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Research Article

Estimation of Success Rate of Treatment of XDR-TB admitted in a Nodal DRTB Centre

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A B S T R A C T

Background: Extensively drug-resistant TB is still a serious challenge in India, and before the introduction of new anti-tuberculosis drugs these patients were treated with a conventional regimen for XDR-TB according to the guidelines of RNTCP at that time for almost 24 to 36 months.

Objective: To estimate the outcome of treatment of XDR-TB patients attended at our DRTB site and put under the conventional regimen during the period 2014-2017 according to protocol laid down by PMDT at that time i.e. 2014 to 2017.

Methods: In this retrospective study, we selected 41 patients admitted with XDR-TB, in our DRTB site from April 2014 to March 2017. We studied their treatment outcomes (cured, treatment completed, treatment failure, death, and treatment after default) 30 to 36 months after treatment initiation according to PMDT (2014 -2017).

Results: Among the 41 cases of XDR-TB that were included in the study 28 were male, 30 resided in rural areas and 28 had a BMI < 18.5 kg/m^2. 13 (32%) patients were successfully treated but 21 (50%) patients died during the treatment and treatment failure happened in 6 (15%) patients. Patients with low BMI (< 18.5 kg/m^2) had poor success rate (7%) and all the 21 patients who died during treatment, had low BMI.

Conclusion: The present study finds that only one in every three XDR-TB cases are successfully treated with conventional second-line antitubercular drugs and this finding is the same as found in the NTEP report. Nearly half of the patients die. The patients with low BMI respond worst.

Keywords: DRTB, XDR-TB, Success Rate, Low BMI

Introduction

Tuberculosis is an age-old disease and still is a major public health problem, particularly due to the emergence of drug-resistant strains. Currently, India bears the burden of the highest numbers of tuberculosis patients (27%) and multi-drug resistant tuberculosis patients (26%) in the world.[1]

MDR-TB is defined as a disease caused by mycobacterium tuberculosis bacilli that are resistant to both rifampicin and isoniazid. Extreme drug-resistant TB or XDR-TB is a variant of MDR-TB with resistance to any one of the 2nd line fluoroquinolones and any one of the 2nd line injectables according to the definition at the time of this study (2014-2017).[2] India has a robust national programme for the treatment of MDR-TB under the National TB Elimination Programme (NTEP) known as Programmatic Management of Drug Resistant Tuberculosis (PMDT) which covers XDR-TB too. Under this programme, drug resistance against rifampicin, INH, fluoroquinolone, and aminoglycosides are detected genotypically by GeneXpert MTB or line probe assay. Before the introduction of the new antitubercular drugs in PMDT, XDR patients were treated by a CAT V regimen consisting of moxifloxacin, capreomycin, linezolid, clofazimine and PAS along with high dose INH, and in a few cases, by clarithromycin or co-amoxyclav. Follow-up was done by monthly sputum culture. The treatment period was at least 24 months which may be extended depending on follow up culture report. The success of treatment depends on several factors like severity of illness, presence of a comorbid condition, general health condition of patients, and most importantly compliance of patients. For this reason, the outcome of treatment of XDR-TB varies widely with a success rate from as low as 18% to as high as 67%.[3] According to the data released by NTEP, the success rate of treatment of XDR-TB treated with the conventional regimen is 29%[4] but there is a paucity of Indian data in this regard. The present study aims to estimate the success rate of management of XDR-TB patients treated by the conventional Cat V regimen that was given under PMDT at that time (2014-2017).

Materials and Method

It is a retrospective and descriptive study conducted after taking approval from the Institutional Ethics Committee of the tertiary care hospital to which the DRTB centre is attached along with the concurrence of the programme administrators. All XDR-TB patients who had initiated treatment from the DRTB centre with valid consent for participation in the study, over a period of 36 months, from April 2014 to March 2017, were considered and included in our study for outcome assessment after 30 to 36 months of initiation of treatment. The patients who were transferred out, and whose outcome data were not available at the time of data analysis were excluded from the study. The total number of participants in this study was 41. The baseline demographic data, clinical features, and relevant co-morbid conditions were recorded from individual case record forms. Treatment outcome was assessed and classified as cured, treatment completed, treatment after default, treatment failure, and death according to the guidelines[5] prevailing during the course of the treatment. A patient was declared cured after completion of treatment for at least 24 months with the last 5 consecutive negative sputum culture results and if one follow-up culture was positive then it should have been followed by at least 3 consecutive negative sputum culture reports. Those patients who had completed treatment and were clinico-radiologically improved but did not meet the definition of cured or treatment failure due to lack of bacteriological results were declared as treatment completed. Cured and treatment completed were together considered as treatment success. Patients having two or more positive cultures out of the last five cultures or any positive culture among the final 3 cultures were considered as treatment failure. If treatment was interrupted for two or more consecutive months for any reason, then it was considered as treatment after default. A patient who died for any reason during the treatment course was termed as death in the outcome. Outcome data of all patients were recorded. All patients were classified according to demographic features and clinical conditions and the outcome data of each group were separately recorded, but as it is a descriptive study, the comparison of outcomes of different groups could not be done.

Results

The age distribution of the participants is shown in Table 1 and the other baseline demographic and clinical properties of the participants have been depicted in Table 2. Majority of our patients were male (68%). Most of the patients had poor nutritional status with BMI less than 18.5 kg/m^2 (68%). Nearly half of the patients (54%) were smokers and one-fourth of them (27%) had history of alcohol abuse. The outcome of these patients has been shown in Table 3.

Table 1.Distribution of Age

Age group (years)	Number	Percentage
01-Oct	1	2
Nov-20	7	17
21-30	20	49
31-40	9	22
41-50	3	7
51-60	1	2
Total	41	100

9 out of 41 patients (22%) were declared cured and 4 more patients had completed treatment (10%) though by definition they were not eligible to be declared cured. So treatment success was achieved in 13 out of 41 patients (32%). 21 out of 41, that is almost half of the patients, died before completing the treatment. A comparison of demographic and clinical parameters of different treatment outcome groups is shown in Table 4. The success rate was lower in patients having low BMI (< 18.5 kg/m^2), in

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comparison to patients having BMI ≥ 18.5 kg/m^2 (7% vs 84%). All 21 patients who had died had low BMI. The success rate was higher in rural patients compared to urban ones (33% vs 27%). There was no difference in treatment success among smokers and alcoholics compared to the overall success rate. As the number of female patients was much less in this study, no conclusion should be drawn regarding the comparison of success rates between males and females. The impact of diabetes mellitus and HIV on the outcome of treatment cannot be compared as only 4 patients had diabetes and no patients had HIV in this study.

Table 2.Baseline Demographic and Clinical Characteristics

Parameters	Total Numbers (n = 41)	Percentage
Median age	28.5 years	
Male	28	68
Female	13	32
Urban	11	27
Rural	30	73
BMI < 18.5 kg/m2	28	68
BMI ≥ 18.5 kg/m2	13	32
Alcohol abuse	11	27
Smoker	22	54
Diabetes mellitus	4	10
HIV	0	0

Table 3.Distribution of Final Outcome

Final Outcome	Frequency	Percentage
Cured	9	22
Treatment completed	4	10
Treatment success (cured + treatment completed)	13	32
Died	21	50
Treatment default	6	15
Treatment failure	1	35

Table 4.Comparison of Parameters of different Treatment Outcome Groups

Parameters	Treatment Success (n = 13)		Death (n = 21)		Treatment Default (n = 6)		Treatment Failure (n = 1)	
	Number	Percentage	Number	Percentage	Number	Percentage	Number	Percentage
Mean age (years)	30		30		31		26	
Male	10	36	11	39	6	21	1	4
Female	3	23	10	77	0	0	0	0
Urban	3	27	6	55	2	18	0	0
Rural	10	33	15	50	4	13	1	3
BMI < 18.5 kg/m2	2	7	21	75	4	14	1	4
BMI ≥ 18.5 kg/m2	11	85	0	0	2	15	0	0

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Alcohol abuse	4	36	4	36	2	18	1	9
Smoker	8	36	8	36	3	14	1	5
Diabetes mellitus	0	0	3	75	1	25	0	0

Discussion

XDR-TB or extremely drug-resistant TB, a variant of drug-resistant TB was first described in 2006 and its prognosis was very poor with a mortality of 80% in HIV co-infected population.[6] But in the following years, the outcome became better, particularly in non-HIV patients. The success rate was found to be between 27% and 60%, and the mortality rate varied from 6 to 20% in a meta-analysis of studies from different countries, published in 2013.[7] In the present study, the success rate was found to be 32%. This study was done with patients who received conventional 2nd line ATD because newer drugs like bedaquiline and delamanid were not available at that time. Our finding i.e. success rate of 32%, is very close to the success rate of 29% found in NTEP, India at that time.[4] The success rate of treatment of XDR-TB depends on the presence of co-morbid illnesses like diabetes and HIV and also on BMI. In a study by Kim DH et al., it has been shown that while the overall success rate is 29.6%, the treatment success is poor in patients having a BMI of less than 18.5 kg/m^2 and mortality is also more in this group.[8] In the present study, majority of the patients were of low BMI (< 18.5 kg/m^2) (68%) and they had a very poor success rate of 7% compared to patients having a BMI of ≥ 18.5 kg/m^2 (85%) and most important is that all mortalities were from this undernourished group. This again highlights the importance of nutrition in the treatment of tuberculosis patients, particularly XDR-TB. No significant difference is found in success rates between urban and rural populations. This study shows that the success rate of treatment of XDR-TB with conventional anti-tubercular drugs is poor and this is particularly observed in patients having low BMI. Most XDR-TB patients are expected to have low BMI. So it underscores the need to introduce newer drugs like bedaquiline and delamanid in the treatment of XDR-TB.

Limitations

There are a few limitations in our study. The most important weakness of our study is that it has a low study population. A large multicentric study would be more reflective of the true situation. Another limitation is that the outcome data of patients who had been transferred out could not be analysed. As bedaquiline and delamanid are introduced in the RNTCP, a new regimen is currently being administered in the treatment. So, a further study with a large study population receiving the newer drugs is necessary for assessing the outcome of treatment of XDR-TB more correctly.

Conclusion

The present study is done with the XDR-TB patients who had received a conventional long course of CAT V regimen under PMDT of RNTCP before the introduction of new drugs, bedaquiline and delamanid. This study shows that success is achieved only in one-third of cases and almost half of the cases die. Majority of the patients in this study were of low BMI and the success rate in those patients is extremely poor. So the introduction of new drugs is of utmost importance along with the improvement of nutritional status among the people. A future study with a large study population can validate the precise role of nutrition and the effect of newer antitubercular drugs in mortality and success of treatment in XDR-TB patients.

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Conflict of Interest: None

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