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Treatment Outcomes and Associated Factors of Childhood Tuberculosis: Treated Under Dots Program in Health Centers of Mekelle Town, Tigray Regional State, Ethiopia

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Abstract: Background: Tuberculosis in children has been less of a public health priority in recent years, despite the fact that TB is an important cause of childhood morbidity and mortality worldwide. WHO report in 2008 estimates 450,000 deaths from TB occurs in children each year, Nevertheless childhood TB remains neglected for various reasons, mainly the difficulty in diagnosing pulmonary TB.Therefore identifying potential risk factors associated with treatment outcomesisimportant activity to improve quality of TB care and treatment. Method: A retrospective cross-sectional study was conducted in Mekelle town on pediatric TB patients treated in three health centers. The study employed a record review of patients registered for TB treatment from September 2007 to August 2011. Health facilities are selected purposively and patient's records were selected by simple random sampling. A total of 226 patients' record was collected from registers using data extraction format. Data entry was done using Epi info 3.5. 1and exported and analyzed by SPSS V 20. Results: According to this study success of treatment was 84%. Among all patients treated under DOTS, 15 (6.6%) of cases had unfavorable outcomes, death 8/226 and default 7/226, 13(5.8%) were transferred out and outcome was unknown in 8 (3.5%) of patients. Deaths were more frequent in older age groups 5 – 14 years, although there is high number of death in HIV co-infection, rural residents and extra-pulmonary tuberculosis than other forms. In multivariate analysis, independent predictors for unfavorable outcomes were HIV co-infection AOR = 5.57 with 95% C.I = [1.6, 18.6] and patients from rural residence were more likely to have unfavorable outcomes OR = 18.6 with 95% C.I = [2.4, 144]. Conclusion: The treatment success rate in this study was come within reach of to the minimum target set by WHO 85%. HIV contributes substantiallyto childhood TB burden and also cases fromruraldistricts associated with high mortality and default from treatment.

Keywords: Tuberculosis, Treatment Outcomes, Children and Mekelle

1. Introduction

Tuberculosis (TB) is one of the leading causes of morbidity and mortality among infectious disease worldwide, with 90% of patients living in resource-limited settings, specifically sub-Saharan African countries. [1] According to the WHO global report 2007, it was estimated that worldwide, there had been 9.27 million new cases and 1.756 million deaths from TB, of which 1.37 million cases and 0.456 million deaths were among HIV infected individuals [2], also more than 9.4 million incident cases and almost 1.8 million deaths in 2008 alone: this is the equivalent of 5000 people dying every day [3]. Moreover, to these new cases one must add the millions already in existence, making it the most prevalent infectious disease [4].

Currently 95% of TB cases and 98% of deaths due to TB occur in developing countries [5]. And Among twenty two highest-burden countries in the world with TB fourteen countries were from Africa [3]. The annual number of death due to TB was 1.6 million, including 195,000 patients infected with HIV. In developing countries, TB comprises

25% of all avoidable adult deaths [6]. Ethiopia is the 7th among the 22 countries with the highest TB burden in the world with incidence estimated at 379/100,000 for all forms of TB and 168/100,000 for smear positive TB according to WHO global TB report on 2008. According to the Ministry of Health hospital statistics data, TB mortality rate is estimated at 84 per 100,000 populations per year [5, 15].

The global burden of childhood pulmonary TB has been underappreciated, in part due to difficulties in obtaining microbiological confirmation of disease. In Ethiopia the diagnosis modalities are basic, culture and sensitivity not performed in many setups. Most HIV-uninfected children can be diagnosed using a combination of clinical and epidemiological features and chest radiography and almost all EPTB was diagnosed clinically in resource limited set up. The HIV epidemic has made definitive diagnosis even more challenging due to nonspecific clinical and radiological signs [6].

Children account for a substantial proportion of the global burden of tuberculosis, WHO estimates 450,000 deaths from TB occurs in children each year [7]. Childhood TB nevertheless remains neglected for various reasons, mainly the difficulty in diagnosing pulmonary TB, the lack of scientific studies on childhood TB, the largely unknown outcome of children with TB, and the belief that childhood TB is not important in TB control [7-9]. Moreover, children in TB-endemic areas suffer severe TB related morbidity and mortality, and a large proportion of cases are diagnosed solely on the basis of medical history and clinical examination [7, 9]. In Ethiopia, childhood TB is still a third cause of hospital admission 9.4% of casesand first cause of death with 27% [9, 10]. Surveillance systems to monitor TB outcome in children are very important in order to know the risk factors associated with an unfavorable outcome the most critical need is for improved capability to Confirm diagnosis in the developing world. Several authors have recommended a prompt and efficient identification of source of transmission, family screening and early initiation of treatment for the prevention and control of tuberculosis in children [8, 9].

Detection and treatment of new cases in Directly Observed Treatment Short course chemotherapy (DOTS) program is believed to be the most valuable strategy for TB control. In 1992 the National Tuberculosis and Leprosy Control Program (TLCP) and DOTS strategy were established in Ethiopia, with guidelines that make it necessary to fill out a TB register [1].

Many DOTS experiences in developing countries have been reported [10-14]. However, specifically outcome and associated factors in childhood TB is limited. Lack of such information makes monitoring and evaluating of control efforts difficult. Therefore, this studyinvestigated for contribution on the prevention and control of tuberculosis by offering pertinent information on treatment outcomes and associated factors of tuberculosis in children in Northern part of Ethiopia urban setting.

2. Methodology

2.1. Study Area and Period

The study was conducted in Tigray region, Mekelle town. According to the 2007 G.C census the population of the region was 3.16 million with annual growth rate of 2.8%.The 2007 projected population of the region is estimated to be 4,314,456 of whom males contribute 49.25%, Females 50.75% and population of under age of 15 years contributes 1,885,390. By place of residence 842,723 are urban and 3,471,733 rural residents [17].

Mekelle town a regional capital of Tigray Regional State located about 783 km from Addis Ababa. According to the 2007 National Population and Housing Census of Ethiopia, Mekelle town has a total population 215,914. Population under 15 years of age accounts 94,354 [17, 18]. The town had five hospitals (2 private and 3 public), one referral hospital, five health centers and thirteen higher clinics, of them all health centers and public hospitals are giving DOTS programcurrently.Despite this little, little evidences exist regarding which factors contribute to undesirable outcome. This data gap is the primary reason for conducting this study in Mekelle town. The study was conducted in Mekelle town, Tigray regional state from June to August 2012.

2.2. Study Design, Source Populationand Study Subjects and Sample Size Selection

A facility basedretrospective cross-sectional studywas conducted involving mainly quantitative data was carried out on patients treated under DOTS program was done for collecting patient information registered for TB treatment from September2007to August 2011 in three health centers.

The source population comprises all children less than 15 years of age who were treated for TB under DOTS strategy between September 2007 to August 2011 at the study health facilities and who had treatment outcome ascertained. The Study population was all randomly selected Children under age of 15 years who are diagnosed with any form of TB whose outcome evaluated during study period, from TB registers of these health centers.

The Sample size required to assess the outcome of interest was calculated using single mean proportion estimate by Prevalence of favorable outcomes (cured and treatment completed) in Ethiopia which is 84% prevalence of favorable outcome [1], with a 5% margin of error, 95% confidence level and 10% non-response rate or incompleteness of data. An overall sample size of 226 patients record was required for the study.

The list (unit TB number) of eligible patients on units TB register was used as a sampling frame to select the study subjects. A Systematic random sampling technique was applied to select eligible patients for the study from list of register of the facilities proportionally according to patient load of each health centers.

2.3. Study Variables

2.3.1. Dependent Variables

The dependent (outcome) was patients' TB treatment outcome categorized as favorable outcomes (cured and treatment completed) and unfavorable outcomes (death, default and treatment failure).

2.3.2. Independent Variables

Age of the patient, Sex, Residence, Pre-treatment weight, Type of TB, HIV status, Patient category (new, relapse, failed, return after default, transfer in, and other) and AFB smears result.

2.4. Data Collection Tools and Procedures

The registration documents of each heath centers contain basic information such as patient's age, sex, address, weight, types of TB (smear-positive PTB, smear-negative PTB, EPTB), AFB smear result at base line, 2nd, 5th and 7th month, treatment outcome (cured, completed treatment, defaulter, failure of treatment, died or transferred out) and HIV status. A structured data extraction format was adopted from units TB register to collect patient information at the selected health centers. The datawas collected from TB registersunits by trained nurses in TB clinic of the facilities.

2.5. Data Management, Quality Assurance and Data Analysis

To ensure quality of the data, one day training was given for data collectors before the start of data collection. In order to check the functionality of data extraction form pretestwas conducted on 10% of the total sample size. The overall activities of data extraction were closely supervised by the principal investigator during data collection. All completed data extraction sheets was checked for completeness before leaving the facility. The collected data was entered into the computer and cleaned using Epi-info software for windows application version 3.5.1 by skilled data encoder and a 10% double data entry was employed to ensure the data quality. The collected data was thoroughly checked for inconsistencies and outliers the data was imported to SPSS for windows version 20 for analysis.

Descriptive statistical methods were used to summarize patients' characteristics and determine the magnitudes of treatment outcomes. Bivariate logistic regression was applied to association was performed to assess the individual effects of predictor variables on treatment outcome of children and multivariate analysis was employed to examine the significance in both scenarios. Variable found to be significant at *P value <0.05* in the bivariate analysis were entered to multiple logistic regression. We used the enter approach in for inclusion into the multivariate model while the Hosmer-Lemeshow statistic was used for model diagnostics. Statistical significance was declared at *Pvalue < 0.05*

2.6. Ethical Considerations

Ethical clearance was obtained from Ethical review Committee College of health science of Mekelle University Tigray region health bureau and approved. Accordingly, permission letter was secured from Tigray region health bureau to respective Health facilities. In order to ensure confidentiality of the information the names or any identifiers of the study participant were not included in data sheet.

2.7. Operational Definitions

Treatment success- the sum of patients who were declared "cured "and "treatment completed"

Unfavorable outcome -this includes patients who were documented as "died", defaulted "and "transferred out"-

3. Results

3.1. Characteristics of Cases

A total of 226 records of patients were reviewed for the analysis. Of these 117(51.8%) of patients had treatment follow-up at Semen health center, 65(28.8%) at Mekelle health center and the rest 44(19.5%) were treated at Kassech health center.

There was slight male predominance 124 (54.9%). The median age was 8 [IQR 5-12] years. Majority of study subjects 173 (76.5%) falls within age groups of 5-14 years. The median weight at start of treatment was 20 kg, with a range of 5 to 41 kg. Pre-treatment weight was not documented in 9 (4%) of patients treated in three health centers. More than half of patients, 118 (52.2%) were urban residents. Sputum smears result at time of diagnosis Positive 16 (20.7%), Negative 61 (79.3%) Unknown/not done, 149 (65.9%).

Almost all study participants 218 (96.5%) had not received any TB treatment previously. The rest were categorized as relapse, return after default and transfer in with cases of 2 (0.9%), 1 (0.4%) and 5 (2.2%) respectively. Extra pulmonary tuberculosis accounts about half of the proportion of patients by tuberculosis type by 115 (50.9%) of cases followed by pulmonary smear-negative 56 (24.8%), 16 (7.1%) of the study subjects were pulmonary smear- positive and 39 (17.3%) cases were either pulmonary smear unknown or not done. HIV counseling and testing after diagnosis of TB was offered for 142 (62.8%) of cases and all are volunteered or gave ascent to be testedfor HIV, of these 22 (15.4%) were positive for HIV, but in 8 (3.8%) patients HIV counseling not offered and for the rest 76 (33.6%) patients HIV status was either unknown (variable not available on pre HMIS registers) or not tested.From positives 4/22 cases were on ART the rest either enrolled on chronic care or started Cotrimoxazole prophylaxis therapy (CPT) prophylaxis.

3.2. Treatment Outcomes of Patients

Success of treatment was calculated as the sum of the cases that were cured and completed treatment. Totalof 10 (4.4%) and 180 (79.6%) patients for cure and completed treatment respectively, gives treatment success of 84%. The proportion of patients with unsuccessful outcomes (death on

course of treatment and default from treatment) was also calculated accordingly died 8 (3.5%), default 7 (3.1%), gives 15 (6.6%) and there was no treatment failure occurred in the study population. Transfer out rate was 13 (5.8%) and outcome of 8 (3.5%) of cases was not known.

From unfavorable outcomes deaths were more frequent in older age groups 5 – 14 years old in comparing to 0 – 4 years old, five and three deaths respectively in each groups, although there is high number of death in extra-pulmonary tuberculosis apart other forms and in patients categorized as new case *[Table 1]*. Almost all patients were categorized and prescribed short course chemotherapy as new cases 218 (96.5%). Sputum-smear was performed in only 77 patients, of them 16 (20.7%) cases were positive by sputum-smear microscopy.

The default rate was higher for rural residents, seven patients default while there were no defaults from urban residents simultaneously death was more frequent in rural residents 7/8 patients whereas only one death from urban residents.Although there was high defaulter (six patients) in HIV negatives alike only one default occurred in HIV positives. There was high transfer out rate for rural residents 11 cases were transferred out, relative to only two from urban residents. Overall, the proportion of deaths was higher in patients co-infected with HIV 5 (3.5%), whereas only one death was occurred in HIV negative patients.From the total of 8 (3.5%) deaths three occurred in males and five in females.

Table 1. *Treatment outcome distribution by sex, age groups, place of residence, type of TB and HIV status for patients treated in health facilities at Mekelle, 2007 – 2011, Mekelle, Ethiopia 2012.*

Treatment Outcomes	Cured	Completed	Default	Transfer out	Death
Sex					
Male	6 (2.7)	100 (44.2)	5 (2.2)	6 (2.7)	3 (1.3)
Female	4 (1.8)	80 (35.4)	2 (0.9)	7 (3.1)	5 (2.2)
Residence					
Urban	5 (2.2)	104 (46.0)	0 (0)	2 (0.9)	1 (0.4)
Rural	5 (2.2)	76 (33.6)	7 (3.1)	11 (4.9)	7 (3.1)
Age category					
0 – 4 years	0 (0)	41 (18.1)	4 (1.8)	3 (1.3)	2 (0.9)
5 -14 years	10 (4.4)	139 (61.5)	3 (1.3)	10 (4.4)	6 (2.7)
Type of TB					
PTB smear Positive	10 (4.4)	3 (1.3)	1 (0.4)	0 (0)	2 (0.9)
PTB smear Negative	0 (0)	49 (21.7)	0 (0)	2 (0.9)	1 (0.4)
PTB Smear unknown	0 (0)	30 (13.3)	2 (0.9)	4 (1.8)	1 (0.4)
EPTB	0 (0)	98 (43.4)	4 (1.8)	7 (3.1)	4 (1.8)
HIV status					
Reactive	0 (0)	15 (10.6)	1 (0.4)	0 (0)	5 (3.5)
Nonreactive	10 (7.0)	89 (62.7)	6 (4.2)	9 (6.3)	1 (0.7)
Sputum smear result					
Positive	10 (4.4)	3 (1.3)	1 (0.4)	0 (0)	2 (0.9)
Negative	0 (0)	51 (22.6)	1 (0.4)	4 (1.8)	1 (0.4)
Not done/unknown	0 (0)	126 (55.8)	5 (2.2)	9 (4.0)	5 (2.2)
Category of patient					
New	10 (4.4)	175 (77.4)	7 (3.1)	12 (5.3)	7 (3.1)
Relapse	0 (0)	2 (0.9)	0 (0)	0 (0)	0 (0)
Default	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Transfer-in	0 (0)	3 (1.3)	0 (0)	1 (0.4)	1 (0.4)

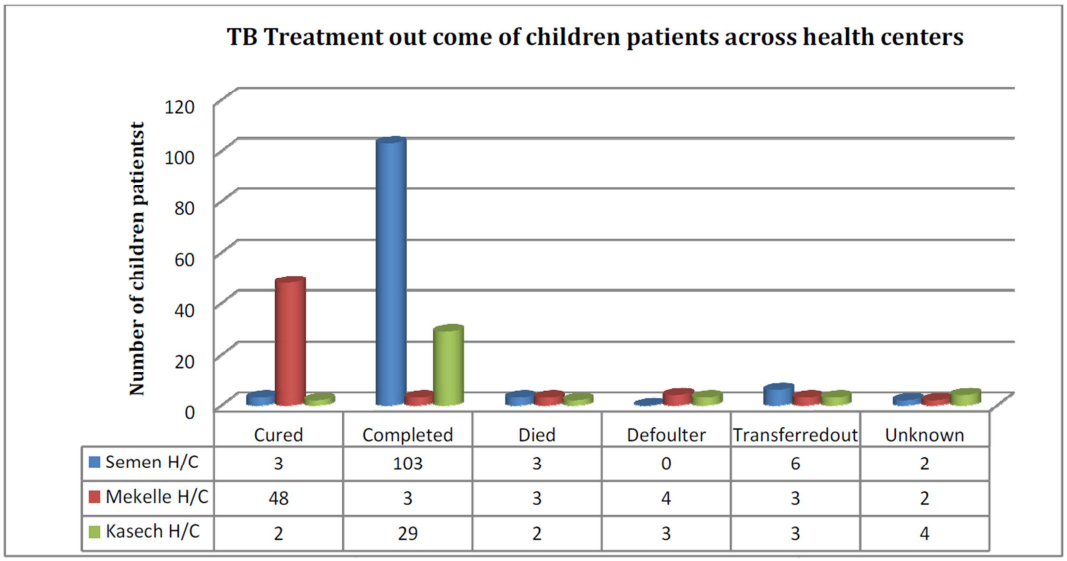

Figure 1. *Distribution of Treatment outcome among children patients across three health centers from sept2007-August 2011, Mekelle Ethiopia, 2012.*

3.3. Predictors of Treatment Outcomes

From the bivariate analysis in [Table 2], the chi-squared test of association showed that being resident of rural district was significantly related to unfavorable outcomes (death and default) during the course of treatment ($\chi2$ = 16.36,OR 18.6 95% C.I (2.4 – 144) p-value < 0.005). Although there was very likely to expect excess of death in HIV positives ($\chi2$ = 7.12, p-value < 0.005). EPTB patients was also more likely to have unfavorable outcome $\chi2$ = 16.36, COR 12.5 95% C.I (6.08, 25.6)

Table 2. *Characteristics of patients associated with treatment outcomes among childhood TB cases in Mekelle health centers, September 2007 to August 2011, Mekelle, Ethiopia.*

Characteristics	COR (95% CI)	AOR (95% CI)
Age (in years)		
0 – 4	1	
5 -14	2.33 (0.78 – 6.91)	
Sex		
Male	1	
Female	0.89 (0.31 – 2.56)	
Residence		
Urban	1	
Rural	18.6 (2.4 – 144)	0.03 (0.003– 0.28)*
HIV status		
Positive	5.57 (1.66 – 18.69)	13.08 (2.73–62.64)*
Negative	1	
Type of TB		
Smear positive	4.33 (1.23 – 15.2)	
Smear negative	1	
EPTB	12.5 (6.08 – 25.6)	
Smear unknown	10 (3.05 – 32.76)	

* Significant predictors of treatment outcomes for study population

In binary logistic regression the independent predictor variables for the two main comparisons groups of patients treatment outcomes; to compare the patients with unfavorable outcomes (death and default) to those subjects with favorable outcomes (cured and completed), since transferred out patients outcomes was not traced and documented, those patients were excluded from binary logistic analysis, although patients with unknown outcome were excluded.In binary logisticregressionanalysis, independent predictors for unfavorable outcomes were HIV co-infection AOR = 5.57 with 95% C.I = [1.66 – 18.6], p-*value*< 0.001 and patients from urban residence were also tend to have less likely unfavorable outcome AOR = 0.05 with 95% C.I = [0.007, 0.42], p-*value* < 0.002.

4. Discussion

This study investigated the treatment outcomes of children registered for TB treatment at health centers of Mekelle in Northern Ethiopia. The reviewed records of 226 patients who were treated under DOTS at the study health centers. The majority 56 (24.8%) of children with PTB were smear negative which is in agreement with previous reports [16, 19, 20]. This is mainly because most children present with primary rather than secondary TB and therefore, are likely to have low bacillary load. Moreover, young children do not produce sputum for smear microscopy and are diagnosed based on clinical and chest x-ray evidences.

However, the proportion of EPTB in our study is much higher compared to reports from Southern Ethiopia (44.8%) [20] and Thailand [16]. The relatively low TB burden together with a high proportion of EPTB among children in our study suggests that further epidemiological study on childhood TB is important.

The overall treatment success of this study was 84%, which is less than target set by WHO a minimum of 85% treatment success. The treatment success rate in this study is higher compared to previous reports both from Ethiopia [18] and elsewhere in Africa [19, 21]. Also study in Thailand the treatment success rate of 72%, but outcomes in India showed the treatment success rate of 95%. This difference might be related to differences in setting, disease presentation as well as prevalence of HIV infection. Besides, there might be differences in the level of adherence which is mainly dependent on the parents' level of supervision and administration of medication especially among young children.

Unfavorable outcomes occurred in 15(6.6%) of cases, HIV infection had also impact on this treatment outcome. There were high rate of death in HIV infected children than negatives. This finding was consistent to study in Uganda on 128 cases of them 48.9% were positives, high affliction of poor outcome was observed in those groups.

There were an increased number of deaths in older age group (5 – 14 years age) and in patients with Extra-pulmonary TB. The default from treatment was also seems to be associated with place of residence, majorities of patients were from countryside. Impact of HIV infection was described in many studies [12, 13, 15 and 22]. From the analysis of this study majorities of TB patients were tested for HIV after counseling offered, but in eight patients HIV test was not offered; since it is recommended approach that all TB patients should have counseling and testing for HIV infection, at least by the time of initiation treatment, if status not known earlier.

5. Limitations of the Study

This study was subjected to certain limitations. Since, it relies on review of routinely collected health service data (secondary data); there was an inherent bias as a result of retrospective nature of data. Thus, the quality of information obtained from this study was highly dependent on the accuracy and completeness of registers. Poor reporting and recording system due to poor old health management information system was also another threat for the findings of this study due to lack of some variables.

6. Conclusion and Recommendations

According to this study, the treatment success rate was approached to the minimum target establishedby WHO. Although all treatment centers had similar structure to follow the same treatment guideline, there was variation in treatment outcome of facilities. More the outcome was considerably varied in HIV infected than not infected, even with limited number of cases found the documented HIV status. Although being rural resident and extra pulmonary tuberculosis were also showed association with poor outcomes. The sputum-smear conversion after two months of treatment was declared in 10 (62.5%) of cases in the rest six cases the 2nd month sputum-smear microscopy was either not done or not known. Based on results from this study we recommend the expansion of DOTS service to increase the patient adherence to treatment especially for rural residents and this accessibility of DOTS service will further increase the treatment success and besides reduces the number of defaulters. Since HIV infection showed association with unfavorable outcomes responsible organization should strengthenprimaryprevention childhood HIV infection, parallel to care and treatment for already infected. Routinely HIV counseling and testing should be offered for all patients at time of diagnosis, except known HIV status and sputum smear-microscopy also should be performed especially in older children who can expectorate. Given retrospective nature of data, lack of completeness and minimal patient information kept the study has drawbacks to come with rigorous conclusion. Therefore we recommend that further wide range and prospective studies should be conducted to explore various factors affecting the TB treatment outcome in children.

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Competing Interests

Author(s) disclose no potential conflicts of interest.

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