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Efficacy of First-Line Antiretroviral Therapy in Jaipur: Predictive role of CD4+T cell count and Viral load count.

[1]Avani Joshi, Microbiology, Mahatma Gandhi Medical College & Hospital, Jaipur, Rajasthan, India.

[2]Dr. Nitya Vyas, Microbiology, Mahatma Gandhi Medical College & Hospital, Jaipur, Rajasthan, India.

[3]Dr. S.K Singh, Microbiology, SMS Medical College & Hospital, Jaipur, Rajasthan, India.

[4]Dr. Babita Sharma, SMS Medical College & Hospital, Jaipur, Rajasthan, India.

Corresponding Author: Avani Joshi, Microbiology, Mahatma Gandhi Medical College & Hospital, Jaipur, Rajasthan, India.

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Abstract

Background: ART has helped in managing the fatal HIV/AIDS with the easy accessibility of effective antiretroviral drugs which helps in maintaining the cellular immunity by inhibiting viral replication in people living with HIV (PLHIV). Routinely monitoring parameters from an early stage {i.e. baseline CD4+T cell count and Viral load count with follow up at every 3 and 6 months respectively} was beneficial in finding the incidence of drug resistance at an early stage. Thus, by determining the efficacy of first line ART also assisted us in predicting drug resistance among PLHIV using CD4+T cells and Viral load as parameters, considering all variables in the study (socio demographic variables, OI, mode of transmission, history of patient etc.)

Aims & Objectives: To predict drug resistance through CD4+T cell and viral load for first line ART in tertiary care facilities in Jaipur, Rajasthan.

Results: Among 300 participants, 65.33% participants achieved Viral load suppression and hence categorized as TND their CD4+T cell count was found >200 cell/µl, 12% participants appeared to fall in the category of LLV with viral load falling in between 50-999 copies/ml and CD4+T cell count <200 cell/µl, 22.67% participants were still found to persist detectable viral load (VL ≥1000 copies/ml) with CD4+T cell count <200 cell/µl viral failure.

Conclusion: Persistent Viral load in LLV patients (50-999 copies/ml) and viral load ≥1000 copies/ml in viral failure patients indicates unsuppressed viral load, viral failure and prevalence of drug resistance at an early stage.

Keywords: Antiretroviral drugs, HIV, Immunity, PLHIV

Introduction

HIV (human immunodeficiency virus) belongs to lentivirus group of retroviruses which plays a major role in decline of T lymphocytes, by interacting with CD4+T cell surface receptors, and thereby infecting T lymphocytes. By attacking and then killing the CD4+ T lymphocyte, immune system suppresses which in turn causes opportunistic infections (OI's) and rare cancers [1].

HIV is the foremost cause of influencing the cell mediated immunity, ultimately resulting in immunodeficiency. The deprivation in the CD+4 T cells and the mediocre performance of remaining helper T cells is the major cause of immunodeficiency [2]. This sort of acute deficiency is caused by decline in CD4+T cells (helper T cells), which overturn the usual CD4: CD8 ratio. CD4+ cells work in a coordinated manner with Antigen Presenting cells (APC), B cells, Cytotoxic T cells (CD8+T cells), and Natural Killer cells thus effecting cellular immunity [3]. Thus, the quantity of CD4 lymphocytes (CD4) in HIV-positive people is a key predictor of HIV progression and AIDS-related death, and a decreased CD4 cell count level suggests that the immune system may be weakened. [4] Therefore, the World Health Organization (WHO) has stressed the need of using CD4 counting to prioritize care for advanced HIV patients, monitor the progression of AIDS, and determine early disease status. [5]

If treatment for an HIV infection is not received, AIDS can develop roughly 10 to 15 years after the infection. Infections, malignancies, and other long-term, severe clinical symptoms are common in AIDS patients. [6] In a healthy individual 500 to 1500 cells/mm3 of CD4+ T cell is considered normal range. According to Center for Disease Control and Prevention (CDC), AIDS is diagnosed when CD4+T cell count falls below 200 cells/mm3 [7].

Antiretroviral Therapy has evidently been proven to be potentially effective in reducing the risk of HIV succession [8]. It is greatly responsible for the reduction in morbidity and mortality worldwide [9]. ART has helped in managing the fatal HIV/AIDS with the easy accessibility of effective antiretroviral drugs which helps in maintaining the cellular immunity by boosting CD4+ T cell count and by inhibiting viral replication and reducing viral load in people living with HIV (PLHIV) [9, 10]. Despite the presence of detectable viremia, routinely determining CD4+T cell count throughout ART has provided an early detection of patients at risk factor [11]. Viral suppression is a primary goal of antiretroviral therapy (ART).

Methods

Total of 300 HIV-1 seropositive patients willing to undergo first line Antiretroviral Therapy, were enrolled for this study. Samples were collected from Mahatma Gandhi Medical College & Hospital and SMS Medical College & Hospital from the period of 2022-2024.Following formula was used for calculating the minimum size of a sample:

$n = (z)^2 - \alpha/2\ p\ (1 - p) / d^2$

Patients were enrolled from 4 April 2023 to 24 July 2023. Eligibility criteria included newly diagnosed HIV-1 seropositive patients who are naïve to ART, patients of all genders, patients of all age, patients willing to provide a valid consent (without, disclosing their identity). Following steps describe the methodology used in the study.

1. Newly diagnosed HIV seropositive patients attending tertiary care facilities in Jaipur, Rajasthan, were taken into consideration with the prior informed consent of the subject and maintaining confidentiality during the study period.

2. Peripheral blood was drawn in EDTA vial from every HIV positive patients.

3. Base line CD4+T cell count was determined before starting the ART regimen using sysmex CyFlow counter.

4. HIV viral RNA was extracted by using Abbott extraction kit and by using Abbott m2000sp (4×24 Preps). And quantification was performed by using Abbott m2000rt for determining baseline HIV viral load.

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5. CD4+T cell count and viral load were monitored routinely at a time span of 3 months and 6 months respectively using the above mentioned techniques.

6. Patients maintaining their low level viremia (LLV) status and patients failing at their First line ART were identified through their CD4+T cell counts and viral load and correlated to determine ART efficacy.

Result

In this study out of 300 patients, 69.67% were male, 30% were female, and 0.33% were from another gender. Most affected age group was from 21-30 years of age out of which 25% were male, and 7.67% were female. Mode of transmission of HIV was 90% sexual transmission and 10% through other mode of transmission (syringes, drug abuse, vertical etc.) 35.67% patient's spouse were found positive for HIV, 5.67% were found negative, 25.33 were unknown for the HIV status. 60.67% patient were employed/self-employed, 11.67% were student, 4.33% were retired, 10.67% were home maker, 5.33% were farmer and 7.33% were unemployed. Among 300 participants, 65.33% participants achieved Viral load suppression and hence categorized as Target Not Detected (TND), their CD4+T cell count was found >200 cell/µl, 12% participants appeared to fall in the category of low-level viremia (LLV) with viral load falling in between 50-999 copies/ml and out of which 41.67% had a CD4+T cell count <200 cell/µl at 6 months. Viral failure (VF) patients were 22.67% participants were still found to persist detectable viral load (VL ≥1000 copies/ml) out of which 22% had a CD4+T cell count <200 cell/µl at 6 months. This study was conducted to determine the efficacy of ART by monitoring baseline CD4+T cell and viral load, CD4+T cell count at 3 months and 6 months, viral load count at 6 months. It gives an insight about drug failure as signs of Low-level viremia and Viral Failure can be observed at an early stage, through this data. LLV, VF patients who have CD4+T cell count <200 cell/µl are proven to be more susceptible to drug resistance in many studies [6]. Studies show that about 10% of the patients in the HIV positive population have HIV drug resistance (HIVDR) [7]. 34.67% of population is LLV and VF combined and are most prone to drug resistance, out of which 29% have a CD4+T cell count <200 cell/µl, making this population a highly susceptible to drug resistance. Thus, using this study an early prediction of drug resistance can be determined which will provide an early modification or changes in drug regimen, leading to better treatment.

Table 1: Age and Gender wise distribution of HIV patients.

	HIV Positive Female		HIV Positive Male		HIV Positive Transgender		Total Positive Patients	
Age Group	No. of case	(%)	No. of case	(%)	TG	In %	No. of cases	(%)
0-10	1	0.33%	1	0.33%		0.00%	2	0.67%
11-20	4	1.33%	12	4.00%	1	0.33%	17	5.67%
21-30	23	7.67%	75	25.00%		0.00%	98	32.67%
31-40	28	9.33%	43	14.33%		0.00%	71	23.66%
41-50	19	6.33%	41	13.67%		0.00%	60	20.00%
51-60	12	4.00%	21	7.00%		0.00%	33	11.00%
61-70	3	1.00%	16	5.33%		0.00%	19	6.33%
Total	90	30.00%	209	69.67%	1	0.33%	300	100.00%

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Table 2: General Characteristics of patients undergoing ART

		No. of patients	Percentage of patients (%)
		n=300	
Sex	Male	209	69.67
	Female	90	30
	Transgender	1	0.33
Marital Status	Married	178	59.34
	Unmarried	96	32
	Other	26	8.66
Transmission	Sexual	270	90
	Other	30	10
Spouse HIV Status	Positive	107	35.67
	Negative	17	5.67
	Unknown	76	25.33
	NIL	100	33.33
Occupation	Business/Service	182	60.67
	Student	35	11.67
	Retired	13	4.33
	Home Maker	32	10.67
	Farmer	16	5.33
	NIL	22	7.33

Table 3: CD4+T cell count over the time in VF, TND and LLV patients

Viral load	No. of Patients (n=300)	Baseline CD4+ T cell count		CD4+ T cell count @ 3 months		CD4+ T cell count @ 6 months	
		>200 cells/µl	<200 cells/µl	>200 cells/µl	<200 cells/µl	>200 cells/µl	<200 cells/µl
TND	196	175	21	188	8	196	
LLV	36	7	29	10	26	15	21
VF	68	2	66	2	66	2	66

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Figure 1: Age and sex wise distribution of HIV positive cases

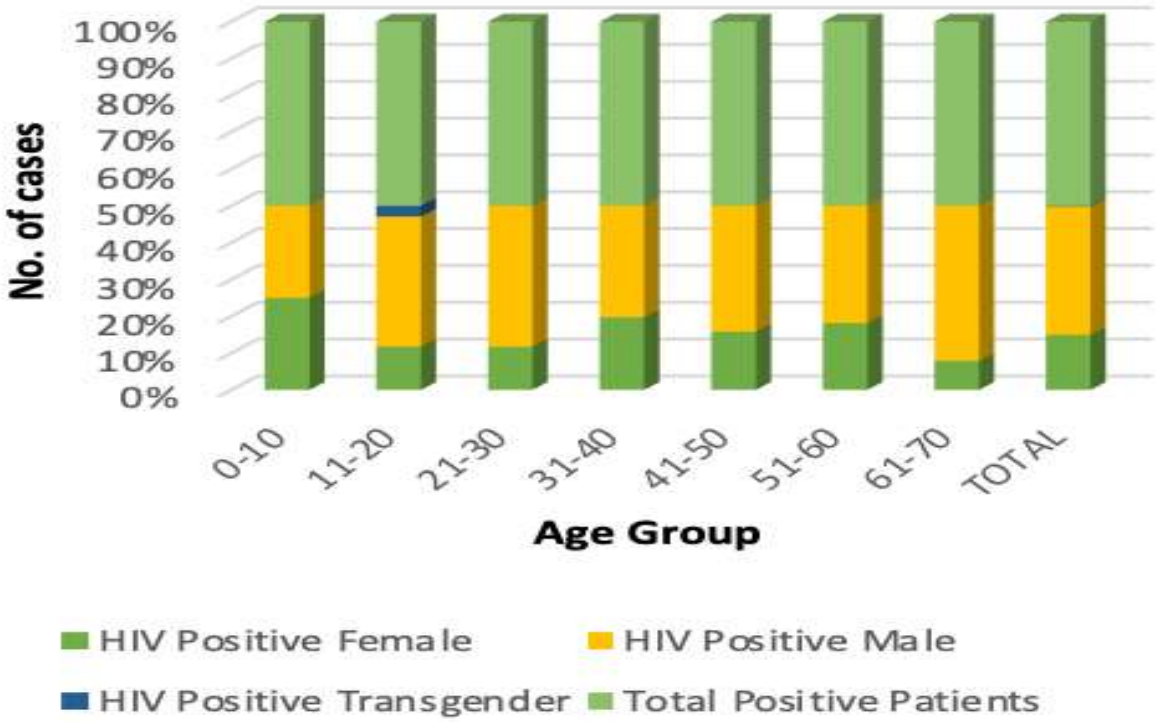
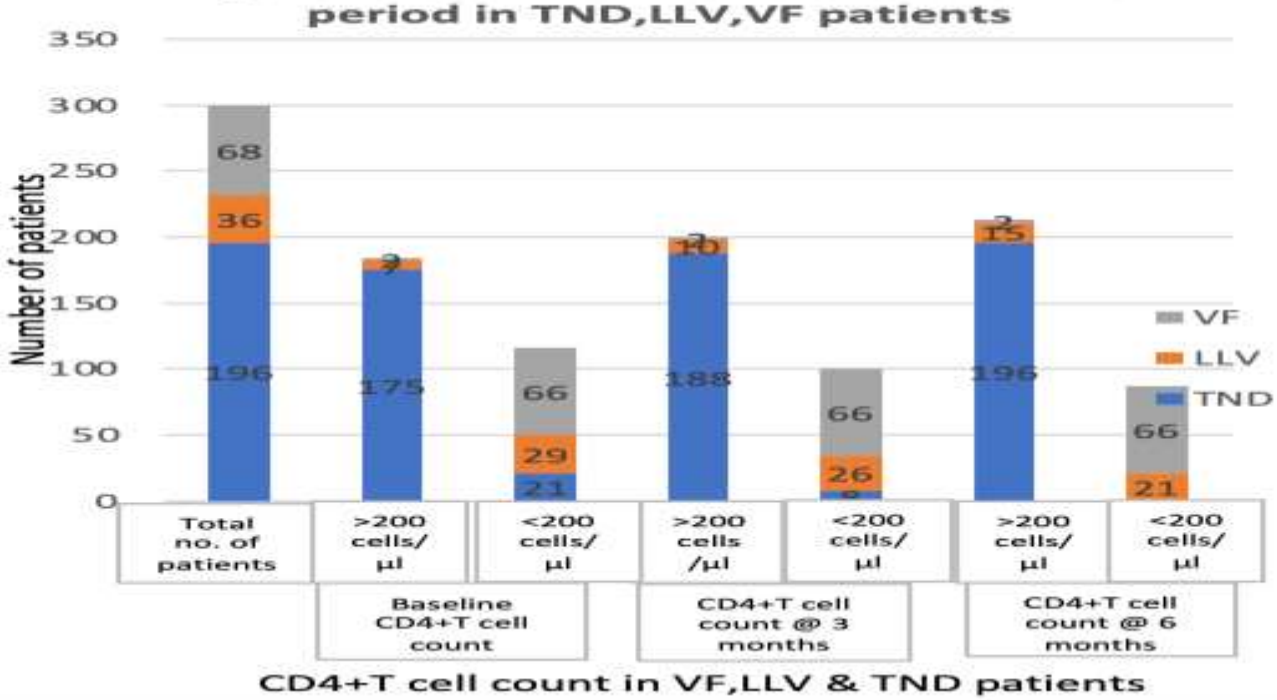


Figure 2. CD4+T cell count over the time period in TND,LLV,VF patients



CD4+T cell count in VF,LLV & TND patients

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