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Evaluation of Treatment Outcome for HIV Patients after TLD Regimen (Tenofovir, Lamivudine and Dolutegravir) using Viral Load Suppression

D. Vasuni Sai Mounika[1], K. Lokesh[2], Md. Salma Sulthana[3], A. Sudharshan Reddy[4]

[1, 2, 3, 4]Students, Department of Pharm-D, QIS College of Pharmacy, Ongole, Prakasam DT, Andhra Pradesh, India

Abstract: ***Introduction: HIV is a virus that weakens the immune system of a person by destroying cells that fight against infection and disease. Dolutegravir-based regimens (TLD/ALD) were suggested by the WHO as the preferred first- and second-line antiretroviral therapy in 2018. Objective: To evaluate the treatment outcome of TLD regimen based on viral load suppression among HIV patients. Methods: A prospective observational study was conducted in government general hospital, Ongole for a period of six months. Efficacy of TLD regimen among 470 patients was assessed. Results: Our study involves 3,110 patients out of which 470 patients are included who are having age between 20-50 years old, undergoing TLD therapy, who are under follow up and whose medication adherence is documented. Of these patients, 321 individuals (68%) had virologic response to the TLD regimen, while virologic response was not achieved in 149 patients (32%). Conclusion: According to the results of our study, we conclude that the TLD regimen is 68% effective, andPatients in clinical stage 1, who had >95% adherence, were working, between the ages of 20 and 30, females showed better results in terms of viral suppression.***

Keywords: HIV (Human immunodeficiency virus),TLD regimen(Tenofovir, Lamivudine and Dolutegravir), viral load,AIDS(Acquired immunodeficiency syndrome), Virologic suppression/improvement

1. Introduction

HIV is a type of lentivirus, means it attacks the immune system. In a similar way, the Simian Immunodeficiency Virus (SIV) attacks the immune systems of monkeys and apes. Research from 1999 revealed that SIV and HIV have a close relationship and share a lot of characteristics. Both HIV-1 and HIV-2 are closely linked to the SIV strains seen in chimpanzees and sooty mangabeys, respectively [(1,2)]. HIV can be passed from person to person through blood transfusions, sexual contact, childbirth, or breastfeeding [(3)]. The signs of HIV infection varies in type and severities from person to person, The WHO classification for adults divided individuals into one of four stages, ranging from stage 1 (asymptomatic), stage 2 (mildly symptomatic), stage 3 (moderately symptomatic), and stage 4 (severely symptomatic) (AIDS) [(4)]. HIV can be diagnosed through blood or saliva testing: Antigen/antibody tests, Antibody tests, Nucleic acid tests (NATs), CD4 T cell count, Viral load (HIV RNA). This test measures the amount of virus in your blood. After starting HIV treatment, the goal is to have an undetectable viral load. This significantly reduces your chances of opportunistic infection and other HIV-related complications [(5)].

Dolutegravir-based regimens (TLD/ALD) were suggested by the WHO as the preferred first- and second-line antiretroviral therapy in 2018. It is a generic combination of Anti-Retroviral drugs Tenofovir disoproxil fumarate, Lamivudine, dolutegravir where Tenofovir & Lamivudine from the Nucleoside Reverse transcriptase inhibitors & the dolutegravir from Integrase inhibitors [(6)]. The US Food and Drug Administration (FDA) just conditionally approved DTG fixed dose combinations (FDC), while the European Medicines Agency (EMA) approved them in the beginning of 2018. Only TB patients who are also on rifampicin need to alter their dose (50 mg twice daily [(7)]. Sleep problems, weight gain, and a rash are all possible side effects. While there are concerns that using it during pregnancy increases the risk of neural tube abnormalities in the new-born by 0.2 percent, this does not rule it out. After the first trimester, use is still advised. It should be avoided in renal impaired patients [(8)].

2. Methodology

Study population:
A prospective observational study was carried out in an ART center in tertiary care hospital. The ART cards of patients were used to collect information about patients'anti-retroviral therapy and viral load data. The exclusion criteria for this study include patients who are above 50 and below 20 years of age, patients who are not receiving TLD therapy and patients whose viral load is not documented before and after 6 months of TLD therapy where as inclusion criteria includes patients of age between 20-50 years old, undergoing TLD therapy, who are under follow up and whose medication adherence is documented. The data was collected by using well designed proforma and data was analyzed.

Variables:
Variables evaluated for the study includes socio-demographic details like age (20-30, 30-40, 40-50), gender (male, female), type of infection (HIV-1, HIV-2), functional status (working, ambulatory, bed ridden),clinical stages (stage-1, stage-2, stage-3, stage-4), medication adherence (<80%, 80-95%, >95%), baseline and latest viral load.

3. Results

In our study, we have collected 3,110 ART cards of HIV/AIDS patients from which 470 patients were included in the study who met inclusion criteria.

Efficacy:
Out of 470 patients, 321 patients (68%) showed virologic response for TLD regimen.

Table 1: Percentage distribution of efficacy of TLD among HIV patients

Parameter	N	%
Virologic response	321	68%
Non virologic response	149	32%

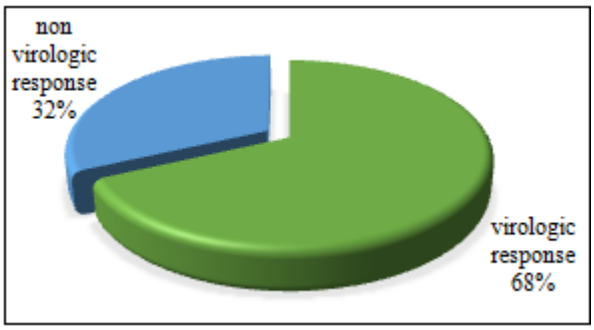

Figure 1: Efficacy of TLD therapy among HIV patients

Adherence:
According to data analysis, majority of patients who showed virologic response for TLD regimen have >95% of adherence (63%) followed by 80-95% (26%) and <80% (11%) of adherence.

Table 2: Percentage distribution of medication adherence among HIV patients

Adherence	No. of patients	Percentage %
>95%	199	63%
80-95%	83	26%
<80%	36	11%

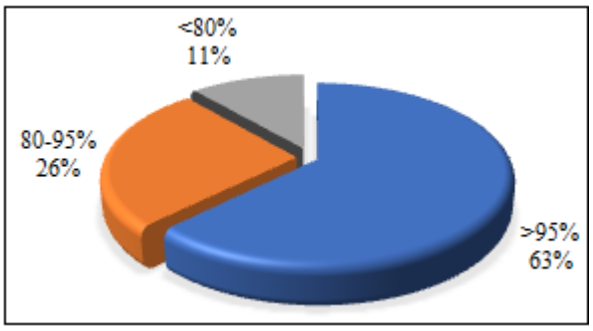

Figure 2: Distribution of medication adherence

Considering the demographic parameters, out of 321 patients, virologic response mostly observed among the patients with 20-30 years of age (40%) followed by patients with 31-40 years of age(32%) and 41-50 years of age (28%). Females showed better improvement (62%) compared to males (38%). Taking clinical parameters into consideration, among the 321 patients, majority of patients were working (75%) followed by ambulatory (24%) and bed ridden(1%). A large proportion of patients with WHO clinical stage 1 showed good therapeutic outcome with TLD regimen followed by stage 2(21%), stage 3 (11%) and lastly by stage 4(2%).

Table 3: Distribution of patients according to sociodemographic factors

Parameters	Frequency	No. of patients	Percentage (%)
Age	20-30	129	40%
	31-40	103	32%
	41-50	89	28%
Gender	Male	122	38%
	Female	199	62%
Clinical stage	Stage 1	212	66%
	Stage 2	66	21%
	Stage 3	37	11%
	Stage 4	6	2%
Functional stage	Working	241	75%
	Ambulatory	78	24%
	Bed ridden	2	1%

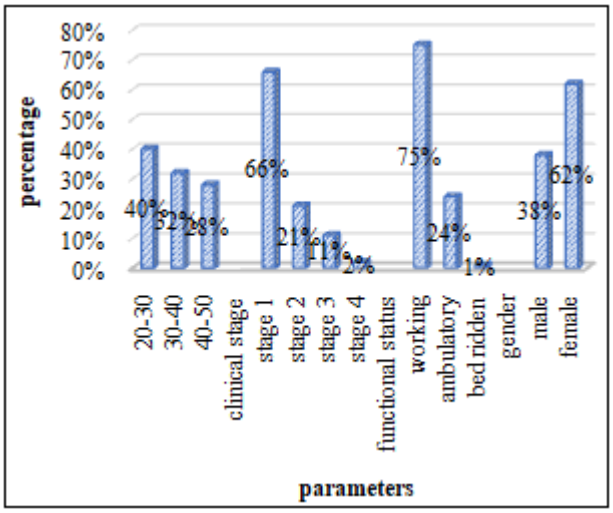

Figure 3: Data analysis of sociodemographic factors

4. Discussion

Our study is aimed to measure the therapeutic outcome of TLD regimen in HIV patients by viral load suppression. We included 470 patients who are having age above 20 years and below 50 years of age and viral load with follow up period for every 6 months.

The efficiency of TLD regimen is with 68%. The efficacy of TLD regimen is high in HIV patients. In a similar study, Analucorreaet.al 2018, reported TLD regimen shown larger efficiency in 12 months period [(9)]. In our study data, females shown better improvement in treatment with TLD regimen when compared to males. Females shown efficiency of 62% and males are 38%.

From our observed data, patient who are having higher adherence with TLD regimen showed greater efficacy. In that, 95% of adherence patients shown 63% of efficiency and 80-95% shown 11% and <80% of adherence shown 26% of efficiency with TLD regimen. The higher adherence levels with TLD regimen have the greater tolerability by a study of Mariana VelosoMeireleset.al 2017[(10)].

From our observed study, the patients with an age at 20-30 years are shown improvement in viral load suppression. 20-30 years of age patient with TLD regimen had 40%, 31-40 years of age patients were with 28% and 41-50 years of age patients shown 32% of efficacy by viral load suppression.

From the study data, working patients showed greater efficacy when compared with ambulatory and bed ridden patients. With TLD regimen, working patients shown 75% of treatment outcome, ambulatory patients shown 24% and bed ridden patients with only 1%.

In our study, stage-1 patients shown better/greater efficacy when compared with remaining stages of patients and with TLD regimen, stage-1 patients shown 66%, stage-2 with 21%, stage-3 with 11%, stage-4 patients with 2%. These results shown that patients with advanced stage had shown better improvement in virologic suppression.

5. Conclusion

From our study, we conclude that the TLD regimen is 68% effective and we observed that patients with high adherence levels have shown greater improvement in achieving viral suppression. Good improvement levels were observed in 20-30 years of age patients. Females have made more progress than males in terms of gender.Working people exhibited better treatment outcomes with TLD regiment compared to ambulatory and bed-ridden patients. TLD therapy improved HIV patients in the earliest stages.

From the study data, literature evaluation and with the support of WHO recommendations, TLD regimen is preferred as first line treatment for HIV patients in the management of HIV and achieving faster viral load suppression.

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Conflict of Interest

The authors show no conflict of interest

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