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Original Research Article

Survival analysis of people living with human immunodeficiency virus: a study in a teaching hospital

S. Bhagyabati Devi, T. Jeetenkumar Singh*, Kshetrimayum Birendra Singh, N. Biplab Singh, Robinson Ningshen, Thiyam Brojendro Singh

Department of Medicine, RIMS, Imphal and SACEP Members of COE, ART Centre, RIMS, Manipur, India

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***Correspondence:**
Dr. T. Jeetenkumar Singh,
E-mail: drjeeten@yahoo.co.in

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ABSTRACT

Background: Antiretroviral therapy (ART) have changed the outlook of people living with HIV (PLHIV) by transforming the dreaded infection to a chronically manageable disease. However, there is scant of reports which analyses quantitatively the survival benefit of PLHIV under ART. Objectives of this study were to determine the survival time of adult PLHIV who are on ARV. To analyse the factors determining survival outcome of PLHIV on ARV.
Methods: This was an observational study in centre of excellence (COE) ART Centre, RIMS, Imphal from April 2004 to December 2009. Details from the data entered in documents of the ART programme were followed up every 3 months for 60 months from the date of initiation of ARV. All PLHIV above 18 years of age and undergoing antiretroviral therapy were included.
Results: Survival rate following initiation of ARV was found to be significantly high among PLHIV. Higher CD4 count at the time of ARV initiation had better prognosis. Mortality was high among IDUs and they had high incidence of co-infections with HCV and HBV. The currently available ARV drugs under NACO programme have better suppression of HIV, are less toxic, low pill burden. The combined regimen used in the earlier days were not much inferior to the current ARV drugs if initiated timely with proper prophylaxis of OIs, good adherence, good nutrition and timely management of toxicities and IRIS.
Conclusions: Timely treatment with ARV drugs provided under the national programme with good adherence and regular follow-up improves the survival of PLHIV.

Keywords: Antiretroviral therapy, National aids control organization, People living with HIV

INTRODUCTION

India continues to have concentrated epidemic for HIV/AIDS since 1986.[1] In fact India has the third largest HIV epidemic in the world.[2] The first case of HIV in Manipur, a state in North Eastern part of India was detected from an intravenous drug user (IDU) in the year 1990.[3] Many youths were infected by this deadly disease by sharing needles among themselves. As the appropriate antiretroviral drug (ARV) was not available at that time and was also unaffordable, many youths of the state died from this disease.

Globally, there were 36.9 million people living with HIV.[4] By the end of 2017, India had an estimated 21.40 lakh people living with HIV of which 0.2% belonged to the adult population. Overall HIV prevalence at National level has continued its steady decline from an estimated peak of 0.38% in 2001-03 following scale up on ART centres across the country. Estimated adult PLHIV

prevalence was 1.15% in Manipur, 0.80% in Mizoram, 0.78% in Nagaland.[5]

The HIV treatment by combined ART since 1996 has forever altered the course of disease among PLHIV in high income countries but has only reached a fraction of people in low- and middle-income countries which bore 90% of the global burden.[6]

Free combined ARV treatment was initiated in India including Manipur under the National AIDS control organization (NACO) in April 2004. Despite of this facility, the number of PLHIV on ARV remains low as many of them face difficulty in accessing ART centres. In 2008, ART Centre, RIMS, Imphal, Manipur was identified as one of the ten Centres of excellence in India and thus started providing free 2nd line (functionally since 2009) and subsequently delivered 3rd Line ART since 2016.

Free ARV delivery as an integral component of the comprehensive antiretroviral service of NACO, GOI has changed the livelihood of many PLHIV, reduced the stigma and discrimination and increased the number of enrolments for ARV. However, there is scant of studies objectively analyzing the survival benefit of PLHIV in the state of Manipur, which has the distinction of having recorded the highest prevalence of PLHIV in this country. Hence, we pursued this study in our centre.

The aim of the study is to determine the survival time of adult PLHIV who are on ARV and analyse the factors determining survival outcome of PLHIV on ARV.

METHODS

This is a retrospective longitudinal observational study done in the centre of excellence (COE), ART Centre, RIMS, Imphal, Manipur from April 2004 to December 2009. Details of each case (anonymous) from the data entered in documents used in the ART programme were followed up every 3 months for 60 months from the date of initiation of ARV.

Out of 2400 PLHIVs on ART since 2004-2009, 1541 PLHIVs of both sexes whose age was more than18 years were included in the study. PLHIVs in terminal illness state, less 18 years, pregnant women, lactating mothers, cancer patients and patients on immunosuppressant were excluded from the study. Cases were analysed for risk factors, OIs, CD4 T cell counts, WHO stage, regimen of ART drugs and followed up every 3 monthly for 60 months from the initiation of the ART. Routine laboratory tests at baseline and repeat tests according to NACO guideline were done.

Test for viral load was not included for this study. In each visit, findings of measurement of weight, physical, clinical check-up were collected. Survival time in months was taken as dependent variable.

Concepts and definitions of variables

Duration of treatment and follow up was time (in months) after initiation of ART. WHO clinical stage I-IV were defined based on the WHO classification for AIDS patients. Survival time was defined as the number of months a PLHIV survived during the study period. Death was defined as recorded by the outreach worker (ORW) and feedback from the care and support centre (CSC) from the lists of LFU cases in the outreach visit which is verified by the family members/local authority.

PLHIVs missing their follow-up for more than 3 months at the centre were labelled as Lost to follow up (LFU). Patients who died from all causes during the study period were recorded as deaths. PLHIVs transferred out to another ART centre were recorded as transferred out cases.

Statistical analysis

The data were systematically collected, entered and statistically analysed by using SPSS version 21. Survival time in 3 months interval was calculated up to 60 months. Probability of survival during 60 months follow-up for all patients were calculated by using Kaplan Meir model based on sex, CD4 count, WHO stage, ART regime, risk factor and opportunistic infections. P-value of <0.05 was taken as significant value. Cox proportional hazard regression model was used to identify the independent predictors (adjusted for potential confounders) of mortality. Estimated hazard ratio (HR), both crude and adjusted hazard ratios (HRs) with 95% confidence interval was reported. Variables which were statistically significant at p value <0.05 were considered as predictors of mortality among PLHIVs.

RESULTS

Total number of adult PLHIV registered in this centre from April 2004 to December 2009 were 2400, of which the number of transferred out cases were 481, lost to follow-up (LFU) were 378. After exclusion of transferred out and LFU, 1541 cases were included in this study. Out of these, more than half i.e. 67.8% (1045) were males while 32.2% (496) were females. The median age at the time of initiation of ARV was 36 years (IQR: 32-40). Enrolment of PLHIV for ART in this centre was increased from 2006 among the age group 25-44 years. Survival rate for an interval of 60 months during the study period were - from 2004-09 (61.5%); 2005-10 (70.0%); 2006-11 (63.0%); 2007-12 (56.3%); 2008-13 (77.2%) and 2009-14 (71.1%) Table 1.

The median CD4 T cell count at ART initiation was 131cells/cumm (IQR: 66-194). The overall baseline median CD4 cell count of deceased patients was 104 cell/cumm (IQR: 46-181) and that of patients who were alive and on treatment was 143 cells/cumm (IQR: 80-204). PLHIV on WHO stage III were 1011 (65.6%) with

a hazard ratio (95% CI of 1.27(0.81-2). WHO stage I and II had better survival rate of 66% than WHO stage III and IV (63.1%). In the beginning of the initiation of ART in this centre, the ARV drugs given were stavudine (d4T), lamivudine (3TC), nevirapine (NVP), efavirenz (EFV), zidovudine AZT). ART regimens Patients were put on were d4T+3TC+NVP (SLN)/d4T+3TC+EFV (SLE), AZT+3TC+NVP (ZLN)/AZT+3TC+EFV (ZLE). TDF+3TC+NVP (TLN)/TDF+3TC+EFV (TLE) was the substitution regimen for any contraindication of the basic NACO regime since 2008 d4T was phased out from 1st line regimen of NACO and reserved for 2nd line regimen since January 2013. TLE was initiated for all new PLHIV according to NACO guideline from November 2014. Number of patients on TLN/TLE were 602 (39%); SLN/SLE were 459 (29.78%) while that of ZLN/ZLE were 433 (28.1%). Out of these, 98% of PLHIVs on TLN/TLE are alive while percentage of alive PLHIVs on ZLN/ZLE and SLN/SLE are 73.7% and 9.2% respectively. Heterosexuality was the commonest risk factor (47.37%), followed by IDUs (46.20%). 583 (37.83%) cases of the study population were associated with one or more Opportunistic Infections (OIs) commonly Tuberculosis and cryptococcal meningitis. commonest co-infection being HBV, HCV, (Table 1).

The median age of patients on ART was 36 years (interquartile range, IQR 32-40)

The median CD4 cell count at ART initiation was 131 cells/mm3 (IQR 66 - 194). The overall baseline median CD4 cell count of deceased patients was 104 cells/mm3 (IQR 46 -181) were comparatively lower than the patients who were alive and on treatment was 143 cells/mm3 (IQR 80 - 204).

Table 1: Demographic and clinical characteristics of subjects (n=1541) (2004-09, 2005-10, 2006-11, 2007-12, 2008-13, 2009-14).

Covariates	Category	Censored (%)	Deceased (%)	Total (n)
Patient level	2004-09	126 (61.5)	79 (38.5)	205
	2005-10	77 (70.0)	33 (30.0)	110
	2006-11	322 (63.0)	189 (37.0)	511
	2007-12	183 (56.3)	142 (43.7)	325
	2008-13	146 (77.2)	43 (22.8)	189
	2009-14	143 (71.1)	58 (28.9)	201
Sex of ART patient	Male	620 (59.3)	425 (40.7)	1045
	Female	377 (76.0)	119 (24.0)	496
Age of patients (years)	15-24	19 (73.1)	7 (26.9)	26
	25-34	369 (65.8)	192 (34.2)	561
	35-44	495 (64.6)	271 (35.4)	766
	≥45	114 (60.6)	74 (39.4)	188
CD4 count at ART initiation (cells/mm^3)	1-50	135 (48.4)	144 (51.6)	279
	51-200	604 (66.2)	309 (33.8)	913
	201-350	228 (75.0)	76 (25.0)	304
	≥ 351	30 66.7)	15 (33.3)	45
WHO stage	I	47 (70.1)	20 (29.9)	67
	II	303 (67.6)	145 (32.4)	448
	III	639 (63.2)	372 (36.8)	1011
	IV	8 (53.3)	7 (46.7)	15
	I and II	350 (68.0)	165 (32.0)	515
	III and IV	647 (63.1)	379 (36.9)	1026
ART regimen	SLE/SLN	42 (9.2)	417 (90.8)	459
	TLE/TLN	590 (98.0)	12 (2.0)	602
	ZLE/ZLN	319 (73.7)	114 (26.3)	433
	Other [w]	46 (97.9)	1 (2.1)	47
Risk factors associated	Injecting drug users	393 (55.2)	319 (44.8)	712
	Heterosexual	531 (72.7)	199 (29.3)	730
	Others [x]	73 (73.7)	26 (26.3)	99
Opportunistic infection(s)	No	625 (65.2)	333 (34.8)	958
	Yes	372 (63.8)	211 (36.2)	583

w (Other) Second-line ART regimen and third - line ART. x (Others) includes mother to child transmission, man having sex with man, blood transfusion and unknown.

Survival analysis

The estimated overall survival probability on ART at 60 months was 71.58% (95% CI 99.52-73.0) with 67.67% (95% CI 65.17-70.33) in males and 79.67% (95% CI 76.33-83) in females. The survival rate was higher among females than males (log rank test <0.001). CD4 T cell count 201-350 cells/cumm in the study group were 80% (95% CI 83-84.17) and ≥351 was 75.83% (p <0.001). The PLHIVs in WHO stage I and II had better survival rate than those in WHO stage III and IV 74.50 (95% CI 71-78.00) p <0.049. PLHIV on ARV regime TLN/TLE had 98.50 (95% CI 97.67-99.33) p <0.001 than other ARV regime. PLHIVs whose risk behaviour is heterosexual had better survival rate than IDUs-76.50 (73.67-79.50) versus 65.50 (62.33-68.67) p <0.001 as many of the IDUs were co-infected with HCV and HBV (Table 2, Figure 1, 2, 3, 4).

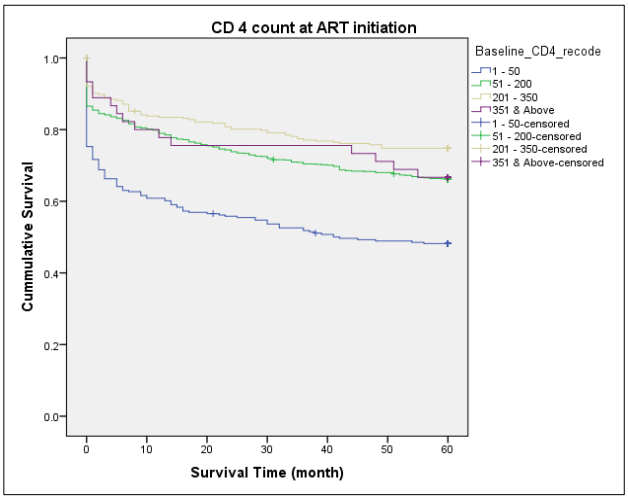

Figure 1: Survival outcomes (Kaplan-Meier analysis) by CD4 count at ART initiation.

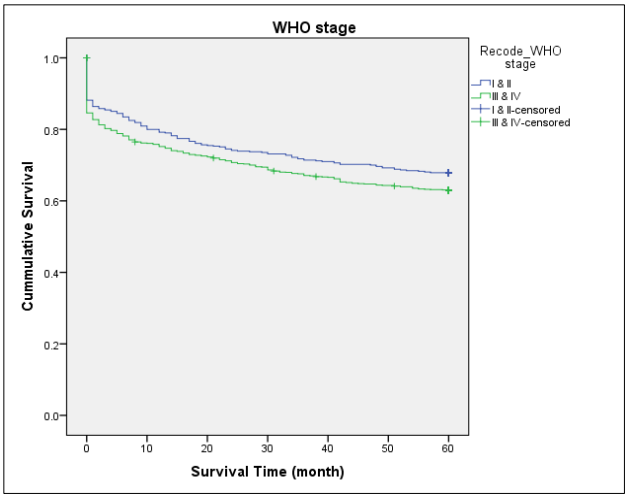

Figure 2: Survival outcomes (Kaplan-Meier analysis) by WHO stages.

Determinants of mortality by using cox proportional hazard model during the study period showed highest incidence of mortality within first three months of initiation of ARV (Figure 5). The probability of mortality could be initiation of ARV at low CD4 T cell count (1-50 cells/cumm), HR 95% CI 1.85 (1.08-3.4), maximum cases belongs to WHO stage III and IV CI 1.27 (0.81-2) and 1.72 (0.73-4.07); PLHIV on SLN/SLE had CI of 96.04 (13.48-684.15); ZLN/ZLE-14.53 (2.03-104.07) with increased number of IDUs CI 1.86 (1.25-2.78) with increased number of OIs, commonest being HBV CI 1.86 (1.01-3.41); HCV CI 1.43 (0.91-2.25), TB CI 1.36 (0.85-2.17); cryptococcal meningitis CI 1.00 (Table 3).

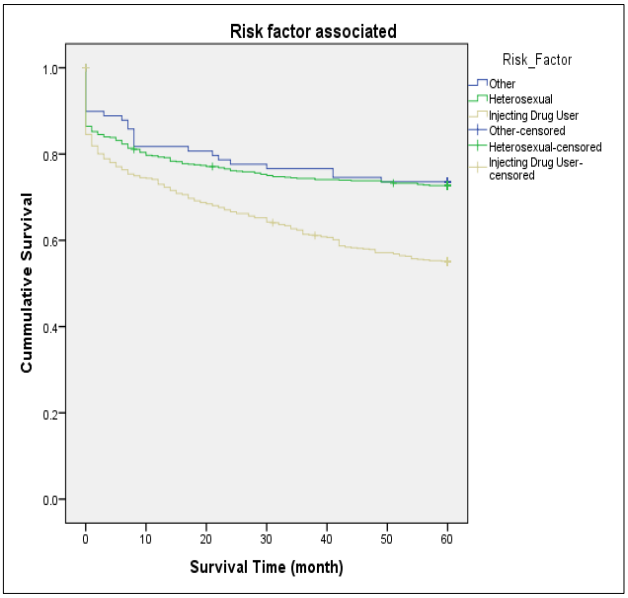

Figure 3: Survival outcomes (Kaplan-Meier analysis) by risk factors associated.

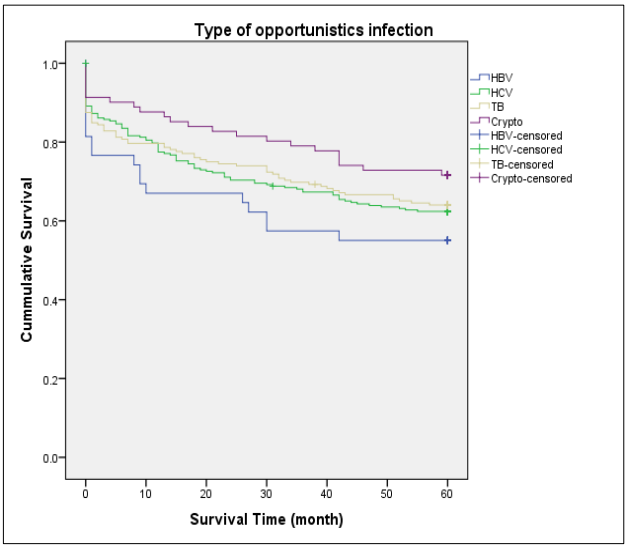

Figure 4: Survival outcomes (Kaplan-Meier analysis) by specific associated/ opportunistic infections.

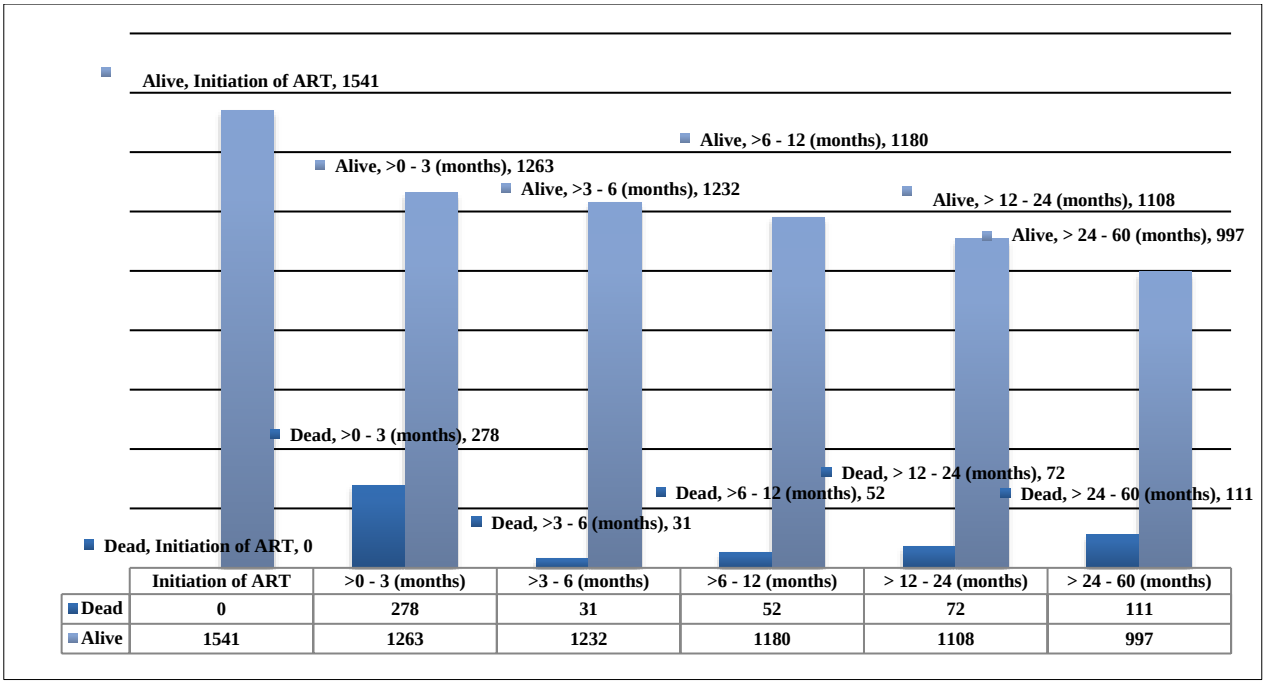

Figure 5: Survival outcomes (Kaplan-Meier analysis) by ART patients till 60 months from initiation.

Table 2: Characteristics and probability of survival during 5 years of follow-up (Kaplan Meier method) in 2004-2009 (n=1541).

Characteristics		Estimated survival probability over 5 years and CI		P-value [a]
Sex of ART patient	Male	67.67	(65.17-70.33)	< 0.001
	Female	79.67	(76.33-83.0)	
CD4 count at ART initiation (cells/mm^3)	1-50	55.17	(49.67-60.50)	< 0.001
	51-200	74.00	(71.00-76.17)	
	201-350	80.00	(75.83-84.17)	
	≥351	75.83	(64.33-87.33)	
WHO stage	I and II	74.50	(71.00-78.00)	0.049
	III and IV	70.17	(67.50-72.67)	
ART regimen	SLE/SLN	26.17	(23.00-29.17)	< 0.001
	TLE/TLN	98.50	(97.67-99.33)	
	ZLE/ZLN	79.33	(75.67-82.83)	
	Other [w]	97.83	(95.67-99.46)	
Risk factors associated	Injecting drug users	65.50	(62.33-68.67)	< 0.001
	Heterosexual	76.50	(73.67-79.50)	
	Others[x]	78.67	(71.17-86.00)	
Type of opportunistic infections	TB	43.65	(40.23-47.07)	0.2
	HBV	37.65	(29.74-45.57)	
	HCV	42.75	(39.84-45.66)	
	Cryptococcal meningitis	48.44	(43.91-52.97)	

[a]Log rank test, [w](Other) Second-line ART regimen and third - line ART, [x] (Others) includes mother to child ransmission, man having sex with man, blood transfusion and unknown.

The estimated overall survival probability on ART at 60 months was 71.58% (95% CI 69.52-73.67) with 67.67% (95% CI 65.17-70.33) in males and 79.67% (95% CI 76.33-83.0) in females. The probability of survival was higher among females than males (log rank test, p<0.001).

DISCUSSION

The use of antiretroviral (ARV) has shown improved survival among people living with HIV (PLHIV) worldwide due to suppression of viral replication, restoration of immunologic function, reduction in HIV

related morbidity and mortality.[1,7-9] The estimated overall survival probability on ARV initiation at 60 months was 71.58%. This result was higher in comparison to study done in Tanzania and lower against that of South Indian and China.[1,10,11] The survival rate for males for this study was 67.67% and females 79.67% indicating survival rate was higher in female than male population. This finding was at par with other studies.[10,12] This could be due to poor adherence of treatment among males, most of them are IDUs as risk behaviour (46.12%) and also associated with HBV/HCV co-infection.[13,14] Male:Female ratio was approximately 2:1 which is in line with Tanzanian study.[11] Study done in South India and Ethiopia, M:F was 3:115.[12]

Table 3: Determinants of mortality among the subjects using cox proportional hazard model (2004-09, 2005-10, 2006-11, 2007-12, 2008-13, 2009-14).

Variables		Hazard ratio (95 % CI)	
CD4 count at ART initiation (cells/mm^3)	1-50	1.85	(1.08-3.14)
	51-200	1.03	(0.61-1.73)
	201-350	0.73	(0.42-1.3)
	≥351	1.00	Ref
WHO stage	I	1.00	Ref
	II	1.08	(0.68-1.73)
	III	1.27	(0.81-2.00)
	IV	1.72	(0.73-4.07)
ART regimen	SLE/SLN	96.04	(13.48-684.15)
	TLE/TLN	0.93	(0.12-7.16)
	ZLE/ZLN	14.53	(2.03-104.07)
	Other[w]	1.00	Ref
Risk factors associated	Heterosexual	1.05	(0.7-1.58)
	Injecting drug users	1.86	(1.25-2.78)
	Others[x]	1.00	Ref
Opportunistic infection	No	1.00	Ref
	Yes	1.02	(0.85-1.21)
Specific opportunistic /associated infection	TB	1.36	(0.85-2.17)
	HBV	1.86	(1.01-3.41)
	HCV	1.43	(0.91-2.25)
	Cryptococcal meningitis	1.00	Ref

The survival rate for 2004-2009 was 61.5%, 2005-2010 was 70%, 2006-2011 was 63%, 2007-2012 was 56.3%, 2008-2013 was 77.2% and 2009-2014 was 71.1%. Similar study is also done in South West China where the follow up was done for 120 months.[11] The improvement in the survival rate was seen from 2008 onwards following good adherence to ARV, timely detection of opportunistic infections (OIs) and side effects of drugs in this centre.

The median age at the time of initiation of ARV was 36 years which was in line with study done in Nepal and Botswana.[16,17] The median CD4 T cell count at ART initiation was 131 cells/cumm. The overall baseline median CD4 T cell count of deceased patients was 104 cells/cumm, comparatively lower than that of alive and on treatment (143 cells/cumm). This finding is at par with study done by Farhani et al.[18]

WHO stage I, II had better survival outcome than stage III and IV. Percentage of cases in WHO stage III was highest in this study. Similar finding was reported by Setegn et al and Tilaye work nets Abebe et al.[12,19] Highest risk factor for this study was IDUs followed by heterosexual. They usually die earlier due to associated HCV, HBV co-infections.[13,14] Commonest OIs found in this study were HBV, HCV, tuberculosis and cryptococcal meningitis. Incidence of tuberculosis was higher in other studies from India and abroad.[1,7,18,20] The baseline ARV regime in the beginning of the study was SLN/SLE and ZLN/ZLE which was switched to TLN/TLE, if any side effects of ZLN/ZLE occurred and d4T was discontinued. The ARV drug TLE was initiated for all PLHIV irrespective of sex, CD4 count since 2014. Thus, number of patients on TLE was 602 during the study with a survival rate of 98%. There were 132 cases on 2nd line ART, 5 cases on 3rd line ART started privately and registered in this study centre. Dispensing of 2nd line and 3rd line ARV for them was initiated since 2008 and 2016 respectively.

Increased rate of mortality was seen in first three months after initiation of ART. This could be due to presence of

OIs, late initiation of ART at low CD4 T cell count; following IRIS and drug toxicities. Similar picture was also seen in low income countries.[6,16,18,21,22] In a study done by Bachani et al, the majority of deaths occurred in the first six months of treatment.[24] Studies done in Ethiopia, Uganda and South India showed majority of death occurred in the first year of ART initiation.[1,12,23]

According to Tricky et al, treatment done by modern ARV drugs containing protease inhibitors with NNRTI or NRTI increases the life expectancy of PLHIV by around 10 years for both sexes in developed countries.[25]

There were a few limitations for this study. Completeness of data entry in different documents under the programme has always been a practical challenge and it adversely affected capturing accurate data especially the record for death. Poor regular physical attendance, adherence and follow-up of patients has also been a realistic challenge for capturing a representative data. Viral load study was not included in this study as it was not available under the programme during the period of study.

CONCLUSION

Anti-retroviral therapy improves survival of PLHIVs. The currently available ARV drugs under NACO programme have better suppression of HIV replications, are less toxic and have low pill burden and fewer side effects thereby improving the survival of PLHIVs. The combined ARV regimen used in the earlier days were not much inferior to the currently available ARV drugs if initiated timely with proper prophylaxis of OIs, good adherence, good nutrition and timely management of drug toxicities and IRIS. In economically poor setting, treatment with any of the available ARV drugs improved the survival of PLHIVs.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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