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ORIGINAL ARTICLE

Determinants of Treatment Outcomes among Drug-Susceptible Tuberculosis Patients on Directly Observed Treatment Short-Course at Federal Medical Centre, Abeokuta, South-West, Nigeria

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Keywords

DOTS;

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ABSTRACT

Background: Surveillance of tuberculosis treatment outcomes is very crucial in evaluating successes of tuberculosis (TB) intervention programmes as well as assessing progress towards achieving the Sustainable Development Goals target of ending TB infection by 2030. The study assessed treatment outcomes of tuberculosis and the determinants among tuberculosis patients on Directly Observed Treatment Short-course (DOTs) at Federal Medical Centre, Abeokuta South-West, Nigeria.

Methods: This was a retrospective review of treatment outcomes of patients managed for Tuberculosis at the facility between January 2015 and December 2019. Data were retrieved from the treatment register and analysed using IBM® SPSS software version 23. Results were presented using frequencies and percentages, while the Chi-square test was used to test for association between the treatment outcomes and the independent variables. Binary logistics regression was used to assess for determinants of treatment outcomes at a level of significance of $p<0.05$.

Results: A total of 726 records were reviewed. The median age of the patients was 35.0 years (IQR 25). The treatment success rate (TSR) and cure rate were 83.2% and 43.7% respectively. TB patients with negative HIV status were about two times more likely to have successful treatment outcomes (OR=1.86, 95%CI=1.20-2.88).

Conclusion: The TSR and cure rate obtained in this study were below the national targets set by the World Health Organization, and HIV co-infection was a threat to successful treatment outcomes among TB patients. Ensuring optimized antiretroviral therapy, prompt diagnosis and treatment of TB in HIV patients will go a long way in improving treatment outcomes.

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INTRODUCTION

Tuberculosis (TB) is an airborne bacterial infection caused by *Mycobacterium Tuberculosis*. It affects many organs of the body, with the lungs being the most commonly affected.[1] Worldwide TB is said to be one of the leading causes of death accounting for 2.5% of the global burden of disease and 25% of all

avoidable deaths in developing countries.[2] It remains one of the major health problems in Nigeria,[3] with an estimated 452,000 cases of tuberculosis occurring annually.[4] Nigeria is ranked 6th among the 30 high TB burden countries globally and 1st in Africa, with a total of 157,009 deaths recorded in 2018.[5] It is also on the high burden list for TB, Multidrug-resistant TB and Human Immunodeficiency Virus (HIV) associated TB.[4]

According to the Global Tuberculosis report of 2021, TB was the 13th leading cause of death worldwide, and the second leading cause of death from infectious diseases after COVID-19.[4] Globally in 2020, about 84% of TB deaths among HIV-negative people and 85% of the combined total of TB deaths in HIV-negative and HIV-positive people occurred in the World Health Organization (WHO) African and South-East Asia regions[4] as a result of widespread poverty, poor living conditions amidst a high population density and reduced immunity, especially from HIV/AIDS.[6] In 2020, there were 10 million recorded cases of tuberculosis and 1.5 million deaths of which 214,000 were attributable to HIV globally.[4] The coexistence of HIV infection and tuberculosis has been considered as one of the most serious threats to human health since the Black Death and hence labelled 'the cursed duet'.[7]

Even though tuberculosis is both preventable and curable, it still poses a serious public health problem in Africa. Several reasons have been adduced to why TB is yet to be eradicated as a public health problem on the continent. Some of these are HIV pandemic, lack of political will, civil strife, poverty, poor housing, and the lack of access to quality healthcare.[8-11]

Over the years, tuberculosis control has been achieved through effective treatment, improved drugs formulations, the development of newer drugs, and programs that support treatment adherence. In the last ten years, about 60 million people have been saved through the prompt diagnosis and treatment of Tb globally.[12] Early detection and prompt treatment of active cases is, therefore, an important priority of the TB control programs.[13] Poorly treated or untreated TB cases constitute a great health risk to the public and the nation at large. This is because such patients remain infectious for a longer

time, and are more likely to relapse or transform to drug-resistant TB (DRTB).[14]

Previous studies in Nigeria on treatment outcomes among TB patients showed that the treatment success rate ranged between 67.4-86.4%, while treatment failure ranged between 1.9% and 6.4%.[15,16] Factors that have been identified to be associated with poor treatment outcomes in Nigeria include the male gender, old age, poor knowledge of TB, residing in rural areas, and cases of retreatment.[11,13,17,18] Therefore, a continuous review of TB patients records with a view of identifying factors that promotes successful treatment outcomes is paramount in achieving the Sustainable Development Goal (SDG) target of ending the TB epidemic by 2030 and in preventing the development of DRTB. This study, therefore, assessed treatment outcomes and its determinants among tuberculosis patients on Directly Observed Treatment Short-course (DOTs) at Federal Medical Centre, Abeokuta South-West Nigeria. The findings from this study will be used in improving TB services at the facility and guide managers in TB programme in the state and the country at large.

METHODOLOGY

This study was conducted in Federal Medical Centre Abeokuta (FMCA), a public tertiary health care institution in the capital city of Abeokuta, Ogun State. The people of Abeokuta belong to the Yoruba ethnic group of Southwest Nigeria. The city has a population of 449,088 according to the 2006 population census figures, and with a growth rate of 1.76%, the projected population for the year 2020 was 574,568.[19] The city is home to Sacred Heart Hospital which is the first orthodox hospital in Nigeria, demonstrating its rich history in healthcare service delivery. In addition, there are several private and public hospitals in the city across the three levels of the healthcare delivery system in Nigeria. The Federal Medical Centre Abeokuta being one of these centres has a DOTs unit established in 2006. The unit provides free TB services through the help of the National Tuberculosis and Leprosy Control Program (NTBLCP) and other non-governmental organizations in charge of TB care. Several other health facilities within the state provide TB services as well. This was

a hospital-based retrospective descriptive cross-sectional study of TB treatment outcomes and the determinants among those that assessed care at the DOTs centre in FMC Abeokuta, Southwest Nigeria. The study population comprised of Drug Susceptible Tuberculosis (DS-TB) cases who received treatment at the centre within a 5year period, (January 2015- December 2019. All cases with incomplete records were excluded.

Hospital records of patients who received treatment within the study period were reviewed. Data were extracted into a proforma. The proforma comprised information on patients' socio-demographic characteristics and clinical profiles. Data were analysed using IBM® SPSS version 23.0. Descriptive statistics (mean±SD, frequencies, and percentages) were used to describe the study population, while the Chi-square test was used to assess for associations between the treatment outcomes (dependent variable) and the sociodemographic and clinical characteristics (independent variable) of patients. The binary logistic regression analysis was used to determine the predictors for successful treatment outcomes among the patients. The level of significance for all tests was set at $p<0.05$. Ethical approval (FMCA/470/HREC/01/2020/06) was obtained from the Research and Ethics Committee of Federal Medical Centre, Abeokuta before proceeding with the study. Also, verbal permission was granted by the heads of the DOTS centre and the Medical records department of the hospital.

TB Diagnosis and Treatment

The diagnosis of tuberculosis was made by using one of the following, either alone or in combination: Gene-Xpert; presence of symptoms suggestive of TB; abnormal chest radiograph; identification of acid-fast bacilli in sputum, gastric or body fluid; positive Mantoux test >5 mm diameter; and histology where necessary. Also, the regimen in use during the period covered in this study were:

Regimen 1 - six-month treatment (2(RHZE)/4(RH): for all forms of TB (PTB and EPTB cases – both new and previously treated) except TB meningitis Osteo-articular and miliary TB cases.

Regimen 2 - twelve-month treatment (2(RHZE)/10(RH): for all cases of TB meningitis (TBM), Osteo-articular and miliary TB cases.

Definition of Terms[20]

Pulmonary tuberculosis (PTB): This is a form of tuberculosis that involves the lung parenchyma (tissues) and tracheobronchial tree.

Extra-pulmonary tuberculosis (EPTB): This type of TB involves one or more organs other than the lung parenchyma.

New patients: TB patients who have never had treatment for TB, or who have taken anti-TB drugs for less than 4weeks.

Previously treated patients: Diagnosed TB patients who have received 4 weeks or more of anti-TB drugs in the past.

Cured: A pulmonary TB patient with bacteriologically confirmed (Xpert MTB/RIF, smear or culture positive) tuberculosis at the beginning of treatment and who completes treatment and was smear-negative in the last month of treatment and on at least one previous occasion

Died: A TB patient who dies for any reason before starting and during treatment.

Treatment failure: A TB patient whose sputum smear or culture is positive at month 5 or later during treatment.

Treatment completed: A TB patient who completed treatment but with no evidence of negative smear/culture results in the last month of treatment and on at least one previous occasion.

Treatment success rate: the percentage of patients who are cured plus those who have completed treatment but without laboratory proof of cure, of new smear-positive patients.

RESULTS

A total of 726 records of TB patients seen in the DOTS clinic between January 2015 and December 2019 were reviewed. The median age was 35years, with an interquartile range (IQR) of 25. A larger proportion of the patients were between 30 to 39 years 194 (26.7%). The majority of the TB patients were males 408 (56.2%) and married 400 (55.1%). Almost all of the patients 673 (92.7%) reside in the urban areas, and a larger proportion of them 297 (40.9%) had secondary education (Table 1). Six hundred and

Table 1: Socio-demographic characteristics of the patients

Variables	Frequency (n = 726)	Percent
Age group (in years)		
≤19	145	20.0
20-29	110	15.2
30-39	194	26.7
40-49	128	17.6
50-59	71	9.8
≥60	78	10.7
Sex		
Male	408	56.2
Female	318	43.8
Marital status		
Married	400	55.1
Single	280	38.6
Divorced/Separated	23	3.2
Widow	23	3.2
Residence		
Urban	673	92.7
Rural	53	7.3
Level of education		
None	133	18.3
Primary	157	21.6
Secondary	297	40.9
Tertiary	139	19.1
Occupation		
Trader	318	43.8
Unemployed	281	38.7
Civil Servant	82	11.3
Retiree	27	3.7
Artisan	18	2.5

Median age (IQR) = 35.0 (25) years

eighty-three (94.1%) of the patients had pulmonary tuberculosis, while extra-pulmonary tuberculosis accounted for only 43 (5.9%). Six hundred and eighty-seven (94.6%) were newly diagnosed, less than a quarter 163 (22.5%) had TB-HIV co-infection, and 701 (96.6%) had the six months regimen (Table 2). Less than half of the patients 317 (43.7%) were categorized as cured, while 287 (39.5%) were categorized as treatment completed. Seventy-five (10.3%) of the patients died, while only a few 6 (0.8%) had treatment failure.

Overall, treatment was successful in 604 (83.2%) of the patients (Table 3). From the bivariate analysis, the proportion of patients with successful treatment outcomes was significantly higher among patients that were forty years and below 405 (86.2%) as compared to those older 199 (77.7%),

Table 2: Clinical characteristics of the patients

Variables	Frequency (n = 726)	Percent
Site of disease		
Pulmonary (PTB)	683	94.1
Extra-pulmonary(EPTB)	43	5.9
Category of cases	687	94.6
New	39	5.4
*Others		
HIV status	563	77.5
Negative	163	22.5
Positive		
Treatment regimen	701	96.6
Regimen 1 (6 months)	25	3.4
Regimen 2 (12 months)		

**Defaulters, Relapse, Lost to follow up & Failure (LTFU)*

Table 3: Treatment outcomes among the patients

Variables	Frequency (n = 726)	Percent
Treatment Outcome		
Cured	317	43.7
Treatment Completed	287	39.5
Died	75	10.3
Loss to follow up	23	3.2
Transferred out	18	2.5
Treatment failure	6	0.8
Overall Treatment Outcome		
Successful	604	83.2
Unsuccessful	122	16.8

X^2=8.44; p=0.004; and among the unmarried 284 (87.1%) compared to the married 320 (80.0%), X^2=6.51; p=0.01. Patients' occupational status was also observed to be associated with treatment outcomes. The unemployed 244 (86.8%), had better treatment outcomes compared to the employed 360 (80.9%), X^2=4.34, p=0.04. Successful treatment outcome was significantly higher among those with negative HIV status 479 (85.1%), compared to those with positive HIV status 125 (76.7%), X^2=6.37, p=0.012 (Table 4).

After controlling for cofounders using the binary logistic regression, only the HIV status was a predictor of treatment outcome. Patients with HIV-negative status were about two times more likely to have a successful treatment outcome compared to those with HIV-positive status (aOR=1.86, C.I=1.20-2.88, p=0.01) (Table 5).

DISCUSSION

Monitoring tuberculosis treatment outcomes is very crucial in evaluating the effectiveness and efficiency of TB intervention programmes as well as assessing progress towards the world's SDG target of ending TB infection by 2030. This study assessed the determinants of treatment outcomes over five years among patients attending the DOTS centre in a tertiary health institution in Southwest Nigeria, a high TB burden country. The average five-year treatment success rate in this study was 83.2%. This is higher compared to the 78.1% reported from a study in Southwest Nigeria,[21] and the 73.3% in Northcentral Nigeria,[22] but lower than the 92.5% and 86.4% reported in similar studies conducted in Eastern Ethiopia and Anambra State of Nigeria respectively.[16,23] The relatively lower TSRs reported in the previous studies may be because both studies were conducted in private hospitals where more often than not the adequate resources and number of trained personnel to implement DOTs may be lacking. The TSR in this study, as well as those in the other studies in Nigeria, fell short of the national TSR target of 90% by WHO, and this underscores the need for policymakers to tailor service improvement towards achieving better outcomes in TB care.[21]

In this study, four out of every ten patients were categorized as cured, with approximately the same number categorized as treatment completed. This means that nearly half of the patients categorized as having successful treatment outcomes did not have a bacteriological diagnosis at 5th month of treatment. This is poor and falls short of the 85% target for cure rate set by the World Health Organization. Similarly, low cure rates have been reported in other studies conducted in TB endemic countries including Nigeria.[23,24,25,26] However, in a study by Nwachukwu et al in Anambra State, a cure rate of 85% was reported.[16] Achieving the set target by the WHO is not only good for TB programmes but is key to reducing household and community trans-mission of tuberculosis. Therefore, there is a need for all stakeholders in the TB programme in the state to identify and address all factors hindering optimal performance in the facility.

The study further lent credence to the "unholy alliance" between TB and

Table 4: Factors associated with successful treatment outcomes among the patients

Variables	Overall treatment outcome		
	Successful (n=604)	Unsuccessful (n=122)	[a]Test statistic, p-value
Age group (years)			
≤40	405 (86.2)	65 (13.8)	X^2 = 8.44
≥41	199 (77.7)	57 (22.3)	+p = 0.004
Sex			
Male	338 (82.8)	70 (17.2)	X^2 = 0.08
Female	266 (83.6)	52 (16.4)	p = 0.77
Marital status			
Married	320 (80.0)	80 (20.0)	X^2 = 6.51
Unmarried	284 (87.1)	42 (12.9)	+p = 0.01
Residence			
Urban	564 (83.8)	109 (16.2)	X^2 = 2.44
Rural	40 (75.5)	13 (24.5)	p = 0.12
Level of education			
Educated	489 (82.5)	104 (17.5)	X^2 = 1.25
Uneducated	115 (86.5)	18 (13.5)	p = 0.26
Occupation			
Employed	360 (80.9)	85 (19.1)	X^2 = 4.34
Unemployed	244 (86.8)	37 (13.2)	+p = 0.04
Site of disease			
PTB	567 (83.0)	116 (17.0)	X^2 = 0.27
EPTB	37 (86.0)	6 (14.0)	p = 0.61
Category of cases			
New	568 (82.7)	119 (17.3)	X^2 = 2.45
****Others	36 (92.3)	3 (7.7)	p = 0.12
HIV status			
Negative	479 (85.1)	84 (14.9)	X^2 = 6.37
Positive	125 (76.7)	38 (23.3)	+p = 0.012
Category (Regimen)			
Reg 1 (6months)	582 (83.0)	119 (17.0)	* X^2 = 0.43
Reg 2 (12 months)	22 (88.0)	3 (12.0)	p = 0.76

*[a]Pearson's chi-square test, *Fisher's Exact, +Statistically significant,*
***(Defaulters, Relapse, LTFU & Failure)*

Table 5: Predictors of successful treatment outcomes

Variables	aOR (95% Confidence interval)	P-value
Age group (years)		
≤40 (RC)	1	
≥41	0.65 (0.41 – 1.02)	0.06
Marital status		
Married(RC)	1	
Unmarried	1.40 (0.83 – 2.39)	0.21
Occupation		
Employed (RC)	1	
Unemployed	1.07 (0.63 – 1.84)	0.80
HIV status		
Negative	1.86 (1.20 – 2.88)	**+0.01**
Positive (RC)	1	

RC- Reference Category, aOR- adjusted odds ratio, +Statistically significant

HIV, as it showed that TB patients without HIV co-infection had a better treatment outcome than those with TB-HIV co-infection. This is consistent with findings in previous studies in Ethiopia and Nigeria.[22,23,27-31] Although the CD4 count and level of viral suppression of the patients in this study were not available in the records, poor treatment outcomes among TB-HIV co-infected patients have been attributed to immune-suppression experienced by these patients as a result of low CD4 count and advanced HIV disease.[28,32,33] Also, the poor treatment outcome could have been due to delayed diagnosis of Tuberculosis among this group of patients. Therefore, early initiation of antiretroviral therapy with enhanced adherence, as well as prompt diagnosis and treatment of TB in HIV patients will go a long way in improving treatment outcomes in TB-HIV co-infected patients.

Aside from HIV co-infection, other factors that have been identified as determinants of treatment outcomes in previous studies include gender, age, and TB classification,[24,26] however, these were not significant in our study.

Limitations of the study: The fact that FMCA is the biggest and major referral centre in the state, the severity of cases seen in the facility may differ from those seen in other centres. Another limitation in this study is that the records do not contain information on the CD4 and viral load of patients, therefore further study that will assess the clinical characteristics of HIV co-infected patients is required.

Conclusion: The TSR of 83.2% obtained in this study is slightly below the WHO target, and nearly half of the patients categorized as having successful treatment outcomes did not have the mandatory 5th-month test. HIV co-infection was the only determinant of poor treatment outcomes among the patients. Therefore, ensuring optimized antiretroviral therapy as well as prompt diagnosis and treatment of TB in HIV patients will go a long way in improving treatment outcomes.

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Conflict of interest: None

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