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Determinants of survival time among HIV-infected patients receiving care at antiretroviral therapy (ART) clinic of a public hospital, Ethiopia

Abstract

Introduction: Even if there are different barriers to HIV testing in developing countries, timely access to care and early diagnosis improves the clinical course of the disease, reduces the transmission rates, and prolongs the survival time of patients.

Objectives: This study aimed to investigate the potential predictors of survival time in a cohort of HIV-infected patients on ART using the parametric survival model perspective.

Data and Methods: A hospital-based retrospective cohort charts-review study design was conducted on 647 patients from a public referral hospital in North-Central Ethiopia from July 2012 to January 2017. Log-rank and Wilcoxon tests, and an Accelerated Failure time (AFT) parametric statistical model were used.

Results: A mean of 22.13months (SD=13.16) and a median of 21.47months (IQR: 11.55-33.30) were found. The median age, baselineCD4 count, and BMI of patients at baseline were 30years (IQR: 25-38years), 247cells/µl (IQR: 120-375cells/µl) and 19.75kg/m2 (IQR: 17.5-22kg/m^2); respectively. At baseline, the patients CD4 count values ranged from 11 to 1764 (mean=289, SD= 233). The study revealed that 192(29.68%) events occurred, while 455(70.32%) were censored. The Gamma model was selected as the best-fit parametric model for the data. The estimated shape parameter of the fitted Gamma model is 1.9983 with 95%CI (1.3426, 2.9741) indicating that significantly determined as the survival time increases over time.

Conclusion: The fitted AFT parametric model (Gamma distribution), the factors such as: higher BMI, higher current CD4 count, being married, starting on AZT-3TC-EFV regimen class significantly increased the survival time of HIV-positive patients attending ART treatment, while; baseline CD4 count and ambulatory functional status reduces the survival time of HIV patients. Moreover, using ART treatment significantly improves the survival time of patients.

Keywords: AFT, gamma model, parametric, survival time

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Abbreviations: AFT, accelerated failure time; AIC, akaike information criteria; AIDS, acquired immune deficiency syndrome; ART, antiretroviral therapy; BIC, bayesian information criteria; BMI, body mass index; DBRH, debre berhan referral hospital; HAART, highly active anti-retroviral therapy; HIV, human immune deficiency virus; IQR, inter quartile range; SD, standard deviation

Introduction

Globally, the rapid distribution and high prevalence rate of HIV/AIDS among the working group of the population is a serious issue. HIV infection prevalence was highly observed in developing countries. Previously, due to the rapid increase of HIV infection in the 1980s and the 1990s, people with HIV have increasingly become infected. The epidemic has spread rapidly in towns and slowly in rural areas.[1]

HIV epidemic in Ethiopia is becoming more concentrated in urban areas and along with the major transport corridors.[2] Currently, AIDS becomes the most leading cause of morbidity and mortality among adults in Ethiopia.[3]

According to the 2016-EDHS (2016-Ethiopian Demographic and Health Survey), HIV prevalence among men and women aged 15-49 is 0.9% [95%CI: 0.7%-1.1%],[4] is lower than 2011 EDHS in which it was 1.9% for women and 1.0% for men with an overall prevalence rate of 1.5% [95%CI: 1.3%-1.7%],[5] while it was 1.4% in 2005.[6] The 2005 and 2011 EDHS reports show that the prevalence of the disease was significantly unchanged. The overall HIV prevalence rate in Ethiopia revealed inconsistent trends, with the majority of areas showing decreasing trends.[7]

Reports of 2005,[6] 2011[5] and 2016[4] EDHS indicated that the prevalence rate of the disease varied from region to region, through socio-demographic factors, among urban and rural areas, and in the economic status of people's. To safeguard the epidemic of the disease Ethiopia launched free ART treatment in 2005.[8] Due to this, the country has observed remarkable progress over the past two decades in reducing HIV prevalence rate by 2.4%, from 3.3% in 2000 to 0.9% in 2017.[9]

For decades, scientists and humanitarian aid groups are working on pharmaceutical medicine for HIV/AIDS, but still not possible. The possible way, which is better than none- is treating patients through a clinical treatment called Highly Active Anti-Retroviral Therapy

(HAART). Since HAART prolongs the lifetime of HIV/AIDS patients.[10] Knowledge of HIV status helps HIV-negative individuals make specific decisions to reduce risk and increase safer sex practices to be free of the disease. For those who are infected with HIV, knowledge of their status allows them to take actions to protect their sexual partners, to seek treatment, and to plan for the future. Several cohort studies and clinical trials have shown that the CD4 count is the strongest predictor of subsequent disease progression and survival.[11]

Even if there are barriers to HIV testing in Africa, including Ethiopia, from volunteer HIV testing through consultation to thinking as HIV is not a risky infection, from fear of being HIV-positive to fear of HIV stigma if HIV-positive, from no available cure to fear of no privacy and no confidentiality and no permission found from partner, especially for women;[12] the timely access of care and early diagnosis improves the clinical course of the disease and it reduces the transmission rates. The presence of a weak care system in low- and middle-income countries makes it difficult for the accessibility of HIV testing.

This study aimed to investigate the potential predictors of survival time in a cohort of HIV-infected patients on ART using the parametric survival statistical model perspective.

Data and methods

Study design, subjects and period

The study considers retrospective cohort study design on HIV-infected patients. The data used for this study were obtained from Debre Berhan Referral Hospital in the North Shoa Administrative Zone of the Amhara regional state of Ethiopia. The hospital serves as a referral center for different health centers in the surrounding districts. It has a unit for ART and gives Voluntary Counseling and Testing (VCT) services in a clinic for both referred and self-referred patients. Data were extracted from the patients' chart, which has been adopted by the Federal Ministry of Health (FMoH) of the country, to be uniformly used by ART clinics to early identify and document laboratory, clinical and epidemiological variables. HIV-infected patients whose ages above sixteen years were included in the study. The study period was between the year 2012 to 2017 and the patients followed until one of the outcomes of event or censored occurred.

Inclusion and exclusion criteria

All HIV/AIDS-patients aged 16 years and above were included. Those patients who started ART before July 2012 or after July 2015 were excluded.

Data

Six hundred forty seven (647) patients, who fulfilled the inclusion criteria, were included in the study.

Data collection

Data were extracted from the patients' medical charts by the ART clinic experts. The author had no accessed the information that could identify individual participants during or after data collection.

Variables

The dependent variable was survival time measured in months. The independent variables considered in this study were baseline age (in years), BaselineCD4 count, Sex (Male, Female), Marital status (Married, Single, Widowed/Divorced), Body Mass Index (BMI)(kg/m^2), Functional status (Working, Ambulatory, Bedridden), current CD4 count, WHO clinical stages (Stage I, II, III, IV) and ART Regimen class (AZT-3TC-EFV, AZT-3TC-NVP, TDF-3TC-NVP, d4t-3TC-NVP, TDF-3TC-EFV).

Statistical data analysis

Statistical modeling of censored followed-up data in determining the potential predictor variables in the prognosis of survival time was commonly focused on employing nonparametric methods of Kaplan-Meier plots and log-rank test,[13] semi-parametric method of Cox-Proportional Hazard (Cox-PH) model,[14] and fully parametric method of Accelerated Failure Time (AFT) model.[15] In the AFT parametric model, the survival time is modeled as a function of predictors or risk factors.[16] This parametric model provides a more flexible result since the hazard rate is not constant with time.[17] When comparing the Cox-PH model and parametric model results, parametric models lead to more efficient estimates.[18,19] The comparison is also done by several studies and the results showed that the parametric model fits the data.[20–22] The estimated coefficients in parametric models are interpreted as accelerating survival times.[23]

In this study nonparametric method of Kaplan-Meier (KM) plots and log-rank tests,[13] and the fully parametric method of Accelerated Failure Time (AFT)[15] have been employed. Variable selection was undertaken based on the recommendations of Hosmer-Lemeshow (H-L).[24,25] Survival analysis is used to describe the analysis of data in the form of time from a well-defined time origin until the occurrence of some particular event or end-point. If individuals did not provide complete information for a variety of reasons; subjects may not have been experienced the event of interest, in this case, the survival data can be censored. The existence of variables that change over time is a distinguishing feature in survival analysis.[15]

Model comparison and diagnostics

There are different methods of model selection, but for this study, we have used AIC and BIC criteria to compare various candidate models, and the model with the smallest AIC and BIC is selected as the better fit.[26] After the model is selected, the adequacy of the model was assessed using the Cox-Snell residuals for the parametric model.

Operational definition

Survival-time: the number of times from the date of enrollment to ART until one of the events of "death", "lost-to-follow-up", "dropped-out", "stopped", "transferred out to other health care centers" occurred.

Statistical software

The data were coded and stored in SPSS version 20 and exported to SAS version 9.4 for analysis.

Results

Exploring the data

The study included 647 individual patients in the treatment of HIV/AIDS from the year 2012 to 2017 for a total of 54 months in the hospital, with a mean of 22.13(SD=13.16) and a median of 21.47months (IQR: 11.55- 33.30). The median age, baseline CD4 count and BMI of patients at baseline were 30years (IQR: 25- 38years), 247cells/µl (IQR: 120-375cells/µl), and 19.75kg/m^2 (IQR: 17.5-22kg/

m^2); respectively. At baseline, the patients' CD4 count values ranging from 11 to 1764 (mean=289, SD=233).

Of the total 647 patients, 423(65.38%) were females, while 224(34.62%) were males. The life-table estimates in the first six months indicates, about 11.34% of patients were failed, and the 54th month is the riskiest, in which 29.68% were failed.

Out of the total subjects, 269(41.58%) were single, 217(33.54%) were married, and 161(24.88%) were had divorced/widowed marital status. Regarding functional status, 303(46.83%) were able to do their day-to-day activities (working), 142(21.95%) were ambulatory, and 202(31.22%) were bedridden. From the total 647 HIV patients, 224(34.63%) had started ART treatment with an initial WHO-clinical stage of stage I, and 126(19.47%), 176(27.20%), and 121(18.70%) were stage II, III and IV; respectively. At baseline, the ART regimen class of patients were AZT-3TC-EFV, 165(25.50%); AZT-3TC-NVP, 137(21.18%); TDF-3TC-NVP, 88(13.60%); d4t-3TC-NVP, 114(17.62%) and TDF-3TC-EFV, 143(22.10%) (Table 1).

Table 1 Baseline Socio-demographic, Clinical and Laboratory information of HIV/AIDS patients initiated ART at Debre Berhan Referral Hospital, North-Central Ethiopia; 2012-2017 (N=647)

Characteristics	Category	Total (%)	Censoring Status	
			Censored (%)	Event Occurred (%)
Gender	Male	224(34.6)	156(69.64)	68(30.36)
	Female	423(65.3)	299(70.69)	124(29.31)
Marital Status	Single	269(41.5)	180(66.82)	89(33.18)
	Married	217(33.5)	137(63.20)	80(36.80)
	Widowed/Divorced	161(24.8)	140(86.96)	21(13.04)
Functional Status	Working	249(82.1)	195(78.31)	54(17.82)
	Ambulatory	142(21.9)	105(73.94)	37(26.06)
	Bedridden	202(31.2)	101(50.00)	101(50.00)
WHO-clinical stages	Stage-I	224(34.6)	127(56.70)	97(43.30)
	Stage-II	126(19.4)	111(88.10)	15(11.90)
	Stage-III	176(27.2)	117(66.48)	59(33.52)
	Stage-IV	121(18.7)	100(82.64)	21(17.36)
ART Regimen class	AZT-3TC-EFV	165(25.5)	131(79.39)	34(20.61)
	AZT-3TC-NVP	137(21.1)	101(73.72)	36(26.28)
	TDF-3TC-NVP	88(13.60)	74(84.09)	14(15.91)
	d4t-3TC-NVP	114(17.6)	59(51.57)	55(48.43)
	TDF-3TC-EFV	143(22.1)	90(62.94)	53(37.06)

Baseline socio-demographic, clinical and laboratory information vs. censoring status

Of the total 647 patients, 192(29.68%) were event occurred, and 455(70.32%) were censored. About 30.36% male HIV patients were event occurred, while about 69.64% were censored. And, on about 29.31% female HIV patients event were occurred, while; on 70.69% individuals censored were observed. There was no much difference between males and females in the occurrence of events. Regarding marital status, 36.80%, 33.18%, and 13.04%, married, single, and widowed/divorced patients events were occurred; respectively. In about half of the bedridden patients event were occurred (Table 1).

Univariable analysis

To determine whether there is a significant difference among different categorical covariates, we have employed the Log-rank and Wilcoxon tests of equality. The tests showed a significant difference is observed in survival situations among the categorical variables of marital status, functional status, WHO-clinical stages and regimen class subgroups (p-value=0.0001).

There were no significant difference in the time-to-event between sex (p-value=0.4587), WHO clinical stage (p-value=0.1301) and BMI (p-value=0.2310) for log-rank test of equality across strata for the predictors (Table 2). For other categorical predictors, the log-rank tests of equality across strata have the p-value of less than the cut-point of 0.25 or 25% significance level.

Multivariable model

In identifying the better-fit parametric model to the data, we have been considered six parametric survival models: exponential, Weibull, normal, log-logistic, Gamma, and log-normal models. Comparison of parametric models was applied to find the most preferred model to represent the data parametrically. After a comparison of the models

using AIC, BIC, and maximum likelihood ratio test values, the Gamma model was selected as the better fit with the smallest AIC and BIC value of 831.067, and the highest maximum likelihood ratio test value of -421.195 (Table 3).

To infer the Gamma model parameters, we have specified dist=gamma in SAS proc lifereg.[27] The main limitation of Proc Lifereg in SAS is it fits for the generalized gamma model rather than the standard gamma model. There is a need for conversion of the generalized gamma model to the standard gamma model. We have applied the grid search technique to get the standard gamma distribution by using the outputs from the generalized gamma distribution (δ=σ). It was done for δ=0.3392 fitting a gamma distribution to the generalized gamma distribution with the dist=gammanoshape1shape1= 0.3392 no scale=0.3392 in SAS with log-likelihood Value -2419.191; for σ=1.9983 fitting a gamma distribution with the dist=gammanoshape1shape1=1.9983noscalescale=1.9983 with log-likelihood value -945.068. Then, the model with the largest log-likelihood value was selected as the best fit of the standard gamma model. The model with a scale and shape parameter of 1.9983 was selected as the better fit model for the standard gamma distribution. Therefore; the estimated gamma model scale/shape parameter is 1.9983 with 95%CI (1.3426, 2.9741), which is significantly indicating the survival time increase over time. The plot of the hazard function looks like U-shaped because of δ=1.9983>1. The standard Gamma distribution parametric model parameter values are shown under (Table 4).

Based on the fitted AFT parametric model (Gamma distribution), the factors such as: higher BMI, higher current CD4 count, being married, starting on AZT-3TC-EFV regimen class significantly increased the survival time of HIV-positive patients attending ART treatment, while; baseline CD4 count and ambulatory functional status reduces the survival time of HIV patients.

Table 2 Log-rank and Wilcoxon tests of survival differences for categorical variables

Variable	Log -rank test			Wilcoxon test		
	Test statistics	**df**	**p-value**	**Test statistics**	**df**	**p-value**
Sex	0.5491	1	0.4587	0.8750	1	0.7706
BMI	2.5230	2	0.2310	2.8901	2	0.3356
Marital status	6.5319	2	0.0001	5.6506	2	0.0001
WHO Clinical stage	3.0687	3	0.1301	4.5145	3	0.0901
ART Regimen class	8.1095	4	0.0001	8.4725	4	0.0001
Functional status	23.9239	2	<.0001	20.2649	2	<.0001
Baseline CD4 Count	5.1270	1	0.000	5.3250	1	0.000
Current CD4 count*	4.1330	1	0.0001	4.3250	1	0.0001

*CD4 count recorded at AIDS-duration or at the end of study time.

Table 3 Comparison of Parametric Survival Models

Parametric Survival model	AIC	BIC	Maximum Likelihood
Exponential	993.085	1292.054	-432.039
Weibull	995.050	1298.290	-424.533
Normal	2762.936	3066.176	-1144.369
Log-logistic	1016.497	1319.737	-423.058
Gamma	**831.067**	**831.067**	**-421.195**
Log-normal	1040.501	1343.741	-423.599

Table 4 AFT Parametric Survival Model (Gamma distribution) parameter estimates

Parameter	Category(if any)	β^	Std.err	95% CL for exp(β^)	exp(β^)	P-value
Intercept		1.1311	1.2096	(0.2895,33.1784)	3.10	0.1981
Sex	Female	-0.1888	0.6684	(0.2234,3.0688)	0.83	0.7776
	Male(Ref)	-	-	-	-	-
Age		0.0570	0.0445	(0.9703,1.1551)	1.06	0.2003
BMI		0.2966	0.0753	(1.1607,1.5592)	1.35	< .0001*
baseCD4		-0.0044	0.0021	(0.9915,0.9997)	0.99	0.0367*
Current CD4 count		0.0055	0.0019	(1.0019,1.0092)	1.01	0.0029*
Functional Status	Working	-1.4262	1.3497	(0.0171,3.3845)	0.24	0.2907
	Ambulatory	-5.9202	1.7337	(0.0008,0.0803)	0.003	0.0006*
	Bedridden(Ref)	-	-	-	-	-
WHO Clinical Stages	StageI	-0.975	1.9721	(0.0079,17.9951)	0.38	0.6210
	StageII	-1.0984	2.0391	(0.0061,18.1415)	0.33	0.0901
	StageIII	-0.5272	1.9638	(0.0126,27.7074)	0.59	0.0883
	StageIV(Ref)	-	-	-	-	-
Marital Status	Married	1.9348	0.9539	(1.0673,44.8983)	6.92	0.0425*
	Single	1.8031	1.012	(0.8350,44.1062)	6.07	0.0748
	Others (Ref)	-	-	-	-	-
Regimen class	AZT-3TC-EFV	3.0126	1.2166	(1.8740,220.7732)	20.34	0.0067*
	AZT-3TC-NVP	-0.3841	1.1598	(0.0701,6.6134)	0.68	0.7405
	TDF-3TC-NVP	-0.6512	1.2391	(0.0460,5.9139)	0.52	0.5992
	d4t-3TC-NVP	3.036	1.8892	(0.5133,844.5737)	20.82	0.1954
	TDF-3TC-EFV(Ref)	-	-	-	-	-
Scale		1.9983	0.4054	(1.3426,2.9741)	.	.
Shape		0.3392	0.3681	(-0.3820,1.0606)	.	.

Remark: - * significance at 0.05 level of significance, confidence limits (CL), Reference Category (Ref).

Discussions

Previous studies on HIV/TB co-infected patients in Nigeria[28] and HIV/AIDS patients' survival in Ethiopia[29] results revealed that Weibull AFT model is the most appropriate. However, for this study the best fit for the data is Gamma parametric model. The estimated shape parameter of the fitted Gamma model is 1.9983 with 95%*CI* (1.3426, 2.9741) indicating that significantly determined as the survival time increases over time. Studies indicated that if the acceleration factor is greater than one, the survival rate has been increased compared with the baseline.[30] The plot of the hazard function looks like U-shaped, since (δ=1.9983)>1.

According to the multivariable Gamma parametric model, the covariates including BMI, baseline CD4 count, current CD4 count, functional status, marital status, and ART regimen class were significant at a 5% level of significance. In the multivariable Gamma regression model, the average survival time for females is exp(-0.1888)=0.83 [0.2234,3.0688], 17% lower than that of males. Females have a 17% decreased in survival time to males. In the present study, survival time for females was slightly worse than males after adjusting other covariates constants. With A one-year increase in the age of the patient, the survival time of patients increased by exp(0.0570)=1.06 units or by about 6%. A unit increase in BMI of a patient would increase by 35% ($e^{0.2966}$=1.35) [95%CI: 1.1607, 1.5592]. It coincides with,[31] in which patients with higher weight have less probability of dying than lower weight patients. Accordingly, a unit increase in the current CD4 count patient would improve the estimated survival- time by 1% ($e^{0.0055}$=1.01) [95%CI: 1.0019, 1.0092]. This coincides with,[31–35]

in which it revealed that patients with higher CD4 counts have less probability of dying than patients with lower CD4 counts.

Moreover, married HIV-infected patients had higher survival time on ART than widowed or divorced patients, and ambulatory functional status HIV-infected patients increased the survival time by 0.3% than bedridden patients. Treatment of ART is effective enough in slowing down the progression of HIV-infection and decreasing the mortality rate of patients, and it is highly recommended to HIV patients start antiretroviral treatment early to track the progression of the disease.[33]

Conclusion

The main aim of this study was to determine the potential predictors of survival time of HIV-infected patients on ART using a parametric survival model. The data best-fit with the Gamma parametric model. The estimated shape parameter of the fitted Gamma model is 1.9983 with 95%*CI* (1.3426, 2.9741) indicating that significantly determined as the survival time increases over time. The gamma model result shows that predictors including BMI, current CD4 count, ambulatory functional status, being married and began on ART regimen class of AZT-3TC-EFV were significant determinant factors of patients' survival time at 5% significance level. Besides, using ART treatment significantly improves the survival of patients.

Limitations

This study has a limitation of using some variables only. It is better for future researchers on HIV/AIDS patients on ART treatment will undergo their study by including more socio-demographic and economic variables.

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Conflicts of interest

The author declares that there was no conflict of interest.

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