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Research Article

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Incidence and Predictors of Mortality Among Adults ART Users on Universal Test and Treat Approach in a Public Health Facility, South Ethiopia 2023

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ABSTRACT

Background: Universal "test and treat approach" (UTT) is a program that commends for all populations those diagnosed HIV positive receive early treatment not considering their CD4 count and WHO clinical stage. However, there are limited studies that assess the incidence and predictors of mortality among adults ART users on universal test and treat approach in public health institution.

Objective: This study was amid to assess the incidence and predictors of mortality among adults ART users on universal test and treat approach in public health facility in South Ethiopia

Methods: Institution-based retrospective cohort study was conducted at Public hospitals in Southern Ethiopia with a total of 802 randomly selected records of ART enrolled adults from March 1, 2013, to February 31, 2020. Data were extracted by using a standardized checklist by trained health professionals, then it was cleaned, entered by epidata version 4.2, and analyzed by STATA version 14. The Cox model was used to estimate survival differences across different study variables.

Results: A total of 790 patients were followed for 1490.8 person-year (PY) of observation. The overall incidence density rate (IDR) of death in the cohort was 3 per-100-PY. The incidence of death was significantly higher in the CD4-based and WHO stage program than the UTT program. The death among CD4-based and WHO stage programs were 3.7 times higher than the UTT program. The log-rank test and Kaplan-Meier survival curve indicated patients enrolled in the UTT program survived longer than patients enrolled in the CD4-based and WHO clinical stage program (log-rank X2 test = 17.6 p-value = 0.001). WHO clinical stage, functional status, Program of ART, New opportunistic infection, Adherence to ART drugs, and Initiation of IPT were predicted mortality from HIV infection.

Conclusion: Mortality was significantly reduced in the universal test and treat program. Hence, intervention to further reduce deaths has to focus on early initiation of treatment and strengthening universal test and treat programs.

Keywords: Incidence of Mortality, Universal Test, Treat, Human Immunodeficiency Virus

Abbreviations

ART	:	Antiretroviral therapy
AOR	:	Adjusted odds ratio
CI	:	Confidence interval
HIV	:	Human immunodeficiency virus
IDR	:	Incidence density rate
IRIS	:	Immune reconstitution inflammatory syndrome
OIs	:	Opportunistic infections
PLWHA	:	People living with HIV/AIDS
UTT	:	Universal test and treat
WHO	:	World Health Organization

Introduction

Background

Globally an estimated 21.7 million people are receiving antiretroviral therapy (ART) of which the World Health Organization (WHO) African Region accounts for 60% [1]. In East and Southern Africa, the average adult ART coverage is 66% [2]. In Ethiopia, the overall ART coverage is 54% of which the adult ART coverage accounts for 58% [3]. In Ethiopia, around 690,000 people were living with HIV in the year. Around

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23,000 people were newly infected with HIV and 11,000 people died from a TB/HIV co-infection. Of all adults aged 15 years and over living with HIV, 66% were on treatment [2].

People living with HIV are particularly at risk, for infectious diseases like tuberculosis, and intestinal worms. The peoples are most likely to be infected with TB by their parents and other close relatives, especially in overcrowded living conditions, which increases individual risk of infection and causes severe disability due to immunodeficiency [4].

Human immunodeficiency virus (HIV) infection remains the leading cause of mortality throughout the world [5]. Antiretroviral therapy has significantly reduced mortality and improved the life expectancy of HIV-infected patients [6]. Ethiopia is one of the HIV hard-hit countries with a prevalence of 1.1% [7]. WHO launch the "universal test and treat" (UTT) program as a strategy for HIV elimination in place of the previous "differed treatment" (CD4 based and WHO clinical staging approaches [8,9].

UTT is a program that commends all populations at risk is screened for HIV infection and those diagnosed HIV positive receive early treatment not considering their CD4 count and WHO clinical stage. Several countries including Ethiopia had adopted the 'test and treat' program [10,11]. Even though, the health care systems have accepted the public health benefit of universal test and treat strategy for the prevention of new transmission, evidence on its impact on clinical outcome and patient survival are limited [8]. Even if, the WHO recommends the universal test and treat program, about 11% of low and middle-income countries do not implement it yet [10].

Accordingly, assuring the individual level benefit of the program in terms of treatment outcome and patient survival is very essential to convey additional evidence useful for supporting program intervention. Some studies conducted abroad in areas of previous approach (WHO clinical staging and CD4 based) have reported different findings. Some studies had shown that test and treat strategy as the effect of early initiation of treatment has an impact on all epidemiological aspects of HIV/AIDS.

UTT has sown reduction in mortality in ART patients that the incidence of mortality in deferred treatment modality is 0.58 times higher than the current UTT program [12]. Yet, there is a shortage of scientific research for clinical decisions [8-10]. Despite all linked concerns, the UTT program has been in practice since 2016 in Ethiopia. Therefore, this study is aimed to assess the incidence of mortality and patient survival, by recruiting a cohort of ART users in the new (UTT) approach and the previous CD4 based and WHO clinical stage programs in South, Ethiopia.

Methods and Materials

Study Design and Setting

The institution-based retrospective cohort study was conducted in seven randomly selected Public hospitals in Southern Ethiopia from the records enrolled from 1st March 2013 to 31st February 2020. All HIV-infected adults who enrolled in adult ART clinics were the source populations. The starting point is from entry to the adult who was in ART service from 1st March 2013 to 31st February 2020, and the endpoint was death or loss to follow up or transferred to another health institution.

Study Population and Sampling Technique

The source population was all HIV-infected adults who enrolled in a treatment program in public hospitals in southern Ethiopia. The sample size is calculated based on estimation for the assessment of survival time using STATA version 14 in considering the following assumptions 95% CI, power of 80%, the ratio of unexposed to exposed 1:1, and Survival probability of unexposed 0.88 and Survival probability of exposed 0.94 with AHR 4.13. Finally, by using 10% for incompleteness the sample size was 802. The sample was allocated proportionally for the seven selected public health facilities and records were selected randomly.

Data Collection Procedure and Data Quality Control

The sources of data for this study were the ART register and the patients' ART follow-up and medical charts. In those registers and follow-up charts, clients' socio-demographic, clinical, and laboratory information, treatments being provided, the follow-up status of each client were recorded. Data was collected from client charts using a structured checklist for records review developed from the registers and follow-up charts. Twenty-one data collectors who are health professionals working in the pediatric ward were recruited for data collection after getting rain on the tool.

Study Variables and Data Analysis

The outcome variable is time to death from enrolment to the ART program. The survival time is measured as the period between the date of enrolment and date of death and it is dichotomized as death and censored. The censored cases include the alive patients, defaulters, and transferred outs. Data were cleaned, coded, and entered into Epi Data version 4.1 and exported to STATA version 14 for analysis. Bivariate analysis was carried out to determine the association between the dependent variable and the explanatory variables. Both the Crude hazard ratio(CHR) and adjusted hazard ratio(AHR) together with the corresponding 95% confidence interval and P-value were used to assess the strength of association and statistical significance. The Kaplan Meier survival curve together with the log-rank test was fitted to determine the survival time. Variables that had a p-value <0.25 in bivariate analysis were considered as a candidate for multivariable analysis and variables which had a p-value <0.05 in multivariable cox regression analysis were considered as statistically significant. The backward stepwise regression method was applied.

Ethical Consideration

Ethical clearance was obtained from the institutional review board (IRB) of the Arba Minch College of health sciences in, South Ethiopia. In addition; a permission letter was obtained from the Arba Minch College of health sciences and public hospital administrations. HIV care clinics' focal persons were informed about the objective and significance of the study before the data collection. Appropriate measures were applied to ensure the confidentiality of the data.

Results

Socio-Demographic Characteristics

A total of 790 randomly selected patient charts were reviewed 395 from those enrolled with the CD4 and WHO clinical staging based program and the remaining 395 from those enrolled with

the current universal test and treat program of HIV care and data was extracted by using a structured checklist. Of the 802 patient charts sampled, 12 charts were excluded from the analysis due to incomplete data. Therefore, 790 charts were included in the analysis. The mean age of the study participants was (31.97 ±8.64 SD) years, patients in the UTT program have slightly higher age (32.46 ± 8.66) than patients in the differed program (31.48 ± 8.61). The majority (61.8%) of the participants were females. More than half(54.9%) of the respondents were urban residents, and 418(52.9%) had formal education. When we see the marital status, 485(61.4%) participants were married whereas 67(8.5%) were divorced. The average weight of participants was (53.48kg ±10.47 SD) with no difference between the two programs. (Table 1).

Clinical Characteristics

Among the total 790 participants, 221(28%) of respondents had baseline WHO stage (III and IV). The proportion of stage III&IV patients in the differed treatment was higher 148(37.5%) than those enrolled in the UTT program 73(18.4%). The median CD4 count during initiation of ART was 395 (IQR: 225.75-588), it was higher among patients in the UTT program 510 (IQR: 291-656) than the differed treatment 316 (IQR: 188-475). Three fourth (75.6%) of the participants has functional status "working", whereas 40(5.1%) were bedridden at the time of enrollment (Table 2).

Incidence of Mortality

Seven hundred ninety patients were followed for different periods with a total of 1490.8 person-year of observation. The minimum and maximum follow-up periods were one month and four years respectively with the median follow-up period of 1.8(IQR: 0.73-29) years. During the follow-up period, 42(5.3) patients died. However, the incidence density rate was 3 per 100 adult ART users year observation (95%CI: 0.025.0.046). Hence it is significantly different for the two comparison groups. The incidence density rate was 5 per 100 people a year of observation in CD 4 and WHO clinical staging whereas the incidence density rate was 1.2 per 100 people a year in a universal treatment program with a p-value was < 0.001. The relative risk of death among CD4 and WHO stage programs were 4.55 times higher than the UTT program. During the follow-up period, 32 (8.1%) patients died, in CD4 based and WHO stage program and 10 (2.5%) ART users died in the UTT program (Table 3).

The Survival Status of Adult ART

In this study, 3 % of the adult ART user were dead at the end of the first year, 4 % at the end of the first two years, and 5.3 % in the first four years of the follow-up period. The cumulative proportion of survival at the end of the first year and the fourth year was 94:(95%CI:0.9204,0.9598) and 89:95%CI :(0.8356,0.9209) respectively. (Table 4).

Comparison of Survival Probability among Categories of Variables

The patients enrolled in the UTT program survive longer than clients enrolled in the CD4-based and WHO stage program (log-rank X2 test = 17.65 p-value <0.0001) (Figure 1).

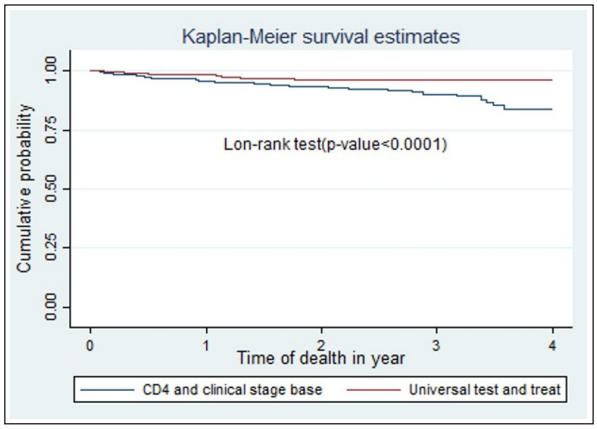

Figure 1: Kaplan - Meier survival estimates of CD4 and WHO stage base among ART user in public hospitals, Southern Ethiopia 2021.

The clients who had adherence to ART drugs were surviving longer than compared to non-adherence of ART ((log-rank X2 test = 47.16 p value <0.0001) (Figure 2).

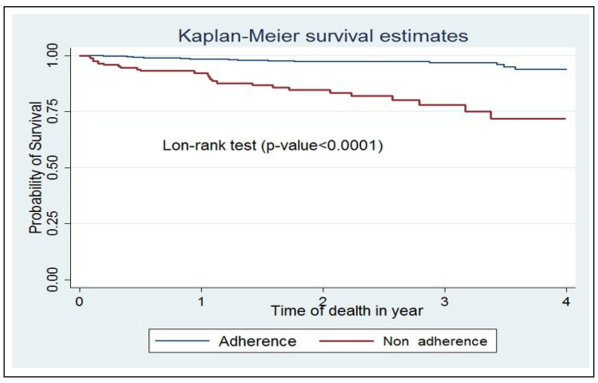

Figure 2: Kaplan-Meier survival curve of ART adherence in public hospitals, Southern Ethiopia, 2021

IPT users was survive longer than compared non-users of IPT ((log rank X2 test = 40.26 p value <0.0001) (Figure 3).

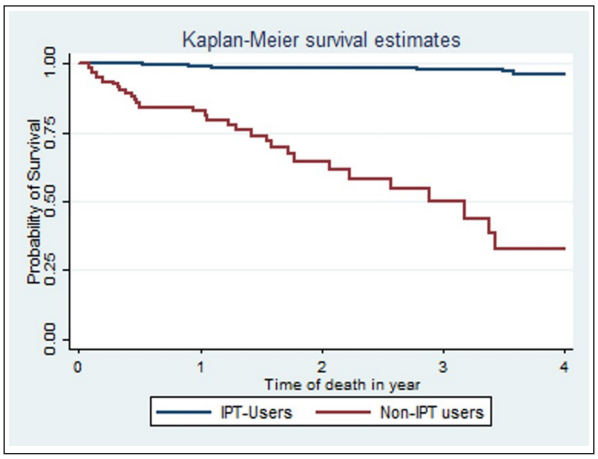

Figure 3: Kaplan-Meier survival curve of IPT users in public hospitals, Southern Ethiopia, 2021

Predictors of Mortality among Adult ART Users

The result of the analysis showed, the WHO clinical stage, functional status, Program of ART, New opportunistic infection, Adherence to ART drugs, and Initiation of, IPT was statistically

significant in the multivariable Cox proportional hazard model. The risk of mortality among adult ART users who had Advanced WHO stage (III&IV) has high risk of mortality than the other mild WHO stage(I&II) was 5.08 times higher as compared with those who had developed mild WHO stage(I&II). (AHR: 5.08;95%CI: 1.39, 18.63).Adult ART users who were functional status was bedridden had 5 times higher risk of mortality as compared with the counterparts, who had Working (AHR: 5; 95% CI: 2.08, 12.01).

The respondent who started ART drug based on CD4 and WHO clinical stage was 3.79 times higher risk of mortality as compared with those who had started ART drug on Universal test and treat approach (AHR: 3.79; 95%CI: 2.00, 8.99).Among the respondent who had newly infected by opportunistic infection was 3.41 times higher as compared with those who had not been newly infected by opportunistic infection (AHR: 3.41; 95%CI: 2.00, 7.29). Adult ART users who have not adhered to ART drugs had a 4.86 times higher risk of mortality as compared with their counterparts, who had adhered to the ART drugs (AHR: 4.86; 95%CI: 2.43, 9.73). The risk of mortality among adult ART users who had not Initiated Isoniazid prophylaxis (IPT) had 3.75 times at high risk of mortality as compared with the counterparts who Initiate IPT (AHR:3.75;95%CI: 1.77,7.96) (Table 5).

Discussion

This study assessed the incidence of mortality on UTT program in comparison with the CD4 and WHO staging of HIV infected patients initiated ART treatment in health facilities of Gamo, South Omo, and Gofa Zone. The incidence of death was significantly higher in the CD4-based and WHO stage program than in the UTT program. It may be because patients on CD4 based and WHO staging after developing serious opportunistic infection [14].

Patients in the UTT law mortality survive a longer period than patients enrolled in the CD4-based and WHO staging program. On universal test and treat program makes patients get medical support in the early stages of infection the response to treatment will be better [15].

In the intervening time, early treatment and prophylaxis prevent the development of fatal opportunistic infections. So that the survival of patients in the test and treat program is longer [8]. The same as sound preceding studies reported that before time appearance and medical care increases the survival of patients [12,15].

It has to be noted that patients who were enrolled under CD4 and WHO staging program were not followed until their CD4 count or WHO stage meet them were eligible to be enrolled for treatment. Though patients on the UTT program were enrolled for treatment soon after diagnosis, consequently these time lapses between diagnosis and enrolment for treatment would have an impact on continued existence time differences.

Cumulative incidence of mortality was significantly higher among patients enrolled in CD4 and WHO clinical staging programs compared to patients enrolled in the UTT program. This can be explained by the increased risk of opportunistic infections, treatment failure, and drug side effects which are more common in the CD4 and WHO clinical stage [16,17].

During the follow-up period, 42 (5.3%) patients died. A lower rate of death was observed in the UTT cohort. The proportion of death in our case is lower than many other studies [15-19] There is also another current study that has reported a lower AIDS-related death rate in Ethiopia [14]. This could be to some extent attributed to the belongings of UTT program implementation in Ethiopia.

WHO clinical stage, functional status, Program of ART, New opportunistic infection, Adherence to ART drugs, and Initiation of IPT are significant to contribute mortality in ART users.

WHO clinical staging scheme was developed by WHO in 1990, and it emphasizes clinical parameters as a guideline for clinical decision making [20]. Many studies show that mortality of HIV-positive individuals with advanced clinical stage is higher than mild clinical stage [21-23]. In this study, the baseline functional status bedridden was five-times higher than those whose baseline functional status was working and ambulatory(AHR: 5;95%CI (2.08-12.01). This is similar to other studies' baseline functional status bedridden was reduce the survival time [23-25].

The study show hazard of death in CD4 and WHO based enrolled individuals were four times higher than those who enrolled in UTT program (AHR:3.79;95CI (1.59-8.99). This is in line with other studies [14]. This could be the low prevalence of co-infection, low probability of drug interaction, and side effects like IRIS, for this reason, the UTT program hazard of mortality has been reduced. In the same way, the risk of death in patients who developed new OIs was three times higher than those who did not develop new OIs (AHR:3.41 (95% CI (1.59-7.29).

The indicated that the risk of mortality among adult ART users who had non-adherence to ART drugs had four times higher as compared with those who had adherence to ART drugs (AHR: 4.86; 95%CI: 2.43,9.73). Similar findings were reported in other studies conducted in Indiana and Addis Ababa Ethiopia [26,27]. The reason behind this might be when the adult takes ART drugs adherently viral replication was suppressed which results from an increase in CD4 cells and increase the survival of ART user. On the other hand, ART user who was unable to take ART drugs adherently had come up with many problems such as treatment failure, a resistance strain which resulted in death outcome [28].

The initiation of isoniazid preventive therapy had a protective effect against death among HIV-positive individuals. In line with the study conducted in South Africa and Nigeria [28]. A study conducted Northwest Ethiopia INH user individuals were 92% at lower risk of developing TB compared to those never on INH and 0.08 times less likely to develop mortality among for ART (AHR:0.08;95%CI:0.02,0.37) [29]. This study revealed that adult ART users who did not initiate isoniazid preventive therapy had three times higher risk of mortality as compared with their counterparts who initiated isoniazid preventive therapy (AHR: 3.7; 95%CI: 1.77, 7.96). This could be because IPT decreases mycobacterium load and reduces the progression of latent bacilli to active TB [30].

Conclusion and Recommendations

In this study, the overall incidence density rate (IDR) of death in the cohort is lower than in other studies. Similarly, IDR is

lower in clients enrolled by the UTT program. The cumulative probability of survival is higher in the UTT program and the overall value is comparable with other research.

WHO clinical stage, functional status, Program of ART, New opportunistic infection, Adherence to ART drugs, and Initiation of IPT. Therefore, intervention to further reduce deaths has to focus on facilitating the UTT program to initiate treatment as early as possible and prevention of new OIs is needed. The finding of this research may provide the necessary information in areas of improvement; however further research is needed to give policy-level recommendations.

Strength and Limitation of the Study

This research evaluated the impact of UTT in clinical setups, which may be limited study in Ethiopia. Consequently, it may help to know the case in the actual situation. In view of the fact that the outcome is death; it is easy to establish temporal relationship with predictor variables that are recognized at time of admission. On the other hand, incompleteness of data and trustworthiness of the recorded information remains a major concern, since the data is obtained from record review..

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Availability of Data and Materials: Data is available and can be found upon request of the corresponding author

Ethics Approval and Consent to Participate: Ethical clearance was obtained from the institutional review board of Arba Minch college of health science. Permission to conduct the study was obtained from Gamo, South Omo, and Goffa Zone public hospitals. Permission was obtained from each clinic's officials. All data obtained from records were kept confidential by using codes instead of any personal identifiers. The finding of the study is believed to benefit the clients indirectly through the improvement of the health care system; which will maximize the benefit and minimize the harm.

Consent for Publication: Not applicable

Competing Interests: The author declares no conflict of interest with anybody.

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