

# Survival Pattern and Its Determinants among Adult HIV-Infected Patients after Initiation of HAART in Dilla Hospital Ethiopia

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## Abstract

**Background:** In resource poor countries like Ethiopia the survival of patients treated with ART depends on a variety of factors, which might vary greatly with economic, demographic, behavioral and health risk factors. However, factors affecting survival in Ethiopia are poorly understood. The aim of this study is to determine causes of mortality in adult HIV-positive patients receiving highly active anti-retroviral treatment (HAART) in Dilla referral Hospital.

**Methods:** The medical records of 1391 ART patients who enrolled at Dilla Hospital between 2010 and 2014 were reviewed and sociodemographic, clinical, behavioral and immunological data were collected. Multivariable Cox proportional hazards regression model was used to measure risk of death and identify the independent predictors of mortality.

**Result:** Out of 1391 cohorts of adults ART patients 1081 (77.7%) were alive and continued their treatment in the hospital, 128 (9.2%) were reported dead, 111 (8%) were transfer out, and 71 (5.1%) were lost follow up. The probability of remaining alive and on treatment after 60 months of follow up was 89.3% for TB/HIV patients and 91.1% for HIV only infected patients. HIV patients who developed TB had shorter survival time than not developed TB. Death occurred 26% and 52% in the first 3 and 12 months of ART initiation respectively. The overall incidence rate of mortality during ART treatment was 3.5 per 100 person year observations (PYO). In multivariate analysis low body weight BMI <18.5 kg/m<sup>2</sup> (HR 3.12, 95% CI 1.39-7.76, P<0.0001), CD4 count less than 50 cells/mm<sup>3</sup> (HR 4.55, 95% CI 1.19 – 8.44, p <0.002), anemia, WHO clinical stage III and IV, drug addiction and presence of active TB infection were predictor of survival and statistically significant association with mortality in HIV patients under ART follow up.

**Conclusion:** The presence of lower baseline CD4-cell, TB infection, WHO clinical stage III and IV, lower body weight, anemia, and drug addiction were factors associated with mortality among ART clients. Improving nutritional status, prevention and control of TB and other opportunistic infections were the recalled recommendations to decrease AIDS-related mortality. These determinants should be taken into account by health care providers to enhance better clinical outcomes of ART attendees.

**Keywords:** Predictors, TB/HIV, HAART, Survival.

## Abbreviation

HAART: Highly Active Anti-Retroviral Treatment; TB: Tuberculosis; HIV: Human immunodeficiency virus; AIDS: Acquired immune deficiency syndrome; ART: Antiretroviral therapy; WHO: World health organization; BMI: Body Mass Index.

## Introduction

Without antiretroviral therapy (ART), most HIV-infected

individuals will eventually develop progressive immunodeficiency marked by CD4 T lymphocyte (CD4) cell depletion and leading to AIDS-defining illnesses and premature death. The primary goal of ART is to prevent HIV-associated morbidity and mortality [1,2].

Globally, an estimated 35.3 million people were living with HIV in 2012, compared with previous years more people are receiving the life-saving antiretroviral therapy. There were 1.6 million AIDS deaths in 2012 [3]. While sub-Saharan Africa is home to only 12.5% of the world's population, it accounts for about 68% of the world's HIV infected population [4]. The region still accounted

for 74% of all the people dying from AIDS-related causes in 2013 [5]. Early mortality rates in sub-Saharan Africa are very high; between 8% and 26% of patients die in the first year of ART, with most deaths occurring in the first few months. Mortality rates are likely to depend not only on the care delivered by ART programs, but more fundamentally on how advanced disease is at program enrollment and the quality of preceding health-care [6,7].

Ethiopia has one of the largest populations of HIV infected people in the world [8]. There are nearly 1.2 million people living with HIV/AIDS. The adult prevalence rate is estimated at 2.4% and the incidence rate is 0.29%. The prevalence and incidence rates significantly vary between geographical areas and gender. The urban prevalence rate is estimated at 7.7%, while the rural prevalence rate is 0.9%. A total of 28000 AIDS death and an estimated 800000 AIDS orphans annually [3].

The study had discovered in resource poor countries like Ethiopia the survival of HIV/AIDS patients treated with ART depends on a variety of factors, which might vary greatly with economic, demographic, behavioral risk and health factors. In other words, even-though ARV treatment has shown significant clinical importance by meeting the goal of therapy, we are still facing a number of deaths that could be avoided by appropriate interventions on certain factors such as socio-economic, demographic, behavioral risk and health factors [6,9,10]. The independent predictors of survival among peoples living with HIV/AIDS and on antiretroviral therapy remain poorly understood in Ethiopia. Therefore, the aim of this study is to determine causes of mortality in adult HIV/AIDS patients receiving ART in Dilla referral Hospital.

## Methodology

### Study Design and Participants

The study was conducted in the Dilla Referral Hospital, Gedeo zone, Southern Nations Nationalities and Peoples' Regional State, Ethiopia. Since 2005, the hospital providing a wide range of HIV prevention, treatment, care, and support services. HIV care in Ethiopia is delivered by a multidisciplinary team. The team normally consists of a clinician (medical doctor, nurse, or health officer), pharmacy personnel, and counselors for support with ART treatment adherence. According to the national ART guideline, eligibility for initiation of HAART is determined using CD4 count and WHO clinical stage. When CD4 count is not available, patients with WHO clinical stage III and IV were eligible for treatment. In addition, patients with WHO clinical stage II conditions with Total Lymphocyte Count (TLC) less than 1,200 cells/ml are considered for treatment [11]. This study was a retrospective cohort study of HIV and TB/HIV co-infected patients who started antiretroviral therapy (ART) at the Dilla Hospital. The current study included adult patients (age>15 years) who enrolled for ART between 2010 and 2014, assessed the mortality on HIV and TB/HIV cohorts and its predictive factors on both population.

### Data collection method

Data were collected by two ART nurses from the Hospital. All

available information on patient records was checked and an appropriate data extraction format was prepared. This period 2010-2014 was selected in order to have the nearest five year follow up study period. In this period the facility started full implementation of standardized formats have been used for patient data record. Pre-ART registers, lab requests, follow-up forms, anti TB record forms, ART intake forms, and patient cards were reviewed to fulfill some of the missed value.

### Study variables

The dependent variable in this present study is survival time. It was defined as the survival of the patients from the month of enrollment in the HIV-care and starts receiving antiretroviral therapy till one of the following events registered; death, lost to follow up, or transferred out to other health institution. This meant that the survival data studied here were censored in month. The predictor variables for dependant variable survival time of HIV were related to independent variables of the socio- demographic, clinical, behavioral and immunological status of the patients.

'Prevalent TB' was defined by any patient with a known TB diagnosis who was currently receiving anti-TB therapy at the time of ART initiation. 'Incident TB' was defined any new clinical episode of TB diagnosed after starting antiretroviral therapy (ART).

### Drug addiction

In present study we defined consumption of alcohols and smoking of tobacco.

### Data process and analysis

Pearson  $\chi^2$  statistic tested used for dichotomous and categorical variables. The Cox model assessed the Hazard Ratios (HR) of potential risk factors. Multivariate Cox models were constructed by clinically significant variables. Kaplan-Meier curve was used to compare survival curves between the different categories. This was done by using EpiData version 3.1 software and it was exported for analysis using the Statistical Package for Social Science version 20.0

### Ethical consideration

Ethical clearance was obtained from the ethical review committee of Zhengzhou University, China, and South Ethiopia health bureau technology and research department review board. The names of the subjects won't be extracted to ensure privacy of patient information and confidentiality was maintained throughout the data collection process, analysis, and manuscript preparation.

## Result

### Baseline socio-demographic Characteristics of study participants

Records of 1391 patients were reviewed, those who initiated ART in Dilla referral hospital, Ethiopia within the period of interest 2010-2014. It Contributing 3648 person-year of observation (PYO) with a median follow up of 3 year. In this study, the two cohorts (HIV & TB/HIV co infected patients) were not statistically

different in any of the identified socio-demographic attributes. The median ages of the subjects were 32 years (range 16-85 years). Male participants with HIV and TB/HIV co-infected occupied 54.7%. More than half (57.2%) of the patients lived in urban area, 56.5% of the attendants in ART clinic have got married, nearly 76% of the patients had at least primary education or more. 19.5% of the patients either drinking alcohols or using tobacco. 1247 (89.6%) patients disclosed their HIV status for their relatives. Table 1 summarized the baseline socio-demographic characteristics of the patients.

Baseline characteristics	Category	Frequency	Percentage	X <sup>2</sup> Value	P value
Gender	Male	761	54.7	0.004	0.951
	Female	630	45.3	1	
Age	16-24	479	34.4	0.007	1.000
	25-34	464	33.3	4	
	35-45	301	21.7		
	46-59	134	8.9		
	60+	23	1.7		
Marital status	Single	403	29	0.009	1.000
	Married	786	56.5	3	
	Divorce	140	10.1		
	Widowed	62	4.5		
Resident	Urban	795	57.2	0.002	0.995
	Rural	596	42.8	1	
Religion	Christian	1771	91.4	0.010	0.995
	Muslim	88	6.3	2	
	Others	32	2.3		
Educational status	No formal education	333	24	0.007	1.00
	Primary education	548	39.4	3	
	Secondary education	344	24.7		
	More than secondary	166	11.9		
Employment	Employed	727	52.3	0.0000	0.996
	Unemployment	664	47.7	1	
Family size	≤ 2	755	54.4	0.01	1.00
	3-4	626	45.0	2	
	> 4	8	0.6		

**Table 1:** Baseline socio-demographic characteristics of HIV patients in Dilla Hospital, Ethiopia from 2010-2014.

### Baseline Clinical and immunological characteristics of the study subjects

The clinical condition of the subject and treatments were difference with their diagnosis type. The mean CD4 counts at baseline were 164 (±8.17) and 186 (±2.48) cells/mm<sup>3</sup> for TB/HIV co-infected and HIV patients respectively. The baseline weight differed significantly between the two cohorts, the mean body mass index were 18.2 kg/m<sup>2</sup> in TB/HIV co-infected patients and 20.5 kg/m<sup>2</sup> in HIV cohorts. From total cohorts 558 (40.1%) of the patients were underweight (defined by BMI <18.5 kg/m<sup>2</sup>), 456 (32.5%) of

HIV and TB/HIV co infected clients were categorized under WHO clinical stage III and IV according to Federal Ministry of Health in Ethiopia treatment guideline. Table 2 shows baseline Clinical and immunological characteristics of the study subjects.

Baseline characteristics	Category	Frequency	Percentage	X <sup>2</sup> Value	P value
Tuberculosis infection	Positive	178	12.8	0.001	0.894
	Negative	1213	87.2	1	
Tuberculosis category	Pulmonary TB	35	19.7	0.010	0.970
	Extra pulmonary	143	80.3	1	
Timing of TB	Incident TB	160	89.9	0.002	0.932
	Prevalent TB	18	10.1	1	
Cotrimoxazole preventive therapy	Yes	1354	97.3	0.000	0.987
	No	37	2.7	1	
WHO clinical stage	Stage I	465	33.4	10.30	0.003
	Stage II	470	33.8	3	
	Stage III	296	21.3		
	Stage IV	160	11.5		
CD4 counts	>200 cells/mm <sup>3</sup>	14	1.0	11.2	0.002
	101-200cells/mm <sup>3</sup>	378	27.2	3	
	50-100 cells/mm <sup>3</sup>	600	43.2		
	<50 cells/mm <sup>3</sup>	398	28.6		
Anemia status	No anemia	8	0.6	19.9	0.004
	Mild anemia	815	58.6	3	
	Moderate anemia	377	27.1		
	Severe anemia	191	13.7		
Body mass Index BMI (kg/m <sup>2</sup> )	<18.5	558	40.1	0.009	0.0001
	18.5-24.9	621	44.6	3	
	25.0-29.9	175	12.6		
	30.0 +	37	2.7		
Isonized preventive therapy	IPT user	712	51.2	0.018	0.93
	Non IPT user	679	48.8	1	
Regimen	1 <sup>st</sup> line regimen	1351	97.1	0.007	1.00
	2 <sup>nd</sup> line regimen	40	2.9	1	
Patient condition	Working	586	42.1	0.001	0.78
	Ambulatory	687	49.4	2	
	Bed ridden	118	8.5		
Addiction	Addicted	271	19.5	8.039	0.045
	Not addicted	1120	80.5	1	
Disclosure status	Disclosed	1247	89.6	0.027	0.868
	Not disclosed	144	10.4	1	

**Table 2:** Baseline clinical, immunological and risk behavior characteristics of HIV patients in Dilla Hospital, Ethiopia from 2010-2014.

### Survival pattern of the cohorts

The median follow-up period was 25 months (survival time for death was 12 months and for alive 26 months), out of 1391 cohorts of adults ART patients were censored 1081 (77.7%) were alive and continued their treatment in the hospital, 128 (9.2%) were reported dead, 111 (8%) were transfer out, and 71 (5.1%) were lost follow up. The probability of remaining alive and on treatment after 60 months of follow up was 89.3% for TB/HIV co-infected patients and 91.1% for HIV only infected patients. HIV patients who developed TB had shorter survival time than not developed TB. Death occurred 33 (26%) and 66 (52%) in the first 3 and 12 months of ART initiation respectively. The overall incidence rate of mortality during ART treatment was 3.5 per 100 person year observations (PYO).

### Predictors of mortality

In multivariate analysis low body weight, CD4 count, anemia, WHO clinical stage, cigarette smokers and presence of active TB infection were statistically significant association with mortality in HIV patients under ART follow up (P value <0.05). Those patients who have BMI <18.5 kg/m<sup>2</sup> were three times more likely to die than BMI more than 25 kg/m<sup>2</sup> at baseline (HR 3.12, 95% CI 1.39-7.76, P<0.0001). Patients with low CD4 cell count less than 50 cells/mm<sup>3</sup> were 4.55 times increased risk of death compared to those presenting with a CD4 cell count >200 cell/mm<sup>3</sup> (HR 4.55, 95% CI 1.19-8.44, p<0.002). Patients with drug addiction were two times more likely to die compared to patients not addicted with alcohols and using tobacco (HR 2.03, 95% CI 1.11- 4.56, P<0.002). WHO clinical stage 3 and 4 were strongly associated with risk of death as compared with those at clinical stage 1 and 2 (HR 11.25, 95% CI 8.67-17.96, p<0.003). Severe anemia in ART clients five times more likely to die compared with those without anemia (HR 5.14, 95% CI 3.12-9.65, p<0.001). Table 3 shows the hazard ratios from the univariate and multivariate analysis of the association between the possible determinants of mortality and risk of death.

Determinants	Univariate analysis		Multivariate analysis (CPH)	
	HR (95% CI)	P value	HR (95% CI)	P value
WHO clinical stage				
Stage I and II (ref)	1.00		1.00	
Stage II and IV	12.34 (7.54-19.8)	0.002	11.25 (8.67-17.9)	0.003
CD4 counts				
>200 cells/mm <sup>3</sup> (ref)	1.00		1.00	
101-200cells/mm <sup>3</sup>				
50-100 cells/mm <sup>3</sup>				
<50 cells/mm <sup>3</sup>	6.32 (2.43- 9.26)	0.001	4.55 (1.19-8.44)	0.002
Anemia status				
No anemia (ref)	1.00		1.00	
Mild anemia				
Moderate anemia				
Severe anemia	6.14 (3.56-11.33)	0.001	5.14 (3.12-9.65)	0.001

Addiction				
Not addicted (ref)			1.00	
Addicted			2.03 (1.11-4.56)	0.002
Negative (ref)	1.00			
Positive	2.45 (1.21-5.65)	0.004		
Body mass Index				
25.0-29.9 kg/m <sup>2</sup> (ref)	1.00		1.00	
18.5-24.9 kg/m <sup>2</sup>	2.9 (1.24-4.2)		2.3 (.74-3.2)	
<18.5 kg/m <sup>2</sup>	4.21 (1.45-8.86)	0.04	3.12 (1.39-7.76)	0.0001
Functional status				
Working (ref)	1.00			
Ambulatory	2.5 (1.74-5.3)			
Bed ridden	4.32 (1.46-8.45)	0.001		

**Table 3:** Hazard ratios (HR) of mortality in Dilla Referral Hospital ART patients. ref. - reference group, CPH- Cox proportional hazard; kg/m<sup>2</sup> -kilogram per meter square; HR- hazard ratio.

### Discussion

Despite from scale up of ART, mortality is a major challenge in sub-Saharan Africa. This study used the Classical techniques to analyze risk factors for the survival time of HIV/AIDS patients under ART follow-up. A number of variables were used to explain the variation in the survival time of HIV patients using the Cox Proportional Hazards Model.

The findings indicate that from the registered cohort, there were 128 (9.2%) deaths, providing an incidence density of mortality during ART treatment was 3.5 per 100 person year observations (PYO). About 111 (8%) were transfer out and 71 (5.1%) patients were lost to follow up. Majority of death occurred in the first 3 and 12 months of ART initiation 26% and (52%) respectively. This was comparable to previous studies in Ethiopia and other country in sub-Saharan Africa [4,12,13]. The overall mortality rate was lower compared to other studies conducted in other regions of Ethiopia, India and Cameroon 14.1%, 13% and 28.5% respectively [9,14,15].

The probability of remaining alive and on treatment after 60 months of follow up was 89.3% for TB/HIV co infected patients and 91.1% for HIV only infected patients. HIV patients who developed TB had shorter survival time than not developed TB. Immunological studies have also shown the host responses to M. tuberculosis enhance HIV replication, thus accelerating the natural progression of HIV and further depressing cellular immunity [16]. Decreased gut absorption of anti-tuberculosis drugs has been suggested by some reports, leading to impaired treatment outcomes including death [17]. Delayed initiation of ART or after advanced stage of the disease in the cohort has also contributed to higher mortality [18]. Low body weight, CD4 count, hemoglobin level, WHO clinical stage, tobacco use, consuming alcohols and active TB during treatment were statistically significant association with mortality in HIV patients under ART follow up ( P-value <0.05).

Previous studies done in sub-Saharan Africa shows that CD4 cell count less than 50 cells/mm<sup>3</sup> was one of the major predictor of



death of patients enrolled in ART [4,6]. This study was consistent with those findings i.e. Patients with low CD4 cell count less than 50 cells/mm<sup>3</sup> were 4.55 times increased risk of death compared to those presenting with a CD4 cell count >200 cell/mm<sup>3</sup> (HR 4.55, 95% CI 1.19-8.44, p<0.002). However, a study conducted in Nepal had contrast findings; the baseline CD4 count was not significantly associated with mortality on ART cohorts [19].

Alcohol consumption and tobacco usage were other influential covariates for the survival of patients. Studies shows drinking alcohol, tobacco or taking other drugs can affect your immune system and may speed up the progression of the disease. Drinking or taking drugs also can affect your HIV treatment adherence [20]. In our study the Cox proportional hazard analysis shows, Patients using alcohols and cigarette were two times more likely to die compared to patients not using alcohols and tobacco.

Regarding baseline anemia in ART clients were five times more likely to die compared with those without anemia (HR 5.14, 95% CI 3.12-9.65, p<0.001). Similar comparable finding showed in Ethiopia that anemia could be an indicator of advanced disease or clinical feature of some opportunistic infections which might aggravate the risk of death in ART patients [21].

This study has both strengths and limitation. Relatively larger sample size from long period of retrospective follow-up and the use of clinical, immunological, behavioral and social data were the strengths of this study. Limitation of the study is that loss to follow-up and transfer out rates are high, and as such, the outcome for these patients is not known. It is possible that patients who were lost to follow-up might have died. Retrospective nature of the study data were lacks the completeness of patient records and author could not ascertain that all recorded death report were AIDS-related mortality.

## Conclusion

In conclusion findings of this study point out that there were 128 deaths giving the incidence of mortality was 3.5 per 100 person-years of follow up. Of these, 66 (52 %) death happened within the first year of ART initiation in 5 years follow up. The presence of lower baseline CD4-cell, TB infection, WHO clinical stage, lower body weight, anemia, and drug addiction were factors associated with mortality among ART clients. Improving nutritional status, prevention and control of TB and other opportunistic infections were the recalled recommendations to decrease AIDS-related mortality. These determinants should be taken into account by health care providers to enhance better clinical outcomes of ART attendees.

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