Research Article
Volume 11:6, 2021
DOI: 10.4172/2161-105X.11.550

Journal of
Pulmonary & Respiratory Medicine

ISSN: 2161-105X

Open Access

HIV/AIDS Associated Tuberculosis Occurance on Art Initiated Children In North West Ethiopia 2020

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Abstract

Background: Tuberculosis (TB) remains the first cause of death from infectious disease worldwide despite available effective therapies. In 2016, there were an estimated 10.4 million new cases of TB,490 000 new cases with multidrug-resistant TB (MDR-TB), and 1.7 million cases died from TB. The aim of this study is to assess HIV/AIDS associated tuberculosis for ART started children in north west Ethiopia 2020

Methods: Hospital based retrospective cohort study was conducted among 421 adult population with HIV/AIDS from to 2009-2018. The Time to develop TB was defined as the time from enrollment for ART care until the development of TB amon on ART. Variables with a P-value <0.25 at bivariate Cox regression analysis, were entered into the multivariable Cox model. Multivariable-Cox-regression model with 95%CI and AHR was used to identify significant predictor variables to develop TB at P< 0.05.

Results: A total of 421 children were followed up for a total of 662.5 Person Years of Observation (PYO). The median age during ART at enrollment was 8 years (IQR,–2-15). The overall incidence density of tuberculosis in HIV-infected children was 9.6/ 100 PYOs 95%CI: (8.06-10.3). Tuberculosis occurrence among HIV-infected children was significantly associated with TB history of contact AHR=3.7, 95%CI (2.89-7.2), not started on Cotrimoxazoles (CPT) AHR=2.4, 95%CI (1.84-4.74), incomplete vaccination AHR=2.4, 95%CI (1.32-4.5), severe stunting AHR =2.99:95%CI (1.2-7.81), hemoglobin (Hgb) ≤10 mg/dl AHR = 4.02, 95%CI (2.01-8.1).

Conclusion: More than 80% of TB cases occurred during two years of follow-up after ART initiation. Therefore, intensified CPT screening and therapeutic feeding are highly recommended for all children.

Keywords: Children • HIV Associated TB • risk factor • Assosa & Pawe • Ethiopia

Abbreviations : AFB : Acide Fast Baccilli • AIDS: acquired immunodeficiency syndrome • AHR: adjusted hazard ratio • ART: highly active antiretroviral therapy • CD4: Cluster of Differentiation 4 • CI: confidence interval • EPTB: extra pulmonary tuberculosis • CPT: cotrimoxazole prophylactic therapy • IPT: isoniazid prophylaxis therapy • PTB: pulmonary tuberculosis • PLWH: people living with HIV/AIDS • OIs: opportunistic infections • WFA: Weight for age • HFA: Height for age • WFH: weight for height • PYOs: Person Years of Observations.

Introduction

The intricate linkage of tuberculosis (TB) with HIV infection for the past three decades has become a major threat and hindrance for international public health efforts to achieve the Millennium development goal [1]. Globally, tremendous progress has been made over the past decades in the diagnosis and treatment of TB, achieving 2% per year of new TB incidence reductions [2]. However, in 2017 6.4 million new incidence cases of TB were reported [3], among this 9% (0.3 million) were new incidence of TB-HIV co-infections and 50% of new infection including inborn seropositive children were located in resource limited settings [4]. This is mainly due to the difficulty in addressing prophylaxis and ART treatment gaps in time [5]. On the other hand, the absence of sophisticated early HIV diagnosis technologies for inborn HIV-infected children [6] increases early mortality due to lethal opportunistic infections. The most common being tuberculosis [7,8]. It is one of the leading lethal opportunistic infections with a 30%–40% lifetime incidence risk for seropositive children [9,10]. A Global systematic review and meta-analysis of the incidence of tuberculosis in people living with HIV/AIDS (PLWHV) in 2013 indicated that the incidence burden varies from a continental perspective [11], which is 31.25% in African countries, 25.06% in Latin American countries, 17.21% in Asian countries, 20.11% in European countries, and 14.84% in the USA [12]. Several studies in African countries have shown that the incidence of TB among HIV-positive children ranges from 1 to 9.9 per 100 person-years [9-11,13] with different times of immunological and pathophysiological response for tuberculosis incidence [14,15]. For instance, tuberculosis occurrence in, Uganda and Zimbabwe 1.9/100 P-Y [11] and Tanzania 5.2/100 P-Y [10].

According to global TB report of 2018, Ethiopia found top 17 twine TB & HIV epidemic countries with 8.6-17/1000 new TB incident including seropositive children [3], With each year, 3900 HIV infected children develop morbidity by opportunistic infection especially by TB [15].Childhood TB incidence during successive follow-ups varied in different regions and health institutions in Ethiopia [16]. For example, in Adama 6.03/100 P-Y [17], Debre Markos 2.63/100P-Y [18], Gondar 4.9/100 PY [19], Northern Ethiopia 4.2/100 P-Y [20] and southern Ethiopia 2.6/100 P-Y [21]. On the other hand, factors associated with TB incidence were identified [17-19,22]. Notably, functional status [20] WHO stage and anemia [20,23], residence [20], nutrition status [17] adherence status [18]. Currently, tuberculosis incidence among seropositive children is an emerging and global concern, in fact due to its one of leading

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Received 05 June, 2021; **Accepted** 23 June, 2021; **Published** 30 June, 2021

lethal opportunistic infections [24]. Although studies have been conducted on TB incidence among children on HIV/AIDS care in Ethiopia [4], the time of TB occurrence among HIV/AIDS care children has not been completely described or overlooked [20,25]. In addition, information on the time of TB development is scarce [11,19]. The main aim of this research was to assess the associated factors and time to occurrence of tuberculosis among seropositive children in Assosa and Pawe General Hospitals in North West Ethiopia.

Research Methodology

Study area, design and population

We conducted a health institutions-based retrospective cohort study among 421 children on HIV/AIDS care from January 1/2009, to December 31, 2018, at Assosa & Pawe general hospitals in the Benishangule Gumuz regions. Both hospitals are located in this regional state in Northwest Ethiopia. This region is one of the nine regions in Ethiopia. Assosa is the capital city of this region and is located at 659 km west of Addis Ababa and is located at a distance of 565 km from Addis Ababa in the northwest direction. This region currently has two general and three primary hospitals with one regional laboratory. These two selected hospitals are routinely diagnosed and treated for tuberculosis based on the clinical findings, chest X-ray, AFB and Xpert-TB for suspected TB patients [26]. In both general hospitals there has been given ART care service 2007 pediatric HIV/AIDS guideline [27]. Following the time of enrollment in the ART care continuum, all children started ARV at both hospitals. Among these, 238 and 191 children were on follow-up and care at Assosa General Hospital and Pawe General Hospital, respectively. From the registration logbook, eight children with incomplete outcome data were excluded from the study.

Sample size determination and sampling procedure

The Sample size for this study was calculated using the EPI INFO software using the following parameters. A) (α) of 5%, power 80%, Z = within 95% CI = 1.96 and AHR=2.39 [20] (P1) =6.6% and (P2) = 15.8% obtained 408 by adding 5% incomplete data, the final sample size was 421. A computer-generated random number was used for the final study subject of the study subjects from two hospitals.

In total, 1230 children started HIV/AIDS care and were registered for SMART data care from January 1st, 2009, 31st December 2018 in Assosa General Hospitals 723 and Pawe General Hospitals 507 children started HIV/AIDS care, proportional sample allocation was used based on their source population for 421 final sample sizes.

Assosa Hospital n_{i1}= (N2)n/N $_{=}$ (421) (723)/1230 = 247

Pawe Hospitals ni_{2}= (N2)n/N = (507) (421)/1230 = 174

First, we used the Unique ART number of each individual card retrieved from the SMART data set of pediatrics wards. Then, using computer-generated random number 247 study participants from Assosa hospitals and 174 study participants from pawe general hospitals were recruited.

Study variables

In this study, the outcome variable was time to develop TB; incident TB cases were only those who developed new TB (EPTB and PTB) during the follow-up period. The outcome variables were ascertained if TB occurred only after ART initiation during ART follow-up.

Independent variables included: Age of children, sex, residence, family size, WHO clinical stage TB contact history, CD4 counts, Hgb, functional status, Isoniazid preventive therapy, Cotrimoxazoles preventive therapy, vaccination status, weight for age (under nutrition), weight -for -height (wasting) and height –for –age (stunting).

Operational definitions

Case ascertainment: The outcome variables (TB) were diagnosed based on bacteriological, molecular, histopathology and clinical methods using (microscopy, sputum culture, chest radiography, and Xpert or combinations) during patient presentation for TB symptoms [28].

Event: New occurrence of tuberculosis during HIV/AIDS care follow up times with study in periods.

Censored: HIV-positive children who did not develop TB during the HIV/AIDS follow-up.

TB history of contact: Children during ART follow-up before TB incidence developed, having a history of survival or contact at any time with active PTB.

Opportunistic infection: For HIV-infected children during the following if any one of the diseases developed registered on ART follow up form by their code (BP= Bacterial Pneumonia, UL= Oral Ulcer, Z= Herpes Zoster, PCP = Pneumocystis Carnie Pneumonia, DC/DA –Chronic/Acute Diarrhea, CT= Central Nervous Toxoplasmosis CM Streptococcal Meningitis [29].

CD4 was classified as below the threshold according to the following age-specific thresholds: less than 15% for children aged 12–35 months, less than 10% for children aged 36–59 months or less than 100 cells/mm3 for children aged 5–15 years [20].

Stunting, underweight and wasting: The child has two standard deviations (SDs) below the normal for height for age, weight for age, or weight for height, according to the WHO 2006 curve. For children under or equal to age 2, wasting was measured by weight for length Z-score; for children above age 2, wasting was defined by Z-score. A Z-score ≥ –2 was defined as non-wasting, –3 ≤ Z-score ≤ –2 was defined as moderate wasting, and Z-score ≤ –3 was defined as severe wasting. Stunting was measured as height/length for the age Z-score. Z-score ≥ –2 was defined as non- stunting; –3 ≤ Z-score ≤ –2 was defined as moderate stunting, and Z-score ≤ –3 was defined as severe stunting [10,17,22].

Data collection tools, procedures, and quality control

Four bachelor nurses and two supervisors were selected for data collection, and all had received ART training. For the quality of the data collection process, one-day training was given in two hospitals with two supervisors for data collectors. The principal investigator and the two supervisors followed the data. Data were collected using the data abstraction tool and medical history sheet prepared from the Ethiopian Federal Ministry of Health HIV/AIDS follow-up forms [15].

Data processing and analysis

Data were entered into the computer using EPI-DATA version 3.1 & exported to STATA 14.1, for cleaning and analysis. Descriptive analyses, such as tables, graphs, Kaplan Meier survival curves and log-rank tests were performed. Hazard ratio with 95% CI and P≤0.05, was used to measure association with independent variables. The overall survival graph and hazard failure estimated curve were used to show the survival and hazed probability of the risk group. A Cox regression model was fitted to identify predictors of the incidence of pulmonary tuberculosis. All predictors that were associated with the outcome variables in the bivariable analysis at a hazard ratio of ≤ 0.25, were included in the multivariable Cox regression model. Variables with adjusted hazard ratio in multivariable Cox regression with their corresponding 95% confidence interval with P <0.05) were considered as significant predictors. The Coxproportional hazard assumption was checked by (log-log plot) and expected versus observed Kaplan Meier graph test for each variable with the schoenfield residuals test for each variable. No variables were <0.05. After multivariable Cox regression was built by transforming from bivariable P<0.25, for finally model selection was finally selected using AIC and BIC criteria [30]. Finally, model adequacy was checked by Nelson Alana and the Cox Snell residual combination was used to check the model adequacy, and it became a straight line with zero origin in the X and Y axes.

Results

Demographic characteristics of study participants

Of the 429-study participants, 421 were included in the final analysis and eight cards were discarded due to incompleteness. The median age of the

children during this time was 9 years (IQR=2-15). More than one-third 39.5% of children were found at 6-10 years age classification group. Slightly more than half 51.54% of the children were female, of whom 52% lived in a rural residence. Among the total study participants, 54.87% lived with 3-4 family groups, and 56.06% of seropositive children lived with their families.

Baseline clinical characteristic

Nearly two-thirds (62.5%) of the study participants were addressed isoniazid. Regardless of HAART initiation after starting HIV/AIDS care in both hospitals, 126 (29.5%) children developed opportunistic infections. The most common opportunistic infections were identified as bacterial pneumonia in 53 (35.9%) and Pneumocystis carnie pneumonia (PCP) 27 (21.6%). More than two-thirds of children (63.9%) had WHO clinical stages 3 and 4. Among the total study participants, 147 (34.92%) had hemoglobin levels of ≤10 mg/dl. In total, two-thirds of children 276 (, 66.27%) completed their vaccinations. Similarly, nearly one-fourth of 113 (26.84%) HIV-infected children had CD4 counts below the threshold level. Eighty percent of the children (80.24%) had good functional status progression. Among the total study participants, 56 (13.4%) had poor ART adherence. During the follow-up period, from 421 total study participants, 199 (47.8%) had a total of 20 (4.75%) children during the follow-up period (Table 1).

Baseline Nutritional status of HIV infected children

Of the 421 study participants, 33 (7.84%) developed severe stunting (HFA<-3 Z score), and 72 (17.10%) developed moderate wasting (HFA) between -3 and -2 Z scores, and 313 (74.35%) HIV-infected children remained above the Z score >-2 Z.

Tuberculosis incidences rate

At the end of the follow up periods, 667.7 Person Years (PYOs) of observation was obtained. During this time, 64 new TB incidences occurred, of which 30 were pulmonary tuberculosis and the remaining 34 were extra pulmonary tuberculosis (Figure 1). A cumulative incidence rate of 64 TB cases was observed (15.64%). In total, 64-event alone took 88.2 PYOs of observation taking during follow-up. The overall incidence density of tuberculosis was found 9.6 person/100 years 95% CI (8.06 -10.3).

Survival status of HIV infected children

Three hundred fifty-seven (84.79%) observations were censored at the end of the follow-up period. During this time, 556.8 person-years of risk, time was observed with minimum and maximum of 0.39 and 4.5 years of observation, respectively (Table 2).

Predictors for Tuberculosis

During the bivariable analysis, 16 variables were selected in the first steps of model building and 10 variables were selected as the best model by comparing their model Asian information criteria (AIC) and Bayesian information criteria (BIC), which included (age, isoniazid preventive therapy, cotrimoxazole preventive therapy, TB history of contact, vaccination status, height for age, clinical stage, CD4 count, hemoglobin, and adherence) involved in multivariable analysis. Five of the predictors, TB history of contact, did not start with cotrimoxazole. Incomplete vaccination, severe stunting, and hemoglobin level ≤10 mg/dl were found to be statistically significant with outcome variables (Figure 2). Based on this, the risk of developing TB among HIV-infected children for not starting cortimoxazole is 2.4 higher than that of taking cotrimoxazole (AHR=2.4: 95% CI, 1.84-4.74) (Table 3).

The risks of developing TB among HIV infected children having previous TB history of contact is 3.8 times increased as compared with no previous TB history of contact (AHR= 3.8: 95% CI, 2.89-7.2). The risk of developing TB among HIV-infected children having incomplete vaccination was 2.4 higher than that of completed vaccination during their lifetime (AHR=2.4; 95% CI, 1.32- 4.5). The risk of developing TB among HIV-infected children with severe stunting 2.99 higher than that among HIV-infected children with normal height for their age (AHR =2.99: 95% CI, 1.2-7.81). The risk of developing TB among HIV-infected children with hemoglobin ≤10 mg/dl increased compared with hemoglobin ≥10 mg/dl (AHR = 4.02: 95% CI, 2.01-8.1). The Model adequacy of this multivariable Cox regression was checked using the Nelson Alan and Cox Snell residual combination test (Figure 3).

Table 1. Base line socio demographic, clinical and laboratory characteristics of children on ART care at Assosa and Pawe General Hospitals since January 2009 – December 2018 EC.

Variables		Frequency N=421	Percent 100%
Sex	Male	204	48.46
	Female	217	51.54
Age	<=5 years	87	20.67
	6-10	146	34.39
	>=11 years	188	43.94
Residence	Urban	205	48.69
	Rural	216	51.31
Hemoglobin	>10 mg/dl	263	62.92
	<=10mg/dl	158	37.92
WHO	stage 1&2	269	63.9
	Stage 3%4	152	36.10
CD4 count	Below threshold	113	26.84
	Above threshold	308	73.16
Functional	Appropriate	338	80.24
	Delay	50	11.89
	Regression	31	7.84
Adherence	Good	224	57.96
	Fair	121	28.73
	poor	56	13.44
Isoniazid	yes	258	61.52
	No	163	38.48
Cotrimoxazoles	yes	321	76.26
	No	100	23.94
Opportunistic infections	yes	126	29.93
	No	295	70.07
Vaccination	Completed	276	66.27
	Defaulted	76	18.2
	Not registered	69	16.05
TB contact history	Yes	135	32.8
	No	286	68.17
Family size	<=2	133	31.83
	3-4	219	52.21
	5-6	50	11.88
	>=7	19	4.09
Children status	Being on follow up	199	47.7
	Lost from follow up	43	10.23
	Transfer in to adult	91	21.62
Transfer out		56	13.30
	Died	12	2.85
	Drop	20	4.75
ART regiment	Changed	85	20.24
	Not changed	336	79.2

Discussion

The findings of this study indicated that the overall incidence of tuberculosis was 9.6/100 person-years (PYOs) 95% CI (8.06 -10.39). This is not comparable with study findings in southern Ethiopia 2.6/100 PYOs [21], Debre Markos 2.63/100 PYOs [17], Gonder 4.9/100 PYOs [18], and Adama 6.03/100 PYOs [17]. In fact, the study area has a predominant distribution of TB [26]. The findings of this study revealed that not starting cotrimoxazole prophylaxis was independently associated with the occurrence of TB. This is

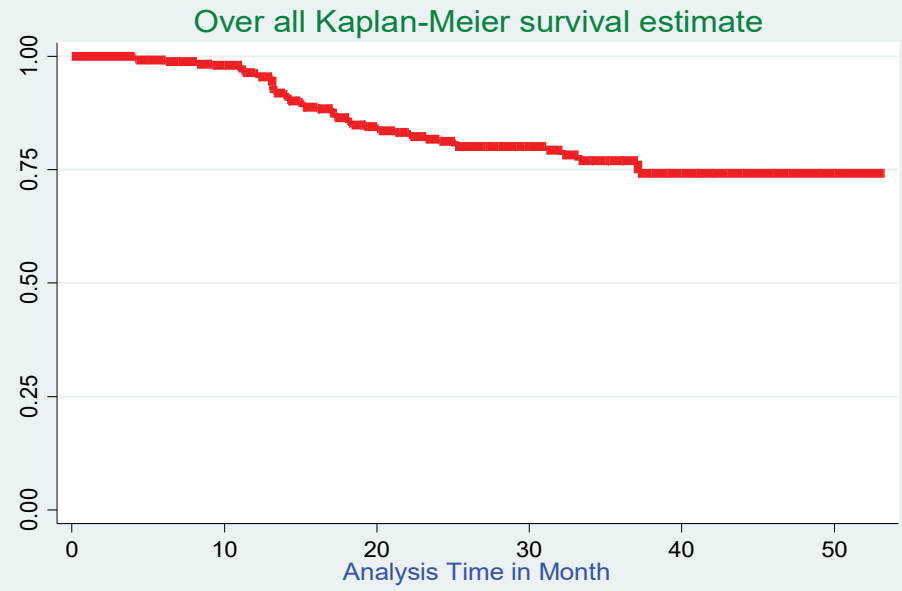

Figure 1. Overall Kaplan Meier Survival estimate for all HIV/AIDS care started children at Assosa and Pawe general hospitals.

Table 2. Summary of TB free survival rates of HIV-infected children at Assosa and Pawe General Hospitals from to 2009-2018.

Time in year	Survival rate	95%CI	New events	Cumulative frequency	Frequency %
1 years	96.04%	93.62--97.56	20	20	31.3%
2 years	82.62%	77.80--86.49	33	53	82.3%
3 years	77.65%	71.57--82.59	10	63	98.1%
4 years	68.92%	53.32 --80.22	1	64	100%
≥ 5 years	68.92%	53.3-- 80.2	0	64	100%

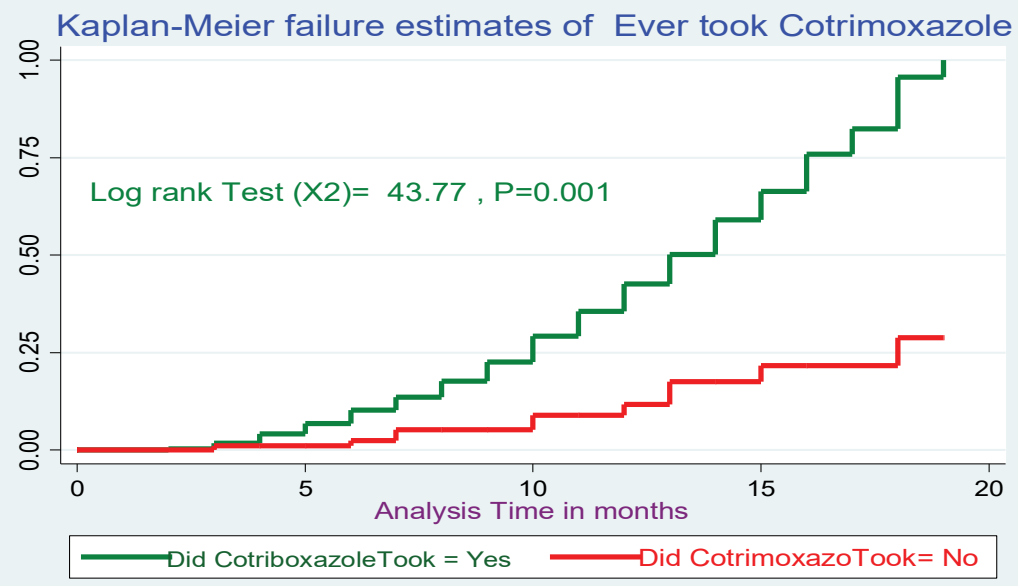

Figure 2. Difference in Hazard not initiated co-trimoxazole for HIV infected children in two hospitals.

in agreement with northern Ethiopia [20] and Adama hospitals [17]. This might be due to cotrimoxazole preventive therapy significantly reducing HIV-related morbidity and mortality from lethal opportunistic infections [3]. On the same way, seropositive children having TB history of contact is associated with TB incidence. This is consistent with South Africa [9]. In fact, a lack of awareness about transmission of TB might easily lead to infection from nearby active patients [30]. In addition, this study indicates that incomplete vaccination is significantly associated with TB occurrence. This is like the findings of Adama [17] and Gondar [18]. On the same way HIV infected children having sever stunting was independently associated with incidence of TB. This is in line with the findings of Tanzania [10] and Uganda and Zimbabwe [11]. The fact that human immune virus increases nutrient malabsorption due to metabolic alterations that culminate in weight loss and stunting with time leads to early exposure to opportunistic infections [28], facilitating rapid viral replication, consuming body energy and creating arena for the incidence of TB [31].This study also showed that children with hemoglobin ≤10 mg/dl were independently associated with TB incidence as compared with children with hemoglobin level > 10 mg/dL. This is consistent with the findings of Adama [16], Gonder [18], Dar es Salaam, Tanzania [10], England and Wales [22]. In fact, hemoglobin levels have a high predictive value for incident TB and death, and TB incidence is directly associated with severe anemia [32]. Regardless of starting HAART,

Table 3. Bivariable and multi variable cox-proportional hazard analysis for predictors of TB among children treated on ART OPD at Assosa and Pawe General Hospitals 2009-2018.

		Survival status of children			Multivariable cox regression	
Variables		**TB incidence**	**Censored**	**CHR 95% CI**	**P-value**	**AHR=95% CI**
Age of children	< =5 years	2	85	1		
	6-10 years	12	134	3.4 (0.7 15.52)	0.68	1.38 (0.28 6.6)
	>=11 years	50	138	12. (12.7 49.6)	0.12	2.89 (0.62 12.)
Isoniazid	yes	15	243	1		1
	No	49	114	6.58 (3.6 11.7)	0.80	0.91 (0 .41 1.9)
Cotrimoxazoles	yes	28	293	1		1
	No	36	64	4.7 (2.87 7.75)	0.003	2.5 (1.4 4.74)*
TB history of contact	Yes	53	82	12.21 (6.6 23.4)	0.002	3.7 (2.89 7.2)*
	No	11	275	1		1
Vaccination status	Complete	23	253	1		1
	Default	33	43	5.75 (3.4, 9.72)	0.005	2.6 (1.32 4.5)*
	Not registered	8	61	1.24 (0.5, 2.87)	0.25	1.68 (0.66 4.1)
CD4 count	Above threshold	28	280	1		1
	Below threshold	36	77	1.58 (0.91 2.74)	0.403	0.72 (0.37 , 1.42)
Adherence	Good	21	223			1
	Fair	15	104	1.9 (0..89 4.07)	0.817	1.2 (0.48 , 2.94)
	Poor	28	30	7.1 (0.37 26.32	0.746	1.19 (0.52 2.71)
Height for age (HFA)	Normal	35	249	1		1
	Moderate	21	83	1.64 (0.95 2.82)	0.06	1.32 (0.62 2.71
	Sever stunting	8	25	1.93 (0.89 4.1)	0.03	2.96 (1.2 7.88)*
WHO	stage 1 & 2	14	255	1		1
	Stage 3 & 4	50	102	9.1 (4.9 16.4)	0.07	2 .1 (0.99. 4.48)
Hemoglobin	>10 mg/dl	12	251	1		1
	<=10 mg/dl	52	106	9.62 (5.13 18.0)	0.001	4.02 (2.1 8.1)*

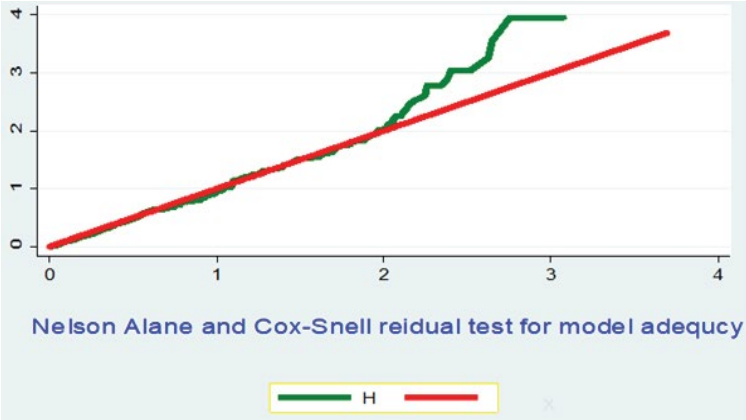

Figure 3. Final model adequacy test by Nelson Alone and Cox Snell residual test.

moderate or severe anemia can be an independent predictor of TB [33].

Limitation of the Study

The Retrospective nature of this study is one of the limitations of this study. As a result, some clinically important predictor variables that were independently associated with the incidence of TB occurrence in other studies, such as the educational status of children and the economic status of the family, were not included in this study.

Conclusion

The Incidence of TB is an important medical problem for children living with HIV antiretroviral therapy (ART) treated in both hospitals. This study concluded that baseline not ever taking cotrimoxazoles, having moderate stunting, haemoglobin level lower than standard, incomplete vaccination, and having a previous history of contact with TB have significantly and independently associated TB incidence. Therefore, intensified screening of cotrimoxazoles and malnutrition is highly recommended for intervention.

Ethics Approval and Consent to Participate

Ethical clearance was obtained from the ethical review committee of the Debre Markos University, College of Health Sciences (Ref. No: HSC/984/16/12). A formal letter was submitted to both Assosa and Pawe general hospitals for permission to be done entitled research articles, time to develop pulmonary tuberculosis, predictors among HIV-infected children receiving antiretroviral therapy, within two general hospitals, and permission was assured. All information collected from patient cards was kept strictly confidential and the names of the patients were not included in the checklist. Confidentiality consent was not needed as it was a retrospective study was conducted on secondary data.

Funding

This research article is retrospective cohort study and did not receive funding.

Authors' Contributions

Fassikaw Kebede (BSc, MPH), Tsehay Kebede(BEd, MA), Birhanu Kebede (BSc, MA), Belete Negese (BSc, MSc), Ayinalem Kebede (BA, BScpharm). All authors read and approved the final manuscript.

Acknowledgment

We would like to thank Pawe and Assosa general hospitals, administrative staff, and data collectors who assisted during data collection.

Data Availability

The datasets analysed during the current study are available from the corresponding author upon reasonable request.

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How to cite this article: Fassikaw Kebede, Tsehay Kebede, Birhanu Kebede, and Belete Negese, et al. "HIV/AIDS Associated Tuberculosis Occurance on Art Initiated Children In North West Ethiopia 2020." *J Pulm Respir Med* 11 (2021): 550. DOI: 10.4172/2161-105X.11.550