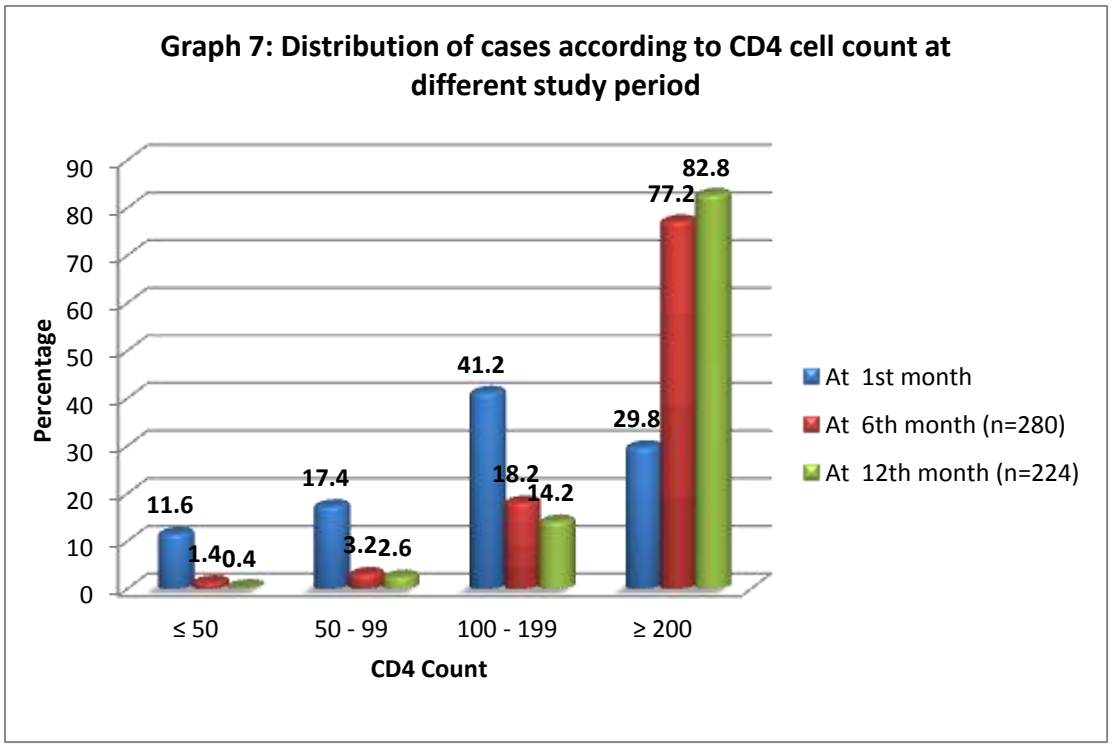
WHO Clinical Stage	At1st month		At 6th month		At 12th month	
	Cases	%	Cases	%	Cases	%
Stage 1	3	0.8	3	0.8	3	0.8
Stage 2	210	56.4	182	48.9	171	45.9
Stage 3	103	27.6	90	24.2	88	23.6
Stage 4	15	4.1	9	2.5	9	2.5
Not come/Death	41	11.1	88	23.6	101	27.2

Most of the cases i.e. 210(56.4%) were seen at stage II at 1st month, 182 (48.9%) at 6th month and 171(45.9%) at 12th month, followed by 103(27.6%), 90(24.2%) and88 (23.6%) at 1st, 6th and 12th month in stage III.

This shows that either there is improvement with ART or more deaths have occurred.

Table – 20(a): Distribution of cases according to CD4 cell count at different study period.(Graph)

CD4 count	At 1st month (n=372)		At 6th month (n=280)		At 12th month (n=224)	
	cases	percentage	cases	percentage	cases	Percentage
≤ 50	43	11.6	4	1.4	1	0.4
50 - 99	65	17.4	9	3.2	6	2.6
100 - 199	153	41.2	51	18.2	32	14.2
≥ 200	111	29.8	216	77.2	185	82.8



In the present study majority of the cases i.e 153(41.2%) had CD4 count in the range of 100-199 at 1st month. Whereas 216(77.2%) and 185(82.8%) cases had CD4 cell count ≥ 200 at 1st, 6th and 12th month respectively. This shows ART is effective as CD4 count ≥ 200 cells has increased from 1st month to 6th month and from 6th month to 12th month.

Table – 20(b): Mean, standard deviation and range of CD4 cell count at different levels.

CD4 levels	Mean	Median	Standard Deviation	Range
At Baseline(n=372)	155.9	158	91.8	6-660
At 6th month(n=280)	332.0	284	195.3	21-1158
At 12th month(n=224)	336.4	308	189.1	10-1756

Table-20(c) Mean change in CD4 count.

CD4 levels	Mean	Standard Deviation	Paired t & p value
Baseline to 6th month(n=280)	166.1	199.2	13.9 P=0.000
Baseline to 12th month(n=224)	174.2	199.4	13.1 P=0.000
6th to 12th month(n=224)	7.2	178.4	0.6 P=0.547

This shows there is mean increase in CD4 count from baseline to 6th month and from baseline to 12th month which was statistically significant while there was no mean increase in 6th to 12th month CD4 count and was statistically not significant.

Table – 21: Distribution of cases according to development of opportunistic infections (OIs) at different study period.

(n = 184)

Opportunistic infections	Within 1st month		1st to 6th month		6th to 12th month		Total
	Cases	%	Cases	%	Cases	%	
None/not come							158(85.8%)
TB	3	1.6	3	1.6			6(3.3%)
Chronic diarrhoea	2	1.1	4	2.2			6(3.3%)
Oral candidiasis	2	1.1			2	1.1	4(2.2%)
CMV retinitis	3	1.6			1	0.5	4(2.2%)
CNS - encephalopathy	2	1.1					2(1.1%)
Herpes infection	1	0.5					1(0.5%)
Multiple							3(1.6%)

In this study , in a total of 184, most of them i.e 158(85.8%) had no OI while 26(14.2%) cases developed OI after initiating ART ,in which 6(3.3%)each developed chronic diarrhea& TB ,4(2.2%) each had oral candidiasis & CMV retinitis . Multiple OI s were seen in 3(1.6%) cases in which one had oral candidiasis, CMV retinitis and lymphadenopathy. Another study participant had chronic diarrhea, CMV retinitis & oral candidiasis, similarly another participant had chronic diarrhea & CMV retinitis.

Table – 22: Distribution of cases according to functional status.

(n = 372)

Functional status	At 1st month		At 6th month		At 12th month	
	Cases	%	Cases	%	Cases	%
Working	302	81.2	267	71.7	257	69.1
Ambulatory	26	6.9	15	4.1	8	2.1
Bedridden	5	1.4	0	0	4	1.0
Not known or Death	39	10.5	90	24.2	103	27.8

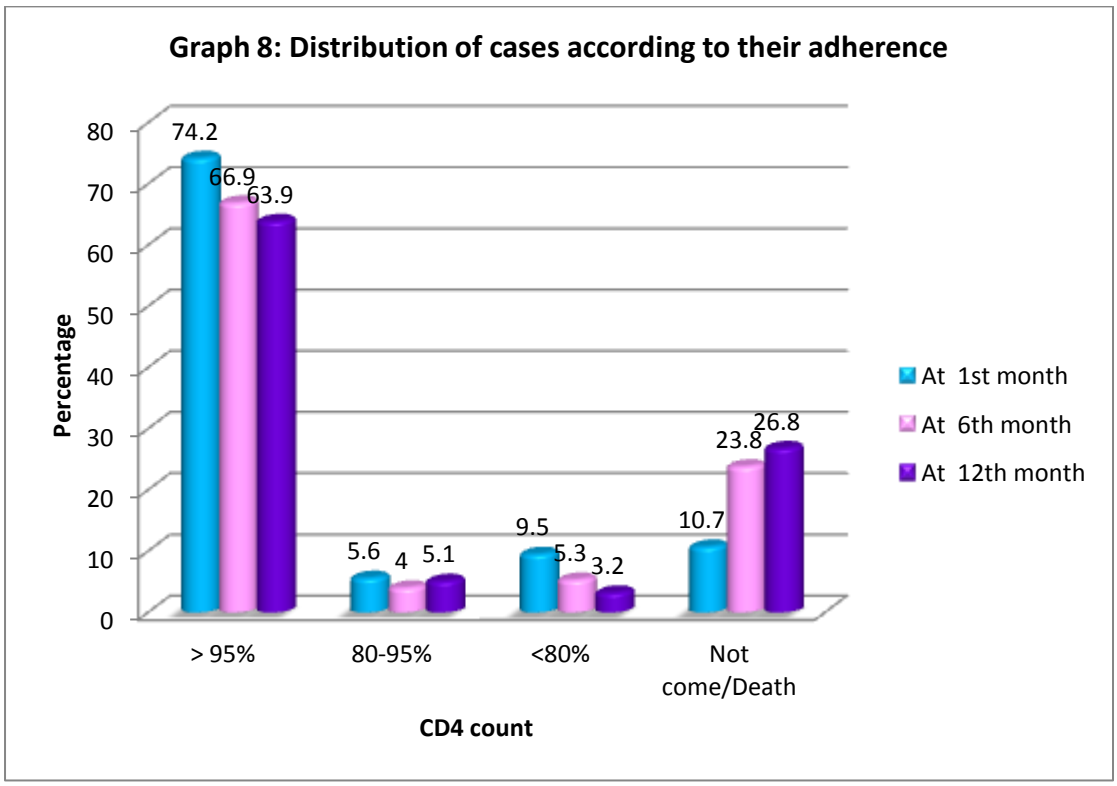
Majority of the study participants i.e 302(81.2%), 267(71.7%) and 257(69.1%) were working functional status at 1st, 6th and 12th month respectively.

This shows more deaths and loss to follow up have occurred, as deaths have been increasing from 1st to 12th month.

Table – 23: Distribution of cases according to their adherence.

(n=372)

Adherence	At 1st month		At 6th month		At 12th month	
	Cases	%	Cases	%	Cases	%
> 95%	276	74.2	249	66.9	238	63.9
80-95%	21	5.6	15	4.0	20	5.1
<80%	35	9.5	20	5.3	14	3.2
Not come/Death	40	10.7	88	23.8	100	26.8



In this study, 276(74.2%) at 1st month adhered to treatment while only 249(66.9%) and 238(63.9%) adhered at 6th and 12th month respectively.

Adherence was maximum at 1st month compared to 6th and 12th month indicating decrease in adherence.

Table – 24: Distribution of cases according to side effects to ART.

(n = 372)

Side effects	No. of cases	Percentage
None	185	49.8
Anemia	141	37.9
Discomfort	6	1.6
Skin rash	5	1.3
Others	2	0.5
Multiple	18	4.8
Not come/Death	15	4.1

Majority of the cases 1.e185(49.8%) had no side effects due to ART and 141(37.9%) developed anemia as side effect .

Table – 25: Distribution of study participants according to voluntary stop of ART and deaths during study period.

(n = 372)

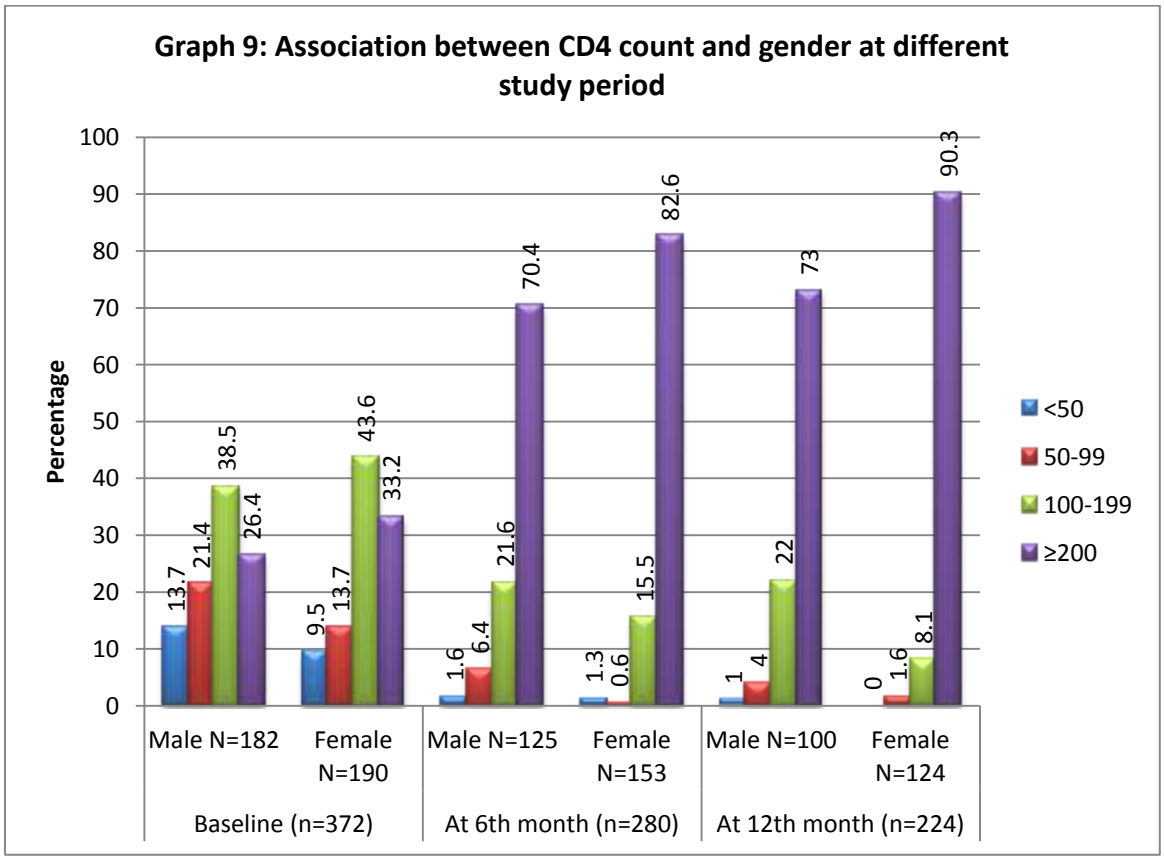
		No. of cases	Percentage
Voluntary stop of ART	No	359	96.5
	Yes	13	3.5
	Total	372	100.0
Death		No. of cases	Percentage
	No	308	82.8
	Yes	64	17.2
	Total	372	100.0

In the present study, 13(3.5%) cases stopped ART voluntarily and 64(17.2%) cases died during study period.

3. ASSOCIATIONS:

Table: 26 Association between CD4 count and gender at different study period.

CD4 cell count (cells/mm^3)	Baseline (n=372)		At 6th month (n=280)		At 12th month (n=224)	
	Male (n=182)	Female (n=190)	Male (n=125)	Female (n=153)	Male (n=100)	Female (n=124)
<50	25 (13.7%)	18 (9.5%)	2 (1.6%)	2 (1.3%)	1 (1.0%)	0 (0.0%)
50-99	39 (21.4%)	26 (13.7%)	8 (6.4%)	1 (0.6%)	4 (4.0%)	2.0 (1.6%)
100-199	70 (38.5%)	83 (43.6%)	27 (21.6%)	24 (15.5%)	22 (22.0%)	10 (8.1%)
≥200	48 (26.4%)	63 (33.2%)	88 (70.4%)	128 (82.6%)	73 (73.0%)	112.0 (90.3%)
	$\chi_3^2 = 6.702$, P=0.082		$\chi_2^2 = 8.233$, P=0.016		$\chi_2^2 = 11.569$, P=0.016	



According to NACO guidelines CD4 count is repeated every 6months after ART initiation. At baseline, most of the male cases i.e. 70(38.5%) & 83(43.6%) of female cases had CD4 count ranged 100-199 which was not statistically significant, while at 6th month majority of male cases i.e. 88(70.4%) & 128(82.6%) of female cases had CD4 count ≥200.Similarly 73(73.0%) males & 112(90.3%) female cases had CD4 count ≥200 at 12th month, which was statistically significant.

In this study good prognosis was seen in both sexes, particularly in females than males at 6th and 12th month after start of ART whose baseline CD4 count was ≥200.

Table:27(a) Association of CD4 count with age at baseline.

(n =372).

Age	<50	50-99	100-199	≥200	Total	
≤15	2(10.5%)	0	9(47.4%)	8(42.1%)	19	$\chi_9^2 = 7.607$, P=0.574
16-30	11(9.1%)	23(19.0%)	48(39.7%)	39(32.2%)	121	
31-45	24(14.0%)	30(17.4%)	69(40.1%)	49(28.5%)	172	
46-60	6(11.2%)	8(14.8%)	26(48.1%)	14(25.9%)	54	
≥60	0	4(66.6%)	1(16.7%)	1(16.7%)	6	

Table:27(b) Association of CD4 count with age after 6 months.

(n =280)

Age	<50	50-99	100-199	≥200	Total	
≤15	0	0	3(18.8%)	13(18.2%)	16	$\chi_6^2 = 3.869$, P=0.574
16-30	3(3.1%)	4(4.1%)	15(15.3%)	76(77.5%)	98	
31-45	1(0.8%)	4(3.4%)	22(18.2%)	95(77.6%)	122	
46-60	0	1(2.6%)	10(25.6%)	28(71.8%)	39	
≥60	0	0	1(20.0%)	4(80.0%)	5	

In this study, at 1st month majority i.e. 69(40.1%) of the cases in between 31-45 years had CD4 count ranged from 100-199 compared to cases of any age group which was statistically not significant. Whereas at 6th month 95(77.6%) of the cases in between 31-45 years had CD4 count >200 compared to cases of any age group which was statistically not significant.

Table: 27(c) Association of CD4 count with age after 12 months.

(n =224)

Age(years)	<50	50-99	100-199	≥200	Total	
≤15	0	0	0	11(100.0%)	11	$\chi_4^2 = 10.309$, P=0.036
16-30	0	2(2.8%)	5(6.9%)	65(90.3%)	72	
31-45	1	2(2.0%)	22(22.0%)	75(75.0%)	100	
46-60	0	2(6.4%)	4(12.9%)	31(83.7%)	37	
≥60	0	0	1(25.0%)	3(75.0%)	4	

While at 12th month 75(75.0%) cases had CD4 count ≥200 in the age group 31-45 years compared to cases of any age group which was statistically significant. Overall improvement was seen in all age group with ART at 12 months but there was far better improvement in CD4 count ≥200 in age group ≤30 years compared to other age groups.

Table: 28 Association between CD4 & alcohol consumption at different time intervals.

CD4 count	Baseline (n=372)		At 6th month (n=280)		At 12th month (n=224)	
	No	Yes	No	Yes	No	Yes
<50	21 (9.8%)	22 (14.4%)	3 (1.7%)	1 (1.0%)	0	1 (1.2%)
50-99	32 (14.7%)	33 (21.6%)	2 (1.1%)	7 (6.9%)	2 (1.4%)	4 (5.1%)
100-199	98 (44.3%)	55 (35.9%)	29 (16.2%)	22 (21.8%)	16 (11.0%)	16 (20.3%)
≥200	68 (31.2%)	43 (28.1%)	145 (81.0)	71 (70.3%)	127 (87.6%)	58 (73.4%)
Total	219	153	179	101	145	79
	$\chi_2^2 = 6.241$, P=0.100		$\chi_2^2 = 5.720$, P=0.057		$\chi_2^2 = 8.295$, P=0.016	

At 1st month 98(44.3%) of cases were non alcoholics and 55(35.9%) alcoholics with CD4 count ranged 100- 199 which was statistically not significant. While at 6th and 12th month 71(70.3%) & 58(73.4%) were alcoholics respectively and 81.0% and 87.6% were non alcoholics with CD4 count ≥200 which was statistically significant.

In this study there was good prognosis in nonalcoholics than alcoholics at 12th month of start of ART.

Table: 29Association between CD4 and smoking at different time intervals in study participants.

CD4 count	Baseline (n=372)		At 6th month (n=280)		At 12th month (n=224)	
	No	Yes	No	Yes	No	Yes
<50	21 (9.5%)	22 (14.6%)	3 (1.7%)	1 (1.0%)	0	1 (1.2%)
50-99	33 (14.9%)	32 (21.2%)	2 (1.1%)	7 (7.0%)	2 (1.4%)	4 (5.1%)
100-199	99 (44.8%)	54 (35.8%)	30 (16.2%)	21 (21.0%)	16 (11.0%)	16 (20.3%)
≥200	68 (30.8%)	43 (28.4%)	145 (81.0)	71 (71.0%)	127 (87.6%)	58 (73.4%)
Total	221	151	180	100	145	79
	$\chi_3^2 = 5.943$, P=0.114		$\chi_2^2 = 5.200$, P=0.074		$\chi_2^2 = 8.295$, P=0.016	

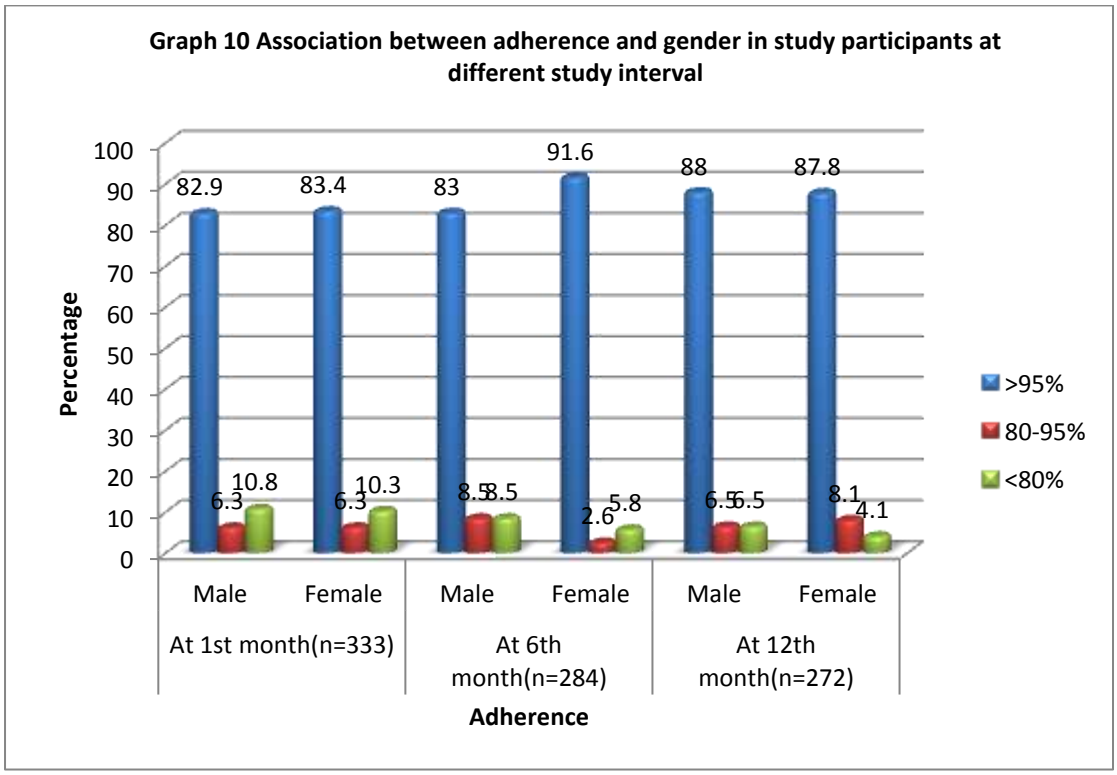
At 1st month 99(44.8%) of cases were non smokers and 54(35.8%) smokers with CD4 count ranged 100- 199 which was statistically not significant. While at 12th month 58(73.4%) were smokers and 127(87.6%) were nonsmokers with CD4 count ≥200 which was statistically significant.

In this study there was good prognosis in nonsmokers than smokers at 12th month after start of ART.

On further analysis ,the association of CD4 count with educational status, religion ,socioeconomic status ,residential place, family type and marital status at different time interval during study period was statistically not significant.

Table: 30 Association between adherence and gender in study participants at different study interval Graph

Adherence	At 1st month(n=333)		At 6th month(n=284)		At 12th month(n=272)	
	Male	Female	Male	Female	Male	Female
>95%	131 (82.9%)	146 (83.4%)	107 (83.0%)	142 (91.6%)	108 (88.0%)	130 (87.8%)
80-95%	10 (6.3%)	11 (6.3%)	11 (8.5%)	4 (2.6%)	8 (6.5%)	12 (8.1%)
<80%	17 (10.8%)	18 (10.3%)	11 (8.5%)	9 (5.8%)	8 (6.5%)	6 (4.1%)
Total	158	175	129	155	124	148
	χ^2= 0.021, p =0.990		χ^2 = 6.057, P=0.048		χ^2= 1.010 p =0.604	



At 1st month & 12th month >95% adherence was observed in case of 131(82.9%) males ,146(83.4%) females & 108(88.0%)males & 130(87.8%)females respectively compared to, 80-95% & <80% adherence in the same month was less which was statistically not significant. At 6th month >95% adherence was observed in case of 107(83.0%) males, 142(91.6%) females compared to 80-95% & <80% adherence which was statistically significant.

In this present study adherence was seen better in females compared to males at 6th and 12th month.

Further analysis showed no statistically significant results with age, educational status, religion, socioeconomic status, alchohol consumption, smoking, residential place, family type and marital status in association with adherence.

DISCUSSION

The present longitudinal study was conducted in ART centre District hospital Belgaum, with an attempt to study the various socio-demographic characteristics and clinical profile of the HIV/AIDS patients, seeking ART and to analyse and compare the outcome indicators with respect to CD4 cell count, opportunistic infections and adherence.

Baseline Socio-demographic characteristics:

Table – 1: Age and sex distribution

In the present study the mean age of the patients was 35.1 years with standard deviation (SD) 11.40 years. The age of the patients ranged between 2 and 71 years. The mean age was 40.4 years in males and 37.6 years in females. There were 48.9% males and 51.1% females. There was gender disparity in distribution of patients in different age groups.

Whereas studies [9,43] done in other parts of India have reported more male participants i.e 65.6% and 80.0% respectively compared to the present study. In our study male and female participants were almost equal ,this can be attributed to the low educational status and ignorance of the disease.

Table – 2: Distribution of occupation of the study participants.

In this study majority 52.7% of the study participants were unskilled workers & unemployed were35.5%.A study by Sharma et al[52] reported similar results in which majority of the participants were unskilled labourer 29.0% followed by businessmen 17.9%, drivers 10.4%, and others 18.0%.

In another study done by Bachani et al[9] ,31.5% were unemployed. The higher prevalence among unskilled workers in the present study is due to the lack of education and awareness regarding the modes of transmission.

Table -3: Distribution of study participants according their educational status.

In the present study majority of the study participants 43.8% were illiterates, followed by primary school educated i.e. 31.2%, 19.1% of them were secondary educated,2.7% were collegiate and 2.7%were graduates .In previous studies [9, 43] majority i.e 35.2% and 21.0% of the study participants had primary education respectively.

In the present study majority of the study participants were Hindus i.e 93.3%, 5.4% were Muslims and 1.3% were Christians.

Table – 4: Distribution of study participants according to type of family.

In the present study, nearly half i.e 48.9% of the study participants belonged to nuclear family, 19.3% to joint family, and 1.9% to third generation family and 29.9% belonged to broken family. Majority of the cases preferred to stay in nuclear family this can be attributed towards disease stigma and the fear of society.

Table – 5: Distribution of study participants according to socioeconomic status.

More than half of the participants 66.4% belonged to Class V, 24.7% belonged to Class IV, followed by 3.3% to Class III, 4.0% to class II and only 1.6 % belonged to socio-economic class I. This can be attributed to illiteracy and ignorance of the disease.

Table – 6: Distribution of study participants according to marital status.

In this study maximum study participants 57.5% were married, 8.4% were unmarried, 27.4% were widows / widowers and 6.7% were divorced/separated.

In a study done by Bachani et al[9],90.6% of the participats were married and in another study[51] married participants were 68.4% .This shows that sexual route is the major route of transmission of the disease.

Table – 7: Distribution of study participants according to their residence.

In this present study nearly half i.e51.6% patients were from rural area and48.4% urban in residence. Other study [51] also showed that 52.7% cases were from rural area and 47.0% were urban residents. This could be because of low levels of literacy status and poverty.

Table – 8: Distribution of study participants according to mode of transmission.

In the present study majority i.e.93.5 % patients had acquired HIV infection by heterosexual route, 4.8% had acquired infection perinatally and only one person acquired the infection by homosexual route and was found to be exploited by his friends as he seemed to be of low IQ and 1.4% patients denied any of the above routes of transmission of infection.

In a previous study done showed that 78.4% of patients had heterosexual route of transmission.[53]

Biswas J et al have similarly reported that 70.0% of the patients had acquired HIV infection by heterosexual route and 5.0% by homosexual route.[54]

Another study also showed that 86.0% of transmission was through heterosexual route.[43] This may be because of not using preventive measures and ignorance about modes of transmission of the disease.

Table – 9: Distribution of study participants according to their referral

In this study, 79.3% patients were referred from VCTC centres .Similarly other study has reported that 71.3% of the participants being referred from the same centre.[53] This shows increasing awareness about the disease .

Table – 10: Distribution of study participants according to the symptoms at the time of initiation of ART.

In this present study, 7.3% had fever/chills, 5.1% complained of weight loss,1.9% had cough, 1.3% each presented with skin rash, diarrhoea and myalgia / joint pain,0.8% patients had nausea/ vomiting, 0.3% suffered from confusion/ depression, 3.2% presented with other symptoms which included throat irritation, pain abdomen, hair loss etc and 66.2% had multiple symptoms at the time of initiation of ART.

In a study done by Pal. J et.al majority of the participants i.e 92.0% had fever as the main symptom.[56]

Table – 11: Distribution of cases according to WHO clinical stage at the time of initiation of ART.

In the present study 58.6% patients were in WHO clinical stage II, 32.3% in stage III and 5.1% patients in stage IV and 4.0% in stage I.

In another study 51.0% of the participants were in stage III.[43]This may be due to difference in treatment seeking behaviour and negligence of the disease progression.

Table – 12 , 13 and 14: Distribution of cases according to functional status,ART eligibility and condom use at the time of initiation of ART.

In the present study, functional status was seen to be working in 91.3% patients, 6.5% were ambulatory and 2.2% patients were bed ridden. In this study, 54.3% patients had both clinical symptoms & CD4 <250 cells as their eligibility criteria to start ART, while39.8% patients had CD4 cell count<250 & 5.9% patients were symptomatic to initiate ART. This shows late treatment seeking behaviour.

In our study, only 11.8% used condoms .This may be due to ignorance of how to use it.

Table – 15&15(a): Distribution of cases according to opportunistic infections at the time of ART initiation.

Tuberculosis was seen in 23.6% of cases as opportunistic infection in the present study which was more compared to other previous study results done by Bachani et al where it showed 9.9% of prevalence.[9] This may be because of decreased immunity and favouring conditions.

Table – 16: Distribution of cases based on HbsAg and VDRL reactivity.

In this study, majority i.e.99.2% of patients were non reactive to VDRL, while 0.8% were reactive. Like that 97.6% patients were non reactive to HbsAg and 2.4% were reactive.

Table – 17: Distribution of cases according to treatment initiated.

Various studies [2,3]showed majority of the participants were initiated with Stavudine, Lamivudine & Nevirapine drugs but, in this study, 62.1% were started with Zidovudine, Lamivudine & Nevirapine combination drugs, which is the preferred first line regimen.

Table – 18: Distribution of cases according to Co-trimoxazole prophylaxsis.

In the present study, 91.1% patients were given Co-trimoxazole prophylaxsis to prevent opportunistic infections & for 8.9% patients did not receive this chemoprophylactic drug.

Table – 19: Distribution of cases according to WHO stage at different study period after start of ART.

In this study, more than half i.e 56.4%, 48.9% and 45.9%cases were seen in stage II at 1st 6th and 12th month respectively, followed by 27.6%, 24.2% and 23.6% cases at 1st, 6th and 12th month in stage III. This shows that either there is improvement with ART or more deaths have occurred.

Table – 20(a),(b) & (c): Distribution of cases according to CD4 cell count at different study period.

In the present study 41.2% cases had CD4 count in the range of 100-199 at 1st month. and 77.2% and 82.8% cases had CD4 cell count $\geq$ 200 at 1st, 6th and 12th month respectively. This shows that ART is effective as CD4 count $\geq$ 200 cells has increased from 1st month to 6th month and from 6th month to 12th month.

The present study shows there is mean increase in CD4 count from baseline to 6th month and from baseline to 12th month which was statistically significant while

there was no mean increase in 6th to 12th month CD4 count and was statistically not significant.

Previous studies also showed median rise of CD4 count of 142 and 184 at 6th month and at 12th month respectively after initiation of ART.[9] In another study median CD4 count was 110.This shows effectiveness of the treatment and improvement in clinical condition of the patients.

Table – 21: Distribution of cases according to development of opportunistic infections at different study period.

In this study, 14.2% of patients had one or more OIs.The frequency of OIs was more in 1st month and 3.3% of the cases reported TB as the most common OI.

These results were similar to the study done in other parts of India where 22.0% of patients had one or more OIs and 9.9% were TB cases .[9] This is because of decreasing immunity with progression of disease and late identification of OI or may be because of non availability of testing centres.

Table – 22: Distribution of cases according to functional status.

Majority of the study participants i.e 81.2%, 71.7% and 69.1% were working functional status at 1st, 6th and 12th month respectively. This shows more deaths and loss to follow up have occurred, as deaths have been increasing from 1st to 12th month which need to be followed up and cause of death need to be studied.

Table – 23: Distribution of cases according to their adherence.

In this study 74.2% adhered to ART after 1st month and later proportion decreased at 12th month to 63.9% which was similar to other study where 73.0% adhered at 1st month and 61.0% were adherent at 12th month.[26] This shows loss of

interest in treatment seeking behaviour, may be because of pill burden, side effects, difficulty in remembering the doses etc.

Table – 24: Distribution of cases according to side effects to ART.

In this present study anaemia was the most common side effect reported in 37.9% which differed in other study result where 31.0% patients had diarrhoea and gastrointestinal adverse effect followed by 10.9% of cases having anaemia as side effect.[9] This may be because of ART drugs causing anaemia.

Table – 25: Distribution of study participants according to voluntary stop of ART and deaths during study period.

In the present study, 3.5% cases stopped ART voluntarily while 2.1% patients stopped attending ART in one previous study .[28]

Deaths reported in one study done in South Africa[28] showed 13.2% deaths within one year while in our study 17.2% deaths were reported.

Whereas in another study 68.0% deaths occurred within the first 6 months of follow up.[9] This may be because of non adherence to ART and opportunistic infections which increases the morbidity and mortality.

Table- 26: Association between CD4 count and gender at different study period.

In this present study 70.4% of male cases & 82.6% of female cases had CD4 count ≥200 and 73.0% males & 90.3% female cases had CD4 count ≥200 at 6th &12th month respectively, which was statistically significant. This improvement may be attributed to better adherence in female cases.

Good prognosis was seen in females than males at 6th & 12th month after the start of ART.

Table: 27(a),(b) & (c).Association of CD4 count with age at baseline, after 6th month and after 12 months of ART initiation.

In this study at 12th month 75.0% cases had CD4 count ≥200 in the age group 31-45 years compared to cases of any age group which was statistically significant.

Obviously ≥200 CD4 cell count improvement was far better in age group <30 years compared to other age groups. This may be because of good adherence and better nutrition.

Table: 28 & 29Association between CD4 with alcohol consumption and CD4 with smoking at different time intervals.

In this study good prognosis was seen in non alcoholics & non smokers at 12th month compared to alcoholics and smokers. This may be because of better immune response in non alcoholics and non smokers.

Similarly, **on further analysis**, the association of CD4 count with educational status, religion ,socioeconomic status ,residential place, family type and marital status at different time interval during study period was statistically not significant.

Table: 30 Association between adherence and gender in study participants at different study interval.

At 6th month >95% adherence was observed in case of 83.0% males, 91.6% females compared to figures of 80-95% & <80% adherence which was statistically significant.

In this present study adherence was seen better in females compared to males at 6th and 12th month. This may be because of more health conscious and better treatment seeking behaviour in females.

Further analysis showed no statistically significant results with age, educational status, religion, socioeconomic status, alcohol consumption, smoking, residential place, family type and marital status in association with adherence.

CONCLUSION

In this present study CD4 cell count improvement with ART was better in patients with good adherence. CD4 count improvement was good from baseline to 6^{th} month and from baseline to 12^{th} month. Opportunistic infections were seen before and also after starting ART which are the main cause of morbidity and mortality. Decreased adherence to ART drugs was observed probably because of long duration of treatment and other reasons.

SUMMARY

The present study titled 'Clinical profile of HIV/AIDS patients seeking antiretroviral therapy at District hospital Belgaum – a longitudinal study' was carried out during the period from January 2010 to February 2011 after obtaining Institutional Ethical Clearance. The intention of the study was to study the clinical profile of HIV/AIDS patients seeking ART with respect to the CD4 cell count, opportunistic infections and adherence.

A total of 372 participants who were seeking ART, during January & February 2010 were included in the study. A predesigned and pretested proforma was used to collect data after obtaining informed consent. Follow-up visits were done according to the NACO guidelines. Secondary data was collected from various records of ART centre, i.e Pre ART Registers, Laboratory Registers, Treatment cards and OPD registers of ART centre.

The baseline socio-demographic profiles of the participants showed that the the age of the patients ranged between 2-71 years and majority of the participants were females i.e.190 (51.1%). The mean age of the patients was 35.1years. More than half of the study participants i.e. 196(52.7%) were unskilled in occupation. Majority, 347 (93.3%), were Hindus and the remaining belonged to other religions.

More than half (66.4%) of all participants belonged to socioeconomic class V. A total of 163 (43.8%) of participants were illiterates and remaining were educated to various levels. Among the participants 182 (48.9%) belonged to nuclear family and remaining to other types of families. Of the study participants, 214 (57.5%) were married. Majority of the study participants, 192 (51.6%) were rural residents and 180(48.4%) belonged to urban area.

A total of 348(93.5%) participants had heterosexual mode of transmission of the disease. More than half of the cases i.e. 295(79.3%) were referred from VCTC and the remaining from other centres. Majority of the study participants 42(11.3%) were asymptomatic at the time of presentation and 246(66.2%) cases presented with multiple symptoms.

Majority, 218(58.6%) cases were in WHO clinical stage II and 120(32.3%) patients were in stage III. Regarding functional status of cases, 340 (91.3%) were working and only 8 (2.2%) were bed ridden. For initiation of ART, 202(54.3%) patients had both clinical symptoms & CD4 <250 cells as their eligibility criteria, while148 (39.8%) patients had CD4 cell count<250 & 22(5.9%) patients were symptomatic. Majority 308(82.8%) of patients were not using condoms.

Nearly half 184(49.5%) patients had no opportunistic infections at the time of initiation of ART. While,88(23.6%)had TB,36(9.6%)patients had herpes / skin infections,12(3.2%) had oral candidiasis,10(2.7%) had chronic diarrhoea and 33(8.9%) patients presented with more than one opportunistic infection.

As per the NACO guidelines, for 231(62.1%)patients Zidovudine, Lamivudine & Nevirapine drug combination was started, followed by 94(25.3%)cases with Zidovudine, Lamivudine & Efavirenz drugs, 28(7.5%) cases by Stavudine, Lamivudine & Nevirapine drugs and in 5.1% patients Stavudine, Lamivudine& Efavirenz drugs were initiated. For 339(91.1%) patients Co-trimoxazole prophylaxis was given to prevent opportunistic infections.

During follow up , 210(56.4%) were seen at WHO clinical stage II at 1st month, 182 (48.9%)at 6th month and 171(45.9%) at 12th month ,followed by

103(27.6%), 90(24.2%) and88 (23.6%) at 1st, 6th and 12th month in stage III indicating improvement with ART.

Follow up of CD4 count showed that 111(29.8%), 216(77.2%) and 185(82.8%) cases had CD4 cell count ≥ 200 at 1st, 6th and 12th month respectively indicating the effectiveness of ART.

During study period, out of 184, who had no opportunistic infections before the start of ART, most of them i.e. 158(85.8%) had no OI while 23(14.2%) of the study participants developed one or the other OI at different time interval and 3(1.6%) had multiple OI's after initiation of ART.

In this study, majority, 276(74.2%) cases at 1st month adhered to treatment while 249(66.9%) and 238(63.9%) cases adhered at 6th and 12th month respectively indicating decrease in adherence because of long duration of treatment and other reasons.

Majority, 185(49.8%), cases had no side effects to ART during study period and about 141 (37.9%) had anaemia as side effect.

In the present study, 13(3.5%) cases stopped ART voluntarily and 64(17.2%) cases died during study period.

In this study good prognosis was seen in both sexes of all ages, particularly in females and in individuals ≤ 30 years at 12 months after initiation of ART whose baseline CD4 count was ≥200.

At 6th and 12th month 71(70.3%) & 58(73.4%) were alcoholics respectively and 81.0% & 87.6% were non alcoholics respectively with CD4 count ≥200 which

was statistically significant indicating that there was a good prognosis in case of non alcoholics.

At 6^{th} and 12^{th} month 71(71.0%) & 58(73.4%) were smokers respectively and 81.0% & 87.6% were non smokers respectively with CD4 count ≥200 which was statistically significant which indicates good prognosis with non smokers.

On further analysis ,the association of CD4 count with educational status, religion ,socioeconomic status ,residential place, family type and marital status at different time interval during study period was statistically not significant.

At 1^{st} month & 12^{th} month >95% adherence was observed in case of 131(82.9%) males ,146(83.4%) females & 108(88.0%)males & 130(87.8%)females respectively compared to, 80-95% & <80% adherence in the same month was less which was statistically not significant. At 6^{th} month >95% adherence was observed in case of 107(83.0%) males, 142(91.6%) females.

Further analysis showed no statistically significant results with age, educational status, religion, socioeconomic status, alcohol consumption, smoking, residential place, family type and marital status in association with adherence.

LIMITATIONS

1. The use of non-probability (purposive) method of sampling was the limitation of this study.
2. Follow up was limited up to the study period.
3. Major limitation of the study was loss to follow up who were transferred out and who changed their telephone numbers and addresses.

RECOMMENDATIONS

1) There is need to intensify the IEC activities, in order to create awareness, especially among illiterates. Innovative methods have to be used to create awareness. All the HIV/AIDS patients on ART should be given periodic health education regarding ART and its adherence.

2) Opportunistic infections should be identified and treated at earlier stage & ART should be initiated as early as possible to reduce morbidity and mortality.

3) ART drugs should be made available at the primary level.

4) Strict adherence to the treatment guidelines by all the medical officers and the staff and patient compliance is necessary to ensure the success of the ART.

5) Overall there is a great need to bring about changes in the non-specific determinants of the disease, such as improvements in the literacy level, standard of living and the quality of life of the people coupled with the application of available technical knowledge and health resources, in order to bring down the morbidity and mortality due to HIV/AIDS.

Further studies can be taken up with a larger sample size, by using non probability method of sampling and longer follow up to get a broader view on these objectives.

BIBLIOGRAPHY

1. Joint United Nations Programme on HIV/AIDS (2006). "Overview of the global AIDS epidemic" 2006 Report on the global AIDS epidemic.*www.unaids.org*

2. Chitra Y, Urgen S, Dayananda I, Brajachand SN. Effect of Anti Retroviral Therapy (ART) on CD4 Lymphocyte count and the spectrum of opportunistic Infections in Manipur. J.Commun Dis. 2009; 41:19-24.

3. Bhat KG, Shenoy RD, Kamath N. Antiretroviral therapy in children-When? What? How? Karnataka Paediatric Journal 2008;23: 8-13.

4. UNAIDS. 2009 AIDS Epidemic update .Available from: URL:

   http://data.unaids.org/pub/Report/2009/JC1700_Epi_Update_2009_en.pdf

   (Access date - October 03, 2010).

5. Kumarasamy N, Vallabhaneni S, Flanigan TP, Mayer KH and Solomon S. Indian J Med Res 2005 ; 121: 377-394.

6. Antiretroviral Therapy Guidelines for HIV-Infected Adults and Adolescents Including post-exposure Prophylaxis. Ministry of Health and Family welfare. Govt of India. NACO-2007.Pp 10-14

7. Belfort R. The ophthalmologist and the Global Impact of the AIDS Epidemic LV Edward Jackson Memorial Lecture. Am J Ophthalmol 2000; 129(1):1-9.

8. Schneider MF, Gange SJ, Williams CM, Anastos K, Greenblatt RM, Kingsley L, Detels R, Munoz A. "Patterns of the hazard of death after AIDS through the evolution of antiretroviral therapy: 1984–2004". *AIDS 2005;* **19** (17): 2009–18.

9. Damodar B, Renu G, Bharat B.R, Lea H,Sikhamani R, Alaka D, Emmanuel K.V,Polin C, Sujatha R. .The National Journal of India 2010; 23:7-12.

10. Sudharshan S, Biswas J. Introduction and immunopathogenesis of acquired immune deficiency syndrome. Indian J Ophthalmol 2008; 56:357-62.

11. Biswas J, Madhavan HN, Badrinath SS. Ocular lesions in AIDS: A report of the first two cases in India. Indian J Ophthalmol 1995; 43:69-72.

12. Current Epidemiological Situation of HIV/AIDS - Department of AIDS Control Ministry of Health and Family Welfare Government of India ANNUAL REPORT 2008-2009.Available from: URL: http://www.nacoonline.org/upload/Publication/Annual_Report_NACO_2008-09.pdf. (Access date 06/09/2010).

13. Steinbrook R. HIV in India - A Complex Epidemic. Perspective. N Engl J Med 2007 March 15; 356(11):1089-1093 Available from; URL: www.nejm.org/doi/pdf/10.1056/NEJMp078009. (Access date 06/09/2010).

14. Folks TM, Khabbaz RF. Retroviruses and associated diseases in humans.In : Brian W J Mahy,Volker Ter Meulen (Eds) Topley and Wilson's Microbiology and microbial infection, Virology, London: Arnold publishers 1998(9th edn).Pp 781-809.

15. Fauci AS, Lane CH. Human Immunodeficiency Virus Disease: AIDS and Related Disorder.In:Fauci,Braunwald, Kasper et al(eds) Harrison's Principles of Internal Medicine, New York: The McGraw-Hill Companies 2008(17th edn).Pp 1137-1204.

16. National AIDS Control Program National AIDS Control Program Phase III (2006-201): Strategy and Implementation Plan: Ministry of Health and Family Welfare, Government of India. 2006. Available from: URL: http://www.nacoonline.org/upload/Publication/Strategy%20and%20Implementation%20Plan%20-%20NACO%20Programme%20Phase%20III%20(2006-2011)%202006.pdf. (Access date 06/09/2010).

17. The 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults In MMWR 1992 December 18, / 41(RR-17) Available from URL: www.cdc.gov/mmwr/preview/mmwrhtml/00018871.htm. (Access date 14/08/2010).

18. World Health Organisation: Interim WHO clinical staging of HIV/AIDS and HIV/AIDS case definitions for surveillance; African region. Geneva, Switzerland: WHO; 2005:2-8. Available from www.who.int/hiv/pub/guidelines/clinicalstaging.pdf . (Access date 20/07/2010).

19. Biswas J, Fogla R, Gopal L, Narayana KM, Banker AS, Kumarasamy N, Madhavan HN. Current approaches to diagnosis and management of ocular lesions in human immunodeficiency virus positive patients. Indian J Ophthalmol 2002; 50:83-96.

20. Simon V, Ho DD, Karim QA. HIV/AIDS epidemiology, pathogenesis, prevention, and treatment. The Lancet 2006; 368: 489 – 504.

21. Grabar S, Kousignian I,Sobel A, Le Bras P, Gasnault J,Enel P ,et al. "Immunologic and clinical responses to highly active antiretroviral therapy over

50 years of age.Result from the French Hospital Database on HIV". AIDS.2004; 18:2029-38.

22. Freedberg K, Kumaraswamy N, Losina E,Cecelia A, Scott C, Divi N et al ."Clinical impact and cost-effectiveness of antiretroviral therapy in India: starting criteria and second-line therapy."AIDS.2007; 21(4):117-28.

23. Nachega J, Leisegang R, Bishai D, Nguyen H, Hislop M, Cleary S, et al. "Association of Antiretroviral Therapy Adherence and Health Care Costs." Ann Intern Med.2010; 152:18-25.

24. Collazos J, Aseni V,Carton J."Sex differences in the clinical, immunological and virological parameters of HIV-infected patients treated with HAART."AIDS.2007;21(7):835-43.

25. Lahuerta M, Lima J,Elul B, Okamura M, Alvim M, Biribonwoha H,et al."Patients enrolled in HIV care in Mozambique: Baseline characteristics and follow- up outcomes."JAIDS.2011;58(3):75-88.

26. Perrine R, Kouanfack C, Cohen J, Marcellin F, Boyer S, Delaporte E,et al. "Adherence to Antiretroviral Treatment in Cameroon context:Promoting the use of Medication Reminder Methods."J Acquir Immune Defic Syndr 2011; 57:40-43.

27. Nachega J, Hislop M, Nguyen H,Dowdy D, Chaisson R, Regensberg L et al. "Antiretroviral Therapy Adherence, Virologic and Immunologic Outcomes in Adolescents Compared with Adults in Southern Africa." J Acquir Immune Defic Syndr 2009; 51:65-71.

28. Coetzer D, Hildebrand K, Boulle A , Maartens G, Louis F, Labatal V et al. "Outcomes after two years of Providing antiretroviral treatment in Khayelitsha, South Africa". AIDS.2004;18:887-95.

29. Micek M,Gimbel- Sherr K, Baptista A,Matediana E,Montoya P,Pfeiffer J et al. "Loss to follow-up of Adults in Public HIV Care Systems in Central Mozambique : Identifying Obstacles to Treatment".J Acquir Immune Defic Syndr.2009;52:397-405.

30. Lal V, Kant S,Dewan R , Rai S, Biswas A. "A Two-site Hospital–Based Study on Factors Associated with Nonadherence to Highly Active Antiretroviral Therapy". Indian J Pub Health. 2010; 54(4):179-83.

31. Hawkins C, Chalamilla G, Okuma J, Spiegelman D, Hertzmark E,Aris E et al. "Sex differences in antiretroviral treatment outcomes among HIV-infected adults in an urban Tanzanian setting". AIDS 2011, 25:1189-97.

32. Zhang F, Haberer J,Zhao Y, Dou Z, Zhao H,He Y et al. "Chinese Pediatric Highly Active Antiretroviral Therapy Observational Cohort". J Acquir Immune Defic Syndr 2007; 46: 594-98.

33. Mannheimer S, Morse E,Matts J, Andrew L, Child C,Schmetter B et al. "Sustained Benefit From a Long – TermAntiretroviral Adherence Intervention. Results of a Large Randomized Clinical Trial". " J Acquir Immune Defic Syndr 2006; 43: 41-47.

34. Greenbaum A, Wilson L, Keruly J,Moore R, Gebo K. "Effect of age and HAART regimen on clinical response in an urban cohort of HIV – infected individuals". AIDS 2008; 22: 2331-39.

35. Nicholas S, Sabapathy K, Ferreyra C, Varaine F,Rodriguez M. "Incidence of Tuberculosis in HIV-infected Patients Before and After Starting Combined Antiretroviral Therapy in 8 Sub-Saharan African HIV Programs". J Acquir Immune Defic Syndr 2011; 57: 311-18.

36. Rie A, Westreich D, Sanne I. "Tuberculosis in Patients Receiving Antiretroviral Treatment:Incidence, Risk Factors ,and Prevention Strategies". J Acquir Immune Defic Syndr 2011; 56: 349-55.

37. Holmes C, Wood R, Badri M, Zilber S, Wang B, Maartens G et al. " CD4 Decline and Incidence of Opportunistic Infections in Cape Town, South Africa: Implications for Prophylaxis and Treatment". J Acquir Immune Defic Syndr 2006; 42: 464-69

38. Burman W, Grund B, Roediger M, Friedland G, Darbyshire J,Wu A. "The Impact of Episodic CD4 Cell Count-Guided Antiretroviral Therapy on Quality of Life". J Acquir Immune Defic Syndr 2008; 47: 185-193

39. Naik E, Casanas B, Pazare A, Wable G, Sinnott J, Salihu H. "Cost of treatment : The single biggest obstacle to HIV/AIDS treatment adherence in lower-middle class patients in Mumbai, India". Indian J Sex Transm Dis & AIDS 2009; 30 (1):23-27.

40. Nirmal B, Divya K, Dorairaj V, Venkatateswaran K. "Quality of Life in HIV/AIDS patients :A cross sectional studyin South India". Indian J Sex Transm Dis & AIDS 2008; 29 (1):15-17.

41. Sivadasan A, Abraham O, Rupali P, Pulimood S, Rajan J, Rajkumar S et al. " High Rates of Regimen Change due to Drug Toxicity Among a Cohort of South

Indian Adults with HIV Infection Initiated on Generic , First – Line Antiretroviral Treatment". JAPI 2009;57:384-88.

42. Naidoo R, Rennert W, Lung A, Naidoo K, Mckerrow N. "The Influence of Nutritional Status on the Response to HAART in HIV-Infected Children in South Africa". Pediatr Infect Dis J 2010;29:511-13.

43. Sharma S, Dhooria S,Prasad K, George N, Ranjan S, Gupta D. "Outcomes of antiretroviral therapy in a northern Indian urban clinic".Bull World Health Organ 2010;88:222-26.

44. Kuppuswamy B. "Manual of Socio-economic status scale (urban), 1976, Manasayan,Delhi-92.

45. Kulkarni AP, Baride JP. Textbook of Community Medicine, 1st Ed. Mumbai; Vora Medical Publications: 1998.Pp 31

46. Park K. Park's Textbook of Preventive and Social Medicine. 20th Ed., Jabalpur, India: Banarasidas Bhanot; 2009.Pp 596-98

47. Insurance Worker. 2011; LIII (6): 28.

48. National Health Interview Survey 1998-2003.http://www.cdc.gov/nchs/data wh/nchsdefs/cigrarttesmoking.htm.

49. National AIDS Control Organisation, Department of AIDS Control. Govt of India. "Revised guidelines on initiation of ART in adults and adolescents including PEP(May 2007)".Pp 1.

50. World Health Organisation, "Patient monitoring guidelines for HIV care & Antiretroviral therapy (ART)" March 2004.Pp 25-31.

51. Sogarwal R, Bachani D. "Assessmant of ART centres in India: client perspectives".JIMA 2009; 107:276-80.

52. Sharma K, Kadhiravan T, Banga A, Goyal T, Bhatia I and Saha PK. Spectrum of clinical disease in a series of 135 hospitalised HIV-infected patients from north India. BMC Infectious Diseases 2004; 4:52 Available from: URL: http://www.biomedcental.com/1471-2334/4/52. (Access date 20/09/2010).

53. Sogarwal R, Bachani D. "Are persons living with HIV timely accessing ART services in India?"JIMA 2009;107:288-307

54. Biswas J, Madhavan HN, George AE, Kumarswamy N, Solomon S. Ocular lesions associated with HIV Infection in India: A series of 100 consecutive patients evaluated at a referral centre. Am J Ophthalmol 2000 ; 129(1):9-15.

55. Pathai S, Deshpande A, Gilbert C, Lawn SD. Prevalence of HIV-associated ophthalmic disease among patients enrolling for antiretroviral treatment in India: A cross-sectional study. BMC Infectious Diseases 2009, **9**:158. Available from: URL: http://www.biomedcental.com/1471-2334/9/158. (Access date 20/09/2010).

56. Pal J, Karmakar P, Ray A, Saha S, Roy K, Talukdar A, Roy M, Debnath N. "Opportunistic infections of central nervous system in AIDS". JIMA2009;107:446-49

ANNEXURE – I: ETHICAL CLEARANCE CERTIFICATE

K.L.E.SOCIETY'S
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELGAUM-590010 (KARNATAKA-INDIA)
(Affiliated to KLE University, Belgaum)

Website: http/www.jnmc.edu
E-Mail : domejnmc@sancharnet.in
: jnmc@sancharnet.in

Phone: (+ 91-(0)831 Office : 2471350
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref. No. :MDC/DOME/ Date: 14/10/2009

To,

Dr. Shilpa K.,
Postgraduate student in
Department of Community Medicine,
J.N.Medical College,
Belgaum.

Dear Dr. Shilpa K.,

The JNMC – Institutional Ethics Committee on Human Subjects Research met on 12th October, 2009 to consider your application for approval of the research project **"AN EPIDEMIOLOGICAL AND CLINICAL PROFILE OF HIV/AIDS PATIENTS SEEKING ANTI-RETROVIRAL THERAPY AT DISTRICT HOSPITAL – A LONGITUDINAL STUDY."**.

After review of the documents submitted by you and satisfactory explanations provided to the members, the committee has provided approval date through October 11th, 2010 at which time the study will be reviewed by the committee.

If you have any questions concerning the above, please feel free to contact the committee office.

Sincerely,

(Dr.V. J.Patil)
Chairman,
JNMC Institutional Ethics Committee on
Human Subjects Research

ANNEXURE – II: CONSENT FORM

CLINICAL PROFILE OF HIV/AIDS PATIENTS SEEKING ANTI-RETROVIRAL THERAPY AT DISTRICT HOSPITAL- A LONGITUDINAL STUDY

INVESTIGATORS: Dr. S. M. Katti, Dr. Shilpa K.

Introduction

You are being invited to participate in this study to know the clinical profile before and after ART.

Explanation of procedure

In this study we will be collecting data and monitoring the effect of ART for one year. If you agree to participate, you will be examined, the moment you don't want to continue you can leave.

Possible benefits

The investigator does not promise or guarantee that you will get direct benefit being in this study. It will benefit the whole community because by this study we will know the various problems faced by HIV/AIDS patients on ART. This study will help in the future for development of the community.

Possible risks:

The tools employed for conducting the tests are safe and as such are not likely to cause any harm to the participants.

Voluntary participation/ withdrawal:

Your participation in the study is completely voluntary. You are free to withdraw your consent and discontinue your participation in this project at any time.

Cost of participation:

The cost of the study will be borne by the researcher. There will be no additional cost to you for participation in this study.

Legal rights:

By signing this consent form, you are not waiving any of your legal rights.

Confidentiality:

The results of the study may be published for scientific purposes. However your identity will not be revealed. All information collected will be coded so that no one other than the investigators will know your identity.

Compensation:

There is no commitment from the researchers involved in the research plan to provide any compensation for research related injury. Your participation is voluntary and you will not be paid any remuneration amount for your participation in the study.

Authorization to publish results:

The Researchers may use the information gathered from this study for presentation in scientific journals. However your identity will not be disclosed in such presentation or publication.

Questions:

If you have question about this study, question about research related injury or experience any problems during the study, you should contact DR. S. M. KATTI, 0831-2473778, DR. SHILPA. K, 9448534035. If you have any questions about the rights as a research participant you may contact DR V.D.PATIL, Principal and Chairman, J. N. M. C. Institutional Ethics Committee on human subjects research 0831-2471701.

Consent Statement:

I am making a voluntary decision whether or not to let myself participate in this study. My signature below indicates that I have decided to let me participate, that I have read (or been read) the information provided above, that I had given the opportunity to ask questions and they have answered to my satisfaction and that I have received a copy of this signed consent form.

Signature or left thumb print of participant or legally authorized representative:

Participant's name_____	Participant's signature / thumb print_____
Investigator's name_____	Investigator's signature_____
Witness' name_____	Witness' signature_____
Guardian's name _____	Guardian's signature / thumb print_____
Date_____	Place_____

ANNEXURE – III: PROFORMA

CLINICAL PROFILE OF HIV/AIDS PATIENTS SEEKING ANTI-RETROVIRAL THERAPY AT DISTRICT HOSPITAL- A LONGITUDINAL STUDY

Note: All the personal information provided during this study will be kept confidential. Only aggregated data will be published.

Principal Investigator: Dr. Shilpa. K
Post Graduate Student,
Department of Community Medicine.

I.P. No: **Date of registration:**

1. **Name:**
2. **Age: ____yrs.**
3. **Sex:** M/F
4. **Occupation:**
5. **Religion:** Hindu/ Muslim/ Christian/ Others
6. **Address & contact number:**
7. **Education:** Illiterate/ Primary/ High school/ Diploma/ College/ PG
8. **Family:** Joint/ Nuclear/ 3rd generation/ Others_____
9. **Total income of family per month: Rs**
10. **Total number of family members:**
11. **Per capita income/month Rs**
12. **Socio economic status:** I/ II/ III/ IV/ V
13. **Marital status:** Unmarried/ Married/ Widow/Widower/ Divorce

14. Family composition:

Sr no	Name	Age	Sex

15. Risk factors:

Heterosexual [ ] MSM [ ] IDU [ ] Blood transfusion [ ]

Mother to child [ ] Needle prick injury [ ] Unknown [ ]

16. Referred from:

VCTC [ ] RNTCP [ ] PPTCT [ ] NGO [ ] Private [ ]

Inpatient [ ] Outpatient [ ] Pediatric [ ] STI clinic [ ] Others [ ]

17. Symptoms:

Cough [ ] Shortness of breath [ ] Difficulty/ painful swallowing [ ]

Unintended weight loss [ ] Fever/ chills [ ] Persistent headaches [ ]

Skin rash [ ] Nausea/Vomiting [ ] Diarrhea [ ] Difficulty sleeping [ ]

Forgetfulness/ confusion [ ] Depression [ ] Myalgia/ Joint pain [ ]

Others: _____

18. Personal history:

Alcohol intake: Habitual [ ] Social [ ] Never [ ]

Smoking: Current [ ] Past [ ] Never [ ]

19. ART eligibility criteria:

HIV test +ve [ ] CD4< 250 [ ]

Symptomatic [ ] Others:_____

20. WHO clinical staging:_____

21. Functional status:

Working [ ] Ambulatory [ ] Bed ridden [ ]

22. Baseline CD4 count: _____

23. Treatment started:

STV + LMV + NVP [ ] STV + LMV + EFV [ ]

ZDV + LMV + NVP [ ] ZDV + LMV + EFV [ ]

Iron supplements [ ]

Drugs for opportunistic infections:

Prophylaxis: CTX [ ] Others: _____

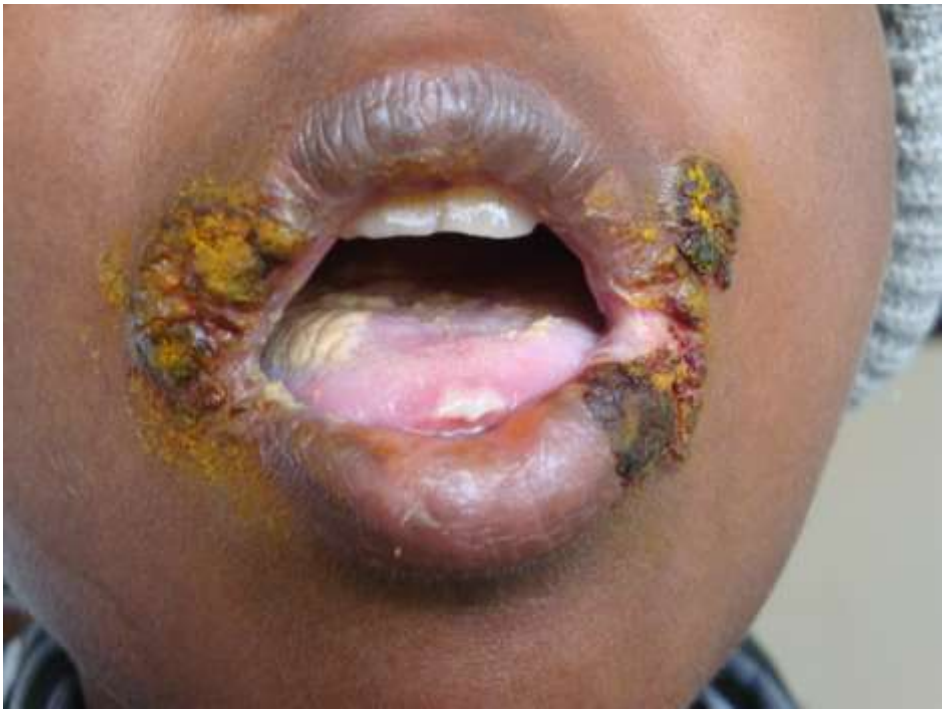
PROFORMA (FOLLOW UP)

Name: _____I.P.No. : _____ Date of treatment started: ----------

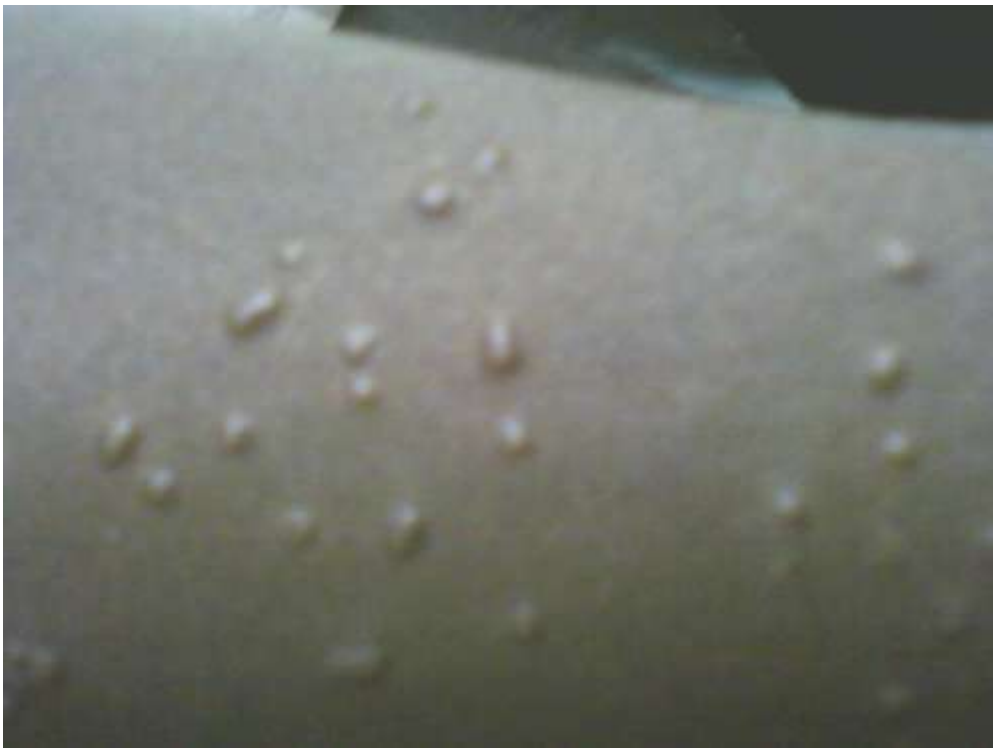
	1	2	3	4	5	6	7	8
Sr no	**Functional status WAB**	**WHO clinical stage**	**Opportunistic infections**	**Adherence to ART**	**TB R_X Yes/ no**	**ART side effects**	**Reasons for stopping ART**	**CD4 count**
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								

ANNEXURE – IV: PHOTOGRAPHS

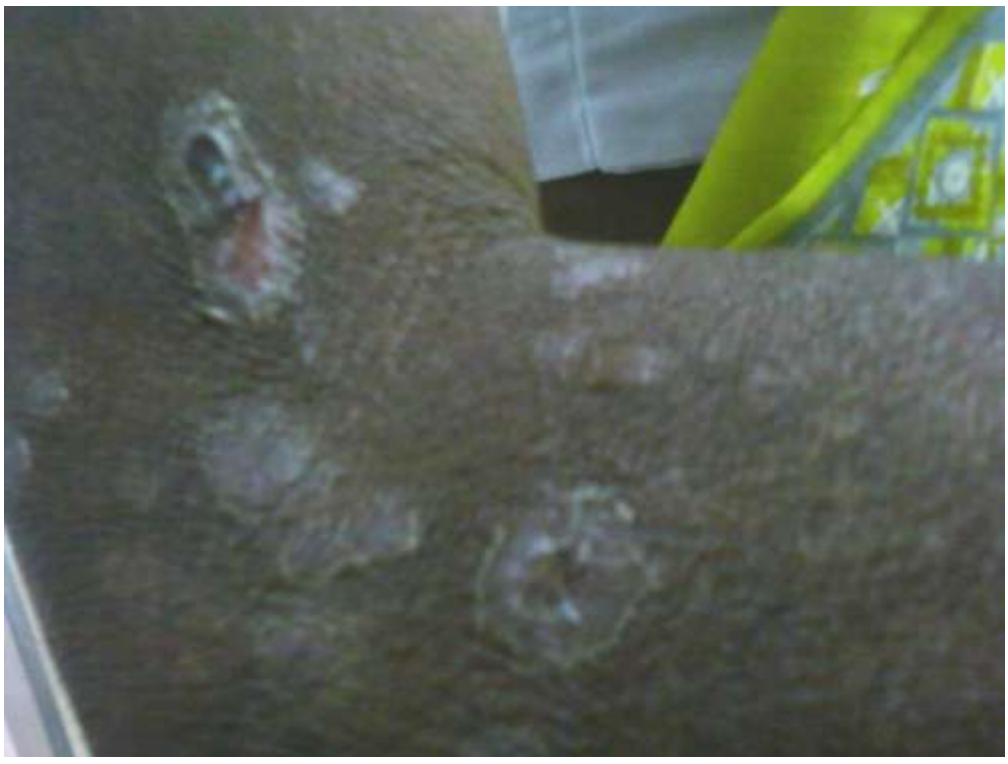
Photograph No1: Flow Cytometer



Photograph No. 2: TB/HIV Patient with Oral Candidiasis & Herpes Labialis



Photograph No. 3: Extensive Molluscum Contagiosum



Photograph No. 4: Pyoderma

ANNEXURE – V: MASTER CHART

KEYS TO MASTER CHART

SL No

Age

Sex- 1.Male

2. Female

Occupation- 1.Unemployed

2. Unskilled worker

3. Semiskilled worker.

4. Skilled worker.

5. Clerk/Shop owner/farm owner.

6. Semiprofessional.

Religion- 1.Hindu

2. Muslim

3. Christian

4. Others

Address- 1.Urban

2. Rural

Education- 1.Illiterate

2. Primary.

3. High school.

4. Collegiate

5. Post Graduate.

Family type- 1.Nuclear

2. Joint family.

3. Third generation family.

4. Broken.

Total income/month.

Total family members.

Per capita income.

Socioeconomic status -1.Class-I
2. Class-II
3. Class-III
4. Class-IV
5. Class-V

Marital status- 1.Unmarried.
2. Married.
3. Widow/widower
4. Divorced/Separated.

Risk factors- 1.Heterosexual.
2. Men having sex with men.
3. Intravenous drug users.
4. Blood transfusion.
5. Mother to child
6. Needle prick injury.
7. Unknown.

Referred from-1.VCTC
2. RNTCP
3. PPTCT
4. NGO
5. Private
6. Inpatient department
7. Outpatient department
8. Pediatric department
9. STI clinic
10. Others.

Symptoms- 1.Cough.
2. Shortness of breath
3. Difficulty / painful swallowing.
4. Unintended weight loss.
5. Fever/ chills
6. Persistent headache
7. Skin rash

8. Nausea/ vomiting
9. Diarrhoea.
10. Difficulty sleeping
11. Forgetfulness and confusion.
12. Depression.
13. Myalgia / joint pain.
14. Others
15. Multiple symptoms
0. Asymptomatic

Alchohol intake-1.Habitual/current
2. Social
3/0.Never

Smoking- 1.Habitual /current
2. Past
3/0.Never

Opportunistic infections-1.TB
2. Herpes and skin manifestation
3. Oral candidiasis.
4. Diarrhoea
5. Pneumonia and respiratory tract infections.
6. Lymphadenopathy
7. STI/RTI
8. Ophthalmic infections
9. CNS infections
10. Multiple infections
0. No infection

Condom use- 1. Yes
2. No.

ART eligibility criteria-1.Symptomatic
2. CD4 cell count <250
3. Both 1 & 2.

WHO Clinical staging-1.Stage-I
2. Stage-II

3. Stage-III

4. Stage-IV

Functional status-1.Working

2. Ambulatory

3. Bed ridden

Baseline CD4 cell count.

Initial ART drugs started-1.Stavudine + Lamivudine + Nevirapine.

2. Stavudine + Lamivudine +Efavirenz

3. Zidovudine + Lamivudine + Nevirapine

4. Zidovudine + Lamivudine+Efavirenz

CO trimoxazole Prophylaxsis given-1.Yes

2. No

Follow up of functional status at 1^{st}, 6^{th} and 12^{th} month respectively-1. Working

2. Ambulatory

3. Bed ridden

-- Not come/ death

Follow up of WHO clinical stage at 1^{st}, 6^{th} and 12^{th} month respectively-1.Stage-I

2. Stage-II

3. Stage-III

4. Stage-IV

--. Not come/ death

Follow up of opportunistic infections at 1^{st}, 6^{th} and 12^{th} month respectively-

1. TB
2. Herpes and skin manifestation
3. Oral candidiasis.
4. Diarrhoea
5. Pneumonia and respiratory tract infections.
6. Lymphadenopathy
7. STI/RTI
8. Ophthalmic infections
9. CNS infections
10. Multiple infections
0. No infection
--.Not come/ death

Follow up of adherence at 1st, 6th and 12th month respectively-1. >95%

2. 80-95%

3. <80%.

Side effects to ART- 1.Anemia

2. Skin rash.

3. Discomfort.

4. Others

5. Nothing

6. Multiple.

Death during study period-1.Yes

2. No.

CD4 cell count at baseline, 6th month and at 12th month of ART.

Voluntarily stop of ART by the study participants-1.Yes

2. No.