

Clinico-epidemiological Profile, Opportunistic Infections and Effects of Antiretroviral Therapy in AIDS Patients

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Abstract

Introduction: Antiretroviral treatment is indicated for all patients who are symptomatic with an acquired immunodeficiency syndrome (AIDS)-defining illness, irrespective of CD4 counts, or viral load levels.

Aim: This study aims to survey the clinical profile and incidence of opportunistic infections (OI) in AIDS patients at the time of start of antiretroviral therapy (ART), to study the effect of ART on clinical status and CD4 count, and to study the adverse effects of ART.

Materials and Methods: This is a prospective study carried out on patients attending the ART center. Total 75 patients were included in this study. Patients put on ART were divided into 4 classes. Class A patients were given zidovudine, lamivudine, nevirapine (ZLN); Class B patients were on stavudine, lamivudine, nevirapine (SLN); Class C patients were on zidovudine, lamivudine, efavirenz (ZLE); Class D patients were given stavudine, lamivudine, efavirenz (SLE).

Results: There were 53 male and 22 female. M:F was 2.4:1. The mean age of the study population was 35.4 years (male 36 and female 33.9 years). The maximum 42.6% of studied patients were in the age group of 35-44 years. Human immunodeficiency virus (HIV) infection was frequently observed in truck/taxi drivers/transporters 16/75; 21% laborer (15/75; 18%). The total of 69% of the studied patients belonged to low socio-economic status. The incidence of symptomatic infection was more in married (68/75; 90.6). Most common mode of transmission of HIV infection both in males and females was by sexual contact (69/75; 92). The most common symptoms of HIV-positive patients on initial presentation were prolonged fever (47/75, 63%) and pallor (40/75; 53) was the most frequent sign.

Conclusion: It can be concluded from our study that with effective highly active ART, HIV infection can be managed as any other chronic manageable infectious disease.

Key words: Acquired immunodeficiency syndrome, Antiretroviral therapy, CD4 count, Highly active antiretroviral therapy, Human immunodeficiency virus

INTRODUCTION

Human immunodeficiency virus disease is an emerging disease only in the early 1980's it has rapidly established

itself throughout the world and is likely to endure and persist well into the 21st century. Acquired immunodeficiency syndrome (AIDS) has evolved from a mysterious illness to a global pandemic which has infected tens of millions in <20 years.¹

The care of human immunodeficiency virus (HIV) infected patients has changed dramatically over the last few years, and it is now being increasingly viewed as any other chronic illness rather than a death sentence.² With currently available therapeutic options, eradication of HIV cannot be achieved.³ However, with the advent of potent

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antiretroviral therapy (ART), HIV infection has now been transferred into a chronic manageable illness.

Antiretroviral treatment is indicated for all patients who are symptomatic with an AIDS-defining illness, irrespective of CD4 counts, or viral load levels. Patients with AIDS have higher rates of mortality unless treated with ART.^{4,5}

Once the decision to start treatment is taken, then how do we assess response of therapy that is the patient adequately treated or not or will the patient require change in therapy with the ushering in of the era of predictive medicine it has been gradually realized that the pharmacokinetics and pharmacodynamics of a drug vary in different subgroups of population. The response to a drug molecule by different subjects is different, based on their varying racial, ethnic, and genetic makeup. Keeping this view in mind, a study has been planned in the N.S.C.B. M.C.H. Department of Medicine with an objective to assess the effects of ART in HIV/AIDS patients. A 6-month follow-up study is planned to assess the clinical as well as pathological and biochemical markers and indicators of HIV infection in HIV/AIDS patients on ART.

MATERIALS AND METHODS

A hospital-based prospective study was carried out on patients attending the ART center associated with the Department of General Medicine, NSCB Medical College, Jabalpur, from June 2007 to July 2008. Total 75 patients were included in this study. The study included HIV patients taking ART including both males and females.

Inclusion Criteria

All HIV-positive patients of either sex aged more than or equal to 14 years who were going to start highly active ART highly active antiretroviral therapy (HAART) were included.

Exclusion Criteria

HIV-positive patients, who were not taking ART, were terminally ill or suffering from life-threatening disease and who were not likely to follow-up were excluded.

Before starting ART, patients were assessed with following parameters: Complete history and physical examination, weight, and clinical stage of HIV infection. Routine laboratory investigations including complete hemogram, serum bilirubin, serum glutamic-oxaloacetic transaminase (SGOT), serum glutamic pyruvate transaminase (SGPT), random blood sugar, blood urea serum creatinine, HIV 1, 2 by ELISA, HBsAg, stool <routine, microscopy as required, CD4 count, X-ray chest, ultrasonography abdomen, identify coexisting medical conditions and treatments that may influence the therapy.

After proper counseling and explaining proper drug adherence, patients were put on antiretroviral drugs.

Patients were examined clinically and biochemically during 6-month follow-up period and assessed on following parameters: (1) General well-being, (2) status of previous complaints, (3) any new presenting complaint, (4) general physical and systemic examination including weight, and (5) assessment of essential laboratory investigations including complete hemogram, serum bilirubin, SGOT, SGPT, and CD4 count.

RESULTS

Total 75 patients were included in the study. 8 patients died during the follow-up period. There were 53 male and 22 female patients. Male to female ratio was 2.4:1. The mean age was 35.4 years (male, 36 and female 33.9 years). The maximum 42.6% of studied patients were in the age group of 35-44 years followed by 34.6% in the age group of 25-34 years. HIV infection was frequently observed in truck/taxi drivers/transporters 16/75; 21% laborer (15/75; 18%), but the infection was also observed in other occupational groups such as private workers (9/75; 12%), shopkeepers (5/75; 6%), teacher and farmer (Table 1). The total of 69% (52 out of 75) of the studied patients belonged to low socio-economic status, followed by 25% (19 out of 75) in the middle socio-economic groups. The incidence of symptomatic infection was more in married (68/75; 90.6) as compared to unmarried (7/75; 9.3%) patients. Most common mode of transmission of HIV infection both in males and in females was by sexual contact (69/75; 92), followed by blood and blood products (2/75; 2.6%), and through vertical transmission (1/75; 10.3). In 3 patients (4%), the mode of transmission was not known (Table 2). The most common symptoms of HIV-positive patients on initial presentation were prolonged fever (47/75; 63%),

Table 1: Occupational status of HIV-positive patients

Occupation	Number of patients (%)
Truck-taxi driver/transporter	16 (21)
Laborer	15 (20)
House wife	14 (18)
Private worker	9 (12)
Shopkeeper	5 (06)
Teacher	3 (04)
Farmer	2 (2.6)
Railway employee	3 (04)
Mechanic	2 (2.6)
Others	6 (08)
Student, tailor, agricultural employee, LIC employees, CRPF employees, clerk	

weight loss (38/75; 51%), generalized weakness (26/75; 34.6%), prolonged diarrhea (24/75; 32%), prolonged cough (18/75; 24%), and oral ulcers (17/75; 22.6) in decreasing order of frequency (Table 3). In the study, pallor (40/75; 53) was the most frequent sign followed by oral thrush (25/75; 22.6) and lymphadenopathy (12/75; 16%) in decreasing order of frequency (Table 4). The common opportunistic infections (OI) on presentation were oral candidiasis (25/75; 33%), pulmonary tuberculosis (21/75; 28%), herpes genitalis (4/75; 5.3%), and tenia infection (3/75; 4%). Molluscum contagiosum (2/75; 2.6%), pneumonia (2/75; 2.6%), herpes zoster, scabies, cytomegalovirus (CMV) retinitis, cryptococcal meningitis, and impetigo were also noted in some patients (Table 5). Patients put on ART were divided into 4 classes (Table 6). Class A patients were given zidovudine, lamivudine, nevirapine (ZLN); Class B patients were on stavudine, lamivudine, nevirapine (SLN); Class C were on zidovudine, lamivudine, efavirenz (ZLE), and Class D patients were given stavudine, lamivudine, efavirenz (SLE). Most of the patients responded satisfactorily to ART. After 6 months of the therapy, there was marked improvement in symptomatology, OI. There was rise in hemoglobin level seen in all the 4 classes. Maximum net gain % age of Hb was seen in Class B patients (31.5%). Weight gain was also seen in all the 4 classes with maximum net gain percentage (18%) of weight was seen in Class D. There was a significant improvement in the CD4 count in all the 4 classes of patients. There was more than 85% net improvement in CD4 count in all the 4 classes. After starting the ART, 2 patients (2.6%) developed hepatotoxicity, 12 patients (16%) developed asymptomatic derangement in liver

enzyme levels, 2 patients (2.6%) developed skin rashes, 4 patients (5.3%) developed decline in Hb level, 2 patients (2.6%) developed abdominal distress, 1 patient developed nausea and vomiting, 1 patient developed tingling and numbness in lower limbs, and 1 patient (1.3%) develop impaired concentration during treatment (Table 7).

DISCUSSION

In this study, 75 patients were selected who were HIV positive and went to start HAART, on the basis of their symptoms/CD4 count.

The mean age of the study population was 35.4 years and the maximum percentage of patients studied were in the

Table 2: Modes of transmission of HIV infection

Modes of transmission	N (%)		
	Male	Female	Total
Sexual method	47 (88.6)	22 (100)	69 (92)
By blood and blood products	02 (3.7)	0 (0)	02 (2.6)
Vertical methods (mother to child)	01 (1.8)	0 (0)	01 (1.3)
Undetermined	03 (5.6)	0 (0)	03 (4)

Table 3: Initial clinical presentation

Symptoms	N (%)		
	Male	Female	Total
Weight loss	31 (58.4)	7 (31.8)	38 (51)
Prolonged fever	38 (71.68)	9 (41)	47 (63)
Diarrhea more than 1-month	16 (30)	8 (36.3)	24 (32)
Prolonged cough	14 (28.4)	3 (13.6)	18 (24)
Oral ulcers	14 (26.4)	3 (13.6)	17 (22.6)
Generalized weakness	22 (41.5)	4 (18)	26 (34.6)
Generalized pruritic dermatitis	7 (13.2)	10 (45)	15 (20)
Genital eruptions	2 (3.7)	7 (31.8)	9 (12)
Others	14 (26.4)	2 (9)	16 (21)

Table 4: Findings of general and systemic examination on initial presentation

Examination findings	N (%)		
	Male	Female	Total
Pallor	28 (53)	12 (54.5)	40 (53)
Lymphadenopathy	9 (17)	2 (13.6)	12 (16)
Oral thrush	18 (34)	7 (32)	25 (33)
Respiratory examination			
Chest creps	6 (11.3)	2 (9)	8 (10.6)
Bronchial breathing	1 (1.8)	1 (4.5)	2 (2.6)
Decrease air entry	1 (1.8)	-	1 (1.3)
Per abdomen			
Liver	10 (18.8)	2 (9)	12 (16)
Spleen	5 (9.4)	1 (4.5)	6 (8)
Ascites	2 (3.7)	-	2 (2.6)
CVS examination			
PSM at mitral area	1 (1.8)	-	1 (1.3)
CNS examination			
Neck stiffness	1 (1.8)	-	1 (1.3)

Table 5: Opportunistic infection on initial presentation

Opportunistic infection	N (%)		
	Male	Female	Total
Tuberculosis	17 (32)	4 (18)	21 (28)
Pulmonary	11 (20.7)	2 (09)	13 (17.3)
Extra pulmonary	4 (7.5)	2 (09)	6 (8)
Disseminated	2 (3.7)	0 (0)	2 (3.7)
Oral candidiasis	18 (34)	7 (32)	25 (33)
Herpes genitalis	3 (5.6)	1 (4.5)	4 (5.3)
Herpes zoster	1 (1.8)	-	1 (1.3)
Scabies	-	1 (4.5)	1 (1.3)
CMV retinitis	1 (1.8)	-	1 (1.3)
Cryptococcal meningitis	1 (1.8)	-	1 (1.3)
Tenia infection of nails	3 (5.6)	-	3 (4)
Molluscum contagiosum	1 (1.8)	1 (4.5)	2 (2.6)
Pneumonia	1 (1.8)	1 (4.5)	2 (2.6)
Bacterial	-	1 (4.5)	1 (1.3)
PCP	1 (1.8)	-	1 (1.3)
Impetigo	-	1 (4.5)	1 (1.3)

CMV: Cytomegalovirus

Table 6: Classification of patients for follow-up according to drug combination used

Drug combination	M	F	Total no (%)	ART used
Class A	20	12	32 (43)	Zidovudine-300 mg BD Lamivudine-150 mg BD Nevirapine-200 mg OD for 14 days than 200 mg BD
Class B	15	6	22 (29)	Stavudine-30 mg BD Lamivudine-150 mg BD Nevirapine-same as above
Class C	8	1	10 (13)	Zidovudine-300 mg BD Lamivudine-150 mg BD Efavirenz-600 mg HS
Class D	7	3	11 (15)	Stavudine-30 mg BD Lamivudine-150 mg BD Efavirenz-600 mg HS

Table 7: Adverse effects of ART

Adverse effects	N (%)			
	Class A	Class B	Class C	Class D
Nausea and vomiting	1 (3)	-	-	-
Abdominal distress	-	1 (4.5)	-	1 (9)
Tingling and numbness in lower limbs	-	1 (4.5)	-	-
Rash	2 (6)	-	-	-
Asymptomatic mild enzymatic derangement in liver function	8 (25)	3 (13.6)	1 (10)	-
Jaundice	-	1 (4.5)	-	1 (9)
Decline in Hb level	3 (9.3)	-	1 (10)	-
Abnormal dreams/impaired concentration	-	-	-	1 (9)

ART=Antiretroviral therapy

age group of 35-44 years. The number of male patients outnumbered the female patients and the male to female ratio was 2.4:1.

The sexually active age group (25-44 years) was most commonly (77%) involved, which is consistent with findings of other studies. According to Rewari Joshi,⁶ about 89% of the reported cases of HIV in our country are from sexually active age group (15-49 years). This is also consistent according to Chakravarty *et al.*,⁷ who find 32.6 years to be the mean age of infection.

The majority of patients in this study were truck drivers (21%), laborer (20%), and housewives (18%). Multiple sex partners are very common among laborer class and truck drivers. Out of 22 females, all were married, 13 of them were already widowed. All have acquired infection through their husband.

About 69% of patients were from the low socio-economic group, whereas 25 were in the middle-income group. The highest prevalence of HIV was in low socio-economic group which corresponds to that of developing country

like India which is consistent with the findings of other studies (Kaur *et al.*).⁸

Most patients affected with HIV infection were married (90.6). In 53 male patients, only 7 were unmarried. All the females were married.

The most common mode of transmission was sexual route in both males (88.6%) and females (100%). Two patients were infected via blood transfusion and one male patient had got infection through vertical transmission. According to Rewari and Joshi,⁶ the predominant mode of transmission of infection in the AIDS patients is through heterosexual transmission (84.5%).

Clinical Characteristics on Initial Presentation

In this study, prolonged fever (63%) was the most frequent symptom observed, and weight loss (51%) was the next common symptoms followed by generalized weakness (37%), prolonged diarrhea (32%), and oral ulcer (24%) in decreasing order of frequency. This is consistent with the study done by Kothari and Goyal⁹ on 30 HIV-positive patients, in which fever was the most frequent symptom followed by weight loss, chronic cough, oral ulcers, lymphadenopathy, skin lesions, and dysphagia.

OI

The common opportunistic infection observed in this study during initial presentation were oral candidiasis (33%), followed by tuberculosis (28%), tinea infection (4%), scabies (2.6%), molluscum contagiosum (2.6%), and pneumonia (2.6%) in decreasing order of frequency. This is consistent with the finding of Singh *et al.*,¹⁰ who studied on 100 patients with AIDS and found that 59% patient had oral thrush and was the most common OI followed by tuberculosis which was found in 56% of patient. This is also consistent with the findings of Giri *et al.*¹¹

Response to ART

The response to ART was monitored using symptomatology, OI, hemoglobin levels, weight gain, and CD4 count.

All the patients of all the four classes responded satisfactorily to treatment and after 6 months, most of the patients became asymptomatic for disease. Two patients continue to have fever low grade on and off despite continuing therapy. One patient having persistent fever was suffering from Miliary. One patient diagnosed to have PTB continue to have cough even after 6 months of therapy. He was taking anti-tuberculous therapy (ATT) simultaneously. Two patients reported to have increased generalized weakness most probably due to drug-induced decline in Hb level. One patient having arthritis on initial presentation

continue to have similar problem after 6 months of ART. During follow-up, eight patients had died, out of these one patient had developed hepatitis during treatment.

OI responded satisfactorily to treatment except in two patients who had persistent pulmonary tuberculosis. Out of two patients with persistent tuberculosis, one patient had multi-drug resistant tuberculosis and in one case, the cause was not known. CMV retinitis was noticed in one patient who complained of diminution of vision and persisted even after 6 months of therapy. Goldberg *et al.*¹² found that AIDS patients with extra-macular CMV retinitis, lose vision while on HAART.

In this study, in Class A patients on an initial presentation, the average hemoglobin level was 10.8 g%. After 6 months of ART, the level was increased to 11.8 gm%. The net gain of hemoglobin was 9.2%. In Class B, net gain of Hb was 31.5%; in Class C patients, net gain was 20%; in Class D patients, net gain was 25.6%. In a study conducted in John Hopkins University School of Medicine, Baltimore, Moore and Forney¹³ concluded that HAART is an effective treatment of anemia in HIV infection. Patients who continue to have symptomatic anemia while receiving HAART may need additional intervention. The above findings of Moore and Forney are consistent with our study. Our four patients developed a decline in hemoglobin level and were diagnosed as cases of nucleoside reverse transcriptase inhibitors (NRTI)-induced anemia.

Our almost all patients showed significant weight gain except for one patient who showed 2 kg decrease in weight. He developed ART-induced hepatitis during treatment. In Class A patients, average weight at the start of treatment was 48 kg that gets increased to 53 kg after 6 months of therapy. The net gain percentage of observed was 10.4. Similarly, in Class B, Class C, and Class D, the net gain was 9.8%, 8.6%, and 18%, respectively. According to Chakravarty *et al.*,⁷ who studied on 438 HIV-positive patients. After taking ART, there was a significant improvement in weight (a mean of 47.4 to 52.1 kg) and Hb (8.7 g% to 10.1 g%). These findings are also consistent with our study.

CD4 count

Almost all patients showed drastic improvement in CD4 count. The average increase in CD4 count in Class A patients was from 118 cells/cumm to 222 cells/cumm. The average increment was 88%. Similarly, in Class B, average increment was 91%; in Class C, it was 90%; in Class D, it was 95.5%. One patient on Class B had shown significant improvement in the CD4 count with increment of 294 cells/cumm. The findings are consistent with findings of Tiwari *et al.*¹⁴

Adverse Effects during Treatment

Most patients tolerated well the antiretroviral treatment except for few who develop some adverse effects. In this study, one patient of Class A taking ZLN develops nausea vomiting within 1-month of starting treatment. Initially, the patient got relieved after taking symptomatic treatment but after few days she again developed similar complaint then she had been shifted to Class B regime containing SLN, after which she got relieved.

During treatment, abdominal distress was observed in two patients; one was taking ART of Class B regime SLN, and another one was on Class D SLE. Both got relieved after taking symptomatic treatment.

Tingling and numbness in lower limbs were observed in one patient taking Class B regime SLN. According to Sharma *et al.*,¹⁵ who studied on 48 patients taking SLN was developed in 39.6% of patients. Moyle and Sadler¹⁶ reported that stavudine-induced peripheral neuropathy is more common at CD4 count <100 cells/cumm.

Two patients of Class A group taking ZLN developed skin rash. It got developed within few weeks of the start of therapy. It was mild in nature, so therapy was continued. Rashes got subsided within 2-3 weeks spontaneously. Severe form of skin reaction was not observed in any of the patients. According to Sharma *et al.*,¹⁷ skin rash is the most common adverse effect of Nevirapine they observed it in 11.8% of patient.

In our study, 12 patients develop mild enzymatic derangement in liver function of which 8 were taking Class A regime ZLN, 3 patients were on Class B regime SLN, and 1 patient was taking Class C regime ZLE. Two patients developed hepatotoxicity; 1 was taking Class B regime SLN and another one patient was on Class D regime SLE, he was taking ATT also simultaneously. The therapy was withheld in these two patients for 2 weeks then started and monitoring was done. Kontorinis and Dietrich¹⁸ described that hepatotoxicity was a serious complication in patients taking HAART. Minor enzyme elevation (<5 fold upper normal limit) are generally safe to tolerate and usually resolve. Stern *et al.*¹⁹ found that there was no significant difference in the rate of the serious hepatic event among antiretroviral regimen including between non-nucleoside reverse-transcriptase inhibitor (NNRTI), nevirapine, and efavirenz.

In our study, four patients had shown decline in hemoglobin level. All the four patients were taking zidovudine-based regime. Koduri and Parekh²⁰ found that zidovudine is known to cause a severe hypoproliferative anemia that resolves promptly when the drug is stopped.

One patient in this study taking Class D regimen SLE complained of abnormal dreams and impaired concentration during therapy. Rihs *et al.*²¹ found that patient on efavirenz develops more stress including increased difficulty in relaxing being more irritable, impatient, agitated, and getting easily upset.

In our study, all the patients were on 2 NRTI and 1 NNRTI regimen and no patient was on PI; therefore, no conclusion could be drawn regarding any effect or adverse effect of PIs.

CONCLUSION

It can be concluded from this study that with effective HAART, HIV infection can be managed as any other chronic manageable infectious disease.

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