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Original Research Article

Effect of ART 2 treatment on biochemical profile during treatment of second line ART

Narendra Singh[1]*, R. K. Varma[1], Richa Giri[1], Punit Varma[2], Seema Dwivedi[3], Lalit Kumar[1]

[1]Department of Medicine, KPS PG Institute of Medicine, GSVM Medical College, Kanpur, Uttar Pradesh, India
[2]Department of Community Medicine, GSVM Medical College, Kanpur, Uttar Pradesh, India
[3]Department of Obstetrics and Gynaecology, GSVM Medical College, Kanpur, Uttar Pradesh, India

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***Correspondence:**
Dr. Narendra Singh,
E-mail: narendrasingh0011@gmail.com

ABSTRACT

Background: AIDS was the first recognized in U.S in summer of 1981 at centers for disease control and prevention reported the unexplained occurrence of pneumocystis jiroveci in previously healthy homosexual men in Los Angeles and Kaposi. First time in 1983 HIV syndrome was isolated from a patient of lymphadenopathy. Person with positive HIV serology who have ever had a CD4 lymphocyte count below 200celles/mcl and CD4 lymphocyte percentage below 14% are considered to have AIDS (CMDT 2017).
Methods: This study was continuous longitudinal, prospective and retrospective, observational, at ART plus Centre, Kanpur K.P.S. institute of medicine (G.S.V.M. medical college) included the all patients on ART1 attending in Centre were screened for treatment failure based on clinical, immunological and virological criteria's as decided by SACEP from 2016 to 2018.
Results: Total numbers of patients are 118 among them 71 female and 47 males, age groups between 30-40 there are 54 patients. In study treatment with ART patients Hb levels more than 10%, Mean value before 10.85±1.31 and mean value after treatment was 10.5±1.31, TLC before 6970.94±6309.93 after treatment 6800.25±2522.99, Serum Bilirubin before and after treatment 0.69±0.49 and 0.95±1.13. Mean value of before and after treatment serum creatinin1.80±11.34 and 0.88±0.38.
Conclusions: There is increased in serum creatinine and SGPT /SGOT and decrease in Hb levels in treatment of second line ART treatment so it should be monitored every monthly interval.

Keywords: AIDS, ART 2, HIV

INTRODUCTION

Human immunodeficiency syndrome (HIV) was isolated from a patient of lymphadenopathy and by 1984 it was demonstrated clearly causative agent of AIDS.

In 1985 a sensitive enzyme- linked immunosorbent assay (ELISA) was developed.[1] From that time scope and evolution of HIV ultimately among developing nations throughout world).[2] HIV1 was transmitted from Chimpanzees and HIV 2 is transmitted from Sooty Mangabey Monkey.[3]

Person with positive HIV serology who have ever had a CD4 lymphocyte count below 200celles/mcl and CD4lymphocyte percentage below 14% are considered to have risk of HIV transmission after single exposure to an HIV infected source.

Sexual

- Vaginal intercourse ; female to male .05%
- Vaginal intercourse ; male to female .1%
- Anal intercource ; insertive 0.05%
- Anal intercource ;receptive 0.5%
- Oral intercource ;insertive 0.005%
- Oral intercource ;receptive .01%

Blood exposure

- Blood transfusion ; 90%
- Intravenous drug user sharing needle ;.67%
- Mucous membrane splash0.09%
- Percutaneouse needle stick injury;0.3%

Mother to child

- Vaginal delivery; 15%
- Breast feeding (per month)0.05% [4]

The advent of highly active antiretroviral therapy has been a boon for human immunodeficient virus infected patient by reducing morbidity and extending life span. The chronic persistent form of the virus with high rate of replication has lead to mutant resulting into antireteroviral drug resistance increasing report of multidrug resistant virus in HIV treatment. Reason of resistant of drug is due to mutation at the majority of M184 that was most common followed by NNRTI Mutation. Standard combination of antiretroviral regimens are two NRTI together with an NNRTI, Protease Inhibitor (PI) or Integrase Inhibitor. Starting regime of dual NRTIs combined with an NNRTI or a PI or an Integrase Inhibitor .These regimen should be monitored for resistant testing. If resistant testing is not available then PI in second line regimens are preferable).[5]

Monitoring of efficacy during art treatment.[6] A base line viral load should be measured prior to initiating treatment .Viral load should be repeated 4 to 8 weeks after starting a new regimen when the count should show at least a ten fold decrease. After six month of ART. The viral load should be suppressed defined as below the detection of the assay (usually less than 50 copies /ml). WHO defined immunological failure as fall in CD 4 COUNT to base line or a 50% fall from peak on ART or persistent count below 100cell/mm. India ranks third among the countries having most number of HIV - infected patients and HIV related deaths in the world..

METHODS

This study was conducted in ART plus center. K.P.S. Post Graduate Institute of Medicine (G.S.V.M. Medical College, Kanpur) tertiary care teaching hospital (G.S.V.M. Medical College, Kanpur). Study was conducted in a period of 2016 to 2018.

This was clinical (assessment with investigation) continuous longitudinal, prospective and retrospective, observational, single center hospital-based study at ART Centre, Kanpur.

Study subject includes all the patient on 1st line ART treating attending in the Centre will be screen for treatment failure of based on clinical, immunological and virological criterias as decided by SACEP.

Inclusion criteria

- Patient over the age of 18 years at pre-inclusion and monitored under outpatient condition.
- Documented HIV-1 (group m) infection regardless of clinical stage and CD4 lymphocyto-count (taken in 6 months)
- Patient with treatment failure after first-line antiretroviral treatment with a combination including a non-nucleoside reverse transcriptase inhibitor and two nucleoside reverse transcriptase inhibitors, failure.
- Adherence (>80%) to first-line antiretroviral treatment (questionnaire) at pre inclusion.
- Patient agrees not to take any concomitant medication during the trial without informing the investigator.
- Informed consent
- For women in childbearing age: negative pregnancy test at inclusion, with no plan of pregnancy in the coming 12 months and agreeing to use mechanical contraception (with or without hormonal contraception) during the study.

Exclusion criteria

- Infection with HIV-2 or HIV-1 groups O or N or HIV 1+2.
- Adherence (<80%) to first-line antiretroviral treatment at pre inclusion.
- Participation in any other clinical trial.
- Presence of an uncontrolled, ongoing opportunistic infection or of any severe of progressive disease.
- First-time treatment with a protease inhibitor, Abacavir.
- Not interested to participate in study.
- Severe hepatic insufficiency.
- Creatinine clearance calculated by Cockcroft-Gault formula <50 ml/min.
- Hb≤8 g/dl
- Platelets <50,000 cells / mm^3
- Neutrophiles <500 cells / mm^3
- Pregnancy or lactation.

Blood sample collection

On admission, 10 ml of peripheral venous blood was collected from the antecubital vein by an autoclaved syringe using 20 gauze needles. The blood was allowed

to clot at room temperature for at least half an hour. The glass tube with clotted blood was centrifuged at 2000 rpm for 20 minutes and the centrifugation was repeated once more to remove the red cells completely. The supernatant serum, devoid of cellular elements, was separated from the clot and placed in two acid cleaned small test tubes.

Measuring

Viral load is typically reported as copies of HIV in a milliliter (mL) of blood. Changes in viral load are usually reported as a log change (in powers of 10). For example, a three log increase in viral load (3 Log10) is an increase of 103 or 1000 times the previously reported level, while a drop from 500,000 to 500 copies would be a three-log-drop (also 3 Log10).

CD4 count is done by BD facts flow machine by kit and report is analysed and given same day.

RESULTS

This study was conducted in ART plus center. K.P.S. Post Graduate Institute of Medicine (G.S.V.M. Medical College, Kanpur) tertiary care teaching hospital (G.S.V.M. Medical College, Kanpur). In this study total number of patients was 118 among then 47 are male patients and 71 are female patients. Among age 30 to 70 years age group patients was selected among them more number of patients are under 30 - 40 years of age there are 54 patients. All 118 patients went to laboratory investigation Hemoglobin, total leucocyte count, serum bilirubin, serum SGOT and SGPT levels and Serum creatinine levels, hemoglobin levels ranges from less than 9 to more than 10%. Hb levels more than 10%, 1 year before starting of 2nd line ART there are 110 patients and after 1 year after starting of 2nd line ART there are 108 patients, total leucocyte count levels ranges from less than 45,00 to more than 10,500. Criteria 4500-10500, 1 year before start of second line ART there are 92 1 year and after start of 2nd line ART there are 97 more number of people are in this criteria. Serum Bilirubin levels ranges less than 1 and more than 1. Less than 1 of 1 year before start of 2nd line ART there are 113 and 1 year after start of 2nd line ART there are 105 patients more patients are in this criteria. Serum SGOT and SGPT levels are Mean Value of SGOT One year before 36.30±22.15, Mean Value of SGPT One year after 35.13±17.80, Mean Value of SGOT One Year after 40.61±21.36 and Mean value of SGPT One year after 37.31±15.03 and serum creatinine levels ranges from less than less than1 to more than 1.5. 1 year before start of 2nd line ART there are 86 and 1 year after start of 2nd line ART there are 84 more number of patients are in this groups. Patients are treated with antiretroviral drugs was TLATV/R - TENOFOVIR +LAMIVUDINE+ ATANZANAVIR+RITONIVIR 63% patients are treatment, ZLATV/R – ZADUVIDINE + LAMIVUDIBNE + ATANZANAVIR + RITONIVIR 30% patients are treatment, TLLP/R – TENOFOVIR + LAMIVUDINE + LOPINAVIR + RITONAVIR 04% patients are treatment, ZLLP/R-ZADUVUDINE +LAMIVUDINE +LOPINAVIR +RITONAVIR 3% patients are treatment %. More number of patients are then TLATV/R.

Table 1: Tabular representation of genders.

Sex	No. of subjects	%age
Male	47	40%
Female	71	60%

Total number of patients are 118 among them 40% patients are male and 60% patients are female, male are more than that of female patients.

Table 2: Tabular representation age groups.

	No. of subjects	%age
30-40	54	45%
40-50	35	29%
50-60	15	12%
60-70	14	11%

In this study age group between 30 to 70 years age patients are selected in this study. Age groups between 30 to 40 years there are 45% followed by 29% in 40 to 50, 12% in 50 to 60 and 14% in 60 to 70.

Table 3: Tabular representation of Hemoglobin levels.

Criteria	1 year before start of 2nd line ART	1 year after start of 2nd line ART
<9	4	5
9-10	4	5
>10	110	108
Mean±SD	10.85±1.31	10.5±1.31

Table 4: Tabular representation of total leukocyte count.

Criteria	1 year before start of second line ART	1 year after start of 2nd line ART
<4500	15	6
4500-10500	92	97
>10500	11	15
Mean±SD	6970.94±6309.93	6800.25±2522.99

In this study Hb levels ranges less than 9 to more than 10%. Less than 9% , range between 9 to 10% and more than 10, 1 year before starting of 2nd line ART there are 4, 4 and 110 patients and after 1 year after starting of 2nd line ART there are 5, 5 and 108 patients and mean reduction between two groups are 10.85±1.31 and 10.5±1.31. In this study total leucocyte count levels ranges from less than 45,00 to more than 10,500. Less than 45,00 , range between 45,00-10500 and more than

10,500, 1 year before starting of 2nd line ART there are 15, 92 and 11 patients and after 1 year after starting of 2nd line ART there are 6, 97 and 15 patients and mean reduction between two groups are 6970.94±6309.93 and 6800.25±2522.99 (Table 4).

In this study Serum Bilirubin levels ranges less than 1 and more than 1. Less than 1 before starting of 2nd line ART there are less than 1 are 113 and more than 1 are 5 and 1 year after starting of 2nd line ART there less than 1 are 105 and more than 1 are 13 and mean reductions between two groups are 0.69±0.49 and 0.95±1.13.

Table 5: Tabular representation of bilirubin levels.

Criteria	1 year before start of 2nd line ART	1 year after start of 2nd line ART
<1	113	105
>1	5	13
Mean±SD	0.69±0.49	0.95±1.13

In this study serum SGOT and SGPT levels are Mean Value of SGOT One year before 36.30 and SD 22.15, Mean Value of SGPT One year after 35.13 and SD 17.80, Mean Value of SGOT One Year after 40.61 And SD 21.36 and Mean value of SGPT One year after 37.31 and SD15.03.

Table 6: Tabular representation of SGPT/SGOT levels.

Criteria	1 year before start of 2nd line ART	1 year after start of 2nd line ART
<40	96	86
40-100	22	32
>100	0	0

In this study Serum creatinine levels ranges from less than less than1 to more than 1.5. Less than 1, range between 1-1.5 and more than 1.5, 1 year before starting of 2nd line ART there are 86, 26 and 6 patients and after 1 year after starting of 2nd line ART there are 84, 24 and 10 patients and mean reduction between two groups are 1.80±11.34 and 0.88±0.38.

Table 7: Tabular representation of serum creatinine levels.

Criteria	1 year before start of 2nd line ART	1 year after start of 2nd line ART
<1	86	84
1-1.5	26	24
>1.5	6	10
Mean±SD	1.80±11.34	0.88±0.38

In this study anti-retroviral drugs included was TLATV/R -Tenofovir +Lamivudine +Atanzanavir+Ritonivir there are 35 patients are given treatment i.e 63%, ZLATV/R -Zaduvidine+Lamivudibne+Atanzanavir+Ritonivir there are 74 patients are given treatment i.e 30% , TLLP/R – Tenofovir+Lamivudine+Lopinavir+Ritonavir there are 5 patients are given treatment i.e 4%, ZLLP/R-Zaduvudine +Lamivudine +Lopinavir +Ritonavir there are 4 patients are given treatment i.e of 3%. More number of patients are then TLATV/R.

Table 8: Tabular representation of regime of second line ART in study subjects.

	No. of subjects	%age
TLATV/R	35	63%
ZLATV/R	74	30%
TLLP/R	5	4%
ZLLP/R	4	3%

DISCUSSION

In this study there was maximum no. of HIV patient in age group of 30 to 40 years that is 54 (45%) and second most common age is 40 to 50 year of age group that is 35 (29%) and minimum no of subject is in age group of 60to 70 year of age group 1(0.001%). It meant there is HIV infection maximaly occurred in more sexually active person and also more economically productive group. There is life span of HIV patient is 50 to 60 year of age. Mary Mahy et al stated that both data sources suggest HIV-prevalence rates among people aged over 50 have increased steadily in the recent years.[7] Care and treatment services need to address the specific needs of older people living Increasing trends in HIV prevalence among people aged 50 years and older: evidence from estimates and survey data. In this study female was having more HIV disease that is 71(61%) out of 118 subjects and male is having les HIV disease that is 47(39%) out of 118 and this study show that mode of transmission is most common is heterogenous mode that is 97(82%).

Blood transfusion mode of transmission is second most common that is 11(9%) last is truck driver and injection drug user is last that is 2 (less than 1%). It means there is more common infection of HIV in receptive group of subject. Anant A. Takalkar et al stated that out of 110 cases, 60.9% were males and 39.1% females.[8] 77.2% of OI Opeodu and TJ Ogunrinde, reported that majority of the respondents agreed that HIV could be transmitted through sexual means (96.2%), blood transfusion (96.7%) and sharing of sharp objects (92.5%).[9]

A few of the respondents believed that HIV can be transmitted through sharing of drinking cups (9.4%) and mosquito bites (13.6%) with HIV. Action mode of transmission of hiv/aids: perception of dental patients in a nigerian teaching hospital Patients were in 26-45 years age, the sexually active age group. Distribution of cases according to mode of transmission Modes Male No.(%) Female No. (%) Total No. (%) Heterosexual multiple partners 53 (61.6) 33 (38.4) 86 (100) Homosexual multiple partners 02(100.0) 00 (00) 02(100) Blood

transfusion 05 drug abuse. Due to HIV infection patient immunity decrease and infection and inflammation increase in our study there is ESR is more than 20 in subject group is 102 (72%) and more than 60 is 6 subject (4%) and also more than 40 is 16 subjects (12%). According to Sanne Jespersen Female 3590 (65) Male 1922 (35) Missing data 2(0.04).[10] In this study group there increase in SGPT /SGOT in the subject group in more than group of 40 to 100 ,it increase from 22 to 32 in study subject and also serum bilirubin is also increase from 5 to 13 in study subject . it is suggestive of that patient treated by second line ART have liver toxicity so liver function test should be monitored every monthly interval Palacios et al studied that lopinavir/ritonavir can cause transient elevations in transaminase levels, but these are usually not clinically significant.[2] The incidence of severe hepatic events in patients receiving lopinavir/ritonavir is very low. Hepatitis C confection and baseline elevations in transaminases may be associated with severe liver events in lopinavir/ritonavir recipients. In our study there was increase in no from 4 to 5 in subject of less than 9 hemoglobin and in the group of 9 to 10 level hemoglobin of subjects no increase from 4 to 5 but more than 10 subject decrease from 110 to 108 patient. It means subject of anemia increase after start of second line ART. This shows second line ART have the adverse effect of anemia and this should be monitored after start of second line ART. According to Tsegaye AT, et al the incidence rate of failure was 61.7/1000 person years.[11] The probability of failure at the end of 12 and 24 months were 5.6% and 13.6%, respectively. Out of 67 total failures, 42 (62.7%) occurred in the first 2 years. Dishank Patel et al overall outcome of A total of 83 ADRs were observed in 69 (55%) patients, the most common being dyslipidemia (57) followed by anemia.[12] In our study there was increase in serum creatinin level more than in the range of >1.5mg /dl and no of subjects increase from 6 to 10 ;this shows that second line ART have the adverse effect on kidney so it should monitored every monthly interval of kidney function test. CD4 count and Viral load at the time of initiation that of second line ART ,there is low CD4 count the mean value is 181.44 in total 118 subject standard deviation that is 85.02 in total subject 118 but at 6 month/12 month of second line ART 2 treatment mean value is CD4 count 413.01 and SD 168.70 . According to Minh D. he reported that proportions of patients on ART who received CD4 monitoring ranged from very low (6%; N = 2145) to very high (95%; N = 488).[13] The median uptake of viral load monitoring was 86% with studies in program settings reporting coverage as low as 14%. Overall, the longer the follow-up period, the lower the proportion of patients who received regular monitoring tests; and programs in rural areas reported low coverage of laboratory monitoring. For this Z TEST applied the Z value is 13.316, p value is 0.0001 ,mean difference 231.5, confidence interval 95%, this shows significance of second line ART treatment and effectiveness of second line of ART IS 127%. Viral load value at time of start of second line ART mean value is 80683.85849 and SD is 293449.2038, after 1 to 6 month of start of second line ART treatment mean value is 350.8559 and SD is 128.1069, for this z value is 2.972, p value is 0.0033, mean difference 80298 ,it is suggestive of significance of value and effectiveness of ART2 is 99%. Dishank Patel et al.[12] Overall outcome of out of 126 patients, 82 received regimen V [zidovudine (ZDV) + lamivudine (3TC) + tenofovir (TDF) + boosted lopinavir (LPV/r)] and 44 received regimen Va [3TC + TDF + LPV/r]. A significant (p <0.0001) increase in mean body weight and marked reduction in number of patients (7) categorized as WHO stage III/IV was observed at 12 months of second line ART. Moreover, a significant immune reconstitution with increase in mean CD4 count and viral suppression (PVL <400 copies/ml) in 103 (82%) patients (p <0.0001) was also observed. A total of 83 ADRs were observed in 69 (55%) patients, the most common being dyslipidemia (57) followed by anemia (9) erostatus disclosure Sciences, Early outcome of second line antiretroviral therapy in treatment-experienced human immunodeficiency virus positive patients. Dishank Patel et al Overall outcome of Out of 126 patients, 82 received regimen V zidovudine (ZDV) + lamivudine (3TC) + tenofovir (TDF) + boosted lopinavir (LPV/r)] and 44 received regimen Va [3TC + TDF + LPV/r].[12] This study show that association of alcoholism with more probability of ART1 failure. In our study there was 35 subjects is taking Tenofovir +Lamivudine +Lopinavir /Retinovir regime, 74 subjects is taking Zaduvudine +Lamivudine +Atanzanovir /Retinovir regime, 5 subjects was taking Tenofovir+Lamivudine +Atanzanavir/Retinovir and 4 subjects was taking Zyduvudine +Lamivudine +Lopinavir /Retinovir regime. Dishank Patel et al overall outcome of out of 126 patients, 82 received regimen V [zidovudine (ZDV) + lamivudine (3TC) + tenofovir (TDF) + boosted lopinavir (LPV/r)] and 44 received regimen Va [3TC + TDF + LPV/r.[12] According to Dorina Onoya.[14] A total of 7708 patients initiated second-line ART, with 44.5% developing at least one AE over the first 24 months of second-line treatment. The highest AE incidence was observed among patients receiving abacavir (ABC) + lamivudine (3TC) + ritonavir-boosted lopinavir/atazanavir (LPVr/ATVr) (52.7/100 person-years (PYs), 95% confidence interval (CI): 42.9-64.8), while patients initiated on a tenofovir (TDF) + emtricitabine (FTC)/3TC + LPVr regimen had the lowest rate of AEs (26.4/100 PYs, 95% CI: 24.9-28.3).

CONCLUSION

Second line ART was most effective in treatment of subject treated after treatment failure of first line ART. CD 4 count increase and viral load decrease clinical feature improve after treatment of ART. at the start of second line ART and after 1 year of second line ART treatment and also opportunistic infection improve in study subject it mean second line ART is effective. Clinical symptoms in this study is decrease in subject

Heterosexual mode of transmission mostly present and patients of HIV have infection more in no in rural area and female are more effected. HIV infection mostly occurred in 30 to 40 year of age group that most economical group of age group and most sexually active group. SGPT /SGOT increase in treatment of second line ART treatment so it should be monitored every monthly interval. Serum Creatinine level was also increase in our study so serum creatinine level should be monitored every monthly interval during treatment of second line ART. Hemoglobin level was decrease in this study group in previously anaemic subject so it should monitor monthly interval during treatment of second line ART.

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