Clinical and Humanistic Outcomes of Tuberculosis Treatment in a Nigerian Directly Observed Treatment Short Course Centre

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Authors’ contributions

This work was carried out in collaboration among all authors. Author DWD conceptualized the idea and designed the protocol for the study. Author CNS designed the questionnaire and the data collection checklist for data collection. Authors MKM and MAA collected and cleaned the data. Author BNJ performed the data analysis and wrote the first draft of the manuscript. Authors APL and SGM searched the literatures. All authors read and approved the final manuscript.

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ABSTRACT

Background: Tuberculosis remains a major global health problem. It causes ill-health among millions of people each year and ranks alongside the human immunodeficiency virus (HIV) as a leading cause of death worldwide. The objective of the study was to evaluate the clinical and humanistic outcomes of tuberculosis treatment at the directly observed treatment short-course (DOTS) centre in Jos University Teaching Hospital.

Methods: Data for clinical outcomes was collected retrospectively at the directly observed treatment short-course centre of Jos University Teaching Hospital from a cross-section of patients’ folders who had been treated for tuberculosis at the study site for at least 12 months as at 1st April to 30th September 2018 while a validated questionnaire was administered prospectively to a census population of tuberculosis patients still undergoing treatment between 1st October 2018 and 31st March 2019 to determine the humanistic outcomes. A descriptive data analysis was done using

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1. INTRODUCTION

Tuberculosis is an important public health problem, it was responsible for 1.5 million death in 2018 [1]. Tuberculosis is caused by a bacterium called mycobacterium tuberculosis and affects the lungs primarily, but can also affect other parts of the body [2]. It is an age – long disease that has defied eradication. Treatment failures pose great challenge to tuberculosis (TB) management. Patients may be clinically stable but the fact that they are confined to chronic use of the drug, that may affect their lives. According to the WHO, TB is the leading cause of death among HIV-infected patients with 84% of the comorbidity deaths occurring in Africa [3].

Tuberculosis is a complex disease that has biological, social, economic and cultural effects on the patient. These factors give different clinical and humanistic perception to the outcome of tuberculosis treatment, thus affecting the treatment outcome [4]. Tuberculosis is a poverty-related disease which disproportionately affects the poorest, the most vulnerable and marginalized population wherever it occurs. Improving access to diagnosis and care are the basic requirements in the fight against TB, and are particularly challenging in these persons [5].

Nigeria is among the 30 high burden counties for TB and the sixth among the 8 countries with two thirds of the world total TB burden [3]. The problem of TB in Nigeria has been made worse by the issue of drug resistant TB and the HIV/AIDS epidemic. It is estimated that 407,000 people in Nigeria have TB each year [6]. According to World Health Organization (WHO), the estimated incidence of TB in Nigeria is 322 per 100,000 populations with only 15% of the total burden of the disease in the country being notified in 2015 [6]. Jos University Teaching Hospital, site of the study is a large tuberculosis and HIV treatment unit in the country with many cases of reinfection, relapse and treatment failure following poor TB diagnostic and monitoring approaches [7].

Tuberculosis infected people who do not receive treatment for latent TB have a 5–15% chance of developing TB in their lifetimes but the risk is much higher with compromised immune systems, such as people living with HIV, malnutrition or diabetes or people who are engaged in substance abuse [8]. The challenges in the management of TB/HIV co-infected individual is pill burden, increase of adverse effects, drug-drug interaction and immune reconstitution inflammatory syndrome. Ending the TB epidemic by 2030 is among the health targets of the Sustainable Development Goals.

TB is a treatable and curable disease. Active, drug-susceptible TB disease is treated with a standard 6-month course of 4 antimicrobial drugs (Rifampicin, Isoniazid, Ethambutol and Streptomycin) that are provided with information and support to the patient by a health worker or trained volunteer. Without such support, treatment adherence is more difficult. Between 2000 and 2018, an estimated 58 million lives were saved through TB diagnosis and treatment [1].

Definitions for the treatment outcomes for drug susceptible tuberculosis include:

**Cured**- Patient initially bacteriologically confirmed by microscopy, culture or molecular tests who completed treatment, shows no signs of continued active disease, has at least 2 negative smears or cultures: - one at 4-5 months and the other at the end of treatment and does not meet the definition of failure.

**Completed** - All Patient who completed treatment, has no signs of continued active
disease and does not meet the bacteriological criteria for cure.

**Failure** - Patient with signs of continued active disease or deterioration requiring a treatment change, patient with positive smear or culture at 4-5 months of treatment or thereafter, patient with no significant clinical improvement, no significant gain of weight after 4-5 months of treatment and for whom the diagnosis of failure is established by a clinician.

**Death** - Patient who died on TB treatment or while awaiting TB treatment, irrespective of the cause of death.

Tuberculosis treatment is said to be successful when the proportion of patients cured and those who completed treatment add up to the target treatment goal. The World Health Organization defines TB treatment as successful when at least 85% success rate is achieved [9].

Several reasons and risk factors for poor TB treatment outcomes have been reported. Advancing age, male gender, low income, no or limited access to transport, distance from home to the treatment center, incomplete treatment compliance, limited interest in information about the disease and its treatment, limited social support, multidrug resistance, and co-morbidity have all been found to be related to unsuccessful treatment outcomes [10].

Tuberculosis treatment presents particular challenges for adherence because treatment is long and involves taking a number of medications, side-effects are common, and patients usually feel better before treatment has been completed [4] and are likely to stop medication. Socioeconomic factors such as having a job, a home, family or other support, being stigmatized or marginalized; psychological factors such as feelings of discouragement; adverse effects and the relationship between the health care worker and the patient all influence adherence to varying extent. Most often people diagnosed with tuberculosis and are on the treatment tends to discontinue their medication probably because of their dissatisfaction with the treatment while others may discontinue their medication once they start feeling better, especially if they are not on the directly observed treatment short course (DOTS).

Patient satisfaction has emerged as an important health outcome and a measure of quality of health-care services and has been defined as the level of congruence between patients’ expectations and their perceptions of care they received [11].

Most often, tuberculosis treatment outcomes measures have focused on mortality and microbiologic cure and have neglected patients’ preferences such as satisfaction with care, which may be crucial in influencing treatment outcomes. Furthermore, knowing patients’ satisfaction would enable TB program managers to understand the gaps in health-care delivery, to understand the specific needs of individual patients so that strategies to meet the needs and expectations of patients and improve access to quality TB services are instituted [12]. Such surveys help to provide insight into health-care service quality and the demand for these services.

The objective of this study was to evaluate the clinical outcomes of tuberculosis treatment at the tuberculosis treatment centre and explore patient satisfaction with TB patient care in the Jos University Teaching Hospital.

2. METHODS

2.1 Study Site

Jos University Teaching Hospital located at Lamingo in Jos North local government area, Plateau state, Central Nigeria is a 600-bedcapacity tertiary hospital and offers various services including serving as reference DOTS centre for tuberculosis treatment for central Nigeria.

2.2 Study Design

Retrospective data extraction from case record folders of tuberculosis patients on directly observed treatment or previously treated using the DOTS strategy and prospective interview of patients currently undergoing treatment or returning for refill. The DOTS strategy or policy is a practice where the tuberculosis patients take the anti-TB drugs as and when due under the direct supervision of the healthcare giver and thus ensure 100% compliance with medication. This is mostly achievable in the health facility.

2.3 Sample Size and Sampling Procedure

A data extraction checklist was used to collect relevant information from patients-case files retrospectively. It included patients demographic
profiles, initial and current clinical assessment, and treatment outcomes. Data retrieved was from case records of all tuberculosis patients who as at the study period of 1st April to 30th September, 2018 had been treated in the facility for at least 12 months and whose treatment outcomes are available. Folders of patients who came to the facility on referral and those whose diagnosis had other chronic conditions like HIV/AIDs were excluded. Data retrieved from patient folders was used to assess clinical outcomes of treatment. Altogether, 245 patient folders that met the inclusion criteria were assessed.

A census population of tuberculosis patients undergoing treatment in the facility were prospectively administered a patient satisfaction questionnaires as they come for follow-up visits and medication refill between 1st October 2018 and 31st March 2019. Questionnaires were designed to capture patient demographics and their satisfaction with care provided at the facility and their clinical conditions following the treatment. Information obtained from the questionnaires was used to assess the humanistic outcomes. Patients who have been on treatment in the facility for at least 6 months as at study period and who consented to fill the questionnaires were included. Patients who started treatment elsewhere before coming to the facility were excluded. During this period a total of 200 patients who met the inclusion criteria and consented to participation filled the questionnaires.

2.4 Data Analysis

Data generated from the study were coded and transferred into the statistical package for social sciences (SPSS) version 23 for analysis. Descriptive analysis was done to summarize the data while proportions were compared using Chi-squared test with significance level set at P<.05.

3. RESULTS

A total of 245 patient folders were studied, 153 (62.4%) were males and 92 (37.6%) were females. Most (57%) were married and 63% are aged above 30 years of age. Seventeen per cent were civil servants and the rest were students, artisans and petty traders while majority (69%) acquired at least secondary education (Table 1). Other important demographic information that could not be assessed due poor records include body mass index (BMI) and educational qualifications of patients.

Table 1. Socio-demographic characteristics of TB patients (N=245)

| Characteristics | Frequency (%) |
|----------------|--------------|
| Sex            |              |
| Male           | 153 (62.4%)  |
| Female         | 92 (37.6%)   |
| Age            |              |
| <20yrs         | 16 (6.5%)    |
| 20-30yrs       | 74 (30.2%)   |
| 31-40yrs       | 67 (27.3%)   |
| >40yrs         | 88 (35.9%)   |
| Marital status |              |
| Married        | 140 (57.1%)  |
| Single         | 105 (42.9%)  |
| Occupation     |              |
| C/servant      | 43 (17.6%)   |
| Student        | 47 (19.2%)   |
| Artisan        | 66 (26.9%)   |
| Business       | 33 (13.5%)   |
| H/wife         | 21 (8.6%)    |
| Farmer         | 31 (12.7%)   |
| Applicant      | 4 (1.6%)     |

Of the 245 folders screened, 147 (60%) TB patients were cured, 40 (16%) completed treatment, 22 (8.98%) died and treatment failure/relapse occurred in 5 (2.04%) patients (Table 2).

Table 2. Tuberculosis treatment outcomes in the facility

| Treatment outcome | Frequency | Percent |
|-------------------|-----------|---------|
| Cured             | 147       | 60.00   |
| Completed         | 40        | 16.33   |
| Defaulted         | 17        | 6.94    |
| Loss to follow-up | 14        | 5.71    |
| Died              | 22        | 8.98    |
| Relapse/failure   | 5         | 2.04    |

Fifty nine per cent of those aged 40yrs and above were cured compared to 64% cured below 31yrs. Death was experienced more (17) among married patients than their single counterparts with 5 deaths. Age, gender, marital status and occupation had no significant influence on treatment outcomes (Table 3).

All the respondents visit only JUTH for their treatment. One hundred and twenty six (88%) get all their drug needs in the facility and 196 (98%) are satisfied with the Tb patient counselling at the centre and are willing to recommend the center for other Tb patients. Overall, 79 (39.5%) of patients are very satisfied with all aspects of tuberculosis care, 120 (60%) are satisfied and 1 (0.5%) is not satisfied (Table 4).
Table 3. Demographic influence on treatment outcomes (N= 245)

| Characteristics | Cured | Completed | Defaulted | Loss to follow-up | Died | Relapse failure | Total | P-value |
|-----------------|-------|-----------|-----------|-------------------|------|----------------|-------|---------|
| Age             |       |           |           |                   |      |                |       |         |
| <20yrs          | 10    | 3         | 1         | 2                 | 0    | 0              | 16    | 0.471   |
| 20-30yrs        | 46    | 10        | 5         | 4                 | 5    | 2              | 74    |         |
| 31-40yrs        | 37    | 16        | 3         | 5                 | 4    | 2              | 67    |         |
| >40yrs          | 52    | 11        | 8         | 3                 | 13   | 1              | 88    |         |
| Sex             |       |           |           |                   |      |                |       |         |
| Male            | 88    | 27        | 14        | 6                 | 9    | 2              | 153   | 0.548   |
| Female          | 59    | 13        | 3         | 8                 | 13   | 3              | 92    |         |
| Marital status  |       |           |           |                   |      |                |       |         |
| Married         | 81    | 22        | 10        | 8                 | 17   | 2              | 140   | 0.878   |
| Single          | 65    | 18        | 7         | 6                 | 5    | 3              | 104   |         |
| Child           | 1     | 0         | 0         | 0                 | 0    | 0              | 1     |         |
| Occupational    |       |           |           |                   |      |                |       |         |
| C/servant       | 26    | 4         | 1         | 2                 | 8    | 2              | 43    | 0.294   |
| Student         | 31    | 6         | 3         | 5                 | 1    | 1              | 47    |         |
| Artisan         | 42    | 12        | 3         | 1                 | 7    | 1              | 66    |         |
| Business        | 18    | 6         | 3         | 4                 | 2    | 0              | 33    |         |
| H/wife          | 10    | 6         | 1         | 1                 | 3    | 0              | 21    |         |
| Farmer          | 18    | 5         | 5         | 1                 | 1    | 1              | 31    |         |
| Applicant       | 2     | 0         | 1         | 0                 | 0    | 0              | 3     |         |
| Child           | 0     | 1         | 0         | 0                 | 0    | 0              | 1     |         |

Table 4. Respondents satisfaction with the facility and staff in JUTH (N=200)

| Variables                                              | Yes (%) | No (%) |
|--------------------------------------------------------|---------|--------|
| This is the only facility I visit for treatment         | 200(100%) | 0(0.0%) |
| Caregivers take time to address my concerns            | 197(98.5%) | 3(1.5%) |
| I usually get all my medications here                  | 126(88.0%) | 74(12.0%) |
| Are you satisfied with the TB counselling?             | 196(98.0%) | 4(2.0%) |
| Would you recommend this facility for other TB patients? | 195(97.5%) | 5(2.5%) |
| Overall, rate your satisfaction with care received     | Very satisfied 79(39.5%) |
| - Satisfied                                           | 120(60.0%) |
| - Not satisfied                                       | 1(0.5%) |

Table 5. Mean scores of patients satisfaction (N=200)

| Measuring items                | Very satisfied | Satisfied | Unsatisfied | Very unsatisfied | Mean±SD  |
|--------------------------------|----------------|-----------|-------------|------------------|----------|
| Quality of services received   | 96(48%)        | 102(51%)  | 2(1%)       | 0(0%)            | 1.5300±0.5 |
| Privacy and confidentiality    | 82(41%)        | 117(50.5%)| 1(0.5%)     | 0(0%)            | 1.5950±0.5 |
| Care provided by the personnel | 98(48%)        | 103(51.5%)| 1(0.5%)     | 0(0%)            | 1.525±0.5  |
| Improvement in condition       | 122(61%)       | 77(38.5%) | 1(0.5%)     | 0(0%)            | 1.3950±0.5 |

One hundred and ninety eight (99%) of respondents are very satisfied or satisfied with the quality of services and care provided at the facility, 91% are very satisfied or satisfied with privacy and confidentiality while 1(0.5%) was unsatisfied with the privacy and improvement in their condition (Table 5).

4. DISCUSSION

This study revealed that majority of the patients studied completed treatment and were cured of tuberculosis as they were smear-negative by the 2<sup>nd</sup> and 6<sup>th</sup> months of treatment. It is possible that these were the patients that strictly followed treatment guidelines with the support of family members, caregivers and the proper implementation of the DOTs strategy. Patients who understood the consequences of their condition, had proper knowledge of the disease and understood the benefits of treatment are mostly likely to adhere to treatment regimens to derived maximum benefits from medications. Several studies have reported varying
tuberculosis treatment successes all of which fall short of WHO definition of success [13-16].

The study also revealed that more males had successful treatment outcomes than females. Gender differences in tuberculosis treatments have been reported [17,18]. This may be due to the fact that women are more at risk of complications due to their predisposition to reduced immunity resulting from hormonal changes in pregnancy or monthly menstruation.

Though low in this study the value of those defaulted/lost to follow-up is not encouraging considering the consequences associated with that. Default and loss to follow-up are other predisposing factors to unsuccessful treatment outcomes. Patients are most likely to default or lost to follow-up due to low income, lack or limited transport from home to the treatment center. Patients who default or are lose to follow-up are prone to increased disease severity and death due to increase bacterial load.

The study revealed that about one in every ten patients died of the disease in the facility majority of them above 40yrs old and females. Death is the extreme outcome of unsuccessful treatment. Factors responsible for patient’s death during treatment is therefore associated with age and gender. Declining immune system with advancing age is a major contributing factor to patients death while on tuberculosis treatment as it is with HIV/AIDS thus giving rise to opportunistic infections and immune reconstitution inflammatory syndrome (IRIS) [19]. Seventy five percent of people affected by TB are within age group of 15-54 years which pose serious obstacle to socio-economic development. The high ratio of male to female tuberculosis patients in this study may be due to occupational exposure, co-infection, poor nutritional habit, lack of adherence and denial to accept the condition associated with male gender.

In this study, majority of the patients studied started treatment immediately (within 1-2 days) they were diagnosed to have tuberculosis while a few others for various reasons started treatment 5-9 days later. Immediate commencement of tuberculosis treatment plays a key role in successful treatment outcome. Reasons for the immediate commencement of treatment for majority of the patients could be because of availability and accessibility of the treatment services as encourage by counselling at the time of diagnosis. First, delay in the commencement of treatment after diagnosis could be due to patient unwillingness to commence treatment because of the misconception about tuberculosis, stigma and the treatment duration. As a result of the complexity in taking the drugs and long duration of treatment for TB, it has been observed that patients don’t commence treatment early [20]. Second, the main symptoms of tuberculosis in infected people include fever, chill, night sweats, loss of appetite, weight loss, fatigue, nail clubbing and anemia. When a person developed active TB disease, these symptoms may be mild for several months and this may lead to delay in seeking care and results in transmissions of the bacteria to others. However, with increasing severity and persistent cough, the patient may develop epigastric pain which moves the patient to seek medical treatment.

Even though TB services were adequately available and accessible to care-seekers, the time spent in accessing the care and staff attitude towards patient in this study was poor. Umar and co reported that long waiting time is associated with higher economic loss to TB patients [21]. Therefore, improving TB services should include reducing the time spent on accessing care.

This study revealed that majority of the patients studied were bacteriologically negative after the second and sixth months of treatment. This accounted for 76.3% while the remaining 23.7% suffered deaths or relapsed/ failure. The World Health Organization reported in 2005 that, patients who take their TB treatment in an irregular and unreliable way are at greater risk of treatment failure and development of resistant TB strains. Additionally, the WHO said, TB drug treatment however relies heavily on the cooperation of the patients for self-administration, as patients adherence is an important conduit between medical process and treatment outcomes [22].

It is likely that majority of the patients that were bacteriologically negative to smear test were patients who adhered strictly to the instructions on the use of their medication, while the other patients that suffered death and relapse/failure were patients who took their treatment in an irregular and unreliable way. In this study treatment failure/relapse is adjudged to be low (2%) of patients studied. Several reasons may account for treatment failure or relapse such as patient's factors (lack of adherence) and economic or social factors (when treatment is not
supported by family members). Another reason could be inadequate information about the disease may be due to poor counseling at the time of commencement of treatment. The tendency of patients having treatment failure is possible when there is recurrent adverse drug effect or side effect of which they don’t have knowledge about.

Majority of the patients affected with tuberculosis and attending the DOTs clinic reported they were satisfied with the quality of services received, privacy or confidentiality, care provided and the level of improvement of their condition. Educational status has been found to be associated with higher level of satisfaction with staff behavior. Patient with higher education are much more likely to appreciate information and services provided by DOTs staff as well as make better informed decision to improve their health [23].

TB patients reported in this study that they are satisfied with accessibility to care and adherence counselling in the facility but most of them are not satisfied with the staff attitude and waiting time. Some contributing factors or reasons for satisfactory access to care and adherence counseling could be attributed to availability of trained staff in providing adequate patient care. High level of satisfaction with adherence counseling could be because of the reassurance it offers to patients suffering from a disease that is often associated with a number of misconceptions resulting in inappropriate care-seeking practices. Because adherence counseling has remained the cornerstone of the success of DOTs services for patients receiving tuberculosis care, the length of time and the limited availability of treatment options need to be considered.

Another reason for the satisfaction in patient’s counseling could be because patient counselling provides patients opportunity for better understanding of their health condition, enhanced provider-patient relationship, stigma reduction, increased confidence in the program and increases frequency of provider-patient contact, which has been found to have a positive effect on TB service satisfaction and improve health outcome [24].

Other patients expressed low satisfaction due to staff attitude. Provider-client relationship has been found to be a significant predictor in satisfaction with healthcare services; hence perceived satisfaction with staff attitude is important in TB services. TB care often involves prolonged contact between staff and client, an unfriendly attitude by health workers will likely result in low satisfaction with TB services and eventually an unfavorable outcome [20].

Difference in satisfaction and clinical outcomes among individuals from different socio-demographic backgrounds could also be explained by the variability in patient expectation. Patients with high expectation tend to be less satisfied with health services. The study advised a need to adapt TB services/care tailored to meet patient expectation while not compromising the efficacy of care.

5. CONCLUSIONS

Clinical and humanistic outcomes of tuberculosis treatment was found to be satisfactory in the facility owing to the high cure rate and patient reported satisfaction with their treatment and improvement in health condition. However, friendliness and staff attitude to patients needs to be improved upon. This can be achieved through motivation and regular training and retraining of staff on the need to show empathy to patients.

CONSENT AND ETHICAL APPROVAL

Ethical approval was obtained from the Health, Research and Ethics Committee of the Jos University Teaching Hospital Plateau State reference number JUTH/DCS/ADM/127/XXVIII/1284 on the 22\textsuperscript{nd} November, 2018 while informed consent was obtained from each patient that filled the questionnaires.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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