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SOCIO-DEMOGRAPHICS AND CLINICAL CHARACTERISTICS OF CULTURE-POSITIVE PULMONARY TUBERCULOSIS PATIENTS:AN EXPERIENCE FROM DRUG-RESISTANT TUBERCULOSIS CENTRE OF INDIA

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Abstract

We aimed to determinecharacterization of culture-positive multidrug-resistant tuberculosis (MDR-TB) patients from a drug-resistant tuberculosis (DR-TB) centre of India. We enrolled 436 TB patients and selected 395 subjects after inclusion and exclusion criteria. Descriptive statistics were employed to investigate the social-demographics and clinical feature of culture-positive TB patients and its risk factors.Mean age of patients was 43.6±12.7 years and 61.5% were males.A total of 108 (27.3%) patients were smokers while 26 (6.6%) were ex-smokers and remaining were non-smokers (66.1%).Most common symptoms were cough with expectoration 365 (92.4%). Complaints like fever (78%), haemoptysis (30%), and weight loss (63%) were present. 21% (n=82) population has family history of TB. Co-morbidities were present in 94 (23.8%) patients and diabetes (n=37) was the most common comorbidity. Out of 395, 125 cases of drug sensitive pulmonary tuberculosis and 270 cases were MDR-TB. In smear grading 204 cases were presented 2+ or 3+ positive, 191 were 1+ or scanty. Out of the 395 sample, 364 samples were found to be culture positive which were further analyzed by drug susceptibility testing (DST) of which 251, 243 and 247 were found to be resistant towards rifampicin (RIF), isoniazid (INH), and ethambutol (EMB), respectively.Our data suggests that there is a sufficient number of MDR-TB patients in the studied. The majority of MDR-TB resulted from people failing to take their anti-TB medications properly. Hence, decreasing alcohol intake, receiving more education, TB advocacy & communication, more testing and notification, and TB control programmes are indispensable to

defeatthe TB.

Keywords: Culture-positive PTB, Risk factors, TB, Comorbidity, Assessment

Introduction

In 1993, World Health Organization (WHO) declared tuberculosis (TB) as a 'public health emergency**[1].** Every year, millions of people become ill with the disease and in 2020, 1.5 million people died from TB (additionally 214 000 people with HIV) [2]. TB is the 13th major cause of death globally as well as it is the second dominant infectious killer after corona virus disease (COVID)-19 [2]. Estimates suggest that 30 high TB burden countries are responsible for 86 percent of new TB cases in 2020 [2]. India leads the pack with two-thirds of the total, followed by China, Indonesia, the Philippines, Pakistan, Nigeria, Bangladesh, and South Africa [2]. According to the Global TB Report 2021, the estimated incidence of all forms of tuberculosis in India in 2020 was 188 per 100,000 population (129-257 per 100,000 population) [3]. The total number of incident TB patients notified in 2021 was 19,33,381, a 19% increase over the previous year (16,28,161) [3]. As per WHO ending of the TB epidemic by 2030 is important health targets of United Nations sustainable development goals (SDGs) [2]. Whereas, in India, our Prime Minister had set a target to eliminate TB from India by 2025 [4].

TB can affect any organ of the body, but the serious clinical problem is pulmonary tuberculosis (PTB). TB spreads through the air from one person to another person. When a person with lung tuberculosis cough, or sneeze, the Mycobacterium tuberculosis are released into the air [2]. Only a few of these germs must be inhaled for a person to become infected [2]. Approximately, one-quarter of the world's population is infected with TB; although they have been infected with TB bacteria but are not (yet) ill by the TB and cannot transmit the disease [2]. Nowadays, due to the emergence of drug-resistant tuberculosis bacteria, this is a big challenge for a clinician to treat the patients. The main reason of TB appearance included person-to-person transmission, endogenous relapse, and treatment failure.

In India, drug-resistant tuberculosis (DR-TB) is common. Its presence has been known since anti-TB drugs were first introduced for the treatment of TB. If a person has MDR-TB, it means that patient is resistant to both rifampicin and isoniazid which are the main tubercular drugs. It was thought that the majority of MDR-TB in India resulted from people failing to take their anti-TB medications properly [5]. MDR-TB has a global incidence of 3.4 percent in new cases and 18 percent in previously treated cases. Across the globe, 78% of rifampicin-resistant tuberculosis (RR-TB) cases were multidrug-resistant [6]. From 2014 to 2016, an Indian government survey estimated the incidence of MDR-TB to be 2.84 percent in new cases and 11.6 percent in previously treated patients [7]. One of the major impediments to achieving the goal of eradicating TB in India is also this drug resistance TB.

Difficulties in disease diagnosis and preventative methods can result in the spread of tuberculosis, among even people who are not at high risk [8]. TB transmission can extend to social

and casual contacts, which are more difficult to track down using traditional epidemiological methods [9,10]. If asymptomatic people go unnoticed for an extended period of time, they can become contagious and become the source of un-recognised TB outbreaks. Among TB cases, MDR-TB is major culprit.

Sputum culture-positive PTB is still a major challenge of tuberculosis transmission, compared with culture-negative or nucleic acid amplification test-negative *Mycobacterium tuberculosis* [11-12]. Clinical characteristics and demographics associated with MDR-TB patients of north India is not clearly understood. The objective of the present study was to determine the socio-demographics and clinical characteristics of MDR-TB cases presenting at drug resistant tuberculosis centre of India.

Materials and methods:

This cross-sectional study was conducted in the respiratory medicine department of a tertiary care hospital. Sputum smear-positive patients in spite of their sex and age attending to out-patient department (OPD) were enrolled randomly in the study. The study protocol was approved by the Institutional Ethics Committee (IEC) of the institution. Prior to enrolling in the study informed written consent was obtained from all the participants.

A total of 436 participants were enrolled in the study. Due to exclusion and other criteria, three hundred ninety-five (395) patients were eligible for final analysis. On the clean side, a smear was made with a wire loop from the yellow purulent portion of the sputum. After air drying for 15-30 minutes, the smear was fixed by passing the slide over the flame 3-5 times for 3- 4 seconds each time. Ziehl and Nelson method of staining were performed for all Samples. Acid fast bacilli stain pink, straight or slightly curved rod shape. Sample processing was done within 24 hours by N-Acetyl L-Cysteine (NALC) Method. Culture was done for 395 cases, sputum samples in Liquid culture medium-*Mycobacterium* Growth Indicator Tubes (MGIT). Liquid culture technique have been endorsed as per WHO- the GOLD standard for the rapid detection of MDR-TB. Further, culture positive subjects which were further analysed by Drug susceptibility testing (DST) to check resistant towards RIF, INH and EMB.

Patients were checked by the chest specialist to confirm the diagnosis of TB.The collected data was analyzed to get significant results with GraphPad Prism 6 (GraphPad Software Inc, San Diego, CA, USA). All the data were presented as mean ± standard deviation (SD), and percentage. Descriptive statistics was employed.

Ethical statement and Patient consent:Study protocol was approved byinstitutional ethics committee. Written informed consent was taken from all the participants prior to enrol in the study.

Results

Demographical characteristics of PTB patients

Mean age of patients was 43.6±12.7 years. Description of demographics was depicted in Table

1. Age of patients ranged from ≤20 to >60 years. Maximum number of cases were aged 51-60 years (n=109; 27.6%) followed by 41-50 years (19.2%), 31-40 years (16.2%), >60 years (14.2%), 21-30 years (13.1%) and ≤20 years (9.6.7%) respectively. Majority of patients were males (n=243; 61.5%). There were 152 (38.5%) females. Out of 395, 12% (n=47) were underweight, and 40.3% have normal body mass index (Table 1). Drinking habit was found in 86 (21.8%) subjects. Married patients (n=260; 65.8%) predominated over unmarried patients (n=112; 28.4%). Rural patients (n=209, 52.9%) predominated over urban patients. Maximum number of patients were farmers/agriculturists/unskilled laborers (n=154; 39%) followed by students (n=66; 16.7%), housewives (n=56; 14.1%), business/shopkeepers and skilled worker/private service (n=48; 12.2% each) and government job/teachers (n=5.2; 20%) respectively (Table 1). Majority of patients were from lower socioeconomic class (n=160; 40.5%, Figure 1).

Risk factors and clinical characteristics associated with culture-positive PTB

A total of 108 (27.3%) patients were smokers while 26 (6.6%) were ex-smokers and remaining were non-smokers (66.1%). Mean of pack years was 18.56±13.27. Tobacco chewers were 38%. Biomass fuel exposure was found in 37% studied population. Most common symptoms were cough with expectoration 365 (92.4%). Complaints like fever (78%), haemoptysis (30%), and weight loss (63%) were present. 21% (n=82) population has family history of PTB.

Associated co-morbidities in PTB patients

Co-morbidities were present in 94 (23.8%) patients. Diabetes (n=37) was the most common comorbidity followed by hypertension (n=23), HIV (n=14) rheumatic heart disease (n=5), thalassemia (n=3) and others respectively (Figure 2).

Resistance profile of the culture positive PTB patients

A total of 251 (69%) patients were rifampicin resistant while 113 (31%) were rifampicin sensitive. On the other hand, 243 (66.8%) patients were resistant to NIH and remaining 121 (33.2%) were sensitive to NIH. A total of 247 (68%) patients were EMB resistant while 117 (32%) were EMB sensitive. Resistance profile is presented in Table 3 and Figure 3.

Discussion

Approximately, half of the world's MDR-TB cases are from India (27%), China(14%), and Russia (9%) [6]. In comparison to the global WHO 2019 report [13], an Indian survey of TB drug resistance in 2016 found a lower incidence of MDR in treated patients (11.6 percent vs. 18 percent) and new cases (2.84 percent vs. 3.4 percent). Here, we demonstrated the demographics, clinical characteristics, risk factors of MDR-TB from a TB centre of northern India. 125 cases of drug sensitive pulmonary tuberculosis and 270 cases were MDR-TB were found. Higher percentage of MDR-TB may be due to selection biasness as suspected MDR-TB patients were recruited and investigated.

In India, the 15–24 year age group has the highest prevalence of tuberculosis. The rates of occurrence in men, women, and children were 60%, 34%, and 6%, respectively. [13]. In the present study 9.6% population was <20 years. Men proportion was 61.5%, while females were 38.5%.

Smoking is a known cause of tuberculosis, which was also found in our study. According to a Ugandan study, 14.7% of men are current smokers [14]. Smoking may be even more prevalent

among unemployed youth. A meta-analysis [15] stated an increased risk of tuberculosis infection, disease, and mortality with tobacco use. As a result, this provides a point to collectively focus on TB and tobacco control in the study areas. In the present study, most common symptoms were cough with expectoration consistent with another study [14].

The emergence of the HIV pandemic has led to an increase in tuberculosis cases. TB seems to be the most common disease associated with HIV, and it exacerbates HIV, reduces treatment efficacy, and leads to drug resistance. Additionally, drug resistance has resulted from the use of substandard drugs, insufficient or irregular drug supply, and treatment interruption. Out of the total 395 pulmonary tuberculosis patients, 3.5% were HIV positive. A meta-analysis study reported that the co-infection rate of MTB in patients infected with HIV was 14.4% [16].

The role of drinking alcohol in the development of TB is well known, and significantly associated with smear positive TB [17-18]. Our data showed that 21.8% subjects were drinkers. This is consistent with studies conducted in most parts in the world [18-20]. As far as educational status is concerned, it is reported that less educated population was higher mortality in adult culture-positive tuberculosis patients in Taiwan [21]. In the present study, 14.1% were house-wives, and 39% were unskilled worker. In socio-economic category, 40% patients were belongs to 'lower' status. Other than this, 52.9% population belongs to rural areas. In parts of Southern-East Asia, African and Western Pacific regions, the ratio of tuberculosis cases among rural district exceeds 50%.[22] Several tuberculosis characteristics such as age, sex, alcohol users, HIV, and education have been explored in various studies [22-25]. However, there were different characterizations in urban areas, including under-nutrition, indoor air population, and low socioeconomic profile [26-27]. These different characteristics can help local tuberculosis control personnel to manage different tuberculosis population.

In our study, major percentage was of MDR-TB cases along with greater rural population. The rural patients had higher rate of MDR TB in culture positive tuberculosis, the reason might be due to poor treatment strategy, lack of economic support, and longer duration of disease course. These findings are similar with Mulisa G[28]and Hutchison C[29]. The reason may be poor treatment adherence and more HIV positive as well as residual pulmonary cavity in rural patients. This finding is consistent with similar studies conducted in Southern Africa [30] and USA [31].

India has already completely eradicated major diseases such as smallpox and polio. But the condition with tuberculosis is different. There are several reasons why tuberculosis could not be eradicated till date. The reasons are related to the causative organism, Mycobacterium tuberculosis, as well as social and host factors. Mycobacterium tuberculosis is the causative organism of any infectious disease that infects nearly one-third of the global population, making it the single largest organism in terms of numbers infecting the human host. This organism is unique in that it can lay dormant for years without causing any harm while waiting for a favourable situation to multiply and cause disease.Here comes the role of social and host factors, such as malnutrition, HIV, diabetes, repeated and early pregnancy in females, poverty, overcrowding, smoking, alcoholism, and other addictions, poor hygiene, and difficulty accessing health care. These are just a few of the issues that concern us.

There are several limitations to this study, such as it was single centre study. Other than this, confounding factors viz quality of TB drugs, cavity interpretation and categorization of TB, could not be controlled. However, the findings are certain to be useful in establishing a public health priority for the development of actions aimed at preventing and controlling TB transmission in India.

Over the years, Indian government, in collaboration with RNTCP/NTEP, has undertaken numerous initiatives to raise awareness, promote health, and control tuberculosis, and by 2006, the entire country was covered by DOTS. In response to rising drug resistance, the DOTS-PLUS programme for MDR-TB treatment was launched in 2010. Recently, the RNTCP achieved the WHO's preliminary target and entered the second phase of TB control and eradication by enforcing the "Stop TB" strategy by ensuring quality state-of-the-art diagnostic laboratory services such as CB-NAAT, GeneXpert, LPA, and first and second line culture and medications. RNTCP has begun to make a difference in the fight against tuberculosis and MDR-TB.The GOI has successfully implemented "Nikshay" – a case-based online software through which more and more cases are being notified and treated as soon as possible. Collaboration with a number of Non-Governmental Organizations (NGOs) has expanded TB care to the periphery. RNTCP has also launched a PPM (Public Private Mix) service to ensure tuberculosis notification, awareness, and proper treatment. Despite all of these precautions, 22 people per lakh people die from tuberculosis each year, amounting to approximately three lakh deaths.This situation compels us to reflect, beginning with the policymakers at the top and working our way down to the microscopists and health visitors at the ground level. Change is required, from the level of political commitment to the level of public awareness of this dreaded disease. The Government of India launched the NikshayPoshan Yojana in March 2018 [32]. Its main goal is to provide incentives (Rs 500 per month for the duration of treatment) to TB patients for nutritional support. The NikshayPoshan Yojana is implemented through the use of a smart card that is linked to AADHAR. This ensures that user and account identities are not tampered with.During the Delhi END TB Summit on March 13, 2018, Hon'ble Prime Minister Shri Narendra Modi declared TB-Free India five years ahead of the target date of 2025.

Conclusions: This study offers some evidences that the population distribution of culture-positive MDR-TB and need some specific measures to prevent and control TB transmission. We know that MDR-TB resulted from people failing to take their anti-TB medications properly. Hence, decreasing alcohol intake, receiving more education, TB advocacy & communication, more testing and notification, and TB control programmes are essential to control the TB. As Goethe’s saying goes “Knowing is not enough; we must apply. Willing is not enough; we must do.” We have to prepare altogether to end the TB by 2030.

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Competing Interest: The authors declare no competing interest.

Ethical statement and Patient consent: Study protocol was approved byinstitutional ethics committee. Written informed consent was taken from all the participants prior to enrol in the study.

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Tables and Figures

Table 1: Socio-demographic profile of the studied participants.

S.No.	Characteristic	Number (n=395)	Percentage (%)
1.	**Age group (years)**		
	≤20	38	9.6
	21-30 Years	52	13.1
	31-40 Years	64	16.2
	41-50 Years	76	19.2
	51-60 Years	109	27.6
	>60 Years	56	14.2
	Age(mean±SD) in years	43.6±12.7	
2.	**Gender (n,%)**		
	Male	243	61.5
	Female	152	38.5
3.	**Body mass index$ (n, %)**		
	<18.00 kg/m2	47	12
	18.0-22.9 kg/m2	159	40.3
	23.0-24.9 kg/m2	143	36.2
	>25 kg/m2	46	11.6
4.	**Drinking habit (n,%)**		
	Alcoholic	86	21.8
	Non-alcoholic	280	70.9
	Unknown	29	7.3
5.	**Marital Status (n,%)**		
	Married	260	65.8
	Single	112	28.4
	Widowed/divorced	23	5.8
6.	**Place of residence (n,%)**		
	Rural	209	52.9
	Urban	186	47.1
7.	**Occupation (n,%)**		
	Housewife	56	14.1
	Farmer/Agriculturist/Unskilled Labourer	154	39
	Business/Shopkeeper	48	12.2
	Government Job/Teacher		

S.No.	Characteristic	Number (n=395)	Percentage (%)
	Skilled worker/Private service	20	5.2
	Student	51	12.9
		66	16.7

Figure 1: Socio-economic status of participants

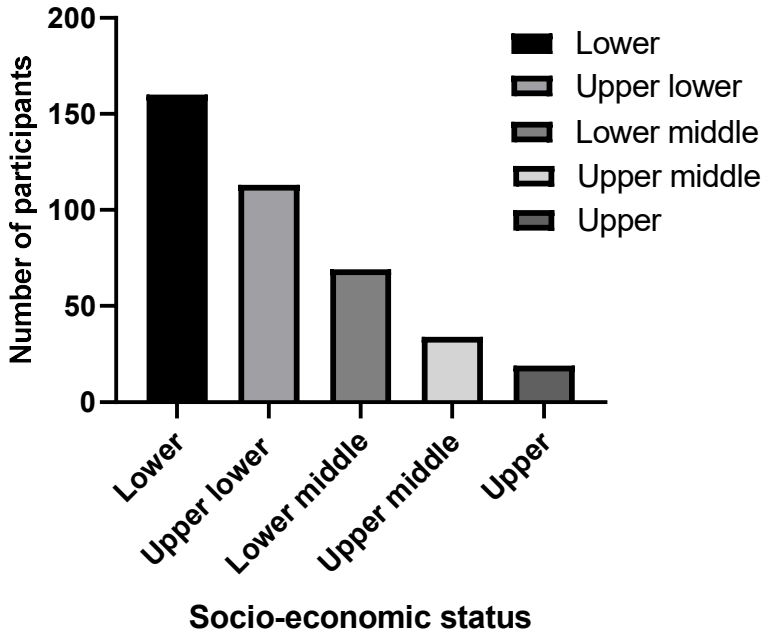

Table 2: Risk factors and clinical characteristics of the participants.

S.No.	Characteristics	Number (n=395)	Percentage (%)
1.	**Smoking history**		
	Smoker	108	27.3
	Ex-smoker	26	6.6
	Non-smoker	261	66.1
2.	**Pack years(mean SD)**	18.56±13.27	
3.	**Tobacco chewer**		
	Yes	149	37.7
	No	246	62.3
4.	**Biomass smoke exposure**		
	Yes	146	37
	No	249	63

S.No.	Characteristics	Number (n=395)	Percentage (%)
5.	**Cough with expectoration**		
	Yes	365	92.4
	No	30	7.6
6.	**Haemoptysis**		
	Yes	118	29.9
	No	277	70.1
7.	**Weight loss**		
	Yes	249	63
	No	146	37
8.	**Fever**		
	Yes	307	77.7
	No	88	22.3
9.	**Family history of TB**		
	Yes	82	20.8
	No	313	79.2
10.	**Diabetes status**		
	Diabetes	37	9
	Non-diabetic	326	82.5
	Unknown	32	8.1
11.	**HIV status**		
	HIV-positive	14	3.5
	HIV-negative	360	91.1
	Unknown	21	5.3
12.	**Smear grading**		
	3+ or 2+	204	51.8
	1+ or scanty	191	48.2
13.	**Culture report**		
	Positive	364	92.7
	Negative	31	7.3

Figure 2: Associated co-morbidities with the patients

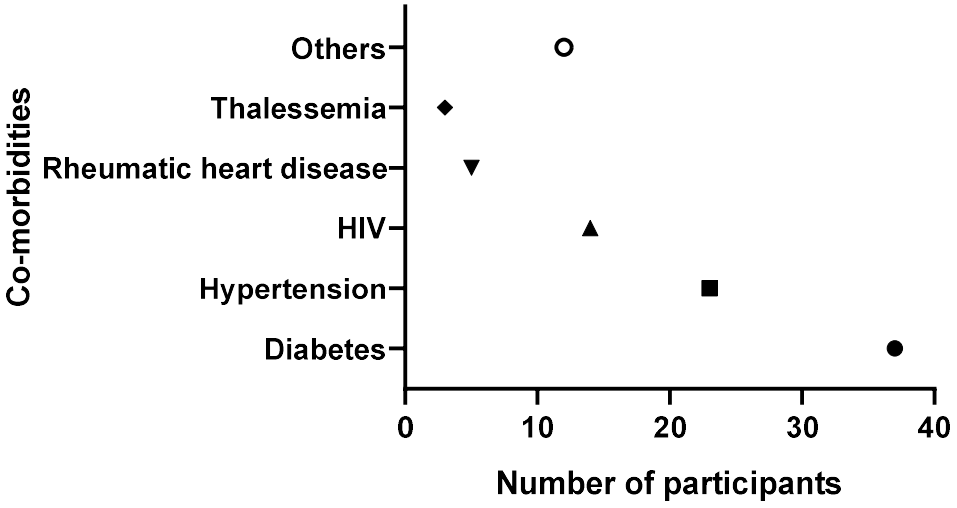

Table 3: Drug susceptibilities of *Mycobacterium tuberculosis* isolates from all cases

S. No.	Drug	Resistance (n, %)	Sensitive (n, %)
1.	RIF	251(69)	113(31)
2.	INH	243(66.8)	121(33.2)
3.	EMB	247(67.9)	117(32.1)

Figure 3: Graphical representation of Drug susceptibilities of *Mycobacterium tuberculosis* isolates from all cases.