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Treatment outcomes among adult drug sensitive pulmonary tuberculosis patients in a private tertiary hospital in Ogun State, Nigeria: a retrospective study

K Sodeinde[1], F Bamidele[1], KO Ogunyemi[1], S Atinge[2], O Adesegun[1], N Nwankwo[1] and O Abiodun[1]

Department of Community Medicine[1], Babcock University Teaching Hospital, Ilishan-Remo, and Department of Community Medicine and Primary Care[2], Federal Medical Centre, Abeokuta, Ogun State, Nigeria

Abstract

Background: Tuberculosis (TB) remains a high burden disease particularly in developing countries. The periodic appraisal of the outcome of treatment and associated determinants is of utmost value, as it serves as a litmus test of the impact of the TB control programme in the facility and its catchment area. This study thus aimed to review treatment outcomes and associated factors among drug sensitive pulmonary TB patients accessing care in a private tertiary hospital in Ogun State, Nigeria.

Methods: A retrospective review of 171 drug sensitive pulmonary TB patients managed from January 2013 to December 2020 at the TB (DOTS) clinic of Babcock University Teaching Hospital (BUTH) was done. The socio-demographic, clinical, and laboratory data were extracted from the presumptive TB register. The analysis was done using SPSS version 20. Relevant descriptive and inferential statistics were calculated with the level of significance set at $p< 0.05$.

Results: The mean age of the drug sensitive pulmonary TB patients was 42.11±14.86 years. More than half (51.5%) of them were females, while 48.5% were males. About two-fifth (38.6%) of the patients were classified as completed treatment, 35.7% achieved cure, 7.0% were lost to follow up, 0.6% had treatment failure and 18.1% died. Overall, 75.4% of the patients had treatment success while 24.6% had unsuccessful treatment. Those who were HIV negative had a statistically significantly better treatment outcome as compared to those who were HIV positive ($p=0.03$). There was also a statistically significant association between usage of HAART and treatment outcomes ($p=0.002$).

Conclusion: The findings on better TB treatment outcomes among HIV negative patients and HIV positive patients on HAART highlight the need for HIV prevention strategies and sustainable provision of HAART during the management of TB.

Correspondence: Dr. K.O. Ogunyemi, Department of Community Medicine, Babcock University Teaching Hospital, Ilishan-Remo, Ogun State, Nigeria. E-mail: ogunyemik@babcock.edu.ng

Keywords: *BUTH, HAART, HIV, Ogun State, Treatment Outcome, TB.*

Résumé

Contexte: La tuberculose (TB) reste une maladie à charge élevée, en particulier dans les pays en développement. L'évaluation périodique des résultats du traitement et des déterminants associés est de la plus haute valeur, car elle sert de test décisif de l'impact du programme de lutte antituberculeuse dans l'établissement et sa zone de desserte. Cette étude visait donc à examiner les résultats du traitement et les facteurs associés chez les patients atteints de tuberculose pulmonaire sensible aux médicaments accédant aux soins dans un hôpital tertiaire privé de l'État d'Ogun, au Nigéria.

Méthodes: Une revue rétrospective de 171 patients atteints de tuberculose pulmonaire sensible aux médicaments pris en charge de janvier 2013 à décembre 2020 à la clinique TB (DOTS) du Babcock University Teaching Hospital (BUTH) a été réalisée. Les données sociodémographiques, cliniques et de laboratoire ont été extraites du registre présomptif de la tuberculose. L'analyse a été effectuée à l'aide de la version 20 de SPSS. Les statistiques descriptives et inférentielles pertinentes ont été calculées avec le niveau de signification fixé à $p <0,05$.

Résultats: L'âge moyen des patients tuberculeux pulmonaires sensibles aux médicaments était de 42,11 ± 14,86 ans. Plus de la moitié (51,5%) d'entre eux étaient des femmes, tandis que 48,5% étaient des hommes. Environ deux cinquièmes (38,6%) des patients ont été classés comme traitement terminé, 35,7% ont guéri, 7,0% ont été perdus de vue, 0,6% ont échoué au traitement et 18,1% sont décédés. Dans l'ensemble, 75,4% des patients ont eu un succès de traitement tandis que 24,6% ont eu un traitement infructueux. Ceux qui étaient séronégatifs avaient des résultats de traitement statistiquement significativement meilleurs que ceux qui étaient séropositifs ($p = 0,03$). Il y avait également une association statistiquement significative entre l'utilisation du HAART et les résultats du traitement ($p = 0,002$).

Conclusion: Les résultats sur de meilleurs résultats du traitement de la tuberculose chez les patients séronégatifs et les patients séropositifs sous HAART soulignent la nécessité de stratégies de prévention du VIH et de fourniture durable de HAART pendant la prise en charge de la tuberculose.

Mots clés: *BUTH, HAART, VIH, état d'Ogun, résultat du traitement, tuberculose.*

Introduction

Tuberculosis (TB) remains highly prevalent particularly in low and middle income countries. According to World Health Organization (WHO), 10 million people fall ill with tuberculosis annually despite being a largely preventable disease [1]. Nigeria is among the top eight countries responsible for about half of the global TB burden, along with India, China, Pakistan, Bangladesh, Phillipines, Indonesia, and South-Africa [1]. In 2016, the incidence rate for TB among HIV-negative individuals in Nigeria was 158 per 100,000 people, prevalence was 27%, with a mortality of 39,933 people [2]. Human Immunodeficiency Virus (HIV) infection stands out as the most significant risk factor for tuberculosis, particularly in Nigeria where the burden of HIV is also significant. [2-4].

The TB response in Nigeria is administered by the National Tuberculosis and Leprosy Control Programme (NTBLCP), which is under the Department of Public Health of the Federal Ministry of Health. The programme brings together public and private partners to maximize the programme's reach. The goal for TB control in Nigeria, as stipulated by the NTBLCP is to half TB prevalence and achieve a 75% decrease in TB deaths (excluding HIV) by 2025, relative to the 2013 levels [5].

As far as treatment outcomes are concerned, the programme targets to achieve by 2020, a minimum treatment success rate of 90% of all new bacteriologically confirmed TB cases [6]. However, TB treatment success rate has been placed at 83% globally, even though there are variations within and between countries [7]. For example a study from Ethiopia stated TB success rate at 43.3% and another study reported 28-54% in various parts of Uganda [8, 9]. In southwest Nigeria, TB treatment success rate and failure rate have been reported as 46.1% and 8.3% respectively [10] while in south east Nigeria, treatment success rates have been placed at 76.0% while failure rate placed at 1.6% [11]. The pre-existing health infrastructure from primary to tertiary level (including public and private) make immense contribution to the delivery of TB services in Nigeria, and offer a means for presumptive and confirmed TB patients and their contacts to access preventive and curative TB care. The periodic appraisal of the outcome of treatment and associated determinants is of utmost value, as it serves as a litmus test of the impact of the TB control programme in the facility and its catchment area.

Regarding the determinants of TB treatment outcomes, male gender, older age, weight, rural dwelling, poor knowledge of TB, retreatment TB cases and HIV seropositivity have been shown to have significant associations with poor treatment outcomes among adult TB patients in Nigeria and other TB high-burdened countries such as Ethiopia [8-10, 11-17].

Although, some previous Nigerian studies have examined the TB treatment outcomes in public tertiary health centres [10, 11-13]. There is scarcity of data on TB treatment outcomes in a private tertiary hospital. Hence, this study aimed to review the treatment outcomes and associated factors among drug sensitive pulmonary TB patients accessing care in Babcock University Teaching Hospital (BUTH), Ogun State.

Methodology

Study design

This study included a retrospective document review of drug sensitive pulmonary tuberculosis patients who accessed care in BUTH, Ilishan, Ogun State, Nigeria between the period of January 2013 to December 2020.

Study setting

BUTH is a 140-bed private tertiary hospital that is run by the Seventh-day Adventist Church. The teaching hospital has about fifteen (15) departments which include the Department of Community Medicine. The department offers several services through various services including the Directly Observed Treatment Short-course (DOTS) clinic for TB and the virology clinic for HIV/AIDS. The DOTS clinic runs every Friday when adequate care is provided for patients with different forms of tuberculosis including pulmonary tuberculosis, extra-pulmonary tuberculosis and drug-resistant tuberculosis [18]. The clinic also serves as a referral site for tuberculosis patients from primary and secondary hospitals in the nearby towns and other parts of the country.

Study population, inclusion and exclusion criteria

The records of all adults (18 years and above) who were registered in the DOTS clinic of BUTH were reviewed in this study. However, we excluded registries that have missing treatment outcomes from

the study. Records of a total of 171 patients were reviewed.

Ethical clearance

Ogun State Ministry of Health Ethics Board with approval number HPRS/381.363.

Data collection tools and technique

Relevant data were retrieved from the patients' records by three medical doctors who have experienced in TB care and data collection. Such data included socio-demographic characteristics of patients (age and sex), clinical characteristics (HIV status and treatment outcomes), and laboratory findings particularly the gene expert results which were retrieved without any form of personal identifier from the presumptive TB register.

Operational definitions

For this study, tuberculosis treatment outcomes were classified as successful and unsuccessful. Successful outcomes were those classified as "cured" and "treatment completed". Unsuccessful outcomes were those classified as "treatment failure", "loss to follow up", "died". Operational definitions were based on the National TB and Leprosy Control Guidelines, Nigeria [19].

TB case

"This is an individual that has been confirmed to have TB disease. A TB case may either be confirmed bacteriologically or diagnosed clinically".

Pulmonary Tuberculosis (PTB)

"This describes tuberculosis that affects lung parenchyma (tissues)".

HIV-positive TB patients

"This is a TB patient with documented HIV-positive result. The documented evidence may be from enrolment in HIV care e.g. a patient on HAART or from HIV test that is carried out during TB diagnosis".

HIV-negative TB patient"

This is a TB patient with a documented negative HIV result from a test carried out during TB diagnosis".

Cured"

A bacteriologically confirmed TB patient (smear or culture positive) at the beginning of treatment and who was smear or culture negative in the last month of treatment and on at least one previous occasion".

Treatment completed"

A TB patient who completed treatment but without evidence of cure (there is no record to show the sputum smear or culture results in the last month of treatment and on at least one previous occasion are negative either because they were not done or because results were not available)".

Treatment failure"

A TB patient whose sputum smear or culture is positive at the fifth month or later during treatment".

Died"

A TB patient who dies for any reason before starting or during treatment".

Lost to follow-up"

A TB patient whose treatment was interrupted for two consecutive months or more".

Treatment success"

The total of bacteriologically diagnosed TB cases cure and those who complete their treatment without a bacteriologically confirmed result".

Defaulter"

A patient who has been on treatment for at least 4 weeks and whose treatment was interrupted for 8 consecutive weeks or more".

TB diagnosis procedure

The diagnosis was made by Xpert/MTB/RIF assay (Gene Xpert test). The early morning sample of sputum collected from the patient was mixed with a reagent after which this mixture contained in a cartridge was loaded into the Gene Xpert machine. The Gene Xpert test consists of amplification of nucleic acid that identifies both the presence of Mycobacterium tuberculosis (MTB) and rifampicin-resistance in the provided sputum sample in less than 2 hours [20]. The Gene Xpert machine classifies the presence of MTB as very low, low, medium, or high. This result is generated automatically and is immediately printed out through a computer that is connected to the machine.

Data management and analysis

The retrieved data were initially entered into an Excel sheet for data cleaning and later moved into IBM SPSS version 20 for data analysis. Descriptive statistics were presented as mean with standard deviation or median with range, and as frequency with percentage using table. Chi-square bivariate analysis was conducted to test for associations of patients' socio-demographics and clinical characteristics with treatment outcomes. Multivariate analysis was performed to test for association while

controlling for the effects of confounding variables at a significance level of $p< 0.05$.

only a few 6 (3.5%) had a pre-treatment weight of between 18-37kg. Over half 94 (55.0%) of the

Table 1: Socio-demographic and Clinical Characteristics of Drug Sensitive Pulmonary TB Patients

Variable	Frequency (n)	Percentage (%)
Age (Years)		
d”19	8	4.7
20-29	27	15.8
30-39	46	26.9
40-49	39	22.8
50-59	28	16.4
≥60	23	13.4
Sex		
Female	88	51.5
Male	83	48.5
Pre-Treatment Body weight (Kg)		
18-37	6	3.5
38-54	69	40.4
55-70	64	37.5
>70	32	18.6
HIV Status		
Positive	77	45.0
Negative	94	55.0
HAART (n=77)		
Yes	75	97.4
No	2	2.6

Mean age 42.11±14.86 years

Results

Table 1 shows the socio-demographic and clinical characteristics of the drug sensitive pulmonary TB patients. More than half 88 (51.5%) were females while 48.5% were males. The highest proportion of patients 46 (26.9%) were in the age bracket of 30-39 years and patients' mean age was 42.11±14.86 years. About two-fifths, 64 (37.5%) of the patients had a pre-treatment weight of between 55-70 kg while patients were HIV negative while 77 (45.0%) were HIV positive among which almost all 75 (97.4%) had been placed on Highly Active Anti-retroviral Therapy (HAART).

Table 2 shows the patients' TB treatment outcomes. About two-fifth 66 (38.6%) were classified as “treatment completed” while over one-third 61 (35.7%) were classified to have achieved “cure”. Less than one-tenth 12 (7.0%) were lost to follow up, one patient (0.6%) had treatment failure and 31

Table 2: Treatment Outcomes of Drug Sensitive Pulmonary TB Patients

Variable	Frequency (n)	Percentage (%)
WHO/NTBLCP Classification		
Completed	66	38.6
Cure	61	35.7
Died	31	18.1
Loss To Follow Up	12	7.0
Failure	1	0.6
Total	171	100.0
Study Classification		
Successful	129	75.4
Unsuccessful	42	24.6
Total	171	100.0

(18.1%) died. Overall, 129 (75.4%) of the patients had treatment success while 42 (24.6%) had unsuccessful treatment.

Table 3: Drug Sensitive Pulmonary TB Patients' Characteristic and Bivariate Relationship with Treatment Outcomes

Variable	TB Treatment Outcome		Chi-Square	p-value
	Successful n(%)	Unsuccessful n(%)		
Age				
≤41	69 (80.2)	17 (19.8)		
≥42	60 (70.6)	25 (29.4)	2.15	0.14
Sex				
Female	64 (72.7)	24 (27.3)		
Male	65 (78.3)	18 (21.73.9)	0.72	0.40
Pre-Treatment Weight				
18-54	56 (72.7)	21 (27.3)		
≥55	73 (77.7)	21 (22.3)	0.556	0.456
HIV Status				
Positive	52 (67.5)	25(32.5)		
Negative	77 (81.9)	17 (18.1)	4.73	0.03
HAART (n=89)				
Yes	52 (70.3)	22 (29.7)		
No	0 (0.0)	3 (100.0)	12.41	0.002

Table 3 shows patients' characteristics and bivariate relationship with TB treatment outcomes. There were statistically significant associations between HIV status (p=0.03) and usage of HAART (p=0.002) with treatment outcome. There were, however, no statistically significant associations between age (p=0.14), sex (p=0.40) and pre-treatment weight (p=0.46), with treatment outcome. A higher proportion (80.2%) of younger patients 41 years and below had successful treatment as compared to 70.6% of older patients of 42 years and above. Also, a higher proportion of males (78.3%) had successful treatment as compared to 72.7% of females. Likewise, a higher proportion of patients with more pre-treatment weight of 55kg and above (77.7%) had successful treatment as compared to 72.7% of those with pre-treatment weight of 54kg and below.

Discussion

An assessment of TB treatment outcomes and patterns of achieving these outcomes is an integral part of a successful TB control programme as this is vital in reducing morbidities and mortalities. TB treatment success rate has been placed at 83% globally [7], though there is a country to country variation. It is fundamental in TB treatment to do an appraisal of treatment outcomes and identify factors associated with the same [7]. Such factors may include age, family size, category of patient, sex and HIV co-infection [8, 21].

TB treatment success rate in this current study was 75.4%. Though this rate was lower than both the global treatment success rate of 83% [7] and the national target of a 90% treatment success rate**,** it was still much higher than the success rate of 46.1% in other parts of Southwestern Nigeria [10]. It was also much higher than the success rate of 43.3% in Hossana Region of Ethiopia [8] and 28-54% in various parts of Uganda [9]. The high success rate reported in our study was however similar to what was documented in Ebonyi, Southeastern Nigeria [11]. Treatment success rate in this study was also not too different from reported findings in Ibadan, Nigeria [12], Northern Ethiopia [22] and Dabat Region of Ethiopia [23].

This higher TB treatment success rate documented in this study as compared to other parts of Southwest Nigeria, the geo-political zone where our study area is located may indicate a better implementation of the DOTS programme in the centre as reflected in a treatment failure rate of only 0.6% and loss to follow up rate of 7.0% as compared to the treatment failure rate of 8.3% and defaulter rate of 66.7% in other parts of Southwest Nigeria [10]. The treatment failure rate in this study was also much lower than what was reported in Egypt [24] and Uganda [9].

There has been an established direct relationship between HIV and TB. People that live with HIV do not only have more chance of developing active TB disease [25], they are also more susceptible to poor TB treatment outcomes [10]. Moreover, each of these two diseases hasten the progression of the

other [26] and therefore mortality risks in individuals with co-infection are doubled as compared to people with HIV alone [27]. This may explain why the prevalence of HIV in our study was 45.0% which was much higher than the prevalence rate of 1.4% among the general population of adults in the country [28]. In the same vein, this established relationship between HIV and TB may explain an increased death rate of 18.1% reported among TB patients in this study as compared to 0.063% among the general population in Nigeria [29].

Furthermore, this study revealed an inverse association between HIV infection and successful TB treatment outcomes while there was a direct relationship between usage of HAART and successful treatment outcomes. Commencement of HAART has been linked with better tuberculosis performance and survival for patients with HIV/TB co-infection [30]. This better clinical improvement among HIV/TB co-infected patients who had been commenced on HAART may be because of improved immune status due to HAART which subsequently helps the patients' body system in fighting the tuberculosis infection. However, for those with HIV/TB co-infection, anti-TB drugs should be commenced first, followed by cotrimoxazole and HAART [31].

The WHO states that tuberculosis mostly affects people in their productive years [32]. Little wonder most (65.5%) of the patients in this study are in the age group 20-49 years with a mean age of 42.11±14.86 years. This age range of highest TB burden also agrees with findings by Nakanwagi-Mukawa *et al* [9], Fatiregun *et al* [12], Oshi *et al* [11] and Tola *et al* [33].

Tuberculosis disease is more prevalent and more severe among men as compared to women [11-12, 32]. According to the WHO approximately 10 million individuals were infected with tuberculosis in 2019 globally with about 60% of them being men and the remaining 40% were women and children [32]. However, our study revealed a higher prevalence of tuberculosis in women as compared to men. The higher female to male ratio among the patients might be a reflection of the population structure of Ogun State where the study area is located which has more females than males [34].

Limitation of study

This study was a retrospective review of secondary data. Some of the important sociodemographic variables such as educational level, occupation and marital status were not documented routinely in the NTBLCP report tools used for this study, which limited the understanding of their associations with TB treatment outcomes.

Conclusion

The high prevalence of TB among adults in their reproductive years and poorer treatment outcomes among HIV/TB co-infected patients not on HAART highlight the need for intervention in the context of health education and lifestyle modification for young people to prevent and control TB. Also, there should be emphasis on HIV prevention strategies among TB patients and sustainable provision of HAART among HIV/TB co-infected patients for improved TB treatment outcomes.

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