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Survival Analysis of HIV Infected People on Antiretroviral Therapy at Mizan-Aman General Hospital, Southwest Ethiopia

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Abstract: ***Provision of intervention with antiretroviral therapy has significantly changed the course of the AIDS epidemic form to less life-threatening chronic disease. Thus, the study was aimed at assessing the survival and risk factors of death in people living with HIV/AIDS after initiation of antiretroviral therapy at the Hospital. A retrospective cohort study design was applied in this study. The cohort was stratified into three age groups: children, adolescents, and adults. Kaplan-Meier method was effectively run to estimate survival after initiation of ART. Hazard ratio and Cox proportional-hazard regression model were used to determine predictors of survival time to death. The cumulative probability of survival time at the 6th months after initiation of ART was 96% and 94%, 96% and 96% for children, adolescents and adults respectively (95%CI). Mortality was significantly higher among patients with a low initial CD4, advanced WHO clinical disease stage III and IV,INH Prophylaxis, TB infection and bedridden. The present study has shown that there has been low cumulative incidence of mortality for HIV patients. Higher priority should be given to HIV-infected individuals by starting ART therapy during the preliminary stage of their illness.***

Keywords: ART, Survival analysis, Cohort, Retrospective, Ethiopia.

1. Introduction

The occurrence of AIDS epidemics are amongst the forefront public health challenges that the world has faced in recent past. Millions of people died of HIV infection during the last three decades. The highest number of deaths occurred in sub-Sahara African countries where antiretroviral therapy was introduced lately [1].

Pharmacological activity of Highly Active Antiretroviral Therapy (HAART) is inhibitory effects on HIV duplication and which has shown significant reduction in AIDS epidemics as well as death. The suppression of viral replication is generally associated with steady increase in the CD_4 count and result in clinical outcome betterment [2, 3].According to 2012 world AIDS Day report, there were 700,000 new cases less worldwide in 2011 than a decade ago and 600,000 cases reduction in deaths than in 2005[4].Greater part of the progress which has achieved recently in AIDS prevention is supposed to be ascribed to the ARV therapy[4].

Evidences suggest that untreated HIV infection is more likely leading to increased morbidity and mortality from non-HIV related conditions, even at high CD_4counts [2, 5-7]. Scholars currently recommend that all patients living with HIV need to be treated with ART to reduce transmission of HIV[2, 3]. This is due to increasing evidence that patient with established HIV infection benefit from ART at all stages of disease and reduction in HIV transmission risk from ART-treated patients because of the fact that lower viral load supposed to reduce transmission risk[8, 9].As a result ART is now part of the strategy in effect that aimed at reducing HIV transmission along with risk reduction counseling[2, 9].In Ethiopia, the HIV epidemic has remained a major public health problem, largely affecting people of productive and reproductive age[10]. Since HIV/AIDS cases reported in the mid-1980sin Ethiopia [11], both governmental and non-governmental organizations have shown commitment to prevent its spread and mitigate its impact, from the early days of the epidemic occurred. Their role in prevention and treatment included expansion of ART services to health facilities located closer to the communities has improved access to ART for vulnerable groups. In Ethiopia, currently about 246,347 PLWHA have started treatment but only 179,183 cases are actively on ART[12].Despite the courage shown to universal access for the treatment, there are scarce data about the results of the treatment in the country. Therefore, this study was designed to assess survival time and factors affecting it in AIDS patients with ART.

2. Methods and Materials

A retrospective cohort study was carried out at Mizan-Aman General Referral Hospital ART clinic on people living with HIV/ AIDS (PLWHA) who has been attending ART follow-up care. This Hospital is geographically located in Southern Nations Nationalities People Region (SNNPR). It is found to be 561 km in distance far away from Addis Ababa, capital of Ethiopia in Southwest direction. ART service was successfully established in 2003 in the Hospital. Record for a total of 2682AIDS patients with ART were retrieved by using distinctive ART identification number from the electronic database and reviewed for the study.

2.1. Data processing and analysis

The data for the research was a secondary data collected routinely in the Hospital for clinical monitoring and evaluation purposes and entered in an ART electronic database during the follow up time. Data recording in the Hospital was done by health personnel working in the clinic. The medical doctors also recorded follow up information about the patients. Data recording starts from the date patients started HIV regular care in the clinic till it was confirmed that patients have experienced one of the final events: death, lost to follow-up, dropped ART from the clinic, and transferred out to new health institutions. The source database was accessed and retrieved with the help of Microsoft Excels. The data retrieved from electronic store system were imported into Epi Info 7for windows. The data after imported were checked for completeness, cleaned and edited to undermine effects of errors. Twenty seven cases with incomplete information were excluded from the analysis. The data were exported from Epi Info 7 to SPSS 20 windows version for analyses. The survival time was calculated in months with the time interval between date of ART start and events experienced.

The cohort was definitely stratified into three age groups: children (age ≤10 years), adolescents (age 11–19 years), and adults (age ≥ 20 years). The characteristics of patient in cohort were described in terms of mean/median statistics for continuous data and percentage for categorical data. Life table and Kaplan-Meier methods were used to estimate survival time after initiation of ART. The log-rank test was used to test the observed differences in survival experience in the groups was significant. Cox proportional-hazard regression model was used to identify predictors of death.

2.2. Measurements

The end point of this study was death from any causes which obtained by reviewing medical records in the Hospital, registration by ART adherence supporters, or by calling using their phone number. Living patients with ART, lost to follow up, drop and/or transfer out were considered as censored on 8th May 2013.

All patients with ART from 2005 were included irrespective of age. For each patient, the following baseline information was recorded: age in years at start of ART, sex, CD_4 cell count, WHO clinical stage, functional status, loss to follow-up status, date last seen for care, and where applicable date of death.

2.3. Ethical Considerations

Ethical approval was obtained from the Institutional Review Board of the Mizan-Tepi University. Patients were anonymized and data were handled confidentially during all phases of research activities. Since the study was conducted through review of medical records, the individual patients were not subjected to any harm, provided confidentiality was maintained.

2.4. Operational Definitions

Censored: includes lost to follow up, transfer out and live beyond the study time.
Lost: Not seen since last appointment ≥ 1 month < 3 months.
Drop: Lost to follow up for > 3 months.
Transfer out: A patient is referred to another health facility for care.

Functional status:
Working: Able to perform usual work in or out of the house.
Ambulatory: Able to perform activities of daily living.
Bedridden: Not able to perform activities of daily living.

3. Result

Generally, the present study was based on data of 2655 patients from 2682 patients with ART since 2005. The analysis showed that there were 168 (6.3%) children, 87 (3.3%) adolescents, and 2400 (90.4%) adults. The median (interquartile range) age of the cohort was 30(IQR 25, 35) years for adults, 18(IQR: 15, 19) years for adolescents and 3(IQR: 1, 7) years for children. The majority 1432(53.9%) of patients were female and there were greater number of females 73(83.9%) in the adolescent and 1289(53.7%)in adult age groups, whereas male constituted higher proportion 98(58.3%) of the cohort in children age group.

Generally, the median weight in kilogram at initial ART was 50 (IQR; 44–56) but in the age stratum it was 51(IQR; 45.5, 57), 42(IQR; 34.7, 50), 13(IQR; 9, 16) for adults, adolescents and children, respectively. Cotrimoxazole prophylaxis (CPT) was given to 88.7% children, 88.5% adolescents, and 88.8%adults. TB co-infection was in 17.9%, 19.5% and 22.2% of children, adolescents, and adults respectively. Greater number in all groups 67.3% children, 66.7% adolescents, 60.1% adults were in WHO clinical stage III whereas 16%children, 11.5%adolescents, and 12.6%adults were in WHO clinical stage IV. CD_4 cell count at the time of initial ART was significantly different across the age groups (P-value = 0.001).The initial median CD_4 Count was 367 cells/ml (IQR: 240, 726) for children, 198 cells/ml, (IQR; 101, 271) for adolescents, and 160 cells/ml (IQR: 85, 245) for adults (Table 1). Kaplan Meier curve showed that generally females had longer survival time in adult and adolescent, whereas male had higher survival time in children cohort.

The cumulative incidence of death during the follow-up time was 5.8%in adults, 6.9% in adolescents, and 7.7% in children. The dropout rate was 17.9% in children, 20.2% in adults, and 25.3% in adolescents (Figure1).

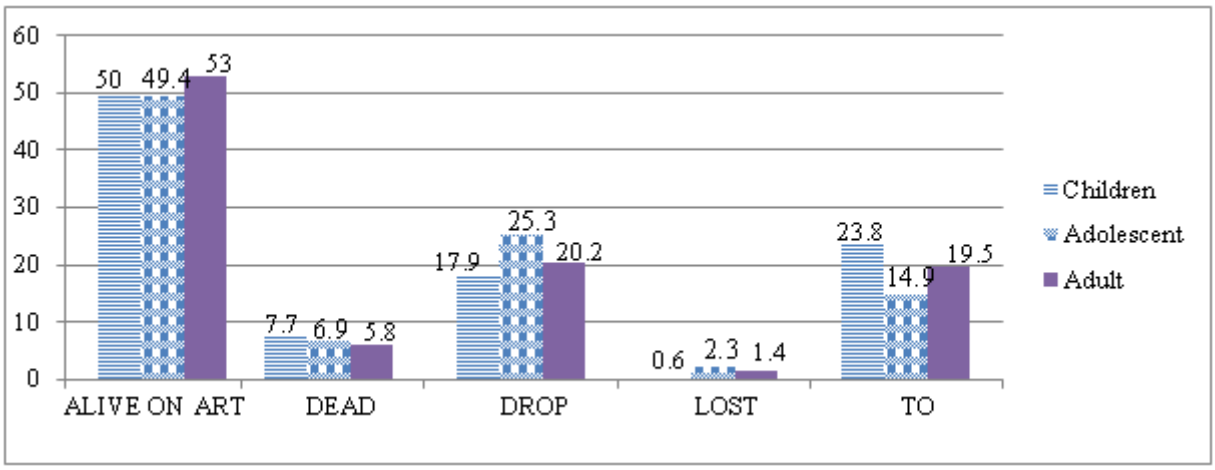


Figure1: Final status of patient on ART at Mizan-Aman General Hospital,Jan 07, 2005 to May 08, 2013.

Table 1: Socio-Demographic and Base line clinical characteristics of ART patients at Mizan-Aman General Hospital,, Jan 07, 2005 to May 08, 2013, (n =2655)

Characteristics	*Age category n (%)*			χ^2 *p-value*
	Children	*Adolescent*	*Adult*	
Sex (n =2655)				0.001
Male	98(58.3)	14(16.1)	1111(46.3)	
Female	70(41.7)	73(83.9)	1289(53.7)	
Age (n=2655, Mean (±SD)	4.1(3.1,3.1)	16.8(2.4 18)	31.5 (8.1)	
Base line CD_4 (IQR)	336(214.5,569)	215(103.5, 270)	162.5(88,	
CD_4 0-49	5(4.9)	6(7.3)	264(11.7)	0.001
50-199	17(16.7)	34(41.5)	1137(50.3)	
≥200	80(78.4)	42(51.2)	861(35.9)	
WHO stage at entry (n= 2655)				
Stage I	11(6.5)	9(10.3)	246(10.2)	0.105
Stage II	17(10.1)	10(11.5)	398(16.6)	
Stage III	113(67.3)	58(66.7)	1443(60.1)	
Stage IV	27(16.1)	10(11.5)	313(13)	
Functional status at entry (n=2655)				0.001
Bedridden	29(17.3)	2(2.3)	145(6)	
Ambulatory	113(67.3)	27(31)	570(23.8)	
Working	26(15.5)	58(66.7)	1685(70.2)	
TB status (n=2655				0.364
Yes (+ve)	30(17.9)	17(19.5)	533(22.2)	
No (-ve)	138(82.1)	70(80.5)	1867(77.8)	
Yes	5(3)	11(12.6)	206(8.6)	
No	163(97)	76(87.4)	2194(91.4)	
Regimen Substitution (n= 2655)				0.191
Yes	22(13.1)	19(21.8)	414(17.2)	
No	146(86.9)	68(78.2)	1986(82.8)	
Cotrimoxazole prophylaxis(n=2655)				0.996
Yes	149(88.7)	77(88.5)	2131(88.8)	
No	19(11.3)	10(11.5)	269(11.2)	

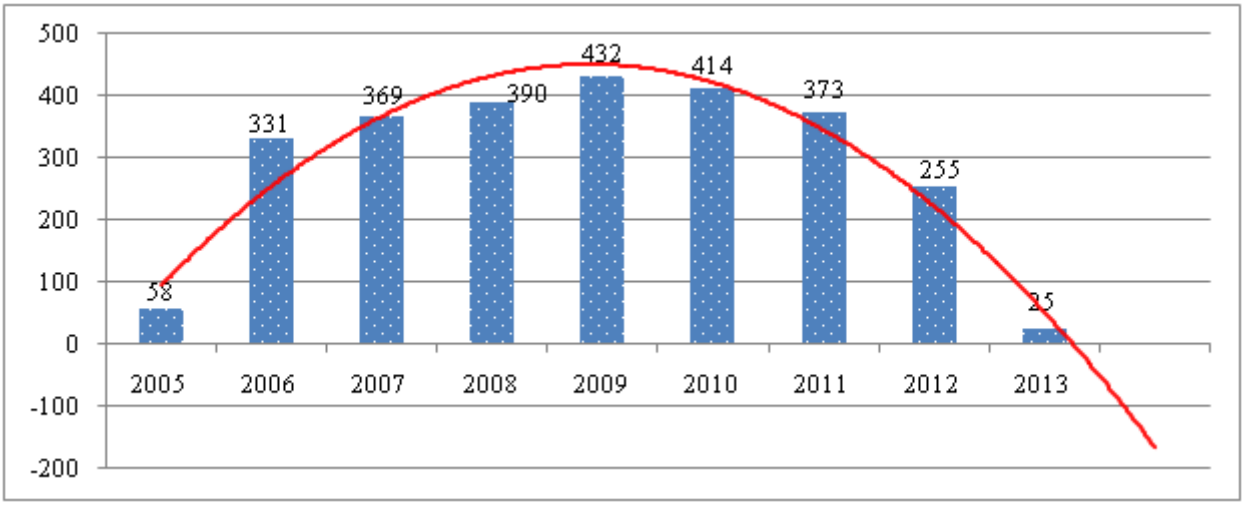
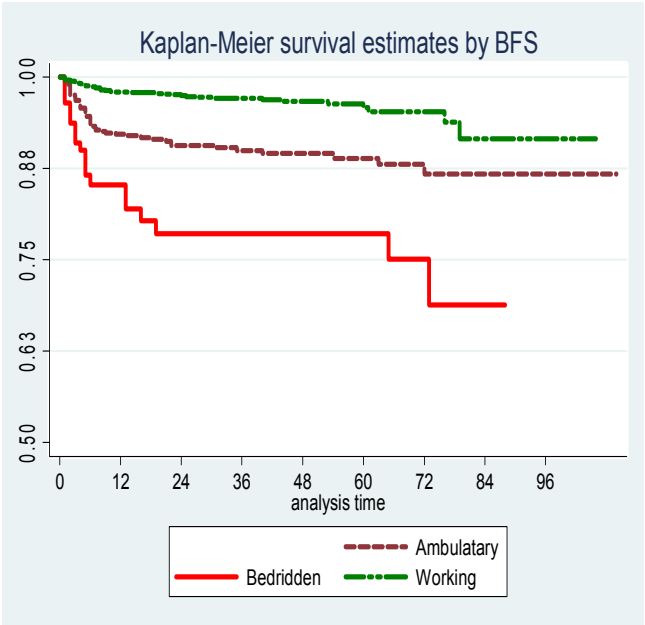


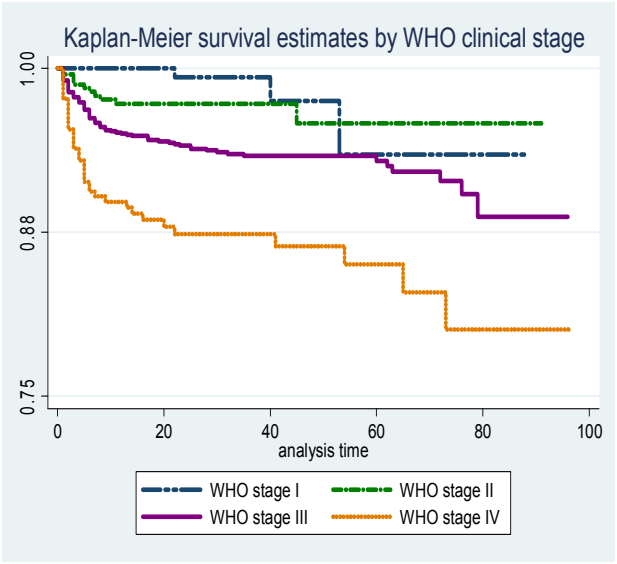
Figure 2: Number of Clients starting ART by the respective year at Mizan-Aman General Hospital, Jan 07, 2005 to May 08, 2013, (n =2655)

Table 2: Actuarial Life Table Cumulative survival of ART patient at a specific time, Mizan-Aman General Hospital, Jan 07, 2005 to May 08, 2013

Months of follow up	*Cumulative probability of survival at a specific time in three age groups*		
	Children(≤10 years) n=168	*Adolescent(11–19 years) n=87*	*Adult(≥20 years) n=2400*
6	0.94(0.89, 0.97)	0.96 (0.88, 0.98)	0.96 (0.95, 0.97)
12	0.91 (0.86, 0.95)	0.93 (0.83, 0.97)	0.95 (0.94, 0.96)
24	0.91 (0.86, 0.95)	0.90 (0.80, 0.96)	0.94 (0.93, 0.95)
36	0.91 (0.85, 0.95)	0.90 (0.79, 0.95)	0.93 (0.92, 0.94)
48	0.91 (0.86, 0.95)	0.90 (0.79, 0.95)	0.93 (0.92, 0.94)

The probability of survival time analysis at the 6th months after initial ART was 96% (95, 97): 94%(89%, 97%) for children, 96% (88, 98) for adolescents, and 96(95, 97) for adults(95%CI) (Table 2).





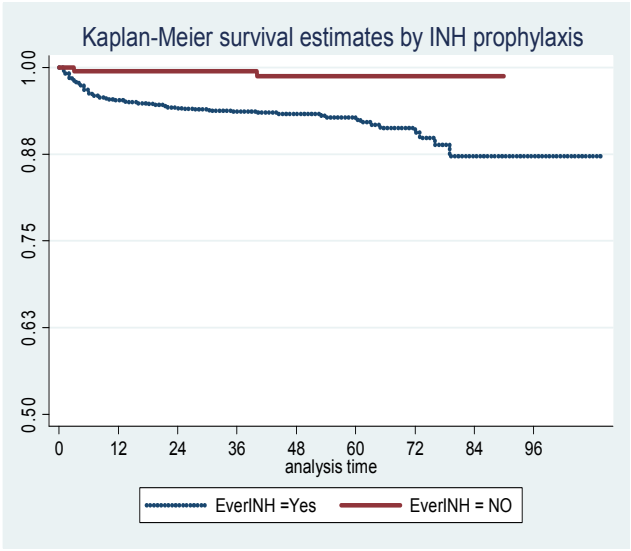


Figure 3: Comparison of survival plots by INH prophylaxis, Clinical stage, and base line functional status of ART patients at Mizan-Aman GeneralHospital Jan-07- 2005 to May-08- 2013.

The average survival time was 89(88, 90) months (95% CI). Children were on average survived premature death for 83(79, 87) months, adolescent for 81(75, 86) months and adults for 89(87, 90). During the follow-up time, 159 patients were died, and 537 patients dropped out (Figure 1). The incidence density of death was 2 per 1000 person/months: 2.8 per 1000 person/months for adolescent, 2.5 per 1000 person/months for Children and 1.9 per 1000 person/months for adults.

In Cox regression model, the main characteristics observed were gender, initial CD_4 count, functional status and WHO clinical stage at treatment initiation, INH prophylaxis for TB co-infection, and age category (Table 3).The model revealed that the risk of death was not significantly different in males and females. Patient in WHO clinical stage IV had HR 4.5(1.364, 14.883) in death level when compared with patient at WHO clinical stage I, and stage III had HR 3.2 (1.06, 10.235) higher risk of dying than stage I whereas there was no significant difference in risk compared to WHO clinical stage II(95% CI). Patient with a history of TBco-infection were HR 1.25(1.027, 1.525) higher risk of death throughout the follow up time. The risk of death in patients without INH prophylaxis was lowered by HR 72%(57%, 82%) when compared with patients who were taking INH throughout the follow-up time(95% CI).

The HR for bedridden and ambulatory patients respectively were 2.626 (2.049, 3.366) and 1.560(1.309, 1.860), which was higher as compared to the reference working category (95% CI). Patients with initial ART at CD_4 count less than 50 cells/ml were 1.977(1.55, 2.52) in HR when compared with patients who initiated ART at CD_4 count >200 cells/ml.

Table 3: Cox regression multivariate analysis, hazard ratio of mortality of ART patients at Mizan-Aman General Hospital, Jan 07, 2005 to May 08, 2013

Variables	*N (%)*	*Adjusted HR (95% CI)*	*p-value*
Age category	2655		
Child (≤10 yrs.)	168	R	
Adolescent (11–19 yrs.	87	1.879(0.704,5.015)	0.208
Adult (≥20 yrs.)	2400	1.412 (0.789, 2.526)	0.245
Gender	**2655**		
Male	1223	0.987 (0.721, 1.350)	0.333
Female	1432	R	
WHO Stage	**2305**		
Stage I	266	R	
Stage II	425	2.142 (0.597, 7.681)	0.242
Stage III	1614	3.209 (1.060, 10.235)	0.049
Stage IV	350	4.506 (1.364, 14.883)	0.014
Functional status	**2655**		
Working	1769	R	
Ambulatory	710	2.848 (1.939, 4.183)	0.0001
Bedridden	176	6.724 (4.253, 10.630)	0.0001
EverINH	**2655**		
Yes	222	R	
No	2433	0.205 (0.065, 0.647)	0.024
CD4 category	2446		
≤50	275	2.262(1.33, 3.82)	0.003
50-199	1188	1.414(0.91,2.2)	0.124
≥200	983		
TB status	2655		
Yes(+ve)	580	1.25(1.027,1.525)	0.026
No(-ve)	2075		

4. Discussion

In the present study the crude mortality rate was not significantly different among the age groups, however relatively lower proportion of children was lost to follow-up when compared to adolescent and adult populations. In multivariate analysis, explanatory variables did not demonstrate a significant risk of death in the three age groups whereas higher proportion of adolescents was lost to follow-up. The study done in Uganda [13] showed that there was no significant differences both in mortality and lost to follow-up among the age groups. However a report from South Africa by Nachega *et.al*. revealed that adolescents had worse outcomes compared to their adult counterparts[14]. Possible explanations for differences might be the socio-cultural characteristics, care protocols, and social support variations in the age groups in different countries.

In the present study gender had no significant effect on the risk of death. The result is in consistent with other studies in Ethiopia, reported that gender showed no significant effect on mortality [15, 16].Contrary to these findings, ample of evidences demonstrated male gender as an independent predictor of mortality[13, 17, 18]. The controversial reports in various studies might be resulted from the socio-cultural differences in study settings.

Bedridden patients who initiated ART had the shortest survival time than working counterparts. This finding is strongly agreed with various reports in regions of Ethiopia [16-18]. The present study showed that bedridden patients were more than 6.7times more likely to die than those patients engaged in their daily activities.

Results from different researchers showed CD_4 cell counts had a strong influence on the survival experience of ART patients [13, 16-20]. The present study also reached on similar conclusion. Recent findings by other researchers showed that those patients with higher CD_4 counts are at low risk for short-term adverse outcomes [7, 21, 22]. There is indication that both morbidity and mortality are reduced by initiation of ART in patients with CD_4 counts above or in normal range. According to New York report on ART all patients with established HIV infection should be evaluated for initiation of ART regardless of CD_4 count[2]. This is due to increasing evidences that HIV-infected patients benefit from ART at all stages of disease [8, 9]. As most studies, mortality was higher among patients with advanced WHO clinical stage III and VI. The result is strongly consistent with other studies reported from Ethiopia [15, 16, 20].

The present study has shown that patients with a history of TB were 1.25 times at higher risk of death than those without it during the follow-up period. Similarly, study done by different researchers demonstrated that HIV-infected patients with TB positive had shorter survival duration [23, 24].Tuberculosis (TB) is additionally responsible for the highest risk of mortality and morbidity among people infected with HIV worldwide[25].The risk of death in patients without INH preventive therapy was lowered by 72%when compared with patients who were taking INH. This finding is controversial as it disagreed with reports that suggest INH prophylactic therapy successfully extend and

improve the quality of life for people living with HIV [26]. The possible reason which counteracted this controversy might be INH prophylactic therapy was not universally given among the cohorts but only patients who were highly suspected for TB infections by health experts and in most case of advanced clinical stages were eligible for INH [25].

5. Conclusion

The present study has shown generally low incidence density of mortality nonetheless there was a high loss to follow-up rate of the cohort. The mortality rate was not different among the age groups, however higher proportion of adolescents was lost to follow-up when compared to child and adult age groups. The probability of survival by 6th month after initial ART was higher for adults compared to children and adolescents. In the present study, it was found that advanced clinical stage, bedridden patients, low CD_4 cell count, INH prophylactic therapy and TB co-infection were independent predisposing factors for mortality. According to these findings, priority should be given to identify HIV- infected individuals and start ART in the early stage of their illness. As children and adolescent population become increasingly important in the epidemic, further investigation into the causes of loss to follow up and mortality are required to devise strategic plan for controlling the HIV epidemic and to improve the positive outcomes of the ART. Moreover, the utilization of routine data should be encouraged in order to facilitate appropriate decision making in time of initiation of ART and tracing of loss to follow ups.

6. Conflict of Interests

Authors declare no competing interests.

7. Authors' contributions

All authors had significant intellectual contribution towards the design of the study, data collection and analysis and write-up of the manuscript. All authors read and approved the final manuscript.

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