Original article

Survival longevity of adult AIDS patients under ART: A case study at Felege-Hiwot Referral Hospital, Bahir-Dar, Ethiopia

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Abstract

Background: Antiretroviral Treatment (ART), although not a cure, can stave off ill health for many years and the treatment has improved the survival longevity of HIV patients. In Ethiopia a total of 249,174 HIV-infected adults were on ART in 2011.

Objective: The purpose of this study was to identify factors affecting the length of survival time of AIDS patients on ART.

Methods: A sample of 387 patients was taken from patients' records at Bahir-Dar Felege-Hiwot Referral Hospital from June 2006 to August 2013. The Kaplan-Meier estimation method and Cox proportional hazard model were employed to describe and analyze the data.

Results: The predictors included baseline CD4 count >200cell/µl, being TB-negative, total lymphocyte count ≥1200 cell/mm^3 and baseline weight ≥45kg, no regimen change, uninterrupted adherence to treatment, WHO stage I, working functional status and being anemia-negative contributed to extended survival at 5% level. Also females and patients with no risk behaviors lived longer.

Conclusion: Females exhibited longer survival than men. Patients with poor health indicators like being TB-positive, being anemia-positive, having low CD4 count, being in WHO stage IV and poor adherence to treatment contributed to lower survival. The survival of patients was almost the same within groups classified by age, marital status, and knowledge of ART, residence, VCT (voluntary counseling and testing), educational level, regimen type, weight, WBC count, condom use, regimen change, partner's HIV status, and risk factor behavior. In other words, the survival duration had no association with all of these variables. [*Ethiop. J. Health Dev.* 2014;28(2):105-115]

Introduction

On a global scale, the HIV epidemic has stabilized, although with unacceptably high levels of new HIV infections and AIDS deaths. An estimated 34 million people worldwide were living with HIV in 2011 among which 23,500,000 people were living in sub-Saharan Africa. The adult HIV infection was about 30.7 million and the remaining 3.3 million patients were under the age of 15 years. Specifically, an estimated 2.5 million became newly infected with HIV and overall 1.7 million people died due to AIDS in 2011. In the same year, an estimated 1.8 million people were newly infected with HIV in sub-Saharan Africa. The epidemic in sub-Saharan Africa is highly diverse and especially more severe in southern Africa (1).

Antiretroviral therapy has been proved to improve the lives of HIV infected persons by reducing HIV/AIDS-related mortality and morbidity (2, 3). There was an estimated 25% reduction in new infections in sub-Saharan Africa in 2011 (a total of 1.8 million new infections was observed) compared to 2001 (2.4 million new infections) (2), and 27% fewer infections in 2010 compared to 1996 figures after introduction of ART (3). In 2012 some 9.7 million of the 34 million people living with HIV (PLWH) were estimated to be on ART in low- and medium-income countries, which is a six-fold increase from 2005 when only 1.3 million people were receiving ART. Between 2003 and 2010 there was an increase in ART coverage from 20% to 47% for low- and middle-income countries (2). By 2010 WHO had planned to put 9.8 million people on ART with the goal of providing universal access to HIV care and ART (1).

HIV infection has changed from a fatal condition to a manageable chronic illness mainly due to the development of ART. The goals of this therapy are: to improve survival; HIV associated morbidity and mortality, quality of life; restore immune function and achieve maximal and sustained suppression of viral replication (4).

To reduce the mortality and morbidity rates caused by the HIV/AIDS epidemic different initiatives were taken by international organizations and donors. One of the initiatives was the launch of WHO's '3 by 5' initiative in 2003. It was estimated that 3 million HIV patients in the world would have access to ART by 2005. The initiative enabled many Sub-Saharan African countries to establish national ART programs. By the end of 2005 an estimated 1.3 million people in low- and middle-income countries had access to treatment, which is about 20% of those estimated to be in need. The WHO target of providing access to ART for 3 million people by 2005 was not achieved. But in mid-2005, the WHO target had already been overtaken by an even more motivated aim. In July

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2005, the G8 group of industrialized countries committed to the goal of achieving "as close as possible to universal access to treatment for all those who need it [ART] by 2010" (5). This program is called UNIVERSAL access 2010. Ethiopia is one of the countries which benefited from this program. To address the problem of provision of a fair access to ART implementation program, the government of Ethiopia launched the free ART program in January 2005. In 2011 a total of 249,174 adults (of which 86% were eligible) were on ART Ethiopia (6).

In the study area, namely Bahir-Dar (and widely the Amhara region), provision of ART was started at Felege-Hiwot Referral Hospital in 2005. An important justification for carrying out this research is that the region has experienced, and still experiences, the highest prevalence of HIV in Ethiopia. In spite of this reality, since the initiation of free ART service, little research has been done to know what factors impact the survival longevity of patients receiving the treatment. The current study has been undertaken with the objective to identify some socio-demographic and clinical variables that affect the survival of HIV patients under ART at Felege-Hiwot Referral Hospital. At this juncture we would like to inform the interested reader that a similar survival study (7) has been done in 2010 based on follow-up data based on 225 HIV-infected children who were on ART from 2007 to 2009 at this hospital.

Methods

The study was based on data obtained from Felege-Hiwot Referral Hospital, in Bahir-Dar City of the Amhara region, Ethiopia. The city is located approximately 578 kilometers northwest of Addis Ababa at latitude and longitude of 11° 36'N, 37° 23'E respectively and with an elevation of 1,840 meters above sea level. The ART clinic of the hospital was established in 2003. The clinic started to provide free ART service to patients in 2005. At the time when the current study was undertaken at the beginning of 2014 the clinic had three physicians, three nurses and four data clerks.

An important fact worth pointing out is that the ARV first line drugs approved by Ministry of Health of Ethiopia were NRTI and NNRTIs (d4T, 3TC, AZT, EFV and NVP). These drugs are combined to form the following four first line regimens taken by more than 95% of adult HIV/AIDS patients in the Felege-Hiwot Referral Hospital: (d4T/3TC/NVP(1a), d4T/3TC/EFV(1b), AZT/3TC/NVP(1c) and AZT/3TC/EFV(1d).

The target population of patients under follow-up from June 2006 to August 2013 was adults; that is, 15 years and older. The study reviewed patient intake forms and follow up cards prepared by the Ministry of Health of Ethiopia to be uniformly used by clinicians to identify and document clinical and laboratory measurements. The secondary data used in this study were obtained from intake forms and patient follow-up cohort on the basis of a questionnaire designed to extract those variables considered in this study. Adult patients under ART were included irrespective of their treatment category during the study period. Patients on ART whose diagnosis duration was missing, who did not have at least two follow-up CD4 measures, and whose date of death was missing were excluded.

There were a total of 11,040 patients in the sampling frame, which is the list of all patients who received ART from the hospital from June 2006 to August 2013. Each patient had a chart/record with a distinctive identification number called ART unique identification number. A systematic random sampling method has been adopted as appropriate to select a representative of the patients based on their ART identification number as in a previous similar study at Adama Referral Hospital, Oromiya Regional State, Ethiopia (8). Accordingly, in the current study a sample size of 387 was obtained (using the proportion of death, a statistical level of significance $\alpha = 0.05$, and an absolute precision of $d = 0.03$).

Ethical clearance to have access to the data was obtained from the hospital management. The authors have kept the personal data of the patients confidential. Integrity and medical ethical standards were adhered to according to the laws of the country.

In this study we used the software packages STATA and SPSS for data analysis.

The response variable in this study is survival time in months (with status dead=1, censored=0). The predictor variables considered in the study (all at the initiation of ART by patients) were: age, place of residence (urban/ rural), marital status (never married, married, divorced/widowed), level of education (no education, primary, secondary and higher), voluntary counseling and testing (yes/ no), partner's HIV status (positive, negative, unknown), knowledge of ART (yes/ no), CD4 count, weight (in kg), total lymphocyte count (<1200, ≥1200), WHO clinical stage (stage I, stage II, stage III, stage IV), functional status (bedridden, ambulatory, working), risk factor (alcohol intake, soft and hard drug use, tobacco use) (yes/ no), condom use (yes/no), TB status (positive/ negative), anemia status (normal/ severe/mild/moderate), ARV regimen (D4T-3TC-NVP, D4T-3TC-EFV, AZT-3TC-NVP, AZT-3TC-EFV, TDF-3TC-EFV,TDF-3TC-NVP), regimen change (yes/ no), and adherence to treatment (yes/ no), and gender. A summary of these by category is provided in Table 1.

Results

Descriptive Results:

A brief description of the distribution of the patients included in the study is as follows. There were 387 (236 female and 151 male) patients in the cohort study out of which 54 (14%) died, and the remaining 333(86%) were censored. Out of the dead: 46.3% were females and 53.7% males; 38.9%, 25.9%, and 35.2% of those who died, respectively, were bedridden, ambulatory and working. There were 89(23.3%) TB-positive and 293(76.7%) TB-negative patients; out of the dead patients 24(44.4%) were TB-negative and 30(55.6%) were TB-positive. Among the dead 70.4% were anemia-positive and 29.6% were anemia-negative. The average CD4 count at the start of treatment for those who passed away was 128.29 cells/ μl , with a maximum of 322 cells/ μl ; censored average CD4 count was 164.38 cells/ μl , with a maximum of 497. There were 65(16.8%) patients in WHO stage I, 95(24.5%) in WHO stage II, 176(45.5%) in WHO stage III and 51(13.2%) in WHO stage IV. From amongst the dead 20(37%), 18(33.3%), 11(20.4%), and 5(9.3%), respectively, were in WHO stages IV, III, II and I. Of the same group, 55% used condom, 37(84.1%) were exposed to substance use like smoking tobacco, drinking alcohol and using hard/soft drugs. There were 233(60.2%) patients whose baseline WBC count was ≥1200 cells/mm^3 and 154(39.8%) with baseline WBC count below 1200 cells/mm^3. In terms of WBC count and bodily weight, 53.7% had WBC count less than 1200 cells/mm^3 and 46.3% had WBC count ≥1200 cells/mm^3; 20(37%) weighed below 45kgs and 34(63%) 45kgs and higher.

A preliminary chi-square test showed that the survival status of a patient was significantly associated with gender, functional status, baseline WHO stage, anemia status, condom use, adherence type, baseline CD4 count, TB status, baseline WBC count, and baseline weight (p-value < .05) (In tables 1 and 2 below – those with asterisk in the last columns).

Table 1: **Summary of results of HIV/AIDS death events versus socio-demographic and substance use at Felege-Hiwot Referral Hospital during 2006-2013 (*n*=387).**

Variables	Number of death (%)	Number of Censored (%)	Total (%)	Chi-Square P-value
Age				0.222
(15-40)	39(72.2)	265(79.6)	304(78.6)	
≥40	15(27.8)	68(20.4)	83(21.4)	
Gender				0.017*
Female	25(46.3)	211(63.4)	236(61.0)	
Male	29(53.7)	122(36.6)	151(39.0)	
Marital status				0.836
Never married	8(14.8)	43(13.0)	51(13.3)	
Married	26(48.1)	173(52.4)	199(51.8)	
Divorced/ widowed	20(37.0)	114(34.5)	134(34.9)	
Educational level				0.209
No education	13(24.5)	100(30.5)	113(29.7)	
Primary	11(20.8)	91(27.7)	102(26.8)	
Secondary and higher	29(54.7)	137(41.8)	166(43.6)	
Functional status				0.000*
Bedridden	21(38.9)	12(3.6)	33(8.5)	
Ambulatory	14(25.9)	56(16.9)	70(18.1)	
Working	19(35.2)	264(79.5)	283(73.3)	
Residence				0.693
Rural	7(13.0)	50(15.0)	57(14.7)	
Urban	47(87.0)	283(85.0)	330(85.3)	
Partner's HIV status				0.384
Negative	2(3.7)	18(5.4)	20(5.2)	
Positive	15(27.8)	66(19.8)	81(20.9)	
Unknown	37(68.5)	249(74.8)	286(73.9)	
Knowledge of ART				0.078
No	4(9.1)	9(3.4)	13(4.2)	
Yes	40(90.9)	259(96.6)	299(95.8)	
VCT				0.846
No	6(13.0)	36(12.0)	42(12.2)	
Yes	40(87.0)	263(88.0)	303(87.8)	
Substance use				0.000*
No	7(15.9)	117(44.3)	124(40.3)	
Yes	37(84.1)	147(55.7)	184(59.7)	

(*) The association is significant at α=0.05

Table 2: **Summary of results of HIV/AIDS death events versus different health and risk behavior variables at Felege-Hiwot Referral Hospital during 2006-2013 (*n*=387).**

Variables	Number of death (%)	Number of Censored (%)	Total (%)	Chi-Square P-value
TB Status				0.000*
Negative	24(44.4)	269(82.0)	293(76.7)	
Positive	30(55.6)	59(18.0)	89(23.3)	
WHO Clinical stage				0.000*
Stage I	5(9.3)	60(18.0)	65(16.8)	
Stage II	11(20.4)	84(25.2)	95(24.5)	
Stage III	18(33.3)	158(47.4)	176(45.5)	
Stage IV	20(37.0)	31(9.3)	51(13.2)	
Baseline WBC count				0.024*
<1200 cells/mm^3	29(53.7)	125(37.5)	154(39.8)	
≥1200 cells/mm^3	25(46.3)	208(62.5)	233(60.2)	
Baseline CD4 count				0.010*
<200 cells/ μl	44(81.5)	203(63.6)	247(66.2)	
≥200 cells/ μl	10(18.5)	116(36.4)	126(33.8)	
Baseline weight				0.017*
<45 kg	20(37.0)	72(22.0)	92(24.1)	
≥45 kg	34(63.0)	255(78.0)	289(75.9)	
Anemia status				0.000*
Normal	16(29.6)	269(80.8)	285(73.6)	
Severe/mild/moderate	38(70.4)	64(19.2)	102(26.4)	
Regimen type				0.154
D4T-3TC-NVP	8(14.8)	88(26.5)	96(24.9)	
D4T-3TC-EFV	12(22.2)	36(10.8)	48(12.4)	
AZT-3TC-NVP	10(18.5)	78(23.5)	88(22.8)	
AZT-3TC-EFV	10(18.5)	42(12.7)	52(13.5)	
TDF-3TC-NVP	7(13.0)	41(12.3)	48(12.4)	
TDF-3TC-EFV	6(11.1)	43(13.0)	49(12.7)	
Condom use				0.022*
Never	22(55.0)	170(73.0)	192(70.3)	
Sometimes/always	18(45.0)	63(27.0)	81(29.7)	
Regimen change				0.194
No	23(42.6)	172(52.1)	195(50.8)	
Yes	31(57.4)	158(47.9)	189(49.2)	
Adherence				0.000*
Good	30(55.6)	307(96.5)	337(90.6)	
Fair	10(18.5)	4(1.3)	14(3.8)	
Poor	14(25.9)	7(2.2)	21(5.6)	

(*) The association is significant at α=0.05.

The following results are based on estimated Kaplan-Meier curves which are given in Figures A to N of this paper. We also used the log-rank test as a standard technique to establish differences in survival longevity.

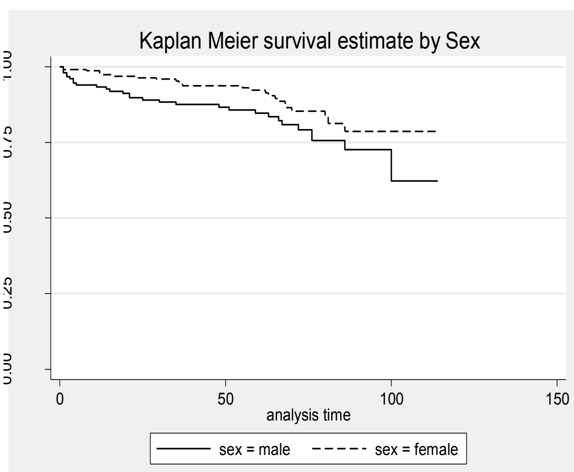
A significant difference in survival was observed between males and females (females had longer survival than males). Patients with risk behaviors like smoking tobacco, drinking alcohol and drug abuse had shorter survival relative to those with no risk behaviors. Patients in WHO stage IV had the lowest survival time. Patients with poor health indicators like being TB- positive and anemia-positive, low baseline CD4 count, low baseline lymphocyte count, and low baseline weight had low survival chances. Those who did not change regimen had a better survival chance than those who did. High level of adherence contributed to longer survival. Those whose functional status was bedridden experienced shorter survival than those patients whose functional status was ambulatory or working. On the other hand, separate analyses were undertaken to investigate differences in survival time among patients with respect to residence, condom use, educational level, VCT (voluntary counseling and testing), age, partner HIV status and marital status revealed that survival time was not different among the categories within each of these variables. These phenomena are depicted by the Kaplan-Meier curves for the various categories crossing each for each of the variables.

Results Based on Cox Proportional Hazards model:

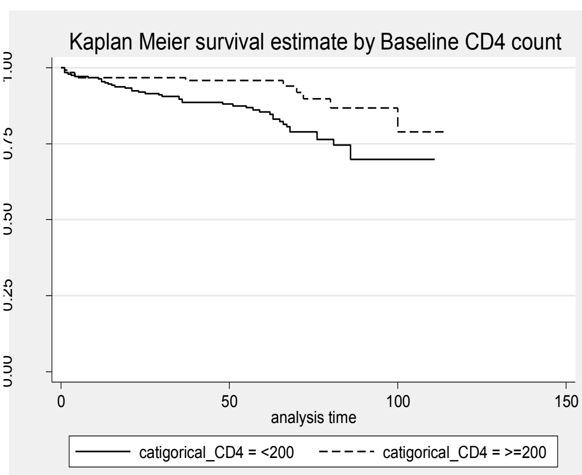
Single covariate analysis: The single covariate versus survival time analysis provided statistical evidence that survival is significantly related with gender, functional status, risk factor, TB status, anemia status, baseline CD4 count, WHO clinical stage, baseline weight, baseline lymphocyte count, adherence to ART and regimen change. The covariates age, residence, educational level, condom use, regimen types and marital status are *not* statistically significant at 5% significance level (details not shown here).

Multiple covariate analysis: In statistical modeling, when the number of variables is relatively large, it can be computationally expensive to fit all possible models. Thus, one of the options is fitting a multivariable model containing the variables that were found significant in the single variable analysis at a modest level of significance (0.20-0.25). In this study we used the value 0.25. Consequently, 20 separate single variable Cox proportional hazard models, each containing one explanatory variable, were fitted. After identifying the significant variables/factors on the basis of the threshold we have adopted, that is 0.25 level, a multiple covariate Cox model was fitted; the results are given in Table 3. We noted that for the data set under study survival is significantly related with TB status, baseline CD4 count, anemia status, functional status, gender and adherence.

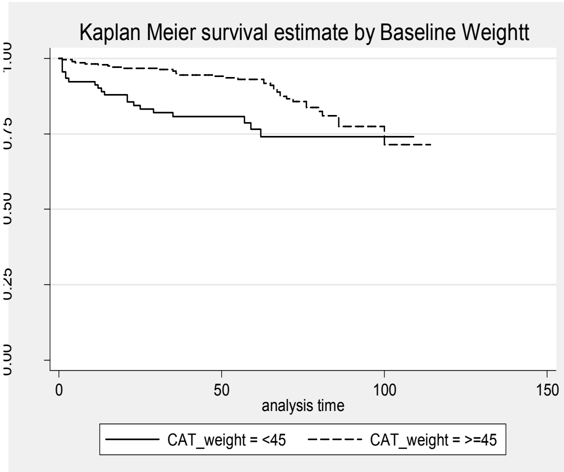
As we cannot take the no-interaction model with time provided in Table 3 as the final model, we performed a test for interaction with time, tests about linearity in parameters, and influential/outlier observations. The formal test performed to check for the existence of time-dependent covariates (interaction of covariates with logarithm of time) was not significant at 5% level. Also plots of the scaled Schoenfeld residuals showed no systematic pattern, and that the smoothed plot approximated a horizontal line. These two checks support that the proportional hazards assumption is tenable. We also checked for interactions between covariates as well as possible confounding; the findings showed no problems with respect to these. Tests for linearity in the model parameters as well as the presence of influential and outlier observations showed that the linearity assumption can be sustained, and that there were no problems with regard to influential/outlier observations. Finally, the results of the likelihood ratio test and the score test suggest that the model fit is good at 5% level of significance. As a result, we concluded that the Cox model with the covariates in Table 3 fits the data well. Hence further analysis was undertaken with this model as the final model, meaning that interpretations of the results would be done using adjusted hazard ratios (aHRs) (Table 3).



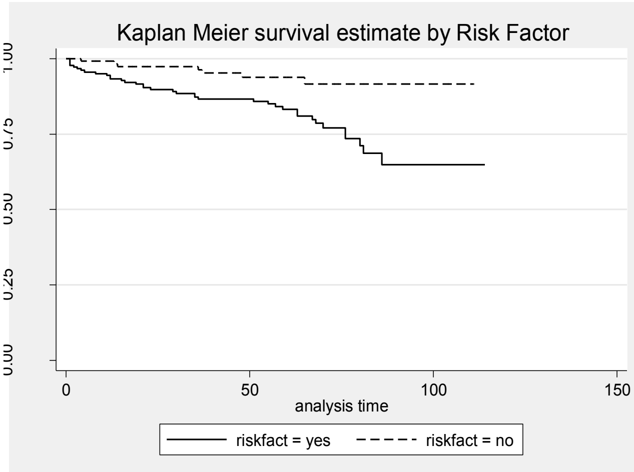
A) KM estimates of survival for the variable sex.



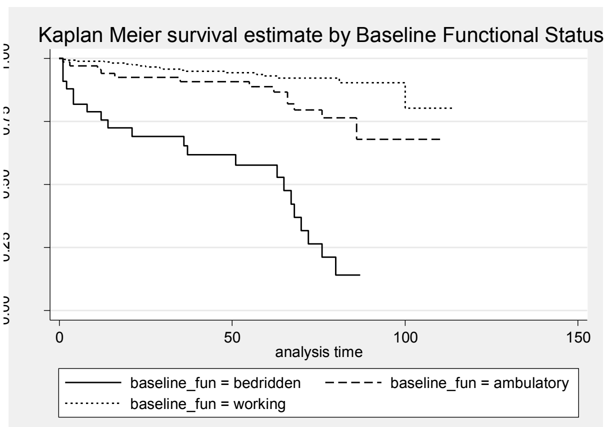
B) KM estimates of survival for the variable CD4 count.



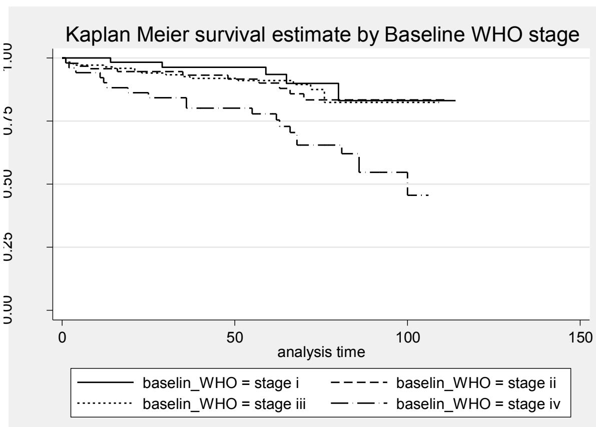
C) KM estimates of survival for the variable baseline weight.



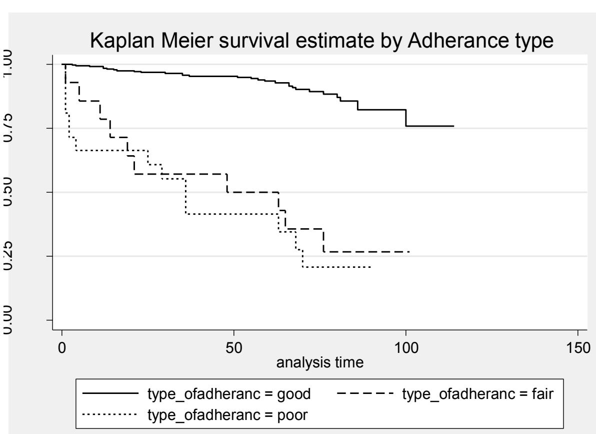
D) KM estimates of survival for the variable risk factor.



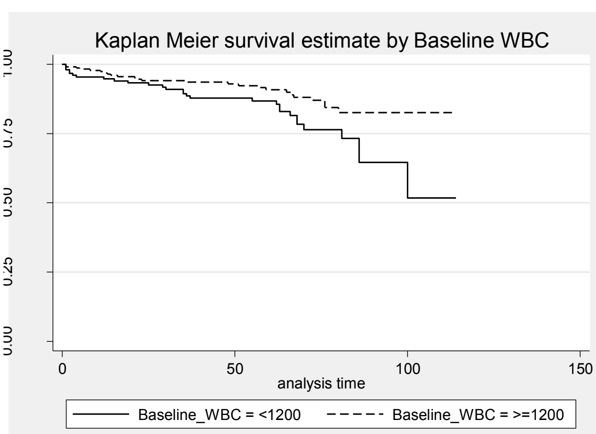
E) KM estimates of survival for the variable baseline functional status.



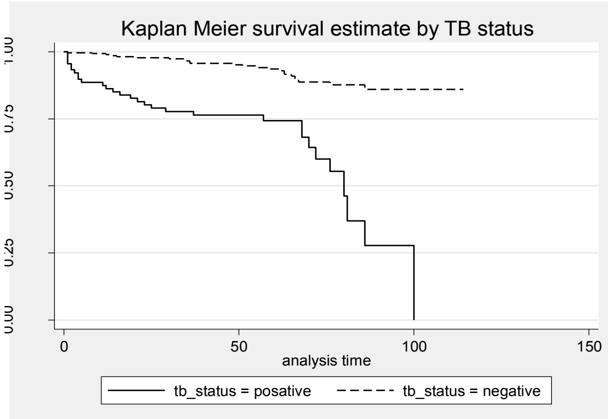
F) KM estimates of survival for the variable baseline WHO stage.



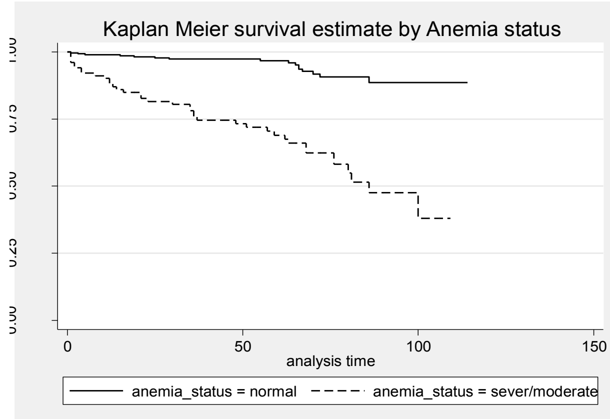
G) KM estimates of survival for the variable adherence.



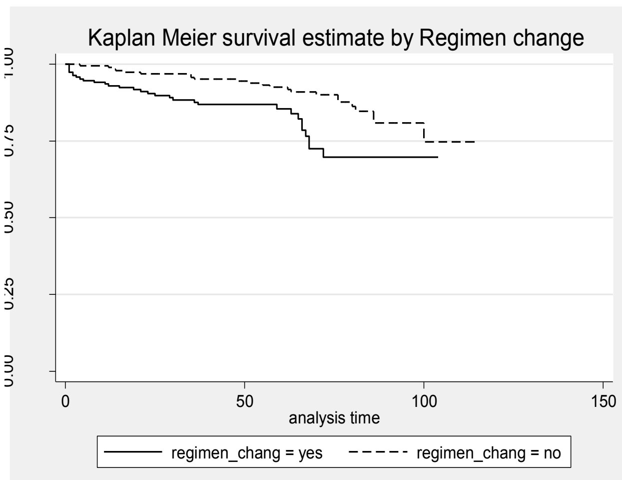
H) KM estimates of survival for the variable baseline WBC.



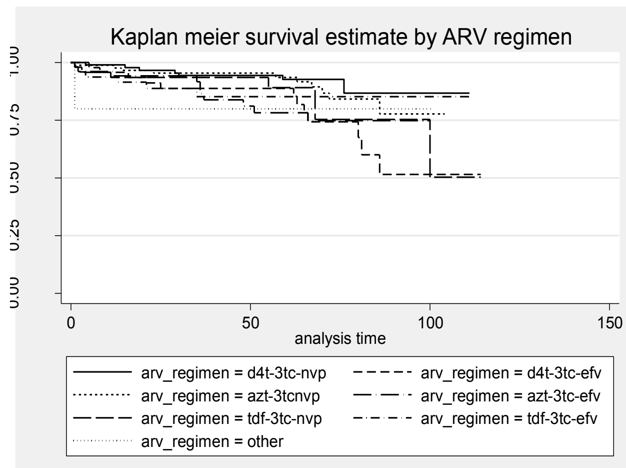
I) KM estimates of survival for the variable TB status.



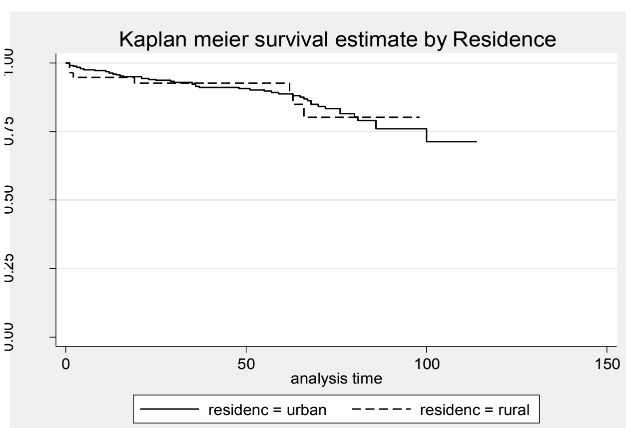
J) KM estimates of survival for the variable anemia status.



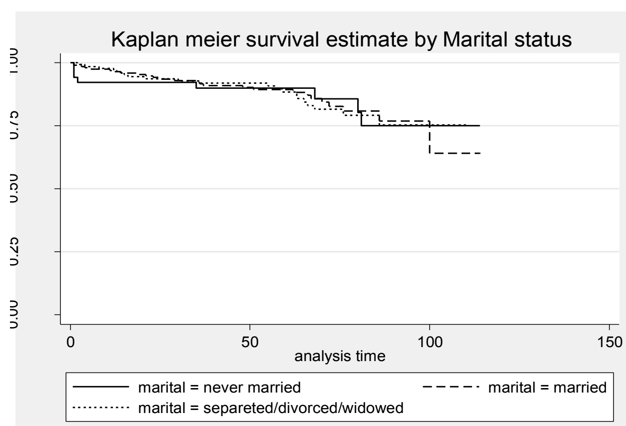
K) KM estimates of survival for the variable regimen change.



L) KM estimates of survival for the variable ARV regimen.



M) KM estimates of survival for the variable residence.



N) KM estimates of survival for the variable marital status.

Kaplan-Meier survivor estimates for categorical variables for AIDS patients.

Table 3: **Multiple covariate analysis of socio-demographic and risk variables that affect survival time of AIDS patients on ART at Felege-Hiwot Referral Hospital during 2006-2013 (*n*=387).**

Variables	Df	$\widehat{\beta}_i$	SE	Wald	Sig.	aHR	95% CI for HR
Gender							
Male	1	0.594	0.304	3.809	0.050	1.812	0.99-3.29
Female (reference)						1	
Baseline CD4 count	1	-0.006	0.002	8.291	0.004	*0.994	0.991-0.998
TB Status							
Positive	1	1.276	0.306	17.359	0.000	3.581	1.96-6.53
Negative (reference)						1	
Anemia Status							
Normal	1	-1.310	0.320	16.780	0.000	0.270	0.14-0.50
Severe/moderate (reference)						1	
Functional status							
Bedridden	1	1.623	0.346	22.028	0.000	5.067	2.57-9.98
Ambulatory	1	0.260	0.392	0.440	0.507	1.296	0.60-2.79
Working (reference)						1	
Adherence							
Good	1	-0.289	0.371	37.998	0.000	0.105	0.05-0.21
Fair	1	-0.757	0.452	2.801	0.094	0.469	0.19-1.14
Poor (reference)						1	

****Note:*** For interpretation of aHR based on a 50 cells/μl increase in the baseline CD4 count, see the last statement in the last paragraph of the section below.

Discussion

The subsequent discussion brings to light some findings from previous research on the same subject from Ethiopia and elsewhere with which we make comparisons and connections with our findings.

According to (6), the survival of AIDS patient decreased as age increased. The results in (10-12) indicate that age and gender are important determinants of HIV disease progression. Younger patients have the advantage of surviving longer than older patients, and male gender was a predictor of mortality with a risk almost double that of females.

A retrospective cohort study in Nepal based on data gathered on patients who were followed up between May 2006 and May 2011 identified a high association between HIV disease progression and the following: male gender; bedridden for half a day compared to normal activity; low WHO clinical stages III and IV compared to stages I or II (13).

A study in Thailand showed that HIV patients with low level of education had a higher risk of death and an increased risk for HIV disease progression (14). A study (15) found that in Brazil the risk of dying for HIV patients who did not have university education was much higher than that for those who had university education.

According to (16) and (17), it was observed that even though HIV-infected drug users are less likely to start taking ART, their response to therapy (in terms of survival) is similar to that for other exposure groups, as long as adherence to treatment is satisfactory.

Opportunistic infections may continue to cause substantial morbidity and mortality in patients with HIV infection (18). Especially, tuberculosis remains one of the major causes of death in patients infected with HIV in resource-limited settings (19, 20). It is possible that up to 50% of HIV/AIDS patients died from opportunistic infections such as tuberculosis (21).

Patients with low baseline CD4 count were exposed to mortality risk twice as high as those with higher CD4 count, and patients in WHO stages III and IV were 2 to 4 times more likely to die than patients in stages I and II (10). The finding in (9) shows that the survival probability of AIDS patients would improve with increased CD4 count.

Turning to research findings pertinent to the Ethiopian situation, a study conducted in Hawassa City in 2006 (22) identified age, gender, marital status, employment status and education level as predictors of survival. Another study in 2007 (10) in Adama City found CD4 count, weight, knowledge about HIV, condom use, drug and alcohol abuse to be significant determinants. Findings from a study on patients who were on ART from 2005 to 2008 in Tikur-Anbessa Specialized Hospital, Addis Ababa indicated that number of medications, baseline functional status, CD4 count at baseline, age, gender and weight have significant impact on survival (23). Another study (24) on AIDS patients followed up between 2003 and 2007 in the Armed Forces Hospital, Addis Ababa, Ethiopia showed that low CD4 count at baseline, employment status, functional status, WHO clinical stages III and IV, TB co-infection, and opportunistic infections are significant determinants of survival. Yet another retrospective cohort study conducted in eastern Ethiopia showed that, previous history of weight loss, bedridden functional status at baseline, low CD4 cell count and advanced WHO status of patients led to higher risk of death (25).

The current study identified *six* variables that independently predict the survival of HIV patients under ART in Felege-Hiwot hospital. These predictors were gender, TB status, baseline CD4 count, baseline functional status, anemia status and adherence to ART. Our findings show that male patients were about 81% more likely to die than female patients. This result agrees with previous studies from Cameron (10) and (11) from the Republic of Korea where men had lower survival time compared to women.

In our study, the hazard rate of TB-positive patients was 3.6 times higher than that of their TB-negative counterparts. This result concurs with the finding of a study (26) in Croatia. We found that the hazard rate of patients who had normal anemia was 73% lower than that of those patients who had severe/mild anemia. This result agrees with a study (27) from England showing that anemia is a significant predictor of survival of AIDS patients. The current study showed that a 50 cells/mm^3 increase in CD4 count led to a reduction of the chance of dying by 26% compared with patients in the immediate lower CD4 count category. This result concurs with results by (28), (8), 23), (24) and (25). Our finding shows that bedridden patients were 5 times more likely to die than working patients; this result is similar to the findings by (24) and (28). The current study also found that the chance of dying among patients with good adherence was 89% lower than of patients with poor adherence; the finding coincides with that in (28).

Conclusion:

The major factors that affect the survival of HIV/AIDS patients were gender, TB status, anemia status, baseline CD4 count, functional status and adherence to treatment. Females experienced longer survival than males. Patients with poor health indicators like being TB-positive, being anemia-positive, having low CD4 count, being in WHO stage IV, and poor adherence to treatment contributed to reduced survival. The results also indicated that the survival probability of patients had no association with age, marital status, and knowledge of ART, residence, VCT (voluntary counseling and testing), educational level, regiment type, weight, WBC count, condom use, regimen change, partner's HIV status, and risk factor behavior.

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