

Socio-demographic profile of multi-drug resistant tuberculosis patients and its association with severity of adverse drug reactions in DOTS plus centre at tertiary hospital in Himachal Pradesh, India**Anita Kumari^{1*}, Parveen K. Sharma², Dinesh Kansal³, Rekha Bansal⁴, Sumita Kumari⁵**¹Department of Pharmacology, Dr. YSP Government Medical College, Nahana, Himachal Pradesh, India²Department of Pharmacology, SLBS Government Medical College Mandi at Nechowk, Himachal Pradesh, India³Department of Pharmacology,⁴Department of Pulmonary Medicine, Dr. RP Government Medical College, Kangra, Tanda, Himachal Pradesh, India⁵Department of Community Medicine, Dr. YSP Government Medical College, Nahana Himachal Pradesh, India**Received:** 18 September 2018**Accepted:** 22 October 2018***Correspondence to:**Dr. Anita Kumari,
Email: anitakumarinegi@gmail.com**Copyright:** © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.**ABSTRACT****Background:** Multi-drug resistant tuberculosis has become major public health problem and obstacle to effective control of tuberculosis. Objectives was to study the socio-demographic profile of multi- drug resistant tuberculosis patients and its association with severity of ADR (adverse drug reactions) in DOTS plus centre at tertiary hospital in Himachal Pradesh.**Methods:** It was a prospective observational study carried out from November 2012 to October 2013 on multi-drug resistant tuberculosis (MDR-TB) patients after approved from Institutional Ethics Committee.**Results:** Out of 104 patients the mean age of patients was 39.9 ±14.26 years. Majority of the patients were in the economically productive age groups. Multi-drug resistant tuberculosis was more in male (76%) than female (24%) and 96% of patients were belonged to rural area. The educational status of the MDR-TB shows 24% patients were illiterate. 63.46% MDR-TB patients were underweight (BMI<18.5%) according to WHO guidelines for obesity. Severity of ADR assessed by Hart wig and Siegel's scale showed 21% patients experienced mild ADRs, 49% patients had moderate and 17% patients had severe ADRs. Severity of ADR is seen more in male, economically productive age group, subjects on vegetarian diet, patients who were underweight (BMI<18.5%) and with lower educational status.**Conclusions:** MDR-TB is a rapidly increasing health problem with major socio-economic and individual consequences. Multi-drug resistant tuberculosis mainly affects middle age that is in the economically productive age group which hampers the social and economic development of individual, society and nation.**Keywords:** Multi-drug resistant tuberculosis, Severity of adverse drug reactions, Socio-demographic profile**INTRODUCTION**

Tuberculosis has remained major global problem and is ninth leading cause of death worldwide and leading cause

from single infectious agent.¹ In 2016, there were 60000 new case of drug resistant tuberculosis of which 49000 had multidrug resistant tuberculosis and 47% occurred in China, India and the Russian Federation.¹ Poverty, under

nutrition, HIV infection and smoking are major influence on tuberculosis epidemic and most of high burden countries have major challenges to reach targets.¹ Patients with MDR-TB required longer duration and costly treatment resulting social isolation, loss of employment, long term socioeconomic effects and experience higher mortality.² Adverse drug reactions on second line anti tuberculosis drugs and poor management of adverse drug reactions led to irregular adherence of treatment, increasing risk of default and may lead to death and permanent morbidity.³ Timely monitoring and management of ADR is required to prevent death and morbidity. Considering all these factors the present study was designed to study Socio-demographic profile of multi-drug resistant tuberculosis patients and its association with severity of adverse drug reactions.

METHODS

It was prospective observational study. The study was carried out at DOTS Plus Centre Dr. Rajendra Prasad Government Medical College, Kangra at Tanda, Himachal Pradesh. Duration of the study was one year from November 2012 to October 2013. Multi- drug resistant tuberculosis patients fulfilled the inclusion and exclusion criteria.

Inclusion criteria

All multi-drug resistant tuberculosis patients registered for category-IV treatment were given written Informed consent.

Exclusion criteria

Patients were not given written informed consent to participate in the study.

Data collection

The written informed consent was obtained from all the patients. A questionnaire was developed through review of literature. Data was collected into two parts:

- Socio demographic profile: age, sex, education, occupation, family history of TB, diet pattern, and BMI
- Severity of ADR assessed by Hart twig scale and Causality was assessed by as per WHO Probability scale.^{4,5}

Ethical clearance was approved by Protocol Review Board and Institutional Ethics Committee DRPGMC Tanda, Himachal Pradesh, India.

Statistical analysis

Data analysis was done using SPSS software version 17. Descriptive analysis was done (mean, proportion and percentages) for demographic variable. Association

between socio-demographic variables and severity of ADR was analysis by Chi square test. P <0.05 was considered as statistical significant.

RESULTS

A total of 104 multi-drug resistant tuberculosis patients were enrolled. Youngest patient in the study was 13 years and oldest was 85 years of age and mean age of patients was 39.9±14.26 years.

Socio-demographic profile

The distribution of the subject according to their age groups shows majority of the patients were in the economically productive age groups (Table 1).

Table 1: Age distribution of multi-drug resistant tuberculosis patients.

Age	Frequency	Percentage
<16	4	3.8
16-25	13	12.5
26-45	54	51.9
>45	33	31.7
Total	104	100

Multi-drug resistant tuberculosis was more in male (76%) than female (24%) and the male to female ratio was 3:1. 96% of patients were belonged to rural area and 4% to urban area. 86% patients did not have family history of tuberculosis and only 14% have family history of tuberculosis and 74% patients were non-vegetarian diet and 26% were vegetarian diet. The occupational profile of patients shows majority of them were (56.7%) farmers followed by skilled professionals (15.4%), housewives were 12.5%, unskilled worker 7.7% and 7.7% were students (Figure 1).

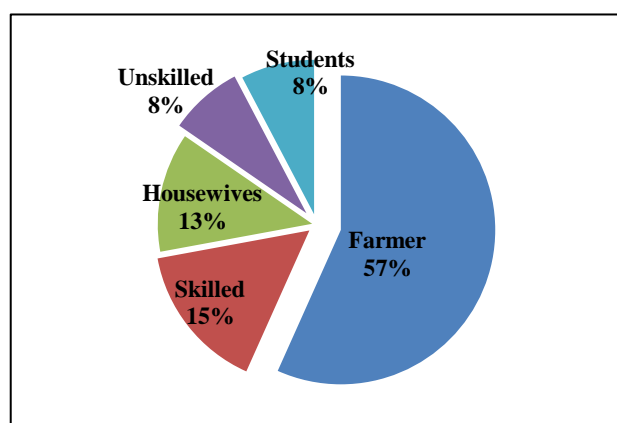


Figure 1: Occupation status of multi- drug resistant tuberculosis patients.

The educational status of the MDR-TB shows 24% patients were illiterate and rest distributed in all the subclasses but less of them are graduate and above (Figure-

2). 63.46% MDR-TB patients were underweight (BMI<18.5%), none of the patients was obese (BMI>30) according to WHO guidelines for obesity.⁶

Severity of ADR

Severity assessment using Hart wig and Siegel’s scale showed 21% patients experienced mild ADRs, 49% patients had moderate, 17% patients had severe ADRs and 13% patients does not experience any ADR shown in (Figure 3).

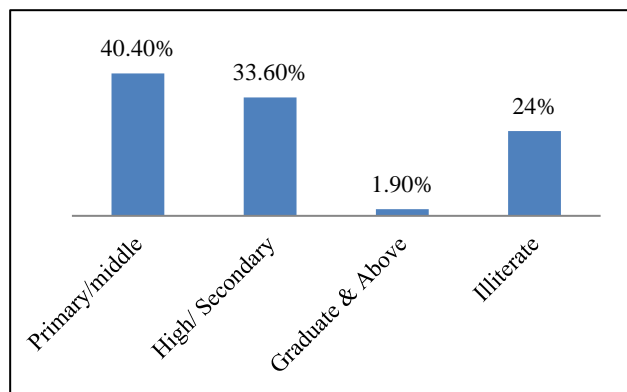


Figure 2: Education status of multi-drug resistant tuberculosis patients.

Association between severity of ADR with the socio-demographic factors

Severity of ADR is seen more in male, economically productive age group, subjects on vegetarian diet, patients who were underweight (BMI<18.5%) and with lower educational status (Table 2). Association between severity of ADR with BMI and educational status was statistically significant (Table 2).

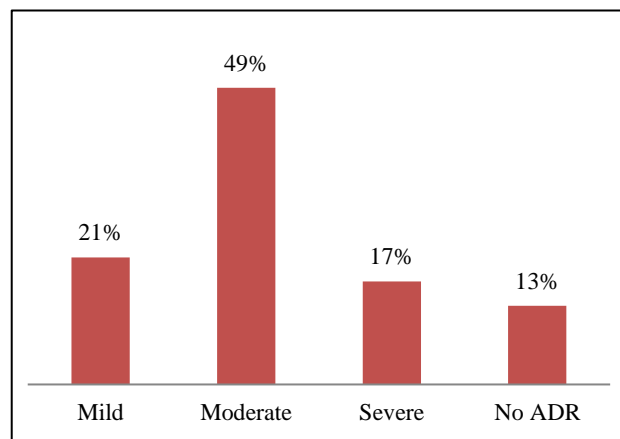


Figure 3: Severity adverse drug reactions multi- drug resistant tuberculosis.

Table 2: Association between demographic profile and severity of ADR.

Demographic Profile		Severity of adverse drug reaction				Chi Square Test
		No (n)ADR	Mild (n)	Moderate (n)	Severe (n)	
Age	<16	1	0	3	0	χ^2 9.886 P (0.360)
	16-25	3	3	6	1	
	26-45	9	12	26	7	
	>45	1	7	16	9	
Sex	Male	10	17	38	14	χ^2 0.617 P (0.892)
	Female	4	5	13	3	
BMI	<18.5%	14	16	27	9	χ^2 15.964 P (0.014)*
	18.5-24.9%	0	4	23	7	
	25-29.9%	0	2	1	1	
Family history of TB	Absent	12	19	45	14	χ^2 0.390 P (0.942)
	Present	2	3	6	3	
Dietary history	Vegetarians diet	11	16	37	13	χ^2 0.281 P (0.964)
	Non- vegetarians diet	3	6	14	4	
Education	Lower	10	11	30	16	χ^2 9.690 P (0.021)*
	Upper	4	11	21	1	

P *<0.005

Causality assessment

According to WHO-UMC scale causality assessment was done among the MDR-TB patients that shows 82% patients were possible in nature followed by 4% patients were certain and 1% probable/ likely (Table 3).

DISCUSSION

MDR-TB is a rapidly increasing health problem with major socio-economic and individual consequences. In the present study multi-drug resistant tuberculosis were more in male (76%) than female (24%) the mean age of patients

was 39.9±14.26 years. This shows that multi-drug resistant tuberculosis is a disease of middle aged males who are in the economically productive age group. Most of the studies conducted in India multi-drug resistant tuberculosis is more prevalent in males with mean age ranging from 32 to 37 years.⁷⁻⁹ This could be due to tuberculosis is more prevalent in males because of their high risk behavior such as smoking, alcoholism as compared to females. Though in this study all of them had stopped smoking and alcohol by the time they were diagnosed as having multi-drug resistant tuberculosis.

Table 3: Causality assessment of ADRs using WHO Probable Scale.

Causality	No of patients	Percentage
No ADR	14	13
Certain	4	4
Probable/Likely	1	1
Possible	85	82
Total	104	100

There were 96% of multi-drug resistant tuberculosis patients in present study belonged to rural area and only 4% were residing in urban areas. This is on expected lines as 89.7% population of Himachal Pradesh resides in rural areas (census 2011).¹⁰

In this study, about 76% were literate and 24% were illiterate Further, it was found that the patients of multi-drug resistant tuberculosis were distributed in all educational status but lowest in graduate and above. Level of education is important factors for knowledge, attitude, prevention and treatment outcome of disease. Majority of the patients in this study were farmers this may be because most of the population in the area is involved in agriculture and other manual activities. In studies conducted in India also shows a trend of drug resistance in tuberculosis being more common in lowest educational status.^{8,11} 63.46% patients in this study were underweight (BMI<18.5%) and finding show in other study conducted in Kolkata 59.9% patients were underweight.¹² This could be due to poor nutritional status.

Only 14% patients had family history of tuberculosis and other study conducted by Wahab et al 23.3% patients had family history tuberculosis.¹³ Family history is important factor in transmission of disease. This could be social stigma attached to disease.

Limitations of the study included population was only those taking treatments from governments DOTs Plus health centre.

Recommendations

There is a need of health awareness, education and communication activities so as to make them aware of

common symptoms, early diagnosis and treatment and also to avail the facilities at government's center.

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