

A Ten-Year Survey of Treatment Outcome in a Tuberculosis and Leprosy Referral Hospital Implementing Directly Observed Therapy Short (DOTS) Course

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Abstract:-

Background: One of the constraints in the treatment of tuberculosis (TB) patients is non-adherence to treatment resulting in low treatment success rate, treatment failure and increasing incidence of multidrug resistance. In order to overcome this challenge, DOTS have been implemented in some settings.

However, the treatment success rate of the implementation of DOTS in this hospital has not been determined. Therefore this study was to determine the success rate in the implementation of DOTS strategy in TB and Leprosy hospital.

Methods: A review of the records of treatment of patients with pulmonary TB in this hospital implementing the DOTS programme over a 10 -year period from January 2003 to December 2012 was retrospectively carried out. A total of 2625 Acid Fast Bacilli (AFB) smearpositive HIV negative TB patients' records were surveyed.

Results: TB treatment success (cure and treatment completion) was recorded in 1774(67.6%) patients while 722 (27.5%) patients either defaulted or were lost to follow up. Sixty four (2.4%) died during the course of treatment.

Conclusion: The use of DOTS in the Tuberculosis and Leprosy Referral Hospital, Igbogene during the period under review recorded some level of success though the success rate was lower than the global average of 85-87%.

Keywords:- Directly Observed Therapy Short course, Human Immunodeficiency Syndrome, Smear positive, Treatment Success, Tuberculosis.

I. INTRODUCTION

Tuberculosis is preventable, treatable and curable yet it is estimated that one-third of the total population of the world is infected with latent tuberculosis with unabated increase in incidence and mortality rate¹. Nigeria is 4th among the 22 high-burden TB countries in the world.²

Many TB patients have difficulties in completing their course of treatment and this serves as an impediment to eradicating the disease.^{3,4} A widely used strategy to overcome the challenge of noncompliance is commonly referred to as Directly Observed Therapy (DOT)^{5,6} which seeks to improve the anti-tuberculosis medications adherence through health workers, family members that observed them directly when they were taking the drugs.

As early as the 1960s this strategy was adopted in studies in Madras, India, and Hong Kong⁷. Indeed, Frieden and Sbarbaro⁸ concluded that that it prevented relapse from occurring and drug resistance developing.

The World Health Organization (WHO) introduced another version of DOT named Directly Observed Therapy Short course (DOTS). It is a very comprehensive TB management programme that targets developing countries. DOTS is a fiveelement strategy for the control of tuberculosis that is made up of political commitment, better and efficient laboratory analysis, observation of patients while taking each dose of anti-TB drug, a free drug supply system with a provision for the correct complete short course anti-tuberculosis drug combination, and a reporting system that makes documentation of the progress made in caring and curing the patient⁵.

Treatment success under DOTS is influenced by treatment completion and cure while unsuccessful treatment are patients who had failed treatment and those who defaulted.

One of the main impediments towards successful treatment is default from treatment. WHO reported 5% default rate for smear positive TB patients in 2006.⁹

In resource poor countries of the world, the main factor that lead to drug compliance is having a false believe of a cure when symptoms have are abated, ¹⁰ lack of patients’ motivation, anti-TB drugs side effects, long duration of treatment, difficulties, ignorance and high degree of poverty of the population¹¹. Default and or interruption of treatment may result in treatment failure, relapse, anti-TB drug resistance ¹² and increase in morbidity and mortality.¹³

DOTS programme commenced in the TB and Leprosy Hospital, Igbogene-Yenagoa, South-South, Nigeria in 2003 and since then the outcome of treatment in this referral hospital is yet to be determined.

Therefore, this research was to assess the treatment success of DOT) in this hospital over the period, January 2003- December 2012.

II. METHODS AND PATIENTS

A. Study Design

A retrospective review of records of PTB patients who assessed care at the DOTS Centre over a ten-year period (January 2003 and December 2012) was carried out following ethical approval by the state Ministry of Health. .

B. Study Subjects

The study looked at only sputum smear-positive patients who had their treatment at the DOTS centre during the period under review.

Excluded in this study were all HIV positives TB patients, and AFB smear negative patients. HIV patients were excluded to avoid confounders in the assessment of treatment outcome since HIV co-infection may influence the treatment outcome. The treatment regimen given to the patients included Rifampicin, Isoniazide (INH), Ethambutol and Pyrazinamide for the 2 months intensive and Isoniazide and Ethambutol for the continuation phase of 6 months.

For relapses, treatment failures and return after default, the regimen dispensed to these group of patients were that of anti-TB category 2 drugs comprising of Isoniazid, Rifampicin, Ethambutol, Pyrazinamide and Streptomycin

for the intensive phase of 2 months then Isoniazid, Rifampicin, Ethambutol, Pyrazinamide for one month and Isoniazid and Rifampicin for the continuation phase of 5 months.

C. Data Collection

The data was obtained from the TB laboratory and treatment registers. The information obtained from the patients' medical records included demography, treatment commencement date, category of patients and treatment, pre-treatment smear result, treatment outcome and HIV status. Patients were classified into different treatment outcome categories based on classification by the WHO and International Union against Tuberculosis and Lung Diseases (IUATLD)⁹ with possible patient outcomes as shown in Table 1.

D. Data Analysis

Statistical Package for Social Sciences version 15.0 (SPSS) software was used to analyse the data. Frequency tables, ratio, proportions and rates were used to review data. Chi-square and t-test was used for discrete and continuous data respectively. P-value less than 0.05 was significant.

III. RESULTS

A total of 2625 HIV negative smear positive TB patients assessed the DOTS centre for healthcare, during the period under review. The patients were registered under different categories: new, relapse, treatment failure, returned after default and transferred in. There were 2359 new patients constituting 90% of the total number of patients registered (Figure 1 Males constituted a greater number of the subjects as against 1013 (38.6%) a ratio of 1:2). Many of the patients were in the age range of 25 to 34 years, 1000 in all making up 38.1% of the patients (Table 3).

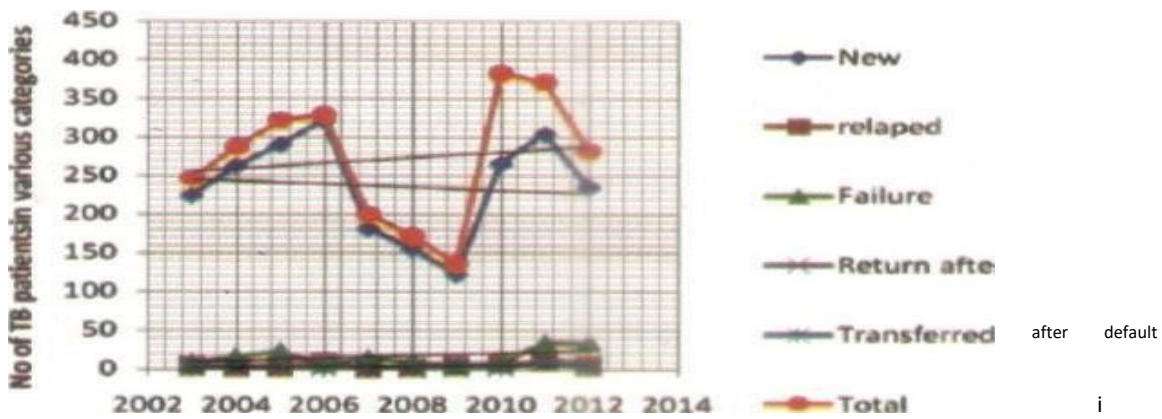
Treatment success rate among the subjects was 67.6% while default and mortality rate were 27.5% and 2.4%

Clinical and demographic characteristic	Treatment Success	Treatment Failure	P- value
Age (Years) Mean ±SD	33.2±13.42	35.5±11.7	0.19
Sex	1041 (58.7)	40 (67)	0.216
Males, no. (%)	733 (41.3)	20 (33)	
Females, no. (%)			<0.0001
TB patient category	1664 (93.8)	46 (76.7)	<0.0001
New patients no. (%)	110 (62)		
Other categories no. (%)		14 (23.3)	
Anti-Koch's regimen	1664 (93.8)	46(76.7)	
Category 1, no. (%)	110 (6.2)	14 (23.3)	
Category 2, no. (%)			

Table 1: Comparison of the characteristics of subjects grouped based on their treatment outcome

Age in Years	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
5-14	12	18	6	21	7	7	7	13	14	6	111(4.2)
15-24	53	74	73	71	26	39	32	55	73	43	539(20.5)
25-34	76	100	120	130	90	61	66	85	132	140	1000(38.1)
35-44	52	50	51	54	36	21	34	35	52	48	433(16.5)
45-54	22	20	42	29	21	23	20	18	72	48	315 (12)
55-64	19	15	15	16	15	10	10	10	15	32	157(6.0)
≥ 65	6	3	10	10	3	6	6	8	8	10	70(2.7)
Total	240	280	317	331	198	167	175	224	366	327	2625(100)

Table 2: Age distribution of tuberculosis patients who had Directly Observed Treatment Short Course at Igbogene January 2003 –December, 2012.



treatment

Year of treatment

Fig. 1: Categories of tuberculosis patients that registered for DOTS at the centre

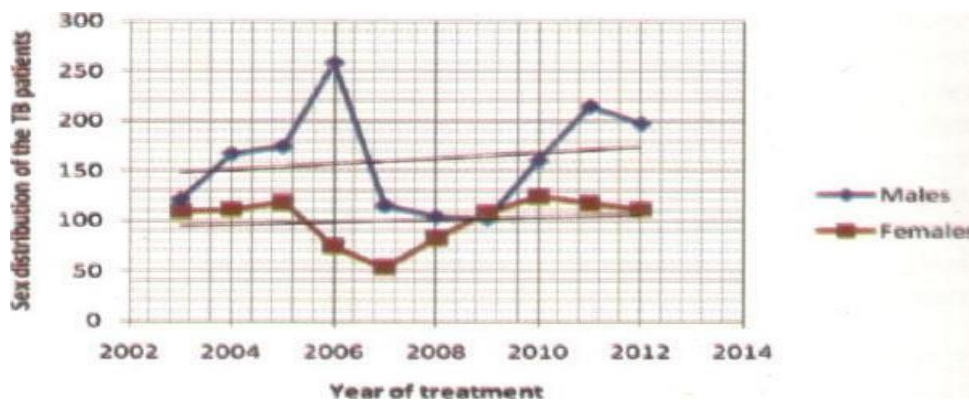


Fig. 2: Yearly sex distribution of the patients who had DOTS at the centre

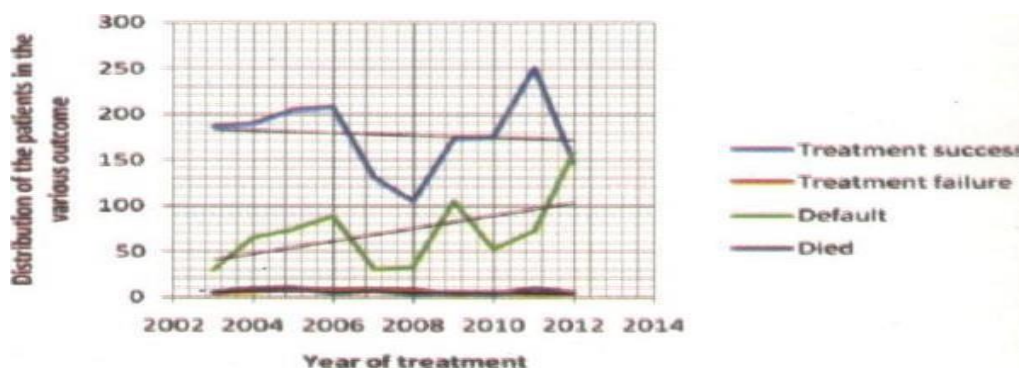


Fig. 3: Treatment outcome of patients who had DOTS at the centre

IV. DISCUSSION

The DOTS centre, Igbogene is a TB referral hospital for patients living in Bayelsa state and some communities in the neighbouring states of Rivers and Delta, South-South Nigeria. Most parts of Bayelsa State are riverine, making movement of people from the rural areas to the state capital where this hospital is located very difficult.

Although pulmonary tuberculosis can develop at any age, case rates vary markedly in different groups. In this study, most of the study subjects fell in the age group of 25-34 years constituting 38.1% of the study subjects. This finding corroborated a study done earlier which showed that the incidence of pulmonary tuberculosis was very high among this age group.

It, however, disagrees with the finding of a 10 year study carried out among Ethiopian Jews migrants to Israel which showed that women had a higher incidence rate of TB that doubled that of men. The reason adduced for the difference in prevalence between the sexes could not be ascertained from this study. Probably a combination of different factors such as biological differences in disease presentation and gender related factors like access to health care could be part of the explanation. There are biological and immunological factors which suggest that men may have more infectious TB than women.

The tuberculosis treatment success rate among the patients during the 10 year period under review was 67.6% with 2012 recording the lowest treatment success rate of 46.7%. According to WHO global TB report, treatment success rates have been maintained consistently high for several years. WHO 2010 report revealed that, the average global treatment success rate among all newly-diagnosed cases was between 85% to 87% among patients with smear-positive pulmonary TB.

However, in our study the overall success rate was much lower than the global tuberculosis success rate of treatment. This could be as a result of the fact that this study included all cases of smear positive HIV negative pulmonary tuberculosis unlike the global TB report that considered only newly-diagnosed cases.

This study also looked at the default rate and it revealed an overall rate of 27.5% with the year 2012

This study showed a gender based disparity in the prevalence of tuberculosis with more males than females among the study subjects. The study subjects consisted of 1612 males compared to 1013 females giving a ratio of 1.6:1. This finding is similar to a study by Jimenez-Corona et al 15 where they observed that compared with women, men had higher incidence of pulmonary TB infection and with more severe clinical presentations when diagnosed with TB.

According to Jimenez-Corona et al 15 men have higher tendencies to have risk factors associated with exposure to TB. Similar finding was shown by the Okonkwo et al 16 who revealed that TB infection was commoner in males than females.

recording the highest rate of 50.5% among the study subjects. The default rate in this study is much higher than the 5% re global default rate that was reported. The high default rate could be attributed to the high level of poverty among the subjects making it difficult for them to afford the cost of the exorbitant riverine transport. The high level of poverty coupled with high cost of riverine transport could be responsible for some patients failure to keep clinic appointments for follow up resulting in high default rate and poor drug compliance. This might have accounted in part for the low treatment success rate.

The year 2012 had the highest default and lowest treatment success rate among the study subjects. This was due to the effects of the ravaging flood that took place in the third to fourth quarters of 2012 which affected most parts of Bayelsa state including the area where this hospital is located. The flood brought about social and economic upheavals rendering many families dislocated and homeless with no source of livelihood.

Another possible reason for the low tuberculosis treatment success rate was the use of Isoniazid and Ethambutol instead of the standard Isoniazid and rifampicin in the continuation phase during the study period. Sixty four (2.4%) patients died during the treatment. This finding is similar to a work done by Yakub et al. in a 3 -year survey of treatment outcome among TB patients in the University of Maiduguri Teaching Hospital.

This study is limited by the fact that it is a prospective study so information could not be obtained to unravel the factors influencing the unimpressive success rate and the high default rate among the study subjects. Our study excluded all smear negative TB and HIV positive patients so the findings may not be representative of all TB patients. However, this does not invalidate the findings of our study.

V. CONCLUSION

The use of DOTS in the TB and Leprosy Hospital, Igbogeneduring the period under review recorded some level of success though the success rate was lower than the world average of 85-87%.

VI. RECOMMENDATIONS

The findings of this study have implications for all stakeholders and policy makers involved in making policies for TB control. The use of the standard Rifampicin and Isoniazid in the continuation phase should be sustained instead of the Ethambutol/Isoniazid combination that was in use during the study period.

There is an urgent need to carry out a prospective study of TB patients attending this health facility with a view of finding out the reasons for the unimpressive success rate and the high default rate.

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