academicJournals

Vol. 10(3), pp. 31-39, March 2018
DOI: 10.5897/JAHR2017.0454
Article Number: 1BE003356171
ISSN 2141-2359

http://www.academicjournals.org/JAHR

Journal of AIDS and HIV Research

Full Length Research Paper

Time for initiation of antiretroviral therapy in HIV co-infected tuberculosis patients in Addis Ababa, Ethiopia

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Received 10 October, 2017; Accepted 4 December, 2017

Provision of integrated care for human immunodeficiency virus (HIV) co-infected tuberculosis (TB) patients is challenging. Many persons with TB and HIV co-infection are not yet receiving anti-retroviral therapy (ART) and initiation of ART is not always timely. This study investigated ART uptake among HIV co-infected TB patients and its time of initiation in an urban primary health care facility in Ethiopia. A retrospective cohort study was conducted using routine program data. All adult HIV co-infected TB patients registered in a large TB-HIV clinic in Addis Ababa from September, 2008 to August, 2014 were included. Both descriptive and inferential statistics were used to summarize and analyse findings. A total of 993 TB patients were registered in the study period and included. HIV counselling and testing was offered to 738 (74.5%) and HIV testing was performed for 678 (68.3%) patients. Of those tested, 226 (33.3%) were HIV co-infected of whom 125 (57.6%) were started on ART. The median period from commencement of TB treatment to starting of ART was 41 days. ART initiation was delayed beyond the period advised in the National TB-HIV Guideline for 31 (27%) of HIV co-infected TB patients. For 109 (48.2%) of co-infected TB patients the ART status evaluation could not be done due to missing data. A considerable proportion of HIV co-infected TB patients did either not receive ART or started it later than recommended by national guidelines. For better outcomes to HIV co-infected TB patients, the actual implementation of national recommendations on when to start ART needs to be monitored closely.

Key words: ART-uptake delay, TB-HIV, primary health facility.

INTRODUCTION

Screening of all tuberculosis (TB) patients for human immunodeficiency virus (HIV) co-infection and referral of HIV positive patients for antiretroviral treatment (ART) initiation and chronic care services are essential

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components of collaborative TB-HIV activities and crucial to reduce mortality and morbidity in TB patients (FMOH, 2007; Sileshi et al. 2013). Medical management of HIV co-infected TB requires standardized anti-TB treatment combined with trimethoprim-sulphamethoxazole (co-trimoxazole) prophylactic therapy (CPT) and ART (WHO, 2010).

The recommended timing of ART initiation after TB treatment start has been adapted several times in the last decade based on the available evidence (Lawn et al., 2009). The latest insights are that early initiation of ART started within 2 weeks of commencing TB treatment, in all HIV co-infected TB patients regardless of CD4 count significantly improves survival (Abdool Karim et al., 2010; Nglazi et al., 2015) and is particularly beneficial for patients with CD4 counts <50 cells/µl (Franke et al., 2011; Salim et al., 2011; Naidoo et al., 2013; Stockdale et al., 2013).

In 2014, globally, 51% of notified TB patients had a documented HIV test result and 77% of TB patients known to be HIV co-infected started ART. In Ethiopia with a high burden of both TB and HIV, 75% of TB patients had a documented HIV test result while only 39% of HIV co-infected TB patients had started ART (WHO, 2014) .

The National Ethiopian TB-HIV guideline was revised in 2007 and 2013 specifically with regards to timing of ART and how to prioritize HIV co-infected TB patients for ART initiation (FMOH, 2007; 2013). The 2007 guideline recommended ART to be started within 8 weeks of commencing TB treatment for patients with a CD4 count <200/µl and at completion of the intensive phase of TB treatment for patients with a CD4 count of 200 to 350/µl while deferring ART commencement for those with a CD4 count >350/µl. The updated Ethiopian TB-HIV 2013 guideline following new global guidance recommends ART initiation as soon as TB treatment is tolerated (usually within 2 to 8 weeks) for those with a CD4 count <200/µl, to start within 8 weeks of starting TB treatment for TB co-infected patients with a CD4 count ranging from 200 to 350/µl, while it is recommended to defer ART and reassess at 24 weeks or at completion of TB treatment for those with a CD4 count >350/µl. Whether or not the National guideline is fully adhered to and TB co-infected patients are started timely on ART, is not known.

The objective of this study was to investigate ART uptake among HIV co-infected TB patients and timing of ART initiation in an urban primary health care facility, against the standard of care as described by the Federal Ministry of Health of Ethiopia in the National TB/HIV guidelines.

METHODOLOGY

Study design and setting

A retrospective analysis of routine program data was carried out in a primary health facility in Addis Ababa. Addis Ababa, the capital city of Ethiopia, has an estimated population of 3 million (FDRE Population Census Commission, 2007). Addis Ababa regional health bureau oversees 11 hospitals and 26 health centers which provide comprehensive health services for its urban residents. Diagnostic and treatment services for TB and HIV are provided at both the hospital and health center level. Patients who cannot be managed at the health center level are referred to the hospital. Bole 17 health center is located in Bole sub-city of Addis Ababa. This health center is one of the first primary health care facilities to start HIV care in the city, including ART initiation and follow up. An average of 40 people living with HIV and TB attend this clinic every year

In Ethiopia, HIV co-infected TB patients are referred to ART clinics to be registered and assessed for ART initiation according to the prevailing National TB/HIV guideline. For the study, delay in starting ART was defined as: eligible HIV-co infected TB patients starting ART beyond the period indicated in the prevailing national guideline for TB/HIV collaborative activities at the time of TB treatment start, which is either the 2007 or 2013 edition of the guidelines. As per the guideline, eligibility is identified based on CD4 count, presence of opportunistic infections and WHO clinical stage. Most of the TB patients are diagnosed and start treatment at the health centre although the health centre also receives TB patients diagnosed elsewhere to start or continue TB treatment. All TB patients are offered HIV testing and counselling and HIV co-infected TB patients are referred to the ART clinic in the same health centre to be enrolled into HIV care. One health officer and one nurse are full time employed in the TB clinic with other trained health professionals providing help based on needs.

Sampling technique and study variables

For this study, all adult TB patients (>18 years) registered at Bole 17 Health Center from 1 September, 2008 to 31 August 2014 were included in the study. Patients who were already on ART before TB diagnosis were excluded. Sources of data were unit TB registers and ART registers. Patients registered for TB treatment from September, 2008 to March, 2013 were assessed against the 2007 guideline and those registered for treatment from April, 2013 to August, 2014 against the revised 2013 guideline (FMOH, 2007, 2013). The main outcome, delay in ART initiation was determined by calculating the difference between start date of TB treatment and start date of ART treatment, which is then compared with national TB/HIV management guideline on when to start ART for co-infected patients**.** Explanatory variables collected were age, sex, site of TB infection, pulmonary TB smear result, TB treatment history, TB treatment start date, HIV test offered, HIV testing done, HIV test result, HIV test date, CPT provision, CPT start date, enrolment to HIV care, date of enrolment to HIV care, WHO clinical stage at enrolment, CD4 cell count, recipient of ART, ART start date, opportunistic infection (OI) diagnosis, outcome of TB treatment, and timing of ART (that is, time between TB treatment start and ART start).

Data management and analysis

The data were double entered and analyzed using SPSS Version 2.0 statistical package (SPSS Inc'). Description of means, frequencies and proportions were used to describe all study variables. Bivariate analysis was performed to test for associations between each explanatory variable and the outcomes of interest. Explanatory variables that were found to be significant in bivariate analysis were included in a multivariate logistic regression model. This estimated the relative effect of the explanatory variables in predicting the outcomes of interest. A P-value ≤ 0.05 was considered as a statistically significant association and the adjusted odds ratio with 95% CI was calculated.

Table 1. Characteristics of tuberculosis patients registered in Bole 17 health center, Addis Ababa, Ethiopia, in 2008-2014.

Patient characteristics	Frequency (n)	Percentage
Sex, n=993		
Male	510	51.4
Female	483	48.6
Age, n=993		
18-24	298	30.0
25-39	447	45.0
≥40	248	25.0
Type of TB* disease by site, n=993		
Pulmonary	606	61.0
Extra-pulmonary	387	39.0
Pulmonary TB, n=606		
Smear positive	340	56.0
Smear negative	266	44.0
Type of TB by treatment history, n=993		
New	947	95.4
Retreatment	46	4.6
Year started TB treatment, n=977		
2008-2009	219	22.4
2010	205	21.0
2011	176	18.0
2012	265	27.1
2013/2014	112	11.5

*- tuberculosis

Ethical consideration

Ethical approval was obtained from the Ethical Review Committee of the Addis Ababa Regional Health Bureau and permission was obtained from the Tuberculosis Research Advisory Committee (TRAC) and the Bole 17 health center.

RESULTS

Patient characteristics

A total of 993 TB patients were registered over the six year period. Their median age was 29 years (inter-quartile range (IQR) 23 to 39) and 510 (51%) were male. The majority 947 (95%) patients had a first episode of TB (so called new patients) and 606 (61%) had pulmonary disease. Of the 606 pulmonary TB patients, 340 (56%) were sputum smear- positive for acid-fast bacilli (Table 1). The majority of TB patients 904 (91%) were evaluated against the 2007 guideline and the rest 88 (9%) were evaluated against the revised 2013 guideline.

HIV status and CPT and ART uptake

HIV counselling and testing was offered to 738 (74.5%) of the 993 TB patients and HIV-test was performed for 678 (68.3%) of whom, 226 (24.4%) tested HIV positive (Figure 1). Of the 226 HIV co-infected patients, 189 (83.6%) were enrolled in HIV care and 125 (57.6%) had started ART, while 200 (94%) were started on CPT. For 203 (89.8%) HIV co-infected TB patients, staging information was available with 165 (81.2%) being WHO stage 3 and 38 (18.7%) being WHO stage 4 (Table 2). Data on CD4 count was available for 191 HIV positive patients (86.7%): 17 (8.9%) had a CD4 count of <200/µl, while 113 (59.2%) had CD4 between 200 and 350, with remaining 61 >350/µl.

Table 2. Clinical stage, CD4 count, and opportunistic infection and ART status of TB positive HIV patients in Bole 17 health center from September 2008 to August 2014.

Characteristic	Frequency	Percentage
HIV testing		
Yes	678	68.3
No	9	0.9
Not recorded	306	30.8
WHO clinical stage		
3	165	81.3
4	38	18.7
CD4 cell count per µl		
<200	17	8.9
200-350	114	59.9
>350	60	31.3
Opportunistic infections (OIs) diagnosed, n=160		
Yes	20	12.5
No	140	87.5
CPT started		
Yes	200	94.3
No	4	1.9
Not recorded	8	3.8
ART started		
Yes	125	57.6
No	73	33.8
Not recorded	19	8.8

Timing of ART initiation

Of the 226 HIV co-infected TB patients, only 121 (53.4%) had information on the start dates of both TB and ART treatment. Timing of ART initiation after start of TB treatment was computed for these 121 patients. The median time period from TB treatment start to ART initiation was 41 days (IQR: 25 to 84 days). Timeliness of ART initiation was analyzed against the 2007 and 2013 national guideline as outlined in the methods. Of the 117 patients assessed against the 2007 guideline, for 31 (26.5%), ART initiation was delayed (Figure 1). The four patients assessed against the 2013 guideline all had started ART within the required timeframe.

Determinants of timing of ART initiation

Of the factors (age, sex, type of TB by site, smear result, treatment history, year that TB treatment started, CD4 cell count, WHO clinical stage and presence or absence of opportunistic infections) evaluated for association with timing of ART initiation, only CD4 cell count was found to be statistically significantly associated in multivariate analysis. Patients with CD4 counts less than 50/µl were three times more likely to start ART in a timely manner when compared to patients with CD4 count greater than 200/µl ($p<0.005$) (Table 3).

TB treatment outcomes among HIV co-infected TB patients

Of the 226 HIV co-infected TB patients, 119 (54.1%) completed TB treatment and an additional 38 (17.3%) had documented cure, resulting in a successful TB treatment outcome for 71.4% of HIV co-infected patients. A total of 61 (27.4%) of the patients had undesirable outcomes (died (9.5%), transferred out (9.5%), defaulted (7.0%) and treatment failure (1.4%)). For 3.2%, no treatment outcome was recorded (Table 4). In HIV-negative TB patients, a treatment success rate of 82.7% was observed (Table 4). TB treatment success rate was significantly associated with HIV status (P value < 0.001)

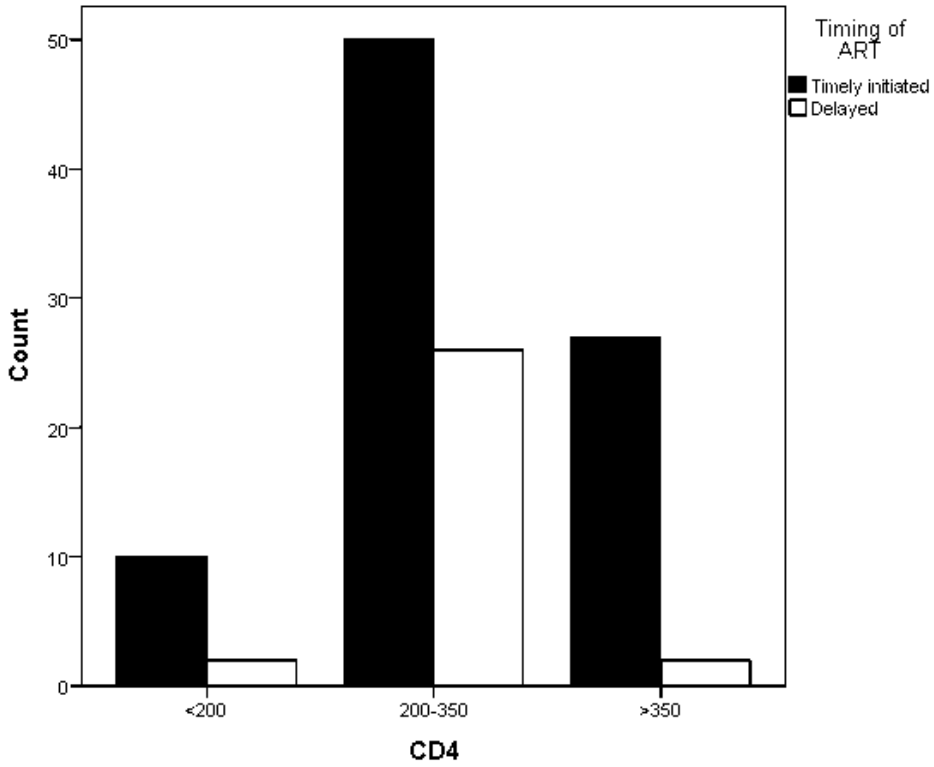

Figure 1. Percentage of patients delayed from ART treatment after they started TB treatment versus CD4 count category in Bole 17 Health centre, Addis Ababa, Ethiopia, September, 2008 to August, 2014.

with HIV negative TB patients being 2 times more likely to have a successful treatment outcome.

Timing of ART initiation and TB treatment outcome

Of the 226 HIV co-infected TB patients, 21 (9.5%) died of whom 7 (36.5%) were started on ART, with one starting ART late. ART initiation showed a significant association with TB treatment success (P value=0.01) with those not started on ART being 2 times more likely to have an undesirable treatment outcome. ART initiation, ART delay and CD4 count showed no significant association with patient mortality (Table 5). Looking at TB treatment outcome in relation to timing of ART initiation indicated no statistical difference in treatment outcome for those starting ART as per guideline compared to those who started ART late in this study.

DISCUSSION

WHO recommends time of initiation of ART uptake in HIV co-infected TB patients in relation to starting of TB treatment as a core indicator for programmatic evaluation of collaborative TB/HIV activities, as indicated by TB/HIV indicators for monitoring and evaluation B8 and B9 (World Health Organization, PEPFAR, UNAIDS, 2015). In the current study the time between TB treatment initiation and ART initiating was a median of 41 days (IQR: 25 to 84 days). Less than two thirds of HIV co-infected TB patients (57.6%) were started on ART of whom 27% started ART later than recommended per the National Ethiopian, as well as the global guidelines. This is a cause for great concern as the latest global guidelines of WHO and UNAIDS of 2015 advise that all HIV co-infected TB patients should be started on ART within 2 months after start of TB treatment, and those with a CD4 counts of less than 50 be started as soon as possible within 2 weeks (World Health Organization, 2015). Other countries in the region have reported much better results in ART initiation. An observational cohort study carried out among HIV positive TB patients in South Africa (Lawn et al., 2011) reported that 87% started on ART while in a study in Kenya this was 70% (Tayler-Smith et al., 2011). Both countries have adopted the recent WHO guideline that all TB patients (irrespective of CD4 count) are started on ART within two months of start of TB treatment. The lower observed proportion of TB patients starting ART in Ethiopia could be due to differences in the national guidelines as the National guideline in Ethiopia does not yet recommend start of ART irrespective of CD4 in line

Table 3. Factors associated with Timely vs. late ART initiation by CD4 cell count with respect to initiation of TB treatment of TB positive HIV patients in Bole 17 health center from 2008 to 2014.

Patient characteristic	Factors associated with earlier vs. late ART initiation with respect to initiation of TB treatment	
	Crude OR, 95% CI	Adjusted OR (95% CI, P-value)
Age		
18-24	0.424 (0.076, 2.373)	0.130 (0.003, 5.156)
25-39	0.986 (0.367, 2.651)	2.430 (0.535, 11.037)
≥40	1	1
Sex		
Male	1	
Female	0.436 (0.183,1.038)	
Type of TB disease by site		
Pulmonary	1.816 (0.727, 4.534)	
Extra pulmonary	1	
Pulmonary TB		
Smear positive	1.148 (0.411, 3.212)	0.882 (0.240,3.232)
Smear negative	1	1
Type of TB by treatment history		
New	0 .999 (0.00)	
Retreatment	1	
CD4 cell count (per µl)		
<50	3.213 (1.896, 5.446)	3.784 (2.073, 6.909)
50-200	1.573 (.0.888, 2.785)	1.09 (0.531, 2.238)
>200	1	1
WHO stage		
3	2.400 (0.936, 6.151)	0.992 (0.126, 7.838)
4	1	1
Opportunistic infections (OIs) diagnosed		
Yes	1.050 (0.259, 4.249)	1.128 (0.193, 6.607)
No	1	1

with the latest global recommendations. The guidelines are currently being updated to be in line with the latest global guidance.

Also, poor recording and reporting could have affected the findings, as for nearly 50% the timeliness of ART could not be determined as both the dates of ART initiation and TB treatment start were not available. This calls for better routine recording and reporting to ensure that program data can be used to asses program performance. At the same time as being a limitation, use of routine data was the main strength of the study as despite the shortcomings, the findings likely reflect the operational reality on ground.

In the current study, CD4 count was found to be a predictor for timing of ART where patients with lower CD4 count were more likely to be put on ART in a timely manner. This was also the case in other studies where ART is not considered when the CD4 count is high (Chilton et al., 2008).

CPT was well implemented, with nearly 95% of eligible patients started on CPT. This was higher than CPT uptake reported in another study carried out in Addis Ababa which reported that only 43.6% patients benefited from CPT (Denegetu and Dolamo, 2014) while in a referral hospital in North-West Ethiopia, 45.9% of patients eligible for CPT actually received treatment (Alemayehu

Table 4. Tuberculosis treatment outcomes of HIV co-infected and HIV-negative TB patients in Bole 17 health center 2008 to 2014.

Characteristic	Frequency (n)	Percentage
HIV positive		
Cured	38	17.3
Treatment completed	119	54.1
Died	21	9.5
Failure	3	1.4
Defaulted	16	7.0
Transferred out	21	9.5
Not recorded	7	3.2
HIV negative		
Cured	201	28.8
Treatment completed	377	53.9
Died	18	2.6
Failure	9	1.3
Defaulted	27	3.9
Transferred out	45	6.4
Not recorded	22	3.2

Table 5. Factors associated with mortality among HIV co-infected TB patients in Bole 17 health center from 2008 to 2014.

Patient characteristic	Factors associated with patient mortality	
	Crude OR, 95%CI	Adjusted OR,95%CI
CPT started		
Yes	0.603 (0.144, 2.532)	-
No	1.000	-
HIV care enrolled		
Yes	0.360 (0.046, 2.808)	-
No	1.000	-
WHO stage		
Stage 3	0.828 (0.266, 2.584)	0.429(0.068,2.724)
Stage 4	1.000	1.00
ART started		
Yes	0.390 (0.147, 1.035)	-
No	1.000	-
OI diagnosed		
Yes	2.035 (0.531, 7.797)	2.318(0.244,22.040)
No	1.000	1.00
Delay ART		
No	2.120 (0.245,18.380)	1.249(0.124,12.557)
Yes	1.000	1.00

et al., 2009). Besides, a 10-year review of the scale-up of TB and HIV program collaborative activities in Zambia revealed CPT coverage of 70% in 2010 (Kapata et al., 2012). The possible reasons for a relatively higher CPT

uptake in the present study might be attributed to trainings provided to health workers on importance of initiation of CPT.

Conclusions

The median time to start ART after commencement of TB treatment was 41 days and 27% of HIV co-infected TB patients started ART late if evaluated against the prevailing national guideline. Early ART initiation in TB patients is a life saving intervention and through consistent follow-up and training of health workers it should be ensured that all HIV positive TB patients receive ART as per the latest national guidelines. Recording and reporting of patient information should be improved through regular follow-up and mentoring of health care providers to ensure that quality data can be used to guide programs. TB/HIV collaborative activities should be strengthened to ensure timely ART initiation.

CONFLICT OF INTERESTS

The authors have not declared any conflict of interests.

ACKNOWLEDGEMENTS

The researchers would like to acknowledge the support of the National Tuberculosis Research Advisory Committee (TRAC) and KNCV Tuberculosis Foundation in Ethiopia for the technical and financial assistance. We would also like to acknowledge the institutions of the participating researchers for providing researchers' time to carrying out this operational research project. Our acknowledgement also goes to the Addis Ababa Health Bureau and Bole 17 Health Center for their support to conduct this research project.

Funding

This study was conducted under the Ethiopia Operational Research capacity building initiative of TRAC/FMOH supported by USAID/TB CARE I project. The Global Health Bureau, Office of Health, Infectious Disease and Nutrition (HIDN), US Agency for International Development, supported this study financially through TB CARE I under the terms of Agreement No. AID-OAA-A-10-00020. This study was made possible by the generous support of the American people through the United States Agency for International Development (USAID). The contents are the responsibility of the authors and do not necessarily reflect the views of USAID or the United States Government. The funding body had no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

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