

Original Research Article

Cd4 count at the time of presentation in newly diagnosed HIV patients in a tertiary care hospital in south India: implications for the programme

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ABSTRACT

Background: Lower CD4 count at initiation of antiretroviral therapy (ART) can have a significant negative impact on subsequent disease progression and mortality among HIV patients. Hence, author assessed the status of the CD4 count at the time of diagnosis and factors associated with lower CD4 count among newly diagnosed HIV cases.

Methods: A prospective observational study was conducted in a single integrated counseling and testing center, affiliated with a Medical College and Hospital, Andhra Pradesh. All newly diagnosed HIV cases in the setting between January to December 2017 were included. The CD4 count was assessed as per national guidelines for enumeration of CD4 2015.

Results: The final analysis included 125 participants. The mean CD4 count at diagnosis was 276.51 ± 228.37 . Only 19 (15.20%) people had CD4 count >500 , 47 (37.60%) had between 200-500 and 59 (47.20%) had CD4 count <200 . Only 20% had appropriate knowledge of treatment. Among the study population, 43 (34.70%) had symptomatic conditions attributed to HIV infection, 44 (35.50%) participants had an AIDS-defining illness at the time of diagnosis. Only 3 (2.40%) had voluntary counseling and testing. Even though male gender, poor educational status, having more sexual partners, poor knowledge related to HIV diagnosis and treatment was associated with higher odds of low CD4 count (<200), none of the associations were statistically significant.

Conclusions: The mean CD4 count was low and almost half of newly diagnosed cases had low CD4 count (<200) at the time of diagnosis. There is a strong need to intensify the efforts to fill the gaps in the screening for the early diagnosis to maximize the benefits of HAART and to stop the spread of the infection.

Keywords: CD4 count, Highly Active Anti-Retroviral Therapy (HAART), Newly diagnosed HIV

INTRODUCTION

There are about 2.1 million people living with HIV and AIDS in India and according to official statistics about 49% of them are on antiretroviral therapy. The HIV and AIDS control initiatives have resulted in substantial impact as new HIV infections have reduced by 46% and

AIDS-related deaths have declined by 22% in the year 2016 as compared to 2010.¹ To further strengthen the fight against HIV, the government of India had recently announced a new test-and-treat policy, as part of wider national strategic plan 2017-2024. This new initiative labeled, 90-90-90 strategies is designed to identify 90% of people living with HIV, place 90% of people identified

as living with HIV on treatment and ensure that 90% of people on treatment have sustained viral load suppression. In contrast to the earlier policy of providing free for only those people with CD4 count <500 cells/mm³, the new policy envisages provision free ART for every person living with HIV and AIDS as per new UNAIDS recommendations.² Apart from documented benefits for the infected person, ART has been proved to significantly reduce the probability of vertical transmission and even transmission of HIV by the sexual route by suppressing plasma HIV-RNA concentration to undetectable levels. Many studies have reported that expansion of access to ART results in decline of aggregate HIV-RNA measures and in turn in reduced incidence of HIV at the population level.³⁻⁸ But as in many countries, the National AIDS Control Programme (NACP) in India has identified crucial gaps in case of detection as about 28% of the people with HIV remain undetected till 2016.

Analysis of programme data has indicated that there is 33-43% gap in the testing of key population around 90% gap in the testing of bridge population, around 65% gap in the testing of STI clients, 23% in TB patients, 45% in pregnant women and 64% in partners of PLHIV.² Published literature provides extensive evidence that delayed initiation of combination antiretroviral therapy (ART) in HIV infection increases the risk of poor treatment outcomes, morbidity and mortality.^{3,9,10} Despite substantial evidence supporting the benefits of early initiation of ART, HIV continues to be diagnosed and treated later than contemporary guidelines recommended.¹¹⁻¹³

Some of the recent large-scale reviews by Gabillard D et al, and Gupta A et al, have highlighted substantial mortality even after the initiation of ART in low and middle-income countries.^{14,15} Delay in diagnosis of HIV and lower CD4 counts at the time of diagnosis is considered as a major reason for this phenomenon. Considering the above-mentioned facts, analysis of CD4 counts and their correlation with the presence of opportunistic infections in newly diagnosed HIV infections may provide vital inputs to the policymakers. But the availability of studies on Indian population is very scarce and not many studies have explored the status of CD4 count and factors associated with the low CD4 count in an Indian setting.

The critical analysis of the profile of the cases with the low CD4 count at diagnosis may help in identifying high risk groups for delayed diagnosis and take appropriate measures to improve the same. The study assessed the profile of newly diagnosed HIV cases, risk behaviors and the reason for testing in a single Integrated counseling and testing center. To assess the status of the CD4 count at diagnosis among newly diagnosed HIV infections in a single Integrated counseling and testing center and analyze the factors, associated with low CD4 count among the study population.

METHODS

The study was a cross sectional observational study conducted in the Department of Dermatology, Venereology and Leprosy, NRI Medical College and General Hospital. The study population included all the subjects who were newly diagnosed with HIV infection in a single integrated counseling and testing center (ICTC) and ART centre under national Aids Control Programme (NACP) affiliated to the study setting.

All the newly diagnosed HIV cases in the study setting between January 2017 to December 2017 were included in the study. To be included in the study, the participants must be adults aged 18 years or above, tested for HIV status and labeled as HIV positive as per the diagnostic guidelines of the national AIDS control programme, not previously tested or treated for HIV in the past and willing to be tested for the CD4 count.

All the relevant data was retrieved from the official records maintained as part of the routine implementation of the programme. Appropriate pre-test counseling was provided as per the standard national guidelines for HIV testing under NACO. HIV was diagnosed by serological tests (antigen and antibody detection) on appropriate specimen serum/plasma/whole blood is used, whereas for CD4 enumeration, 3 milliliters of blood was collected in a K2/K3 EDTA evacuated tube. Once collected, the blood specimens were processed immediately within a maximum of 48 hours. During this time, the blood specimen was kept at ambient temperature and not in the refrigerator. The CD4 enumeration was done as per the national guidelines for enumeration of CD4 2015 guidelines issued by national aids control organization (NACO), India. The method involved flow cytometry method, using single platform technology.¹⁶

The study was approved by the institutional human ethics committee. Informed written consent was obtained from all participants. Strict confidentiality of the study participants was maintained throughout the reporting of the study findings. The key outcome parameters included the CD4 count at the time of diagnosis. The other variables of interest considered for analysis include demographic parameters of the participants including their level of education and occupation, the particulars regarding the participant's sexual preferences and sexual behavior, knowledge related to various aspects of HIV/AIDS and the clinical presentation at the time of diagnosis. Baseline demographic and clinical characteristics of participants were summarized using mean and standard deviation for continuous variables and frequencies and proportions for categorical variables. The association between various demographic, HIV knowledge related factors and low CD4 count (<200) was assessed by univariate logistic regression analysis. Unadjusted odds ratio along with its 95% Confidence interval and P value was presented. A p value <0.05 was

considered as statistically significant. Data analysis was performed by IBM SPSS version 23.

RESULTS

A total 125 people were included in the final analysis. The mean age was 36.56±10.17 in the study population. The proportion of females was slightly higher (55.2% vs 44%) in the study and there was only one transgender subject. The educational standard of the study population was poor as 18.5% of the reported no formal education and another 47.6% reported have completed only the primary school.

Table 1: Summary of the demographic characteristics of study population (N=125).

Demographic parameter	Frequency	%
Age (mean (SD))	36.56	10.17
Gender N (%)		
Male	55	44.00
Female	69	55.20
Trans gender	1	0.80
Education		
None	23	18.50
Primary	59	47.60
Secondary	24	19.40
Tertiary	18	14.50
Employment		
Employed	51	42.10
Unemployed	51	42.10
Self employed	19	15.70
Marital status		
Married	87	69.60
Divorced	32	25.60
Single	6	4.80
Occupation		
House wife	31	24.80
Agricultural and Non-agricultural labour	44	35.20
Skilled worker in construction industry	17	13.60
Business	7	5.60
Skilled worker (Tailor/Gold work/Weaver)	6	4.80
Driver / Local transport worker/ Truck driver	6	4.80%
Domestic servant	3	2.40%
Others (Clerical staff)	11	8.80%

The proportion of the unemployed population was 42.1% and the majority of the study population were married (69.60%). Majority of the study population (24.80%) were housewives.

The proportion of participants as agricultural labour and non-agricultural labour, a skilled worker in construction industry/painter, business, and tailor/ gold worker/

weaver was 35.20%, 13.60%, 5.60%, and 4.80% respectively (Table 1). The analysis of sexual behaviors showed 124 (99.20%) participants to be heterosexual and 86.40% have never used condoms.

Alcoholism was reported by 46 (36.80%) participants and 40% and 12.4% respectively have reported having 2 and 3 or more sexual partners. The mean age of onset of sexual activity was 19.26±1.58 years (Table 2).

Table 2: Summary of the demographic characteristics of study population (N=125).

High risk behaviours	Frequency	%
Sexual preferences		
Heterosexual	124	99.20
Homosexual	1	0.80
Condom use		
Never	108	86.40
Sometimes	15	12.00
Always	2	1.60
Alcohol use	46	36.80
Number of sexual partners since being sexually active		
1	47	37.60
2	50	40.00
3 or more	28	22.40
Age of onset of sexual activity (mean, SD)	19.26	1.58

Even though the proportion of participants heard of HIV and AIDS (97.60%) and have appropriate knowledge on modes of transmission (61.60%) was high, the proportion of participants having appropriate knowledge regarding treatment (20%) and preventive measures (18.4%) was very low.

Only 3 (2.40%) people were healthy adults screened by voluntary counseling and testing. The number of subjects presenting with symptomatic conditions attributed to HIV infection and AIDS-defining illness was 43 (34.70%) and 44 (35.50%) respectively (Table 3).

The most common clinical presentation was weight loss among 23 (18.40%) participants followed by fever (17.60%), LRTI (15.20%), and TB (11.2%). The analysis of CD4 count showed, 59 (47.2%) people to have CD4 count <200, 47 (37.60 %) to have CD4 count between 200 to 500. Only 19 (15.2%) had a CD4 count above 500.

The mean CD4 count at diagnosis was 276.51±228.37cells/cmm (95% CI 236.08-316.94) (Table 4).

The factors which had shown a positive association with low CD4 count (<200) were male gender, poor educational status, working for population, single/divorced, people with more sexual partners and people with poor knowledge regarding HIV/AIDS. But none of the associations were statistically significant (Table 5).

Table 3: Descriptive analysis of knowledge of HIV and reason for HIV testing in the study population.

Parameter	Frequency	%
Knowledge of HIV		
Heard of HIV or AIDS	122	97.60%
Appropriate Knowledge about routes of transmission	77	61.60%
Appropriate Knowledge about treatment	25	20.00%
Appropriate Knowledge about preventive measures	23	18.40%
Reason for testing		
Symptomatic conditions attributed to HIV infection	43	34.70%
AIDS-defining illness	44	35.50%
Antenatal screening	26	21.00%
Positive consort	5	4.00%
Voluntary counselling and testing of healthy adults	3	2.40%
Sexually transmitted infection	3	2.40%

Table 4: Descriptive analysis of presenting clinical diagnosis in the study population.

Presenting clinical diagnosis	Frequency	Percentages
Weight loss	23	18.40%
Fever	22	17.60%
LRTI	19	15.20%
TB	14	11.20%
Oral thrush	9	7.20%
STI	6	4.80%
Weakness	6	4.80%
Pregnancy	3	2.40%
Tinea corporis	2	1.60%
Toxoplasmosis	1	0.80%
Cough	1	0.80%
Genital herpes	1	0.80%
HIV associated nephropathy	1	0.80%
CD4 count		
Less than 200	59	47.20 %
200 to 500	47	37.60 %
More than 500	19	15.20 %
CD4 count at diagnosis (Mean, SD)	276.51	228.37

DISCUSSION

Highly Active Antiretroviral therapy (HAART) has been proved not only to have a significant positive impact on the morbidity and mortality of the HIV affected individual but also significantly reduces the disease transmission. CD4 count at the diagnosis and initiation of HAART is found to be a key determinant of the success of HAART. Siegfried N et al, in their systematic review, they have reported that, a statistically significant reduction in death when starting ART at higher CD4 counts.¹⁷ Risk of death was reduced by 74% (RR=0.26; 95% CI: 0.11, 0.62; P=0.002). Risk of tuberculosis was reduced by 50% in the groups starting ART early. They have reported an evidence of moderate quality that initiating ART at CD4 levels higher than 200 or

250cells/microL reduces mortality rates in asymptomatic, ART-naive, HIV-infected people. Anglaret X et al, have also reported ART initiation at entry into care would improve long-term survival of patients with high CD4(+) T-cell counts, provided higher treatment adherence.¹⁸

So, early diagnosis of the disease, at the asymptomatic stage with relatively higher CD4 counts is vital for maximizing its benefits, both at individual and community level. So, voluntary counseling and testing are vital in this regard but in the current study, only 3 (2.40%) of newly diagnosed HIV subjects were diagnosed by voluntary counseling and testing. The majority were diagnosed when presented with symptomatic conditions attributed to HIV infection (34.70%) or with AIDS-defining 35.50%). Similar to the

current study, a study done in Barbados by Kilaru KR et al, have reported majority (57.6%) of the newly diagnosed HIV patients to be presenting with HIV/AIDS-related illness as in the current study.¹⁹ As per this study,

the median CD4 cell count at the time of diagnosis was 183/microL and 50.5% of adult population with a newly diagnosed HIV infection had a CD4 cell count that was <200.

Table 5: Factors associated with CD4 count in study population univariate logistic regression analysis.

Factor	Un adjusted odds ratio	95 % CI of odds ratio	P-value
Age	1.016	0.982 - 1.053	0.360
Age of onset of sexual activity	1.102	0.880 - 1.379	0.398
Gender (base line= female)			
Male	1.226	0.605 - 2.485	0.572
Education (base line= secondary/ tertiary)			
None	2.074	0.736 - 5.849	0.168
Primary	1.051	0.473 - 2.334	0.904
Employment (base line= self-employed)			
Employed	1.674	0.577 - 4.854	0.343
Unemployed	0.963	0.331 - 2.800	0.944
Occupation (base line= house wife)			
Agricultural and Non-agricultural labour	2.100	0.806 - 5.469	0.129
Skilled worker in construction industry	3.000	0.881 - 10.210	0.079
Business	2.800	0.524 - 14.959	0.228
Skilled worker (tailor/gold work/weaver)	2.100	0.358 - 12.312	0.411
Driver / local transport worker/ truck driver	1.050	0.085 - 12.995	0.970
Domestic servant	1.050	0.164 - 6.724	0.959
Others (clerical staff)	3.675	0.870 - 15.525	0.077
Marital status (base line= married)			
Single/divorced	1.175	0.548 - 2.520	0.679
Condom use (Baseline= never)			
Always / sometimes	1.720	0.609 - 4.854	0.306
Alcohol use (Baseline= No)	1.194	0.577 - 2.474	0.632
Number of sexual partners since being sexually active (baseline=1)			
2	2.072	0.917 - 4.678	0.080
3 or more	2.036	0.786 - 5.274	0.143
Knowledge related to HIV			
Heard of HIV or AIDS	0.438	0.039 - 4.964	0.505
Appropriate Knowledge about routes of transmission	0.833	0.405 - 1.716	0.621
Appropriate Knowledge about treatment	1.272	0.529 - 3.059	0.591
Appropriate Knowledge about preventive measures	1.031	0.417 - 2.551	0.947

In the current study, close to half (47.2%) of newly diagnosed HIV subjects had CD4 count <200 and another 47 (37.60 %) had CD4 count between 200 to 500. Only 19 (915.2%) had a CD4 count above 500. The mean CD4 count at diagnosis was 276.51±228.37cells/cmm (95% CI 236.08 to 316.94). The mean values are comparable to the mean CD4 counts reported from various underdeveloped nations.

Mutimura E et al, have reported a median CD4 cell count of 211 in their study conducted in Rwanda. Kilaru KR et al, have reported a median CD4 cell count at the time of diagnosis as 183/microL and 50.5% of with a newly diagnosed HIV infections with a CD4 cell count <200 in

Barbados. Keiser O et al, have reported that, even though the median baseline CD4 count increasing in recent years, still the majority of patients in Asia, Africa, and South America continued to be initiated on ART with counts well below the recommended threshold.^{19,20,21} Kiertiburanakul S et al, based on data from multiple Asian countries, the overall median (IQR) CD4 cell count at ART initiation has shown an increasing trend over time from as low as 115cells/mm³ in 2008 to a peak of 302cells/mm³ after 2011 (p for trend 0.002).²² But the lower mean CD4 count of the current study, compared to this study, in 2017 shows the high likelihood of regional variations within a nation. But in contrast to above study, Siedner MJ et al, in their recent meta-analysis reported a

mean estimated CD4 count as 251cells/microL at presentation and 152cells/microL at ART initiation in the year 2002, which had shown no significant increase by the year 2013.²³ This indicates, unless organized efforts are made, transition in the sociodemographic profile of population and increased awareness levels may not translate into an early diagnosis of HIV infections.

In the current study, the factors which had shown a positive association with low CD4 count (<200) were male gender, poor educational status, working for population, single/divorced, people with more sexual partners and people with poor knowledge regarding HIV/AIDS. But none of the associations were statistically significant. In a study by Mutimura E et al, factors associated with a higher odds of advanced HIV disease at ART initiation were male sex and older age.²⁰ As per the study by Kiertiburanakul S et al in Asia, the factors associated with late ART initiation were male gender, (male vs. female OR 1.51, 95% CI 1.18-1.93; p=0.001) and HIV exposure risk (heterosexual vs homosexual OR 1.66, 95% CI 1.24-2.23; p=0.001 and intravenous drug use vs. homosexual OR 3.03, 95% CI 1.77-5.21; p<0.001).²² Late ART initiation was associated with higher mortality than early initiation of ART in this study (HR 2.13, 95% CI 1.19-3.79; p=0.010). Lahuerta M et al, in have also reported, male sex, living single and poor educational status to be associated with late initiation of HAART. Nash D et al, have assessed program-level and contextual-level determinants of low-median CD4+ cell count in cohorts of persons initiating ART in eight sub-Saharan African countries.^{24,25}

Program-level factors associated with low cohort median CD4 cell count included urban setting (adjusted odds ratio (AOR) 2.1, 95% confidence interval (CI) 1.3-3.3), lower provider-to-patient ratio (AOR 2.2, 95% CI 1.3-4.0), no PMTCT program (AOR 3.6; 95% CI 1.0-12.8), outreach services for ART patients only vs both pre-ART and ART patients (AOR 2.4, 95% CI 1.5-3.9), fewer vs more adherence support services (AOR 1.6, 95% CI 1.0-2.5) and smaller cohort size (AOR 2.5, 95% CI 1.4-4.5). Contextual-level factors associated with low cohort median CD4 cell count included initiating ART in areas where a lower proportion of the population heard of AIDS, tested for HIV recently, and a higher proportion believed limiting themselves to one HIV-uninfected sexual partner reduces HIV risk.

As per the study findings, the mean CD4 count was very low and almost 1 in 2 newly diagnosed subjects had CD4 count <200. Majority of the subjects sought diagnostic services after the onset of symptomatic disease attributed to AIDS or AIDs defining illness. The proportion of subjects seeking voluntary counseling and testing services when they are apparently healthy is negligible in this study population, in spite intense IEC activities by the government. Poor knowledge regarding the nature of the disease, preventive measures, diagnosis and treatment facilities available are responsible for the delay in

utilization of voluntary screening services. The study findings pave the way for further large-scale studies to study the status and long-term impact of the CD4 count at initiation of HAART. Population-specific IEC interventions, considering the heterogeneous nature of Indian population, the differences in the educational, socio-economic and cultural aspects have to be designed and implemented.

The key limitation of this study was the inadequacy of sample size to perform multivariate analysis to rule of the role of confounding. Even the lack of statistical significance of many associations observed in the study could be attributed to chance, due to lower sample size. The generalizability of study findings to other population groups in India is limited.

CONCLUSION

At the time of HIV diagnosis almost half of the newly diagnosed patients had Cd4 count less than 200. This pattern indicates a clear need for enhanced educational efforts regarding the importance of early HIV testing for at-risk individuals. This early diagnosis could reduce HIV transmission as well as improve the prognosis for patients receiving HAART. The lack of statistical significance of many associations observed in the study could be attributed to lower sample size.

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