

ORIGINAL ARTICLE

Socio-Demographic and Clinical Profile of Drug Resistant Tuberculosis Patients in a Tertiary Care Centre of Kolkata

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Abstract

Background: Drug resistant tuberculosis is a major public health threat that hinders progress in tuberculosis control worldwide. In 2019, India contributed highest cases of TB (27%) Worldwide. In 2019, 3.3% of new TB cases and 18% of previously treated cases had MDR/RR-TB worldwide and India (27%) had the largest share of the global burden. This study was done to find out the sociodemographic and clinical profile of drug resistant TB patients. **Methodology:** It is an observational descriptive study with cross-sectional design, conducted at the drug resistant tuberculosis centre of R. G. Kar Medical College of Kolkata, West Bengal. Study Population consisted of the patients who were registered for the DR-TB regimen. Study duration was July 2016 –March 2017. Pre-tested, semi-structured schedule was designed to capture their sociodemographic profile, treatment history, clinical findings and available medical records. Data were compiled in MS Excel and analyzed in IBM SPSS 23.0. **Results:** Out of 159 cases, 27% patients were between 21-30 years. Males were predominant (68.6%). Most patients (56.6%) were underweight (BMI<18.5kg/m²). HIV seropositivity was found in 4 (2.5%) cases. Among all cases, 81.1% had history of taking ATD and 34.4% was cured in previous episode of treatment. The commonest associated comorbidity was DM (15.7%). Rifampicin resistance (93.1%) was most common followed by Isoniazid (8.2%). Pallor was found among 94.3% patients. Most patients had bilateral (62.3%) and moderately extensive (57.2%) lesions in chest x-ray. **Conclusion:** DR-TB control should focus adequately on younger age group as numbers of resistance is increasing among them. Relapse in previously cured cases was found to be major contributor of DR-TB suspect cases. Though, Rifampicin resistance was so common but prevalence of resistance to 2nd line drugs is still low. Focus should be given on early detection of drug resistance in all TB cases and improvement of nutritional status of the TB patient.

Keywords

Tuberculosis; Drug Resistance; Extensively Drug-Resistant Tuberculosis; X-rays; India

Introduction

Drug resistant tuberculosis (TB) is a major public health threat that hinders progress in tuberculosis care and control worldwide. India ranks first worldwide in terms of estimated incident cases per year. Although notifications of people newly diagnosed with TB rose from 1.2 million to 2.2 million between 2013 and 2019, India contributes

41% of the global gap between treatment enrolments and the estimated number of new cases of MDR/RR-TB in 2019.(1) Multidrug-resistant TB (MDR-TB) is defined as resistance to at least both Isoniazid (INH) and Rifampicin. When Rifampicin resistance is detected, it is implied that patient is resistant to Isoniazid also, as INH resistance is more common than Rifampicin resistance. Rifampicin-resistant TB (RR-TB) is resistance to Rifampicin detected

using phenotypic or genotypic methods. It includes any resistance to Rifampicin, whether monoresistance, multidrug resistance, polydrug resistance or extensive drug resistance.(2)

Worldwide in 2019, close to half a million people developed Rifampicin-resistant TB (RR-TB), of which 78% had multidrug-resistant TB (MDR-TB). Globally in 2019, 3.3% of new TB cases and 17.7% of previously treated cases had MDR/RR-TB.(1) The estimated tuberculosis incidence rate in India in the year 2019 was 193 per 1 lakh population. Within TB, the new threat is multi-drug resistant (MDR) and in India, about 2.8% of new cases and 14% of previously treated cases are MDR/RR-TB. In India human immunodeficiency virus (HIV) associated TB incidence in the year 2019 is 5.2 per 1 lakh population.(3) Few risk factors have been identified as main attributes to many new cases of TB and these are undernutrition, HIV infection, alcohol use disorders, smoking (especially among men) and diabetes.(1) Prior history of TB infection, alcohol and smoking increases the risk for MDR-TB.(4) The new data has undoubtedly raised concerns about the present scenario regarding the disease.

Aims & Objectives

To describe clinical profile and socio demographic factors associated with DR TB in a drug resistant tuberculosis centre.

Material & Methods

It was an observational descriptive study with cross-sectional design, conducted at the drug resistant tuberculosis centre of R. G. Kar Medical College of Kolkata, West Bengal, India. R. G. Kar Medical College is situated in northern part of Kolkata. Majority of patients come from North 24 Parganas district. The Study Population consisted of the patients who registered for the DR/MDR/XDR-TB regimen. Those who gave their consent after proper explanation of the purpose of this study were included in the study for interview. The study was conducted over a period of 21 months (July 2016 –March 2017). Pre-tested, pre-designed, semi-structured schedule was administered to all the patients diagnosed with DR TB in R G Kar Medical College, who were all from North 24 Pargana district of West Bengal. The schedule was designed to capture their sociodemographic profile, past tuberculosis treatment history, resistance pattern, clinical findings, radiological findings and other available laboratory investigation records. After obtaining written informed consent, data were collected by carrying out personal interviews, review of medical records and clinical examination. Necessary information were also collected by reviewing the PMDT treatment register, PMDT treatment card and clinical information booklet. Detailed history was taken including screening for drug or alcohol abuse. Weight and height were measured. Screening for HIV at Integrated Counselling and Testing Center and chest X-ray were done at baseline. Few investigation

reports like hemoglobin, fasting blood sugar, TSH, blood urea and creatinine were collected from available medical records. Ethical clearance was obtained prior to the study. Data obtained, were properly coded, compiled and were put in excel spreadsheet. IBM SPSS (version 23.0) software was used for data analysis. The results are presented in terms of proportions and percentages. Continuous data were summarized using mean (\pm SD) or median (\pm IQR).

Results

(Table 1) shows the distribution of the study subjects according to their sociodemographic characteristics. Out of 159 cases, majority (27%) were between 21-30 years (Median age = 35 years, IQR 24 years; range 15 – 70 years). Males were predominant (68.6%). The male to female ratio was 2.8:1. Mean age of females (30.40 ± 14.46 years) was less than that of males (37.88 ± 13.83 years). Majority of them completed their primary education (35.8%), followed by illiterate (16.4%). The occupational profile of patients revealed that a majority of them were labourer (25.8%), followed by household workers (18.2%), skilled workers (17%), students (12.6%), service (12.6%), business (7.5%), and unemployed (6.3%). Among all the patients, 96 (60.4%) were residing in an urban area and rest 63 (39.6%) were from rural area.

(Table 2) shows the distribution of the study subjects according to their substance use history. History of smoking, tobacco chewing and alcohol intake were taken and 87 patients had history of having at least one of them. The most common form was smoking tobacco (44%), followed by smokeless tobacco (27%) and alcohol (26.4%). A further bivariate analysis was done to find out any association between duration of substance use and chest X-ray grade of Koch's lesion. Among the participants who were smoking tobacco for more than 20 years, 77.8% and 11.1% were having moderately extensive Koch's lesion and extensive Koch's lesion in chest X-ray respectively. Similarly, among those who were consuming smokeless tobacco for more than 20 years, 87.5% and 12.5% were having moderately extensive Koch's lesion and extensive Koch's lesion in chest X-ray respectively. In case of history of alcohol intake for more than 20 years, 90.9% and 9.1% were having moderately extensive Koch's lesion and extensive Koch's lesion in chest X-ray respectively. But, Chi-square test result shows that duration of alcohol intake ($p=0.002$) was having statistically significant association with grade of Koch's lesion in chest X-ray, whereas duration of smoking tobacco ($p=0.148$) and smokeless tobacco ($p=0.181$) consumption didn't have statistically significant association with the same.

(Table 3) shows the distribution of the DR-TB cases according to their past anti-tubercular treatment history. As per available medical records, 129 (81.1%) study subjects had taken anti-tubercular treatment previously. Among them ($N_1=129$), majority (42.6%) had taken ATD for 6 months or less and 61.2% patients undergone one

episode of treatment. 80.6% patients were treated under RNTCP, 15.5% were treated by private practitioners and 3.9% took treatment both from RNTCP and private set-up. Outcome details of these past treatment episodes was taken from available records. Among 129 previously treated patients, outcome details were available with 94 in their records. As per the previous records, outcome of majority treatment episodes was cured (24.8%). Among all participants, 18.9% didn't take ATD previously and details of drug history weren't available among 17% patients.

(Figure 1) shows the drug resistance pattern of the study group. If there is Rifampicin resistance then it is also considered to be Isoniazid resistant. So, Rifampicin resistance was checked in every patient but Isoniazid resistance was not tested in every patient. So, there is limited data on Isoniazid resistance. Most of the cases were Rifampicin resistant [149 (93.7%)], followed by INH [14 (8.8%)], Kanamycin [8 (5%)], Capreomycin [5 (3.1%)], Amikacin [3 (1.9%)], Levofloxacin [1 (0.6%)], Ofloxacin [8 (5%)], and other Fluoroquinolones [3 (1.9%)].

(Table 4) shows the distribution of the MDR-TB cases according to their clinical characteristics. The median body mass index (BMI) was $17.5 \pm 4.9 \text{ kg/m}^2$. Among all the patients 90 patients (56.6%) were undernourished with BMI less than 18.5 kg/m^2 . Most common presenting symptom was cough (87.4%), followed by fever (67.9%), chest pain (37.1%), hemoptysis (6.9%), shortness of breath (5%), anorexia (3.1%) and vomiting (3.1%). There were other presenting symptoms like, neck pain, swelling over neck, spinal pain and weight loss in 6.9% patients. On examination, pallor was present among 150 (94.3%) patients. There were no oedema, clubbing, icterus, cyanosis and neck vein engorgement among any patient. Four patients (2.5%) were HIV reactive and others were non-reactive. Diabetes Mellitus was the commonest comorbidity (15.7%), followed by hypertension (0.6%), asthma (0.6%) and chronic obstructive pulmonary disease (0.6%).

Medical records were reviewed and available laboratory investigation reports were collected. Haemoglobin level report was available among 144 patients and mean Hb level was $11.5 \pm 1.78 \text{ gm/dl}$. All the patients had fasting blood sugar level report and median FBS level was $96 \pm 37 \text{ mg/dl}$. FBS level was $>110 \text{ mg/dl}$ among 45 (28.3%) patients. Serum creatinine report was available among 142 patients and median creatinine level was $0.84 \pm 0.28 \text{ mg/dl}$. Serum urea report was available among 137 patients and median urea level was $23.8 \pm 9.37 \text{ mg/dl}$. Serum TSH report was available among 126 patients and median TSH level was $2.3 \pm 2.23 \text{ mIU/L}$. USG whole abdomen report was available among 152 patients and all were within normal limits.

During respiratory system examination, air entry into the lungs were diminished in left among 12.6% patients and diminished in right among 11.9%. Bilateral equal air entry

was present among 75.5% patients. Adventitious sound was audible among 4.4% patients. In chest X-ray, majority had moderately extensive Koch's lesion 91(57.2%) while mild and extensive lesion was noted in 48 (30.2%) and 20 (12.6%) respectively. Bilateral lesion (62.3%) was more than unilateral lesion (37.7%). A total of 74 (46.5%) cases had cavitory lesions.

Discussion

Control of tuberculosis still remains a challenge among public health personnel though there is availability of thorough treatment worldwide. In the present study majority of the DR-TB cases (27%) were in the younger age group (21-30 years); median age was 35 years. In a retrospective study done in the two designated drug resistant tuberculosis centers (DR-TB center) of Kolkata, Mukherjee et al. noted that majority of the cases (30.23%) were in the age group 21-30 years with a mean age of 32.52 years.(5) Udwadia and Moharil, Sharma et al. also reported prevalence of younger age group among MDR-TB patients with the mean age of their study groups being 29.7 years and 33.25 years respectively.(6, 7) In the present study males were predominant. Male predominance among MDR-TB cases has been also reported by other authors.(5, 8) The occupational profile of our patients revealed that a majority of them labourer followed by household workers and skilled workers. Mukherjee et al. observed a higher prevalence of pulmonary TB in household workers followed by labourer and skilled workers.(5) The most common form of substance use were smoking (44%), followed by smokeless tobacco (27%) and alcohol (26.4%), with duration of 1-10 years was most common among all groups. A study by Mukherjee et al found that history of smoking (28.48%), tobacco chewing (36.04%) and alcohol intake (28.48%) were present.(5) In the present study, prevalence of moderately extensive and extensive Koch's lesion were higher among those who had longer duration of substance use. Duration of alcohol intake was associated with grade of Koch's lesion in chest X-ray. Further study is proposed to find out cause-effect relationship between substance use and severity of Koch's lesion.

In our study majority subjects had taken anti-tubercular treatment previously and majority of them were cured previously. In a prospective study conducted by Sethi et al. in North India major proportion of MDR-TB cases was due to treatment failure.(9) Another study conducted by Azhar revealed that relapse rate is high (almost 10%) in India and the risk factors for relapse included drug irregularity, initial drug resistance, smoking, and alcoholism.(10) In this study, 18.9% didn't take ATD previously and 17% didn't have any records of taking ATD. Majority (80.6%) of cases was treated under RNTCP previously and 57.4% got ATD for 6 months or more. Similar findings were found in another study also. (11) This

result may indicate failure of TB control programme to detect the DR-TB cases at the earliest. Also, there is a need of evaluation of TB control programme at the local level to identify the factors effecting failure of treatments. Re-orientation training of all staffs involved in TB control programme may be helpful also.

The drug resistance pattern of the study group indicates most of the cases were Rifampicin resistant (93.7%). Mukherjee et al. demonstrated a low proportion of resistance to pyrazinamide (1.16%), ethambutol (1.74%) and streptomycin (1.74%) and among the second line drugs (SLD) only 2.90% resistance was found to both ofloxacin and kanamycin.(5) In another study reportedly the proportion of resistance to pyrazinamide, streptomycin and fluoroquinolone was greater.(6) Similar findings were reported by other studies also.(12, 13, 14) Among all the patients 56.6% were undernourished with BMI less than 18.5 kg/m². Another study reported 59.88% were undernourished among MDR-TB cases.(5) In this study, pallor was present among 94.3% cases. Along with treatment of DR-TB, focus should be given on improvement of nutritional status of the patient. In the present study the commonest comorbidity was diabetes mellitus followed by hypertension, asthma and chronic obstructive pulmonary disease. Datta et al. found diabetes was present as a comorbid illness among 7.6% in their study.(15) In other studies the commonest comorbidity was reported to be chronic obstructive pulmonary disease (COPD).(5)

Datta et al. reported 1.9% HIV seropositivity among MDR-TB cases.(15) However in the present study 2.5% DR-TB patients were found to be HIV seropositive, 94.3% were having pallor.

Radiologically majority had moderately extensive Koch's lesion with 62.3% having bilateral lesion. Similar findings have been reported by other observers in their studies.(5,6,16) The major limitation of the study is that it is conducted on MDR-TB patients who belonged to North 24 Parganas. Hence it may not be representative of the population at large. As first line LPA facility for detection of INH resistance is not routinely available to the patients, so we did not get true picture of INH resistance.

Conclusion

The present study showed that younger age group particularly in the females were more affected with DR-TB. Smoking history was found in a majority of patients. Duration of alcohol intake was associated with severity of Koch's lesion. Undernutrition and pallor were quite prevalent among the DR-TB patients. Relapse of previously cured tuberculosis patients, was found to be the major contributor of DR-TB cases. Resistance pattern suggested low level of resistance to second line drugs, whereas prevalence of Rifampicin resistance was also found to be very high. Early detection of drug resistance

in all TB cases can be helpful to identify DR-TB cases at the earliest.

Recommendation

Awareness campaign and re-orientation among newly diagnosed TB patients, regarding adherence to treatment and drug resistance, may be helpful to prevent DR-TB cases. Further evaluation of TB programme at local level is proposed to identify the factors leading to relapse and treatment failure of DR-TB cases. A longitudinal study can be done to investigate the determinants of drug resistance.

Limitation of the study

As it was conducted among DR-TB patients of a particular geographic location in West Bengal, representation of whole state was not possible. The data was collected in a cross-sectional survey. Therefore, we cannot describe causality to any of the factors.

Relevance of the study

Drug resistance is going to be a challenge in elimination of TB in India. Younger age group is being affected by DR-TB more frequently. Early detection of drug resistance in all TB cases can be the key to overcome the burden of drug resistance. Determinants of drug resistance among TB cases needs to be addressed in this part of the country. This study will help other researcher to plan further studies.

Authors Contribution

RB: concepts, design, manuscript preparation, manuscript editing, and manuscript review. SK: concepts, design, data collection, manuscript preparation, manuscript editing, and manuscript review. DB: design, literature search, data collection and manuscript review. SN: concepts, design, literature search, manuscript editing, and manuscript review. AS: data analysis, statistical analysis, manuscript preparation, manuscript editing and manuscript review. AB: data analysis, statistical analysis, manuscript preparation, manuscript editing and manuscript review

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Tables

TABLE 1 SOCIO-DEMOGRAPHIC PROFILE OF DR-TB PATIENTS (N= 159)

Variables	Categories	Number	Percentage (%)
Age (Completed Years)	11-20	28	17.6
	21-30	43	27
	31-40	30	18.9
	41-50	32	20.1
	51-60	19	11.9
	61 and above	7	4.4
Sex	Male	109	68.6
	Female	50	31.4
Caste	General	78	49.1
	SC	24	15.1
	ST	6	3.8
	OBC	51	32.1
Education Status	Illiterate	26	16.4
	Just Literate	23	14.5
	Primary Completed	57	35.8
	Secondary Completed	24	15.1
	Higher Secondary Completed	15	9.4
	Graduation &above	14	8.8
Occupation	Unemployed	10	6.3
	Student	20	12.6
	Household Work	29	18.2
	Labour	41	25.8
	Skilled Work	27	17.0
	Service	20	12.6
	Business	12	7.5
Location	Urban	96	60.4
	Rural	63	39.6

TABLE 2 SUBSTANCE USE HISTORY* OF DR-TB PATIENTS (N= 159)

Variables	Categories	Number	Percentage (%)	
Type of substance	Smoking tobacco	70	44	
	Smokeless tobacco	43	27	
	Alcohol	42	26.4	
Duration of substance use (completed years)	Smoking tobacco	1-10	33	20.8
		11-20	19	11.9
		21-30	15	9.4

		≥31	3	1.9
Smokeless tobacco		1-10	24	15.1
		11-20	11	6.9
		21-30	7	4.4
		≥31	1	0.6
Alcohol		1-10	23	14.5
		11-20	8	5
		21-30	9	5.7
		≥31	2	1.3

*There were multiple responses

TABLE 3 PAST ATT# HISTORY OF MDR-TB PATIENTS

Variables	Categories	Number	Percentage (%)
History of ATT (N= 159)	Yes (N ₁)	129	81.1
	No	30	18.9
Total duration of treatment in months (N ₁ = 129)	≤6	55	42.6
	6-12	36	27.9
	12-18	8	6.2
	>18	30	23.3
Number of previous treatment episodes (N ₁ = 129)	1	79	61.2
	2	40	31
	3	10	7.8
Source of ATD (N ₁ = 129)	RNTCP	104	80.6
	Private	20	15.5
	Both	5	3.9
Outcome of previous treatments* (N ₁ = 129)	Treatment after default	6	4.7
	Defaulter	6	4.7
	Cured	32	24.8
	Regimen change	5	3.9
	Switch to Category IV	29	22.5
	Switch to Category V	5	3.9
	Failure	24	18.6
	Relapse	1	0.8
Not Known	35	27.1	
Drug history* (N = 159)	Not taken any ATD [§]	30	18.9
	Isoniazid	102	64.2
	Rifampicin	101	63.5
	Pyrazinamide	100	62.9
	Ethambutol	101	63.5
	Streptomycin	44	27.7
	Not known	27	17

*There were multiple responses; # Anti-tubercular treatment; § Anti-tubercular drug

TABLE 4 CLINICAL CHARACTERISTICS OF DR-TB PATIENTS (N=159)

Variables	Categories	Number	Percentage (%)
BMI	<18.5	90	56.6
	18.5-24.9	50	31.4
	≥25	19	11.9
Presenting symptoms*	Cough	139	87.4
	Fever	108	67.9
	Chest pain	59	37.1
	Hemoptysis	11	6.9
	Shortness of breath	8	5
	Anorexia	5	3.1
	Vomiting	5	3.1
	Others	11	6.9
Pallor status	Present	150	94.3
	Absent	9	5.7
HIV status	Non-reactive	155	97.5

	Reactive	4	2.5
Air entry into lungs	Bilateral equal	120	75.5
	Diminished in left	20	12.6
	Diminished in right	19	11.9
Adventitious sound	Present	7	4.4
	Absent	152	95.6
Chest X-ray laterality	Unilateral	60	37.7
	Bilateral	99	62.3
Chest X-ray Grade	Mild	48	30.2
	Moderate	91	57.2
	Extensive	20	12.6
Cavity on chest X-ray	Yes	74	46.5
	No	85	53.5

*There were multiple responses

Figures

FIGURE 1 DRUG RESISTANCE PATTERNS OF DR-TB CASES

