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Original Research Article

Tuberculosis and human immunodeficiency virus co-infected patients' mortality rate and its predictors in Dire Dawa, Eastern Ethiopia, 2018

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ABSTRACT

Background: Tuberculosis and human immunodeficiency virus (TB/HIV) co-infection is an important global public health problem and result multidirectional tricky. The mortality rate of co-infected patient's comes from many aspects or factors. Identification of these factors is important for planning and for the intervention of care and treatment. The aim of this study was to examine the co-infected patients' mortality rate and its predictors.
Methods: A five-year retrospective cohort study was employed among 471 randomly selected TB/HIV co-infected patients enrolled from January, 2012 to December, 2016. Relevant variables of data were collected from patients 'medical cards. The collected data were entered into Epi-data 4.2.0.0 and exported to SPSS version 24 for analysis. Univariate analyses were used to describe the baseline characteristics of the patients. Kaplan Meir curve were used for the comparison of time to recovery among the different groups of patients and Cox model was used to identify independent predictors.
Results: A total of 79 (16.8%) deaths occurred during the median follow-up period of 685 days. being infected with pulmonary tuberculosis (PTB) [AHR=1.99 (95% CI:1.16-3.41)], WHO clinical stage III [AHR=2.88 (95% CI:1.56-5.30)], IV [AHR=4.20 (95% CI:2.21-8.01)], ambulatory functional status [AHR=4.15 (95% CI:1.57-10.98)], bedridden functional status [AHR=6.34 (95% CI:2.43-16.59)] and delayed Co-trimoxazole preventive therapy [AHR=2.45 (95% CI:1.54-3.91)] were important predictors associated with high mortality rate of TB/HIV co-infected patients.
Conclusions: about one to six TB/HIV co-infected persons died in their course of treatment follow-up. Important contributing factors were PTB infection, WHO clinical staging III and IV, ambulatory and bed ridden functional status and delayed co-trimoxazole preventive therapy.

Keywords: Dire Dawa, Ethiopia, Retrospective cohort, Mortality rate, TB/ HIV co-infection

INTRODUCTION

Tuberculosis and human immunodeficiency virus (TB/HIV) co-infection is a significant global public health problem. When people have HIV infection, and either latent or active TB disease considered as TB/HIV co-infected. Rapid growth of the human immunodeficiency virus (HIV) epidemic resulted in an equally dramatic rise in new tuberculosis (TB) cases. Which leads now a day's co-infection of TB/HIV is common in many parts of the world, especially, in sub-Saharan Africa including Ethiopia.[1-3] The relation of the con-infection of TB and HIV is bidirectional. HIV infection is a leading risk factor for TB over-diagnosis of sputum smear-negative PTB and under-diagnosis of sputum smear-positive PTB. The HIV infection also threat for inadequate supervision of anti-TB chemotherapy, high morbidity and mortality during

treatment, high default rates, high rates of TB recurrence and relapse, poor adherence due to pill burden.[4] Similarly, TB increases viral load and replication. This fallouts in more rapid progression of HIV disease.[4] The consequence of co-infection is multidirectional, started from the increasing of burden for the health workers to the loss of patients' life.[5,6] Mortality rate of TB/HIV co-infected comes from many aspects or factors like weight, WHO staging, place of residence, CD4 count, age, types of and recurrence of TB, time of initiation of treatment.[7-10] Global efforts to combat TB/HIV co-infection have improved the mortality of patients after initiating TB and HIV treatment in different countries.[2,7,11-14] However in Ethiopia, few available evidence showed that insignificant decline of mortality rate and little predictors was known.[5,7,15] This study aimed to identify predictors and examine the mortality rate of the TB/HIV co-infected patients using retrospective cohort follow-up study.

Objective

The aim of this study was to determine TB/HIV co-infected patients' mortality rate and its predictors in Dire Dawa, Eastern Ethiopia 2018.

METHODS

Study setting and period

Institution based retrospective cohort study design was used.

This study was conducted in the Dire Dawa town, Eastern of Ethiopia which is 515 km far from Addis Ababa. The patients were followed retrospectively from January 2012 to December 2016.

Setting: the study was implemented at both primary and secondary health institution; number of participating centres for follow-up were 471 individuals from those entered participants 244 were females and 302 participants were completed this study while 167 not completed (died, lost follow-up, or transfer out).

The baseline data were taken when the participants enter to the follow-up. The baseline data taken were sex, age, educational status, marital status, and residence, weight, WHO clinical stage, functional status, prophylaxis therapy status, other opportunistic infection status, hemoglobin count, CD4 count and the like variables were measured. While the secondary outcome were whether patient was died or survive in the follow-up period.

Populations

Source population

All TB/HIV co-infected patients treated in Dire Dawa public health institution from 1st January 2012 to 31st December 2016.

Study population

TB/HIV co-infected patients' medical records in the period of 1st January 2012 to 31st December 2016 in the sampled institution.

Inclusion criteria

For this study All TB/HIV co-infected patients' 1st January 2012 to 31st December 2016 were included. The inclusion criteria were being co-infected with TB/HIV and have started TB treatment.

Exclusion criteria

TB/HIV co-infected patients who have multidrug resistance. Patients' records which has incomplete information and illegible handwriting, transfer in or truncation and interval censored patients were excluded from the study.

Sample size

Sample size for the survival status of TB/HIV co-infected patients followed to the anti TB treatment was used a two steps processes to determine the sample size the first one is determining the total number of expected event (death) and the second one is the total sample size required to get this number of events. Determined by the following consideration with a two-sided significance level of 5 percent and 80 percent power.

$$M=\frac{(Z\alpha/2+Z\beta)^{\wedge}2}{\theta^2\Pi(1-\Pi)}$$

Were - M=is number of expected events (death)

- Z α/2=is the significance level two side (5% the value is 1.96)

- Z_β=80% power=0.842

-Ɵ is logarithm of the hazard ratio=9.1 (Abrha, et al).

- Π is the fraction of subjects allocated to the first group (by general cohort study expected ratio of 1 to 3 exposed-non exposed ratio)

$m=(1.96+0.842)/[\text{Log}\ (9.1)]^2 *0.25\times0.75$

m=47

$$n=\frac{M}{p(event)}$$

Where – n= is the number of subjects to be followed.

M= is the number of events (47)

P= s the over all probability of an event (death) at the end of the study= (20.2%).[16]

n=m/ P (events) = 47/0.202
n=280

The sample size for predictors of mortality rate of TB/HIV co-infected patients was calculated by Stata version 13 and one regression slope model by considering the following assumptions: confidence level 95%, power 80% and exposed to unexposed ratio of 1, standard deviation and correlation of covariates 0.5 and 0 respectively. From the calculated figures, taking the higher value that is 392 and add 20% of loss to follow up the final sample size will be 471 and taking it as finale sample size.

Data collection

Data were collected using a pretested check list which was adapted from different literatures. The check list has contained socio-demographic characteristics, TB related factors, HIV related clinical factors and drug related factors. Data were gathered from patients' TB registers, ART registers, and laboratory requests, follow-up registration, pre-ART registries and clinical data were identified from medical file of patients for a five years follow-up.

Operational definition

Event: A TB/HIV patient who died from any cause after starting TB/HIV treatment.

Censored: patients who do not known a disease endpoint during their period of follow-up.

Survival status: time in days transpired from the date of initiation of TB treatment to death, lost follow up, transfer out or in the case of individuals who did not die (censored) the time in days transpired to complete follow up.

Patient and public involvement

In the process of this research informed consent were taken from all the heads of hospitals and health institutions. Patients' directly involvement or direct contact with data measurer or data collector was not applicable since the data collection were from secondary document. However, the data collection process were realized with full consent of the institutions and confidentiality were fully appreciated. After the accomplished of the research the result were presented to the all institutions' representatives and health berou officers. Moreover, it was presented to scholars of Haramaya University.

Data quality assurance

The collected data were checked, cleaned and compiled by the investigators as soon as data collectors reported on daily basis. If unfilled or missed data reported, the data collectors were asked to revisit and check the file the next day before proceeding to the next step. Finally, double data entry was done by two data clerks and consistency of the entered data was cross checked by comparing the two separately entered data.

Data processing and analysis

After the data were checked, entered into Epi-Data version 4.2.0.0.win.64, and exported to SPSS version 24 for analysis. The data were cleaned and edited before analysis. Data exploration was undertaken to see if there are odd codes or items that were not logical and then subsequent editing was made. The main end point or event in this study is death from TB/HIV co-infection. The response variable was mortality rate, defined as "time in days transpired from the date of initial TB treatment to death" or, in the case of individuals who were not die (censored), "the time in days transpired to complete study period, defaulter, lost follow-up, transfer out". Variables were considered as a candidate if it shows marginal association ($p<0.045$) in the bivariate analysis. Multicollinearity was checked with standard error. Standard error (SE) less than 1.3 taken as non-collinearity and enter in to the multivariate analysis. Goodness of fit were checked by Schoenfeld residuals test and greater than 0.05 is taken as fitness of model or fulfilment of proportional hazard assumption. Time interaction were check by using cox time dependent covariance.

The patient cohort characteristics were described in terms of mean, median, standard deviations, and range values for continuous data; percentage, frequency tables and charts/graphs for categorical data.

For the comparison of time to recovery among the different groups of patients, Kaplan Meir curve were used. Log-rank test were used to compare survival curves of groups defined by categorical covariates. The Cox proportional hazard model were used to determine predictors of death after TB diagnosis. The crude and adjusted Hazard Ratio (HR) and its 95% confidence interval (CI) were estimated. Cox regression analysis were done with the identified candidate independent predictors.

RESULTS

Socio demographic characteristics of study participants

A total of 471 TB/HIV co-infected patients were followed for a median of 685 days from January 01/2012 to December 31/2016. The data were measured at baseline when patients enter to the study and followed till the end of study period for censored cases or till event happens. The mean age of the study subjects were 32.43 (SD±11.38) years with a majority of them lying between 15-45 years. Nearly one fourth, 106 (27%) had primary level of education. Almost two fifth study patients, 153 (40.5%), were self-employed (Table 1).

Clinical characteristics of the study subjects

Among study participants nearly three fourth, 340 (72.2%) were new TB cases. Four fifth of patients, 385 (81.74%), had weight between 30 to 60 kg. About 63.9% and 56.7% participants had >200 gm/mm^3 CD4 counts and >10 gm/dl hemoglobin level respectively. Half, (50.5%) of study patients had PTB and from them 117 (24.8%) positive for AFB. More than 2/3rd of participants, 327 (69.4%) initiated ART, out of them greater than half, 195 (59.5%), have initiated before 2 weeks of taking anti TB drug. Thirty-seven ART and 46 anti-TB patients were develop side effects. Approximately two fifth of case, 138 (37.5%) were had bedridden functional status. Concerning WHO clinical stages, 126 and 65 cases were in stage III and IV, respectively. Half of participants, 236 (50.5%) has started isoniazid and more than three forth, 360 (77.1%) started co-trimoxazole preventive therapy. Among all study subjects 93 (19.9%) developed other than TB opportunistic infection in study period (Table 2).

Table 1: Socio-demographic characteristics of TB/HIV co-infected patients from 01/2012-31/2016 in Dire Dawa, 2016.

Socio-demographic variables		Frequency	Percent (%)
Sex, (n=471)	Male	228	48.4
	Female	243	51.6
Age, (Years) (n=471)	≤14	24	5.1
	15-24	75	15.9
	25-34	183	38.9
	35-44	114	24.2
	≥45	75	15.9
Educational status, (n=392)	Illiterate	53	13.5
	Can read and write	98	25.1
	Primary education	106	27.0
	Secondary education	86	21.9
	Higher education	49	12.5
Residence, (n=385)	Urban	268	69.6
	Rural	117	30.4
Occupational status, (n=378)	Government employed	86	22.8
	NGO	27	7.1
	Bar/hotel worker	33	8.7
	Self employed	153	40.5
	Other	79	20.9
Health facility, (n=471)	Hospital	280	59.4
	Health center	191	40.3

Table 2: Clinical characteristics of TB-HIV Co-infected patients from January 01/2012 to December 31/2016 in Dire Dawa, Eastern Ethiopia, 2016.

Variables	Category	Frequency	Percent (%)
TB treatment outcome, (n=462)	Cured	92	19.9
	Treatment completed	240	51.9
	Died	73	15.8
	Lost follow up	15	3.2
	Failure	17	3.7
	Transfer out	25	5.5
WHO staging, (n=444)	I	108	24.3
	II	145	30.6
	III	126	28.4
	IV	65	16.7
Functional status, (n=368)	Working	101	27.4
	Ambulatory	129	35.1
	Bed ridden	138	37.5
Baseline weight, (n=471)	<20	12	2.5
	20-29	9	1.9
	30-39	50	10.6
	40-49	166	35.3
	>49	234	49.7

Continued.

Variables	Category	Frequency	Percent (%)
ART initiated, (n=471)	Yes	327	69.4
	No	144	30.6
Time ART initiated, (n=327)	Before two weeks of anti-TB	194	59.3
	At the same time of anti-TB	70	21.4
	After two weeks of anti-TB	63	19.3
Type of TB infection, (n=471)	PTB	213	45.2
	EPTB	233	49.5
	Mixed	25	5.3
AFB sputum result, (n=471)	Positive	117	24.8
	Negative	354	75.2
chest x-ray result, (n=51)	Cavitary pattern	23	45.1
	Non cavitary pattern	28	54.9
complain side effect of anti TB, (n=450)	Yes	46	10.2
	No	404	89.8
Hemoglobin level, (n=471)	>10g/dl	267	56.7
	≤10g/dl	204	43.3
CD4 counts, (n=471)	>200g/mm3	301	63.9
	≤200g/mm3	170	36.1
CPT, (n=467)	Yes	360	77.1
	No	107	22.9
INH, (n=467)	Yes	236	50.5
	No	231	49.5
Complain ART side effect, (n=321)	Yes	37	11.5
	No	284	88.5
ART side effect types, (n=47)	Skin allergic	10	21.3
	Respiratory infection	22	46.8
	*Other	15	31.9
sputum result at the end of 2nd /3rd month, (n=109)	Positive	13	11.9
	Negative	96	88.1
sputum result at the end of 5th month, (n=110)	Positive	5	4.5
	Negative	105	95.5
Sputum result at the end of 6/8 month, (n=97)	Positive	7	7.2
	Negative	90	92.8

Mortality rate

Our hundred seventy-one patients followed for 344,972-person day observations (PDO) with median follow up of 685 days. A total of 79 (16.8%) TB/HIV co-infected patients were died during the study period with overall mortality rate 23 per 100,000 person-days of follow up. About half 40 (50.63%) of the deaths were occurred within the first 219 days of follow up and survival of 0.91 (95% CI: 0.88-0.93) after started anti-TB drug. Median survival time probability of patients were 0.82 (95% CI: 0.78-0.86). The overall survival rate of the patients were 83.2% (95% CI: 79.4-86.4) with 30 days minimum and 1822 days maximum survival rate of time length.

In this study participants who were infected by pulmonary TB 99 % more risk to death when compared to the extra pulmonary infected patients (log rank, x^2=17.83, df (2), p<0.001) (Figure 1).

This study indicate that patients those not start CPT 2.45 times more likely risk to death as compared to those patients started CPT treatment (Log rank, x^2= 20.25, df (1), p<0.0001) (Figure 2).

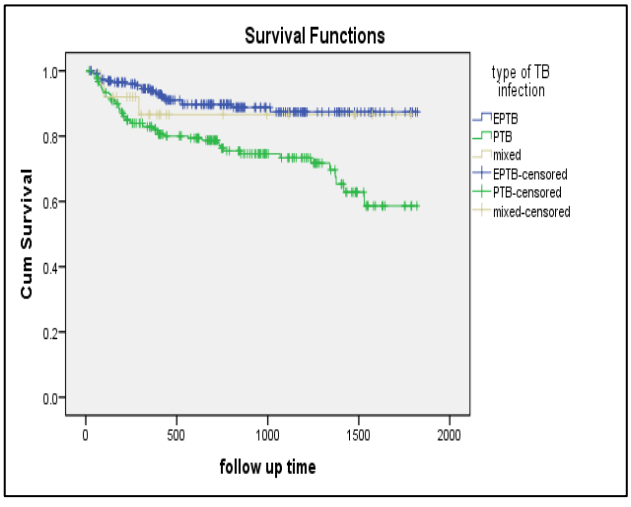

Figure 1: Survival status of TB/HIV co-infection by tuberculosis type.

Based on this finding functional status was significantly related to the survival of patients (log rank, x2=22.53, df (2), p<0.001). Being bedridden six times, being

ambulatory 4.2 times more risk to death to compared working patients at baseline respectively (Figure 3).

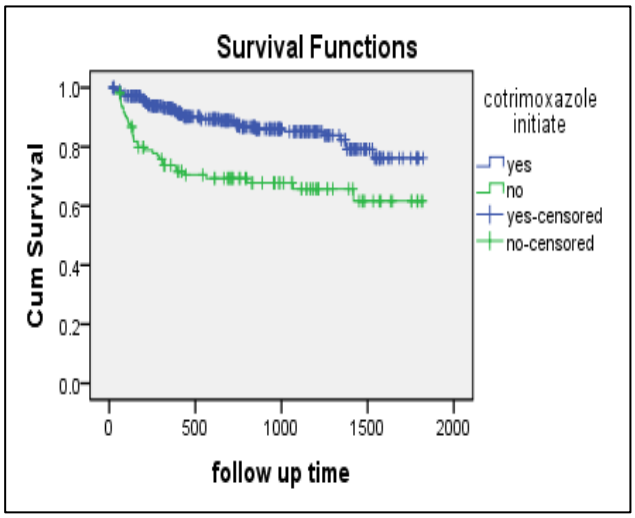

Figure 2: Survival status of TB/HIV co-infection by early co-trimoxazole initiation.

Predictors of mortality

Patients who were infected with pulmonary tuberculosis 99% more risk to death than extra pulmonary infected patients [AHR=1.99 (95% CI:1.16-3.41)]. The mortality risk among bedridden about six times [AHR=6.34 (95% CI: 2.43-16.59)] and ambulatory functional status four times [AHR=4.15 (95% CI: 1.57-10.98)] more likely to get death as compared to those working functional status. Regarding WHO clinical staging, patients who were in stage III and IV while starting anti TB treatment compared to stage I and II (combined), about three [AHR=2.88 (95% CI:1.56-5.30)] and four [AHR=4.20 (95% CI:2.21-8.01)] times more likely to have hazard of death respectively. In addition, patients who do not start CPT were more than two times more likely a risk to death as compared to those patients who already started CPT treatment [AHR=2.45(95%CI:1.54-3.91)] (Table 3).

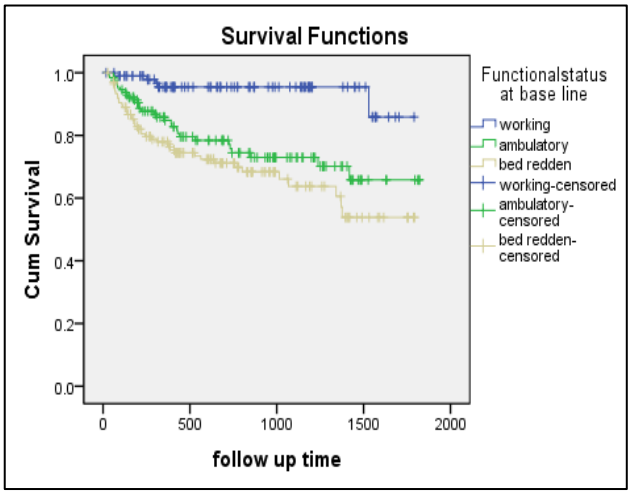

Figure 3: Survival status of TB/HIV co-infection by functional status.

Table 3: Predictors of mortality in TB/HIV co-infected patients, Dire Dawa Ethiopia, 2016, (n=471).

Variables		TB/HIV Co-infected patients mortality status, n (%)		CHR (95%CI)	AHR (95% CI)
		Died	Alive		
Sex	Male	51 (22.5)	176 (77.5)	1.92 (1.21-3.05)	1.60 (0.98-2.61)
	Female	28 (11.5)	216 (88.5)	1	1
Age (years)	≤14	2 (8.3)	22 (91.7)	1	1
	15-24	6 (8.0)	69 (92.0)	1.01 (0.20-5.01)	0.57 (0.11-3.01)
	25-34	38 (20.8)	145 (79.2)	2.86 (0.69-11.85)	1.89 (0.43-8.41)
	35-44	22 (19.3)	92 (80.7)	2.68 (0.63-11.43)	1.22 (0.26-5.66)
	≥45	11 (14.7)	64 (85.3)	1.79 (0.40-8.09)	0.57 (0.11-2.83)
Facility level	Hospital	39 (13.9)	242 (86.1)	1	1
	Health center	40 (21.1)	150 (78.9)	1.75 (1.12-2.72)	1.41 (0.88-2.26)
Type of TB infection	EPTB	22 (9.4)	211 (90.6)	1	1
	PTB	54 (25.4)	159 (74)	2.75 (1.68-4.52)	1.99 (1.16-3.41)*
	Mixed	3 (12.0)	22 (88.0)	1.39 (0.42-4.65)	2.62 (0.73-9.43)
ART initiated	Yes	47 (14.4)	279 (85.6)	1	1
	No	32 (22.2)	112 (77.8)	1.58 (1.01-2.48)	1.47 (0.91-2.37)
Functional status	Working	5 (5.0)	96 (95.0)	1	1
	Ambulatory	30 (23.3)	99 (76.7)	4.99 (1.94-12.87)	4.15 (1.57-10.98)*
	Bed ridden	43 (31.2)	95 (68.8)	7.09 (2.81-17.91)	6.34 (2.43-16.59)**
WHO staging	I/II	21 (8.6)	223 (91.4)	1	1
	III	35 (27.8)	91 (72.2)	3.63 (2.11-6.24)	2.88 (1.56-5.30)*
	IV	23 (31.1)	51 (68.9%)	4.41 (2.44-7.96)	4.20 (2.21-8.01)**
Hemoglobin level	>10g/dl	28 (10.5)	239 (89.5)	1	1
	≤10g/dl	51 (25.0)	153 (75.0)	2.73 (1.73-4.30)	1.67 (0.99-2.82)
CPT	Yes	45 (12.5)	315 (87.5)	1	1
	No	34 (31.8)	73 (68.2)	2.66 (1.70-4.16)	2.45 (1.54-3.91)**

*=(p<0.05), **=(p<0.001), CI=confidence interval, CPT=co-trimoxazole prophylaxis therapy CHR= crude hazard ratio, AHR=adjusted hazard ratios.

DISCUSSION

This study determined that the mortality rate and predictors of TB/HIV co-infected patients under anti-TB treatment. Near to 1 to 6 (16.8%) TB/HIV co-infected patients were died during the follow up of 344,972 PDO. Our finding was dissimilar with the studies conducted in Ethiopia, Ambo (15.77%) and Jimma (20.2%).[16-18]

Malaysia 21.2%.[13] However this finding was lower than studies conducted in Barcelona Spain (36.9 %), and Brazil (35%).[11,19] The difference could perhaps improvements in the health care systems and study time difference.

This study demonstrated that the PTB infection type significantly associated with the mortality of the TB/HIV co-infected patients and the finding come to an agreement with study conducted in the Ambo referral.[17] This possibly will be related to meanwhile lung is vital organ delaying few days make patients susceptible to high hazard of death. The current study indicated that being ambulatory and bedridden functional status significantly affected the mortality of HIV/TB co-infected patients. This finding is consistent with other previous studies.[17,20] In this study, WHO clinical staging III and IV were 2.88 times and 4.2 times more likely at risk of dying compared to WHO clinical stages I and II. This finding is paralleled with the study conducted in Central and North West Ethiopia.[17,20] The possible explanation could be CD4 depletion, since patient's body remains with poor defense and then opportunistic infections will get favorable condition to develop. Early initiation of cotrimoxazole prophylaxis has significant association with mortality of TB/HIV co-infected patients. This finding is in line with similar study conducted in North-West Ethiopia Bahir Dar town.[20]

CONCLUSION

The findings of the current study illustrates that the mortality rate of TB/HIV co-infected patients were 23 per hundred thousand PDO. Therefore, special attention should be given for health education and early case detection. Supply of cotrimoxazole prophylaxis therapy is other alternative given attention. Interested researchers conduct prospectively and by increasing sample size to overcome the limitation of this study.

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