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Original Article

Comparison between Two Regimens of Art in Human Immunodeficiency Virus Patients at Tertiary Care Art Centre Jabalpur: A Prospective Observational Study

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Abstract

Objective: The objective of the study was to assess the effectiveness of two regimens (Tenofovir + Lamivudine + Efavirenz [TLE] and Zidovudine + Lamivudine + Nevirapine [ZLN]) on the basis of CD_4 count changes among human immunodeficiency virus (HIV) patients along with occurrence of adverse drug reactions (ADRs) by these regimens.

Materials and Methods: A prospective observational study with a sample size of 200, divided equally into two groups of 100 each jointly conducted in the Tertiary Care ART Centre Jabalpur, from April 2016 to June 2017. Group A contains TLE regimen, and Group B contains ZLN regimen. Various ADRs were observed in both the groups.

Results: Most of the patients were male (124) in our study with a maximum incidence of HIV found among 21–40 years of age group. The average increase in the CD4 count was significant only in Group A (<0.05). 83% and 93% patients of Groups A and B, show a total of 137 and 165 ADRs, respectively. Group A shows major central nervous system and gastrointestinal tract and Group B shows mainly dermatology and hematological type of ADRs. Using Modified Hartwig and Siegel severity assessment scale, we found that in Group A, ADR was mild to moderate in nature while in Group B, ADR was mainly moderate in nature.

Conclusion: It was concluded that Group A containing TLE regimen was more effective as their CD4 count was significantly increase after a follow-up of 6-month treatment with least ADR and the patients who develop ADR was mainly mild in nature.

Key words: Adverse drug reaction, CD4 count, Tenofovir + Lamivudine + Efavirenz, Zidovudine + Lamivudine + Nevirapine

INTRODUCTION

Human immunodeficiency virus infection/Acquired immunodeficiency syndrome (HIV/AIDS) is a disease of the human immune system caused by the HIV.[1] The HIV, a lentivirus (subgroup of retrovirus), infects cells (specifically the CD_4 cells/helper T cells, a type of white blood cell) of the immune system, destroying or impairing their function. Infection with the virus results in progressive deterioration of the immune system, leading to "immune deficiency." Infections associated with severe immunodeficiency are known as "opportunistic infections," because they take advantage of a weakened immune system. Acquired immunodeficiency syndrome (AIDS) is a term which applies to the most advanced stages of HIV infection. It is defined by the occurrence of any one among more than 20 opportunistic infections or HIV-related cancers.

Virus can be transmitted through unprotected sexual intercourse with an infected person, transfusion of contaminated blood, and the sharing of contaminated needles, syringes, surgical equipment, or other sharp instruments. It may also be transmitted between a mother and her fetus during pregnancy, childbirth, and while breastfeeding.[2]

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AIDS is a global problem. It has been reported from more than 190 countries around the world and a pool of HIV infected persons in Africa and Asia is large and expanding.[3]

In India, approximately 2.1 million people are living with HIV in 2016, which is estimated to be the third largest population of HIV affected people in the world. In 2016, HIV prevalence in India was estimated to 0.3% and 62,000 people died from AIDS-related illnesses. Estimated numbers of new HIV infections in 2016 were 80 thousand and 1 million people are on ART who are living with HIV. The number of people newly initiating ART in 2016 was 176969.[4]

The world has committed to end the AIDS epidemic by 2030. UNAIDS recommends a Fast-Track approach to achieve the 90–90–90 treatment target by 2020, whereby 90% of people living with HIV should know their HIV status, 90% of people who know their HIV-positive status are accessing treatment and 90% of people on treatment have suppressed viral loads. Global consensus and leadership have driven greater investment of financial and human capital, and mounting clinical experience and research, improved treatment regimens and diagnostics, and reductions in the price of medicines have created gains in efficiency and effectiveness.[5]

Antiretroviral therapy (ART) became the keystone of National AIDS programme. With the advent of new antiretroviral drugs, there has been decline in morbidity and mortality due to AIDS.[6] Most of the drugs which are available and approved for use in highly active ART have some **o**f the other adverse effects; thus, the treatment of HIV infection has become a complicated balancing acts between the benefits of durable HIV suppression and the risks of drug toxicity.[7]

This study was to assess the effectiveness of two regimens (Tenofovir + Lamivudine + Efavirenz [TLE] and Zidovudine + Lamivudine + Nevirapine [ZLN]) on the basis of CD_4 count changes among HIV patients along with occurrence of adverse drug reactions (ADRs) by these regimens.

MATERIALS AND METHODS

It was an observational study and was conducted on 200 HIV patients for the duration of 15 months from April 2016 to June 2017 in Tertiary Care ART Centre Jabalpur. The cases were selected on the basis of inclusion criteria, i.e.,age >20 years and take well-informed consent from all participants. The patients who were switch to other therapy due to intolerance were excluded from the study. Details of the participants were kept confidential.

All participants were divided into two groups 100 each.
Group A (n = 100) (TLE regimen)
Group B (n = 100) (ZLN regimen)

Suitably structured pro forma was used to assess the details of the patients, family history, and duration since HIV diagnosed. Baseline CD_4 count, type of regimen and essential laboratory investigations such as complete blood counts, liver function tests, renal function tests, lipid profile, blood sugar tests, and chest X-ray (P-A view) was also done. The recent CD_4 counts and other investigations of all participants were done during follow-up of 6-month period as the patients usually visited at 6 months for their CD_4 count. Any associated ADR was also noticed during therapy and assessed for their severity using Modified Hartwig and Siegel scale.[8]

Tools in the Study

Modified Hartwig and Siegel scale.[8]

Hartwig *et al.* categorized ADRs into seven levels as per their severity level 1 and 2 fall under mild category, level 3 and 4 under moderate, and level 5, 6, and 7 fall under category severe.

Mild

Level 1: An ADR occurred but required no change in treatment with the suspected drug.

Level 2: The ADR required that treatment with the suspected drug be withheld, discontinued, or otherwise changed. No antidote or other treatment requirement was required. No increase in length of stay.

Moderate

Level 3: The ADR required that treatment with the suspected drug be withheld, discontinued, or otherwise changed.

AND/OR

An antidote or other treatment was required. No increase in the length of stay.

Level 4: Any level 3 ADR which increases length of stay by at least 1 day.

OR

The ADR was the reason for the admission.

Severe

Level 5: Any level 4 ADR which requires intensive medical care.

Level 6: The adverse reaction causing permanent harm to the patient.

Level 7: The adverse reaction either directly or indirectly led to the death of the patient.

Statistical Analysis

The data were analyzed using SPSS 20. Appropriate method was used during analyzing such as mean, standard deviation (SD), Chi-square test, and Paired *t*-test.

RESULTS

Most of the patients were male (124) in our study [Table 1 and Figure 1]. Maximum incidence of HIV was found among 21–40 years of age group (80%) followed by 41–60 years of age group (20%). The mean age ± SD was 34.08 ± 9.21 years [Table 2 and Figure 2]. These demographic data were not statistically significant.

The average increase in the CD4 count was significant only in Group A (<0.05) [Table 3]. 83% and 93% patients of Groups A and B show a total of 137 and 165 ADRs, respectively [Table 4 and Figure 3].

Table 5 and Figure 4 show the system involved in ADR. In Group A major central nervous system (CNS) and gastrointestinal tract (GIT) system were involved and in Group B major system involved was dermatology and hematology. Table 6 and Figure 5 show severity assessment of ADR in patients using Modified Hartwig and Siegel severity assessment scale and found that in Group A, ADR was mild to moderate in nature while in Group B, ADR was moderate in nature.

DISCUSSION

This is an observational study, with the male predominance in both the groups. The maximum patients were belongs to 21–40 age with the mean ± SD of 34.08 ± 9.21 years. This is concordance with the study of Sehgal *et al.*[9] The immunological response is measured by CD4 count. It was seem that Group A who receive TLE regimen, average raise of CD4 count after the follow-up of 6 months, was 189.51 ± 234.95 SD of mean value, which was statistically significant ($P < 0.05$) than Group B who receive ZLN regimen where average raise of CD4 count was 191.82 ± 191.48 which was statistically not significant ($P > 0.05$). It seems that patients, who were on TLE therapy, were effectively increased in their CD4 count compared to ZLN therapy. Our study was accordance with the Rajput *et al.*[10] study who also found that the TLE regimen was effective than ZLN in term of CD4 count. Another study by Krishnan *et al.*[11] also found similar observation in their study. The incidence of ADR in Group A was 83% and in Group B was 93% with the total of 137 and 195 ADR in both the groups, respectively. Group A found maximum of CNS- (49.6%) and GIT (22.6%)-related ADRs. CNS

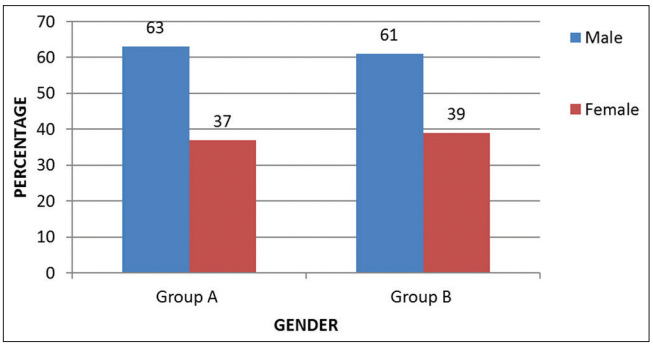

Figure 1: Gender distribution

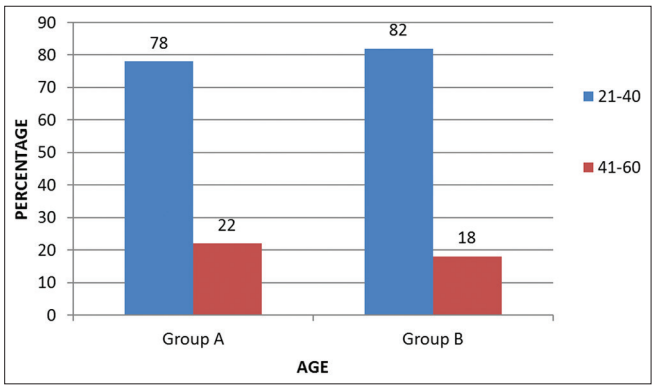

Figure 2: Age distribution

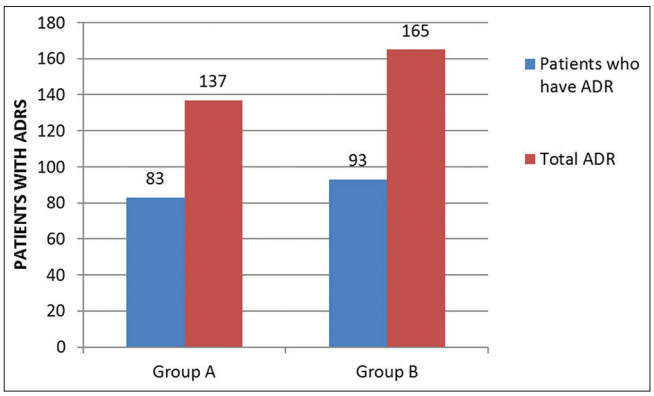

Figure 3: Patient found adverse drug reaction in both the groups

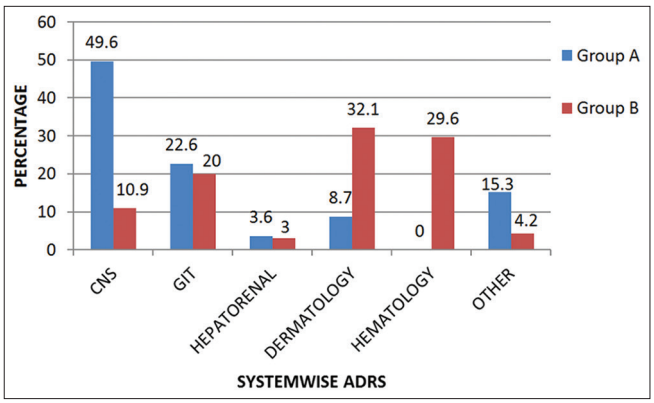

Figure 4: System involved in adverse drug reaction

Table 1: Gender distribution

Gender	Group A (*n*=100)	Group B (*n*=100)	Total
Male	63	61	124
Female	37	39	76

χ^2=0.084; *P*>0.05 at 1 df

Table 2: Age distribution

Age	Group A (*n*=100)	Group B (*n*=100)	Total
21–40	78	82	160
41–60	22	18	40
Mean±SD	34.34±9.85	33.83±8.56	34.08±9.21

t=0.70; *P*>0.05. SD: Standard deviation

Table 3: CD4 count before and after the therapy

Regimen group	Baseline CD4 count (cell/μL)	CD4 count after 6 month (cell/μL)	Average increase in CD4 count	*P* value
Group A	272.6±190.25	462.11±220.84	189.51±234.95	0.0046
Group B	275.6±204.66	467.42±201.38	191.82±191.48	0.3022

Table 4: Patient found ADR in both the groups

Parameter	Group A (*n*=100)	Group B (*n*=100)
Patients who have ADR	83	93
Total ADR	137	165

ADR: Adverse drug reaction

related ADR were mainly dizziness, headache, neuropathy and psychosis and GIT associated ADR were mainly nausea and gastritis. Similar finding was also observed by Jain *et al.*[12] where they found that majority of ADR were related to CNS (40.3%) followed by GIT (37.5%). Lorio *et al.*[13] studied too endorsed with our study who found that 45.5% of ADRs were pertaining to CNS, 27.3% to gastrointestinal system. Group B found dermatological (32.1%), i.e., rashes and itching, and hematological (29.6%), i.e., anemia and neutropenia as the most common ADRs. Sharma *et al.*[14] observed cutaneous ADR (44.4%) as the most common ADR followed by hematological (32.2%) in their study.

In Group A, maximum ADR was mild to moderate in nature, and only 6 patients have develop severe in nature compare to Group B where the majority of ADR was moderate in nature, and only 8 patients develop a severe reaction, using Modified Hartwig and Siegel severity assessment scale. Similar type of results was found by Anwikar *et al.*[15] where 8.77%, 77%, and 14.02% ADRs were mild, moderate, and severe, respectively.

CONCLUSION

It was concluded that both the regimen were effective in the treatment of HIV. In term of the CD4 count after follow-up of 6 months, the TLE regime shows the better outcome with least ADR. The patients who develop ADR were mild in nature and subsided spontaneously after few weeks without switch off the therapy or either managed by counselling and or symptomatic treatment.

Table 5: System involved in ADR

System involved	Group A *n*=137 (%)	Group B *n*=165 (%)
CNS	68 (49.6)	18 (10.9)
GIT	31 (22.6)	33 (20)
Hepatorenal	5 (3.6)	5 (3)
Dermatology	12 (8.7)	53 (32.1)
Hematology	0 (0)	49 (29.6)
Other	21 (15.3)	7 (4.2)

CNS: Central nervous system, GIT: Gastrointestinal tract

Table 6: Severity assessment (modified Hartwig and Siegel severity assessment scale)

Severity of ADR in patients	Group A (*n*=83)	Group B (*n*=93)
Mild	36	13
Moderate	43	72
Severe	4	8

ADR: Adverse drug reaction

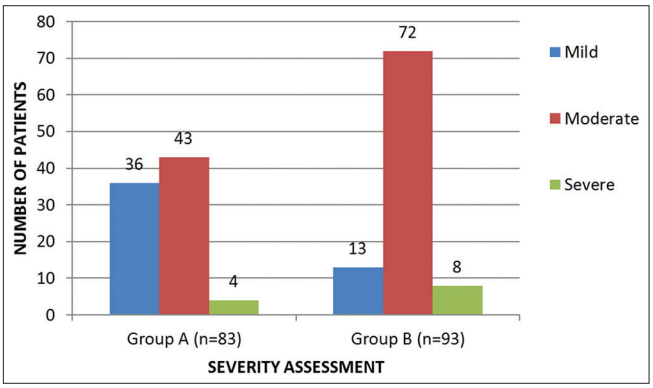

Figure 5: Severity assessment

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