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Identifying Factors Related to the Survival of AIDS Patients under the Follow-up of Antiretroviral Therapy (ART): The Case of South Wollo

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Abstract The expansion of HIV/ADIS epidemic has now become a burning issue globally. HIV infection has changed from a fatal condition to a manageable chronic illness mainly due to the development of antiretroviral therapy (ART). Even if ART treatment has shown significant clinical importance by meeting the goal of therapy, we are still facing a number of deaths due to certain socio-economic, demographic, behavioral risk and health factors. The aim of this study is for identifying determinant factors for the Survival of HIV/ADIS Infected Patients under the follow-up of antiretroviral therapy (ART) at Boru Meda and Dessie Referral Hospitals and Kombolcha Health Center. The data for this research were collected during the follow-up time from January 1, 2008 to December 31, 2011. Out of a population of HIV-patients who were taking antiretroviral therapy in the hospitals and health center in that period, 654 patients were selected based on simple random sampling technique for this study. The study subjects were people in the age range from 15 to 75 years. The Kaplan-Meier Method was employed to estimate survival; the Cox Proportional Hazards Regression Method was used to identify determinants of survival. After initiation of the antiretroviral treatment, HIV-positive patients the estimate median survival age was found to be 48 months (CI: 2.98-4.97 years). Living rural, order baseline age, not working due to illness, smaller CD4 count, weight, and lymphocyte count, HIV-TB co-infection developing and being in WHO clinical Stage IV were identified as a documented risk factors for shortened the survival experience of the HIV-patients who are in care of ART. The mortality among our patients was comparable to that reported from other low-income countries. Earlier initiation of ART may reduce the high mortality rates observed. Similar studies in the future need to consider predictors in addition to those considered in this study and the clinical advantage of ART that brings improvement on the clinical characteristics in the follow up period.

Keywords: *antiretroviral, bacterial, infection, global, patients*

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1. Introduction

Acquired Immune Deficiency Syndrome (AIDS) which is believed to be caused by the Human Immunodeficiency Virus (HIV) has been the major problem worldwide. The rate of spread of the HIV/AIDS epidemic has reached a shocking level. The expansion of the epidemic has now become a burning issue globally and this is particularly so more in developing countries; specially, in Sub Saharan Africa [1]. In fact, Sub-Saharan Africa accounts for 22.4 million infections, which is about 67% of the total HIV burden. The number of people estimated to acquire new infections is around 1.9 million accounting for 68 % of the total number of new infections [2]. This was noted as a significant reduction in the number of new cases since 2001. However, it was also reported that HIV/AIDS has become the leading cause of death in the region [1]. Ethiopia is one of the Sub-Saharan African countries most severely affected by the HIV/AIDS pandemic. Currently, the national adult prevalence rate is estimated at 2.3 percent and an estimated number of 1.2 million people are living with HIV/AIDS. An estimated 67,000 lost their lives due to AIDS at the end of 2007 [3].

The world is now above the third decade of AIDS epidemic since elapsed. During these years HIV infection has changed from a fatal condition to a manageable chronic illness mainly due to the development of antiretroviral therapy (ART). ART for the treatment of HIV infection has been shown to profoundly alter HIV disease progression, including incidence of opportunistic infections in people living with HIV [4]. The goal of this therapy is to improve survival; to reduce HIV associated morbidity and mortality, to increase the quality of life, to

restore immune function and to achieve maximal and sustained suppression of viral replication [5]. By 2010, WHO has planned to put 9.8 million people on ART with the goal of providing universal access to HIV care and ART [6].

Accurate estimates of expected survival times, survival rates of AIDS patients and variables that influence survival are important for projecting future numbers of AIDS cases, increasing understanding of the patho-physiology of the disease, clinical decision making and planning health service interventions [3,7]. In addition for monitoring the progress of the HIV/AIDS epidemic as new treatments, previous studies have shown that survival studies of patients with AIDS provide information on the response of different subgroups to the syndrome, and enable mathematical modelers and health care professionals to estimate future needs [8].

However, most of the studies in Ethiopia focused on the prevention and factors that increase the chance of contracting the disease. It can be said that limited works were conducted on the survival of HIV positives taking ART [9]. Although the current HIV/AIDS surveillance estimates indicate some encouraging signs in that the epidemic is stabilizing, the observed changes are not sufficient enough compared to the desired goals of the response against the epidemic. It is believed that, in resource poor countries like Ethiopia the survival of patients with AIDS treated with ART depends on a variety of factors, which may also vary greatly with economic, demographic, behavioral risk and health factors. In other words, even if ART treatment has shown significant clinical importance by meeting the goal of therapy, we are still facing a number of deaths that can otherwise be avoided by appropriate interventions on certain socio-economic, demographic, behavioral risk and health factors. Thus this study was undertaken with objectives to identify predictors that have impact on the survival of HIV AIDS patients with the hope that the results would contribute to existing knowledge.

2. Method

2.1. Study Area

The study was conducted in selected governmental health institutions in South Wollo, Amhara region, Ethiopia from January 01 to December 31, 2012. It is 401 Kilo meters far from Addis Ababa the capital city of Ethiopia. The selected institutions are Dessie referral Hospital, Boru Meda Hospital and Kombolcha Health Center.

2.2. Data

The target populations for this study were patients under the follow up of ART at Boru Meda and Dessie Referral Hospitals and Kombolcha Health Center from 1 January, 2008 to 31 December, 2011. At the Hospital's ART clinic the data were recorded using the standardized data collection formats and registers prepared by the Ministry of Health. Data recording was done by health officers and nurses working in the clinic. The examining medical doctors also recorded follow up information about their patients. Based on this record of the patients who had complete information, the variables which are important for the study was collected using the patients' medical registration number (MIR) without any direct contact with the patients, instead by communicating with the nurses and counselors to get the medical record and other information important for the study.

2.3. Sample Size

In determining required sample size there are a number of issues/points one has to take into account. Some of the issues are: objective of the research, design of the research, cost constraint, degree of precision required for generalization and etc. Accordingly, the sample size determination formula

$$n = \frac{\frac{Z^2 p(1-p)}{d^2}}{1+\frac{1}{N}\left(\frac{Z^2 p(1-p)}{d^2}-1\right)} \quad (1)$$

Above equation was adopted for this study (Cochran, 1977), where Z is the upper $\alpha/2$ points of standard normal distribution with α =0.05 significance level, which is Z =1.96. The degree of precision *d* is taken to be 0.023. The parameter p represents proportion of death. *P = 0.10* is used in this study obtained from previous study at Tikur Anbessa Specialized Hospital, Addis Ababa [9]. Accordingly, the sample size using the given formula becomes n = 594. 10% of the sample size, which is 60, is added to the determined sample size 594 to compensate for the random errors and the sample size, with population size *N=7165* for the current study become 654.

Next, we carried out sample size allocation to each Hospital and health center with proportional allocation. Then, patients were selected from each Hospital and Health Center using systematic sampling based on their Medical Registration Number (MRN) which is given to each patient who is taking ART.

2.4. Variables of the Study

The response variable in this research that was the "survival time" was defined as the number of months from the month of enrollment of a patient in the HIV-care till one of the events "death", "lost to follow up", "dropped out", "stopped", "transferred out to other health centers or hospitals" occurred. This meant that the survival data studied here were "right-censored".

The predictor variables relate to the social, demographic, medical and clinical background of the patients having these respective classifications; gender (male, female), residence (rural, urban), age at the start of ART (in full year), marital status at the start of treatment (single, separated, divorced, widowed), level of education at the start of treatment (no education, primary, secondary and above), CD4 count at the start of treatment(/mm3), weight at the start of ART (in kilograms), employment status at the start ART (unemployed, not working due to illness, on the job), total lymphocyte count at start the treatment, WHO clinical stage at start the treatment (stage I, stage II, stage III, and stage IV), and TB status at starting ART (negative, positive).

2.5. Statistical Analysis

The statistical analytic method used in this study is known as Survival Analysis. Survival data analysis involves the modeling and analyses of data that have a principal end point the time until an event occurs (time-to-event data). Survival Analysis considers conditional information on the remaining time of a subject's survival given current survival time. Survival data were censored in the sense that they did not provide complete information since, for a variety of reasons, subjects of the study may not have experienced the event of interest. The existence of variables that change over time is also a distinguishing feature in survival analysis.

Descriptive analysis of survival data utilizes non-parametric methods to compare the survival functions of two or more groups. The Kaplan-Meier estimator (product-limit-estimator) of the survival function [10] was employed for this purpose. The log-rank test was utilized to test whether observed differences in survival experience between/among the groups was significant or not.

The multivariable model used was the semi-parametric regression model known as the proportional hazards regression (PHR) model [11]. When a study involves multiple characteristics, appropriate statistical techniques must be used to select variables that have significant effects on survival and which are judged to be clinically meaningful for inclusion in a PHR model. Hence, the model development process identifies the relevant variables following model scrutiny as discussed in [12].

3. Results

3.1. Results of the Descriptive Statistics

A sample of 654 of the 7163 patients was selected that were followed during 1 January, 2008 to 31 December, 2011 using an appropriate sample size determination formula. Of those, about 87% were right-censored (dropout, transferred, loss and alive till the study period) and the remaining 13% uncensored (Died). A summary of the data for each level of variables is provided in Table 1. In order to investigate if there is significant difference between the survivals of a patient between categories of covariates, Kaplan-Meier survivor estimates all significant covariates in the log-rank test. In line with this, the log-rank statistical test is made in Table 1.

Table 2 gives the mean survival time and the results based on the log-rank test for each covariate. From the mean survival time in Table 2 HIV-positive patients lived for an average of 41.81 months (CI: 40.61-43.00 months. The p-values in Table 2 show differences in survival experience between two or more levels of predictors. All predictors with the exception of gender and education level manifest differences in levels of survival functions. A résumé emanating from descriptive analysis with reference to the seven predictors (leaving out sex, study site and education level) that manifest differences in survival are provided as follows.

Married patients lived for an average of six months longer than widowed patients whereas they live for an average of four months longer than single and divorce patients. Patients who were from rural residence, lived on average three months shorter than those from urban residence. Patients who are on job and unemployed lived on average 18 and 17 months longer than those didn't work due to illness, respectively.

Table 1. Socio-demographic and clinical characteristics of HIV-positive patients at ART start in Boru Meda Hospital, Dessie Referral Hospital and Kombolcha Health Center, 2008-2011, South Wollo, Amhara Region (n =654)

Variable	Category	Censored	Failed	Total	Percent censored
Gender	Male	204	27	231	88.3
	Female	361	62	423	85.3
Study area	Boru Meda Hospital	68	9	77	88.3
	Dessie Referral Hospital	335	54	389	86.1
	Kombolcha Health Center	162	26	188	86.2
Age Group	15-29	224	35	259	86.6
	30-40	249	29	278	89.5
	>= 45	92	25	117	78.6
Residence	Rural	273	53	326	84
	Urban	292	36	328	89
Marital Status	Single	77	15	92	83.7
	Married	318	34	352	90.3
	Divorced	127	25	152	83.6
	Widowed	43	15	58	74.1
Level of Education	Illiterate	168	29	197	85.3
	Primary	208	32	240	86.7
	Secondary and above	189	28	217	87.1
Base line CD4 Count	< 200/mm^2	309	57	366	84.4
	>= 200/mm^2	256	32	288	88.9
Base Line weight	< 44	112	26	138	81.2
	45 - 59	347	53	400	86.8
	>= 60	106	10	116	91.4
Employment Status	Unemployed	306	39	345	88.7
	Not working due to illness	21	19	40	52.5
	On job	238	31	269	88.5
WHO Clinical Stage	Stage I	114	19	133	85.7
	Stage II	235	28	263	89.4
	Stage III	176	28	204	86.3
	Stage IV	40	14	54	74.1
TB Status	Negative	532	74	606	87.8
	Positive	33	15	48	67.8
Base line lymphocyte count	< 1200 cells/mm^3	74	23	97	76.3
	>= 1200 cells/mm^3	491	66	557	88.2

HIV Patients, who developed TB, had shorter survival time than not developed TB: 12 months shorter than patients didn't develop TB. HIV-positive patients, with WHO clinical stage IV had an average of 8, 6 and 5 months shorter survival time than those in stages II, III and I, respectively. Those patients in clinical stage II had an average of 3 and 2 months longer survival time than stage I and III, respectively. Patients were having weights 45 and above kilograms lived four months longer on average than those having weight below 45 kilograms.

Patients, who had ages 15 to 29 years and 30 to 40 years, respectively, lived 3 and 5 months longer on average compared with those people who had ages greater than 40 years. Those patients having base line CD4 cell count above 200/mm^3 lived three months longer on average than patients with base line CD4 cell count below 200/mm^3. Similarly patients having base line lymphocyte count greater or equal to 2000 cells/mm^3 had on average 8 months longer than those had less than 2000 cells/mm^3 base line lymphocyte count.

Table 2. Mean survival time and Log-rank test p-values based on socio-demographic and clinical characteristics data of HIV-positive patients at ART initiation in Selected South Wollo Hospitals and health Centers, Amhara Region, 2008-2011, (n =654)

Variables	Mean Survival time	Chi-square	Log-rank p-value
Sex			
Female	42.406	.571	.450
Male	41.478		
Age			
15-29	41.785	7.532	.023
30-40	43.352		
>= 41	38.274		
Marital Status			
Single	40.232	11.888	.008
Married	43.452		
Divorce	40.786		
Windowed	37.655		
Educational level			
No education	41.536	.201	.904
Primary	42.181		
Secondary and above	41.701		
Residence			
Rural	40.265	6.339	.012
Urban	43.308		
Employment Status			
Unemployed	42.599	50.787	.000
Not working due to illness	24.783		
On Job	43.119		
TB Status			
Negative	42.418	16.252	.000
Positive	33.699		
Baseline CD4 Count			
<200	40.403	5.617	.018
>= 200	43. 485		
Baseline Weight			
<= 44	38.842	8.187	.004
> 45	42.893		
WHO Clinical Stage			
Stage I	40. 670	13.932	.003
Stage II	43.416		
Stage III	41.797		
Stage IV	35.345		
Baseline Lymphocyte count			
<1200	36.224	15.212	.000
>=1200	42.725		

Table 3. Estimated parameters for the preliminary Proportional Hazards Regression Model Containing variable significant at 25% level in the bivariate analysis for the data from selected South Wollo Health centers and Hospitals, Amhara region, 2008-2011, (n =654)

Variable	B	SE	Wald	df	Sig.	HR	95.0% CI for HR	
Age_cat								
Age_cat(1)	-.445	.262	2.879	1	.090	.641	.383	1.071
Age_cat(2)	-.732	.273	7.173	1	.007	.481	.282	.822
Residence	-.536	.216	6.144	1	.013	.585	.383	.894
Marital_Status								
Marital_Status(1)	-.674	.310	4.713	1	.030	.510	.277	.937
Marital_Status(2)	-.179	.327	.299	1	.585	.836	.440	1.589
Marital_Status(3)	.273	.366	.556	1	.456	1.314	.641	2.694
CD4	-.003	.001	10.161	1	.001	.997	.996	.999
weight	-.033	.013	6.362	1	.012	.968	.943	.993
employee								
employee(1)	1.602	.282	32.243	1	.000	4.964	2.855	8.630
employee(2)	-.125	.241	.268	1	.605	.883	.550	1.416
Lymphocyte count	-.911	.243	14.095	1	.000	.402	.250	.647
WHO								
WHO(1)	-.396	.298	1.766	1	.184	.673	.376	1.207
WHO(2)	-.130	.298	.190	1	.663	.878	.490	1.575
WHO(3)	.765	.353	4.706	1	.030	2.149	1.077	4.290
TB Status	1.088	.284	14.635	1	.000	2.967	1.700	5.179

3.2. Results of the PHR Model

The Cox model procedure that includes model selection, tests, diagnosis and fit confirmed that there were no problems with regard to interactions of main effects and confounding (see appendix B). Therefore, the results in Table 3 and Table 4 are based on the main effects and the following elaboration details survival experience based on estimated hazard ratios (HR). It should be pointed out that variables with p- values below 0.05 were considered as statistically significant. The relationship between each covariates and survival time of AIDS patients which are significant using a modest level of significance 25% to be included for further investigation in the multiple covariates model are presented in Table 3. P-value in Table 3 indicates survival of the patients is significantly related with all the proposed covariates except gender, study area and education level of the patient.

Table 4. Estimated parameters for the final Proportional Hazards Regression Model for the data from selected South Wollo Health Centers and Hospitals, Amhara Region, 2008-2011, (n=654)

Variable	B	SE	Wald	df	Sig.	HR	95.0% CI for HR	
Age group								
15-29	-.508	.268	3.585	1	.058	.602	.356	1.018
30-40	-.715	.279	6.560	1	.010	.489	.283	.846
>=41				0		1		
Residence								
Rural	.556	.231	5.798	1	.016	1.743	1.109	2.740
Urban				0		1		
CD4 Count	-.002	.001	7.720	1	.005	.998	.996	.999
weight	-.033	.013	6.320	1	.012	.968	.943	.993
Employee- Status			25.516	2	.000			
Unemployed	-.155	.247	.396	1	.529	.856	.528	1.389
Not working due to-illness	1.286	.313	16.905	1	.000	3.619	1.960	6.682
On Job				0		1		
Lymphocyte Count	-.031	.013	5.904	1	.015	.969	.945	.994
WHO clinical stage								
Stage I	-.178	.382	.217	1	.641	.837	.396	1.769
Stage II	-.867	.348	6.208	1	.013	.420	.212	.831
Stage III	-.863	.342	6.373	1	.012	.422	.216	.824
Stage IV				0		1		
TB Status								
Negative	-.627	.304	4.244	1	.039	.534	.294	.970
Positive				0		1		

The covariates in Table 2.3 were further investigated in the final model and seven were statistically significant at 5 % level of significant. Details of the variables of the final model were displayed in Table 2.4. Interpretations were made using final model as follows.

3.2.1. Socio-Demographic Characteristics

The referent category for age was the age group greater than 40 years. The estimated HRs for the age groups (15-29) and (30- 40] were 0.602 (CI: 0.356, 1.012) and 0.489 (CI:. 283,. 846), respectively. The age group (30-40] was significant (p-value = 0.01), meaning that patients whose age greater than 41 years were dying at a rate of 48.9% greater than age group (30-40). The hazard rate of rural residence patients was 1.74 times greater than urban residence patients (CI: 1.109, 2.74). For not working due to illness patients, the estimated HR was 6.19 (CI: 1.96, 6.682) as compared to the referent category “on Job” at the time of starting ART. The status of being unemployed did not have a significant contribution at 0.05 level. A 5 kilogram increase in weight resulted in an estimated HR of 0.968 (CI: 0.943-0.993).

3.2.2. Clinical Characteristics

less in CD4 count (HR: 0.998; CI: 0.996,. 999; p=0.005) and lymphocyte count (HR:. 969; CI:. 945,. 994; p=0.015) at start of ART were significant risk factors associated with the survival of HIV patients. The referent category pertaining to the WHO clinical stage was stage IV. Stage II and III are statistically significant and estimated HRs for those stage II and III, respectively, are 0.42 (CI: 0.212-0.7831) and 0.422 (CI: 0.216-0.824). The estimated hazard ratio for Negative TB status was 0.534 (CI: 0.294-0.974) relative to the category Positive TB status, meaning that patients TB develop were dying at a rate of 53.4% greater than not develop TB.

4. Discussion

This 4-year retrospective cohort study of HIV/AIDS patients on ART gives an insight into survival and its determinants in a hospital setting in Ethiopia. In this cohort, 14.1% of the patients died even if they were taking ART. The overall mortality rate was higher compared to other studies in Ethiopia, in which it was shown that in Addis Ababa Tikur Anbessa Specialized Hospital and at two district hospitals, Assela and Shashemene, located in the southern part of the Oromiyaa region, 10.0 and 10.3%, respectively [9,13]. On the other hand it was smaller compared to other studies conducted outside Ethiopia in which in Korea, Tanzania and Cameroon, 20.8, 29.7 and 23%, respectively [14,15,16]. Similarly, based on 564 sampled HIV patients who are taking ART, the mean and median survival time was almost 42 and 48 months. The median survival time was similar with [9] a four year period study but larger than [16] a five year follow up study whereas the mean survival time in the current study was smaller than [9] and larger than [4] a three year follow up retrospective cohort study.

Rural HIV-positive patients had shorter survival on average compared to urban. It was observed that the survival time of patients under ART varied along differences in employment status. Not working due to illness patients had the least survival time compared to patients who are on job. Those patients aging in between 30 and 40 years had on average better survival experience than patients aging greater than 40 years. People living with HIV/AIDS under ART did not develop TB had better survival time on average than patients who were develop TB.

In this study baseline CD4 count, baseline weight and baseline lymphocyte count were determined as risk factors for the survival of HIV patients. Thus, as the hazard rate of death risk are high for those with lower baseline weight, CD4 and lymphocyte count, the lower the danger of being at risk of HIV death. Accordingly, baseline CD4 cells counts showed a strong influence on the survival status; patients with counts of larger/mm^3 had higher survival experience than those with counts smaller/mm^3. Baseline Weight showed a strong influence on the survival status; a patient with 5 kg weight gain reduces mortality by 16.5 percent. Similarly, baseline lymphocyte count showed a strong influence on the survival status; patients with counts of higher cells/mm^3 had higher survival experience

than those with counts smaller cells/mm^3. Patients who were in WHO clinical Stage IV had the highest risk of mortality than stage II and III.

Residence has a significance influence on survival, meaning that HIV patients living urban or near town had lower risk of mortality compared to far from town or rural [18,19,20]. The current study also shows that patients living rural experienced higher mortality rate than urban. Results in [9,17,20] showed that the survival time was reduced among individuals infected at older ages. This study has also come up with similar conclusions as in [9,17,20].

The studies [4,9,16,18,19,21] showed that CD4 count is a laboratory predictor of mortality in the sense that higher CD4 counts are associated with longer survival time. The current study concurs with conclusions above. Weight loss is a cause for reduced longevity [9]. This study agrees with the foregoing conclusion; it also shows that a 5 kg weight gain reduces mortality by 16.5% percent. The findings of the study [4,17,19] showed that WHO clinical stage remained significantly associated with survival of patients taking ART. It was evident that patients in WHO clinical Stage IV had the highest risk of mortality. The current study comes up with the same conclusion [4,17,19] except with stage II didn't statistical significant from Stage IV. Results in [18] showed that HIV-TB co-infected patients had short survival time than negative in HIV-TB. The current study concurs with conclusions above.

5. Conclusions

The study revealed that after initiation of the treatment, HIV-positive people had estimated nearly 4 years median survival time. From among the variables included in the study, four of them (Education level, marital status, study area and gender) did not have significant impact on survival. Residence, CD4 count, age, employment status, weight, WHO clinical stage, lymphocyte count and HIV-TB co-infection status had significant impact on the survival experience of patients. Living in rural had shortened the survival of patients. Patients, who were on job lived longer compared to not working due to illness patients. Higher body weight did indicate longer survival, whereas low weight was associated with shorter survival. Older age was associated with higher risk of death. Higher CD4 cell counts were observed to have an association with better survival experience. Likewise higher lymphocyte counts were observed to have an association with better survival experience. HIV-TB co-infected patients had shorter survival time. And WHO clinical stage IV had the highest risk of mortality.

Mortality due to AIDS was strongly associated with small amount or count of clinical characteristics, people living with HIV were often diagnosed at a late stage and delayed initiation of treatment until they were severely ill or the clinical laboratory predictors' reduced to small count. Promotion of testing services, which are widely available in Ethiopia, is needed for earlier diagnosis and enrollment in treatment services and earlier initiation of ART with improved adherence counseling is in advance. Improvement of the clinical characteristics has strong association with longer survival of HIV patients, furthermore, further study required on the implication of ART service that brings improvement on clinical factors thorough the study period.

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