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Late Commencement of Anti-Tuberculosis Drugs in Three Directly Observed Treatment Short Course Centres in Benue State Nigeria: A Neglected Correlate of Tuberculosis Management

Onyemocho Audu[1*], Shember AgelaIgbabul[2], Joseph Anejo-Okopi[3], Istifanus A. Joshua[4], Gabriel O. Anefu[2], Samson Ejiji Isa[5]

[1]Department of Epidemiology and Community Health, College of Health Sciences, Benue State University, Makurdi, Nigeria
[2]Benue State Epidemiology and Disease Control Unit, Makurdi, Nigeria
[3]Department of Microbiology, Faculty of Natural Sciences, University of Jos, Jos, Nigeria
[4]Department of Community Medicine, Kaduna State University, Kaduna, Nigeria
[5]Department of Medicine, Faculty of Medical Sciences, University of Jos, Jos, Nigeria
Email: *audeeony@yahoo.com

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Abstract

Background: Most researches on the correlate of Tuberculosis (TB) treatment outcomes place emphasis on sociodemographic characteristics of the patients, Human Immunodeficiency Virus status and $CD4^+$ count of patients and nutrition among others. This study assessed the effect of delay in commencement of anti-TB regimen on the treatment outcomes of all Tuberculosis patients treated between 2011 and 2014 in three directly observed treatment short course centres in Benue State, Nigeria. **Methodology**: A retrospective cohort study with convenient sampling technique was used for all registered Tuberculosis patients enrolled for treatment within the reviewed period. Chi-square ($\chi 2$) test was used for test of association between the independent variables and the main outcomes of the study, with statistical significance set at p-value of 5%. **Results**: Of the total 1711 cases reviewed, the males to females ratio was 3.9:1. The mean age for the males' patients was 39.0 ± 15.3 years and the females 33.7 ± 14.2 years. Majority of the patients were new pulmonary Tuberculosis cases and they commenced their treatment after 3 weeks of diagnosis. Higher failure and death rate were reported amongst the patients who commenced their treatment late (78.7% and 42.5% respectively). The relationship between the treatment outcome and the time of commencement of anti-TB drug regimen was statistically significant ($p < 0.005$). **Conclusions**:

Commencement of anti-TB drugs in all diagnosed Tuberculosis patients is an important correlate that must be addressed in order to achieve the global goal of reducing Tuberculosis prevalence to the level at which it will no longer constitute a public health problem in Nigeria.

Keywords

Tuberculosis, Treatment, Late Commencement, Outcomes

1. Introduction

It has been almost 20 years since Nigeria adopted the Directly Observed Treatment Short course (DOTS) Tuberculosis (TB) strategy and is now implementing the STOP TB strategy aimed at reducing TB prevalence to the level at which it will no longer constitute a public health problem in the country [1]. One of the specific objectives of these programmes is early case finding via sputum smear microscopy and proper case management [2]. As a result, the number of new smear positive TB cases notified had increased from 8449 in 1994 to 92,818 in 2012 [3]. By the end of 2014, there were over 5300 TB service points and 1602 Microscopy centres distributed across the entire country [4]. In Benue State, the TB DOTS programme was started in 2001 as a pilot project in four Local Government Areas (LGAs); Gwer, Otukpo, Logo and Ohimini. The State has 214 DOTS clinics and 72 Microscopy centers by the end of 2014 [5] [6]. In recent time, Gene Xpert MTB/RIF has narrowed the gaps in laboratory diagnosis of TB patients, with the state now having 3 Gene Xpert laboratories [6].

In spite of the implementation of DOTS and introduction of new diagnostics, TB still remains a public health issue in Nigeria [7]. With an estimated population of about 174 million people and a TB prevalence rate of 323 per 100,000 population, Nigeria is ranked the 4th among the 22nd high burden countries worldwide [1] [8]. The increasing prevalence of HIV among TB cases would further complicate TB diagnosis in Nigeria. HIV prevalence among TB patients increased from 2.2% in 1991 to 19.1% in 2004, and was estimated to be 23% in 2013 [9] [10]. Concomitant treatment of Tuberculosis and HIV comes with other challenges such as a higher pill burden and overlapping drug toxicities, which may in turn affect adherence and treatment outcomes for both diseases, including the emergence of multi-drug resistant tuberculosis among these patients [10] [11].

The Public Health Act of 2005 stipulates that all patients diagnosed with TB (smear positive pulmonary TB patients) should commence treatment within 7 days, while smear negative and extrapulmonary TB cases should commence treatment in not later than 28 days [12]. However, there are challenges with speedy diagnosis due to non-availability of laboratory reagents or the commencement of treatment either as a result of drug stock-out or patients' compliance to counseling on anti-TB drugs among others [1] [8] [13] [14].

Most TB treatment outcome researches place emphasis on socio-demographic

characteristics of the patients, TB/HIV co-infections, CD4+ count and nutrition among others. But those concerning delays in initiation of TB treatment are under-represented [13]-[18]. In the current study, we determined the effect of delays in commencement of TB treatment on outcomes of all TB patients between 2011 and 2014 in three DOTS pilot's centres in Benue State, Nigeria.

2. Methodology

2.1. Study Setting

Benue State, our study area is located in the north central geographic zone of Nigeria with a capital at Makurdi. It shares boundaries with Nasarawa to the north, Taraba to the east, Cross River, Ebonyi and Enugu to the south, and Kogi on the west. Benue State has an estimated population of 4,712,020 in 2010 (*i.e.* 2.8% projection from 2006 National population figures of 4,219,244) [19]. There are two main ethnic groups, Tiv and Idoma. Other ethnic groups include Igede, Etulo and Jukun. The Benue people are mostly farmers engaged in subsistence and commercial farming. Netherlands Leprosy Relief (NLR) supports the TB programme in Benue State.

2.2. Study Design

A retrospective study design with convenient non-probability sampling technique involving three of the four pilot DOTS centres.

2.3. Study Population

All registered TB patients, enrolled for treatment at the DOTS centres between January 2011 and December, 2014, were included for the study. Three high TB burden facilities were selected by convenience. These include: General hospital Gboko, Saint Vincent's hospital Alaide and General hospital Otukpo. Patients with incomplete information on date of diagnosis, date of treatment and outcome of treatment were excluded from the study.

2.4. Data Collection

The data sources used in each of the selected center was the routine National Tuberculosis and Leprosy Control Programme (NTBLCP) standardized facility reporting registers, LGA TB registers, patients TB treatment cards, TB suspects registers and patients sputum follow up registers. The relevant independent variables used were the age of patients, sex, disease sites and treatment category, sputum microscopy at baseline, date of diagnosis, and date of commencement of anti-TB drugs. The TB health facility registers were provided by the facility research participants and the information seen was exported to Extraction sheet. The Nigerian NTLCP guideline [2] adopted from WHO, was used for treatment outcome definitions.

2.5. Data Analysis

Data that were extracted from the data sources were entered into predesigned

software in Statistical Packages for Social Sciences (SPSS) version 19 (IBM corp. Released 2012. IBM SPSS statistics for windows, version 19.0, Armonk, NY: IBM Corp). Confidence interval was calculated using open epi. Software. Frequency tables, charts, mean and standard deviation were used to summarize the independent variables of interest. The main outcome of the study was compared with the time of commencement of the ant-TB treatment after diagnosis. Pearson chi-square ($\chi 2$) test was used for test of association between the independent variables and the main outcome of the study, with statistical significance set at p-value of 5%.

2.6. Ethical Considerations

Ethical approval for the surveys was obtained from Benue State Ministry of Health (SMOH) before the commencement of the study. Approvals from the management of the selected health facilities were also obtained.

3. Results

3.1. Socio-Demographic Characteristics of Surveyed TB Patients

Table 1 shows the age/sex distribution of the patents. Of the1711 cases seen, males' were 1360 (79.5%) while females were 351 (20.5%). The patients were between 1 - 94 years old. The modal age group for both male and female was 27 - 39 years (38.5% and 34.8% respectively). The mean age for the males was 39.0 ± 15.3 years and the female was 33.7 ± 14.2 years.

3.2. Disease Sites and Treatment Categories

The distribution of patients by disease site and treatment category revealed that the highest number of the patients had pulmonary TB (99.4%). Of the total 1711 TB cases managed, majority (95.2%) were new TB cases, followed by relapse (1.8%), return after default (1.1%), others (1.1%) and the least category was failure (0.9%).

Table 1. Age, sex distribution of TB cases (n = 1711).

Age group (In years)	Sex n (%)		Total
	Male	Female	
1 - 13	24 (1.8)	16 (4.6)	40 (2.3)
14 - 26	240 (17.6)	100 (28.5)	340 (19.9)
27 - 39	524 (38.5)	122 (34.8)	646 (37.8)
40 - 52	330 (24.3)	81 (23.1)	411 (24.0)
53 - 65	154 (11.3)	19 (5.4)	173 (10.1)
66 - 78	65 (4.8)	10 (2.8)	75 (4.4)
≥79	23 (1.7)	3 (0.9)	26 (1.5)
Total	1360 (100.0)	351 (100.0)	1711 (100.0)

Mean age = 37.9 ± 15.2 years; $p = 0.000$.

3.3. HIV Status of the Patients

Table 2 represents the summary of HIV status of all the reviewed TB cases. Of the 1711 patients on anti-TB treatment, 831 (48.6%) were TB/HIV co-infected, 820 (47.9%) were sero-negative for HIV and 3.5% of the patients HIV status was not known. Of the total 831 TB/HIV co-infected patients, the male predominated 604 (72.6%) and majority of them were between 27 - 39 years of age (47.7%). The age and sex distribution of the co-infected patients was statistically significant with their HIV status ($p < 0.05$).

3.4. Commencement of Anti-TB Drugs

The time interval between when the bacteriological or clinical diagnosis of TB was made and the time anti- TB was commenced by patients varied. Amongst 1700 patients who had pulmonary TB, 700 (41.2%) commenced their drug regimens within the first week, 277 (16.3%) commenced within 1 - 2 weeks, while 723 (42.5%) commence treatment after three weeks of diagnosis of TB. On the other hand, 3 (27.3%) of the patients with Extra-pulmonary TB commenced anti-TB after 29 days of diagnosis. Overall, 726 (42.4%) of the patients commenced anti-TB drugs after 29 days of diagnosis (Figure 1).

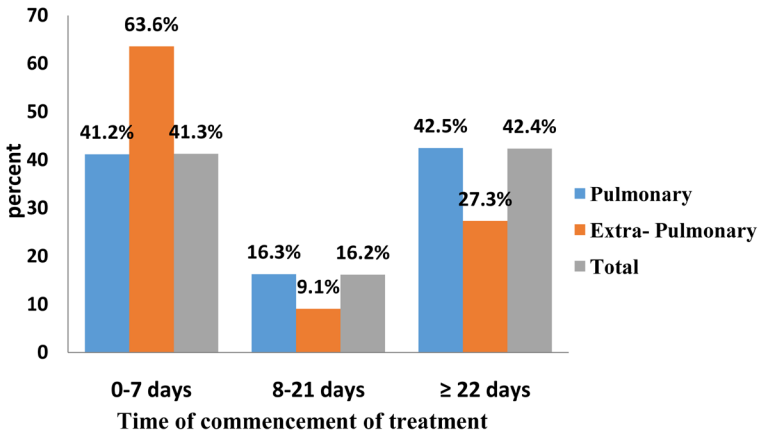

Figure 1. Period of commencement of anti-TB drugs by patients (n = 1711).

Table 2. HIV Status of the patients (n = 1711).

Variable	Positive	Negative	Not done	Total	*p*-value
		Age group (in years)			
1 - 13	26 (3.1)	14 (1.7)	0 (0.0)	40 (2.3)	
14 - 26	129 (15.5)	200 (24.4)	11 (18.3)	340 (19.9)	
27 - 39	396 (47.7)	228 (27.8)	22 (36.7)	646 (37.8)	
40 - 52	221 (26.6)	177 (21.8)	13 (21.7)	411 (24.0)	0.000
53 - 65	47 (5.7)	117 (14.3)	9 (15.0)	173 (10.1)	
66 - 78	11 (1.3)	60 (7.3)	4 (6.7)	75 (4.4)	
≥79	1 (0.5)	24 (2.9)	1 (1.7)	26 (1.5)	
Total	831 (100.0)	820 (100.0)	60 (100.0)	1711 (100.0)	
		Sex			
Male	604 (72.7)	699 (85.2)	57 (95.0)	1360 (79.5)	
Female	227 (27.3)	121 (14.8)	3 (5.0)	351 (20.5)	0.000
Total	831 (100.0)	820 (100.0)	60 (100.0)	1711 (100.0)	

3.5. Treatment Outcome

Table 3 represents the summary of the overall treatment outcome of the patients over the reviewed period, 2011-2014. Successful treatment outcome accounts for 66. 6% followed by default (18.5%), death (8.9%), treatment failure (4.4%) and transferred out cases (1.6%). The treatment outcome varies with age. The relationship between the treatment outcome and the treatment category, age and sex of patients was statistically significant ($p < 0.05$). Of the total 467 cured cases, 45.6% commenced treatment within the first 7 days after diagnosis, 15.4% between 8 - 21days and 38.8% after 22 days of diagnosis. Similarly, the proportion of patients who died in the course of treatment and those who were reported to have had a failure treatment were more amongst the patients who commenced their treatment after 22 days (42.5% and 78.7% respectively). The relationship between the treatment outcome and the time of commencement of anti-TB drug

Table 3. Percentage distribution of overall TB treatment outcome by age, sex, category and time of commencement of treatment.

Variable	Cured (N = 467)	Treatment Completed (N = 672)	Failure (N = 75)	Defaulted (N = 316)	Transferred out (N = 28)	Died (N = 153)	Total (N = 1711)	*p*-value
	%	%	%	%	%	%	%	
Age group (in years)								
1 - 13	0.9	3.9	2.7	0.6	3.6	3.3	2.3	0.011*
14 - 26	24.2	17.7	21.3	20.6	25.0	13.1	19.9	
27 - 39	39.0	38.7	34.7	36.4	42.9	33.3	37.8	
40 - 52	20.8	23.1	24.0	26.9	17.9	33.3	24.0	
53 - 65	38.4	11.2	12.0	9.5	10.7	11.1	10.1	
66 - 78	5.1	3.6	5.3	5.1	0.0	4.6	4.4	
≥79	1.7	1.9	0.0	0.9	0.0	1.3	1.5	
Sex								
Male	77.1	74.9	82.7	93.7	85.7	75.2	79.5	0.000[1]
Female	22.9	5.1	17.3	6.3	14.3	24.8	20.5	
Treatment category								
New	93.8	97.5	96.0	93.7	96.4	92.2	95.2	0.012[1]
Retreatment	26.2	2.5	4.0	6.3	3.6	17.8	4.8	
Treatment commencement after diagnosis								
0 - 7 days	45.8	42.9	14.7	40.5	28.6	37.9	41.3	
8 - 21 days	15.4	15.9	6.7	19.0	14.3	19.6	16.2	0.000[1]
≥22 days	38.8	41.2	78.7	40.5	57.1	42.5	42.4	
HIV Status								
Positive	32.3	59.5	33.3	42.1	57.1	69.3	48.6	
Negative	66.8	37.2	61.3	50.3	39.3	27.5	47.9	
Not done	0.9	3.3	5.3	7.6	3.6	3.3	3.5	0.000[1]

[1]probability using Pearson chi-square test; *probability using fishers exact test.

regimen was statistically significant (p = 0.000). Of the total cured cases 66.8% were HIV-negative as compared to 32.3% who were TB/HIV co-infected. Death rate among the TB/HIIV co-infected patients was also higher. The prevalence of TB/HIV co-infection was 48.5%, and it accounts for about 33.3% of treatment failure, 42.1% of default and 69.3% death due to TB. The treatment outcome and the HIV status of the patients was statistically significant ((p = 0.000).

4. Discussion

The demonstrated treatment success rate of 66.6%, default rate of 18.5% and failure rate of 4.2% in the selected DOTS centers in our study (**Table 3**) is far short of the national success rate of 85.0% [20]. It is also far lower than the success rate reported for Enugu (82%) a neighboring state [21], Kano (81.0%) and Cross Rivers (78.0%) [22], all in Nigeria. The findings in our study may be consistent with the reported national operational changes over the years [20]. However, the low success rate as compared to the national target and the high default rate in this study is a serious threat to the entire goal of the global TB management programme. Based on the convenient sampling technique applied in the selection of the DOTS centres in this study, our findings may not be a true representation of the state treatment outcome, but since the selection was based on the TB burden of the sites as indicated in the state annual epidemiological report, the reasons for the disparity in the treatment success rate need to be properly evaluated as to improve the TB control programme in Benue State.

In the current study four variables were found to have significant relationship to the outcomes of TB treatment. These includes: the socio-demographic characteristics of the patients, the treatment category, HIV status of the patients and finally the time between the date of bacteriological or clinical diagnosis of TB and the time of commencement of anti-TB drugs.

Regarding the socio-demographic characteristics of the patients, the gender and age differences demonstrated in this study are consistent with the documented global epidemiology of tuberculosis [1] [2] [8] [9] [10]. Majority of the TB cases were amongst those in the 27 - 39 age group and were predominantly males. These are consistent with some Nigeria studies [1] [21] [23]. The age and gender has significant relationship with the prevalence and the treatment outcome (p < 0.05). Considering the high prevalence of TB/HIV co-infection among males in our study, the predominant male TB in our study is inconsistent with the WHO report. In that report countries with HIV prevalence greater than 1% (like Nigeria) have female TB cases predominating [24]. We do not know the reason(s) for the difference in prevalence between the sexes and the ages in our study population. However, it is probable that a combination of factors such as biological differences in disease predisposition and disease presentation, together with gender related factors like access to health care may play a role [22] [25] [26].

All the stipulated TB control guidelines are aimed at early case finding via sputum smear microscopy and proper case management. However, adherence to

the stipulated rules in the selected DOTS centre in our study was not optimal (Figure 1). Based on the 99.4% cases of pulmonary TB seen in the current study (Table 4), one would have expected a similar proportion in terms of commencement of anti-TB regimen, but the reverse was the case as only 41.3% of the diagnosed cases commenced treatment within the first 7 days as compared to 42.5% who commenced treatment after 22 days of diagnosis. These findings are not in line with reasons for the implementation of DOTS strategy in Nigeria [2]. AS a result of reasons highlighted, in our study, the death rate and treatment failure amongst the patients who commenced treatment late was higher as compared to patients who commenced treatment within stipulated time after diagnosis. Due to limited number of literatures on the concept, limited comparative analysis of other literature and our study could not be done. However, since bulk of anti-TB drugs are supplied by donor agencies, out of stock could be the probable reasons for the late commencement of the regimen which is statistically demonstrated in our study as a strong factor responsible for treatment outcome in the selected DOTS centres in Benue state. Paucity of documented literatures on the concept by investigators despite its significant relationship with treatment outcome is an indication that it is a neglected correlate of TB treatment outcome. With Benue state now ranked as 4th in terms of TB burden in Nigeria [6], if treatment is not commenced immediately after diagnosis, TB will become another serious re-emerging disease even if the country manage to control it in some states. This is an important issue in this research.

Also in this study, HIV is found to have strong association with the TB treatment outcome. In the advent of concurrent HIV infection, if the outcomes in our patients are not improved, achieving the overall goal of eliminating TB so that it will no more be considered as a disease of public importance will be a mirage as development of Multi-Drug Resistant (MDR) TB may further jeopardized the efficacy of the available standardized tuberculosis chemotherapy thereby worsening the outlook for better tuberculosis control in Nigeria. By implication the emergence of MDR –TB will in turn pose serious challenge to the control of TB globally.

Table 4. Disease site and type of treatment category (n = 1711).

Disease Site/treatment category	Frequency	Percent
Disease Site		
Pulmonary	1700	99.4
Extra-Pulmonary	11	0.6
Treatment Category		
New	1629	95.2
Relapse	31	1.8
Return after Default	18	1.1
Others	18	1.1
Failure	15	0.9

5. Limitations of Study

The first limitation the researchers considered in this study is the methodology. The study sites were purposely selected on the basis of the SMOH TB records of the high patient numbers in the selected facilities. Hence the data may not be the true representative of all the health facilities in Benue State. Secondly, due to limited number of literatures on the concept of time of commencement of anti-TB drugs, there is limited comparative analysis of this present study with other studies. In further understanding, since anti-TB drugs are provided by donor agencies, out of stock may affect the early commencement of the regimen.

6. Conclusion

This study has demonstrated a favorable TB treatment outcome among patients who commenced treatment within the first one week of bacteriological or clinical diagnosis of TB as compared to TB patients who commenced treatment three or more weeks after diagnosis, indicating that time of commencement of anti-TB regimen is an important correlate in the TB control programme, but it is neglected.

7. Recommendation

Efforts should be made by the three tiers of government in their response to TB control programmes to ensure early case finding via sputum smear microscopy and prompt case management. There should be maximal involvement of public, volunteer and private providers through public-private mix approaches in order to ensure continuous supply of anti-TB drugs.

Conflict of Interests

The authors declare that there is no conflict of interests regarding the publication of this paper.

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